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Quality management in the Pangasius export supply chain in Vietnam

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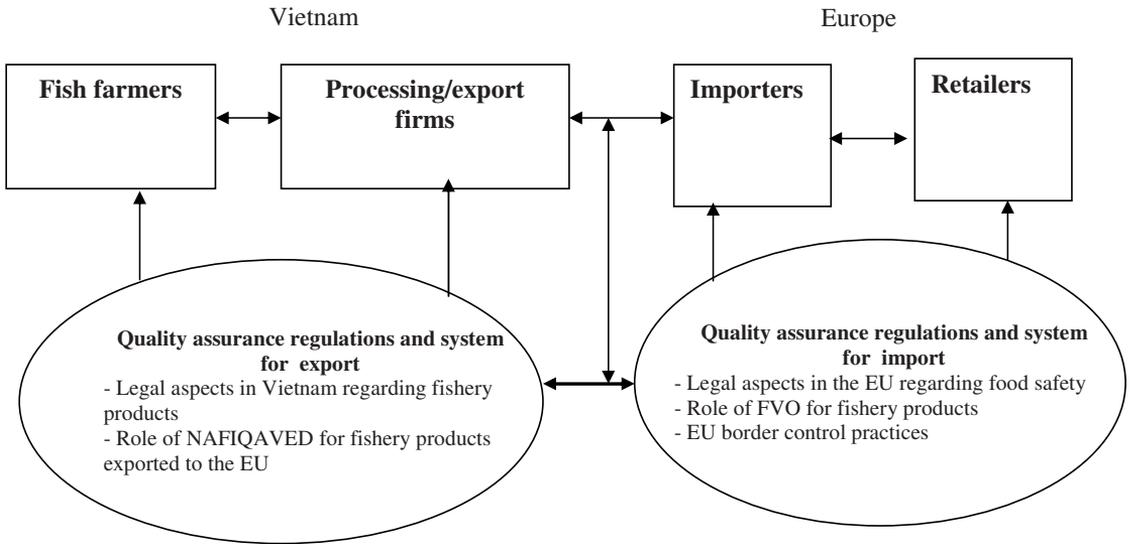
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6 Legal Aspects and Quality Assurance

6.1 Introduction

This chapter focuses on fish safety and quality issues. Figure 6.1 represents an integrative approach for the study of quality assurance at the chain level. First, the chapter provides the legal aspects of food safety in the EU markets. Subsequently, the EU food safety policy is described. Second, the institutional environment for fish export in Vietnam is presented. This chapter focuses on the fish processing sector and government control services. Finally, the chapter concludes with the main findings.

Figure 6.1 Quality assurance at chain level for fish safety and quality



Source: Developed by the author

6.2 Legal aspects of EU markets for food safety and fishery products

This section focuses on the EU legislation concerning food safety and quality as this is the major export market for Vietnam (refer to chapter 2). First, the development of the current EU food safety perspective is described. Next, the regulations and directives of fishery products imported from third countries are analyzed. Finally, the practices at border inspection posts for veterinary control are presented.

6.2.1 Description of the EU food safety perspective

Food safety has become a top priority for the public and the private sector in Europe (Luning et al., 2006). European food legislation has been shaped by a blend of scientific, societal, political and economic forces to establish and maintain a high level of protection of human health (FAO, 2002). This task must be accomplished in such a way that it does not arbitrarily discriminate against any international trading partner (Van Plaggenhoef et al., 2003).

The principle of EU food safety is based on a comprehensive and integrated approach (Knura et al., 2006). This covers the total food chain (from farm to table) across all food sectors to ensure a high level of consumer protection. The farm to table policy is based on the general food law (GFL) and aims to harmonize food safety laws for the EU. The GFL seeks to accomplish three objectives namely (1) to lay down the principles on which modern food legislation should be based in the EU; (2) to establish the European Food Safety Authority; and (3) to establish procedures for reactions to food safety crises including the so-called Rapid Alert systems.

6.2.2 EU legislations governing fishery product safety and quality

The European Commission's Directorate-General for Health and Consumer Protection (DG SANCO) is responsible for food safety in the European Union. The EU import rules for fishery products seek to guarantee that all imports fulfill the same high standards as products from the EU member states with respect to hygiene and consumer safety and quality. The European Union bases its system on government-to-government assurance. Hence, imports of fishery products into the European Union are subject to official certification, which is based on the recognition of the competent authority (CA)¹² of the non-EU country by the European Commission (EC). This formal recognition of the reliability of the CA

¹² Competent authority is responsibility for checking the safety and quality of fish exports

is a pre-requisite for the country to be eligible and authorized to export to the European Union. Key elements include the following:

- The exporting country must be on a positive list of eligible countries for the relevant product.
- The exporting country must have a competent authority (CA) who is responsible for official controls throughout the production chain.
- A control plan on residues of veterinary drugs must be in place to verify compliance with EU requirements for veterinary checks. The often-amended regulation 2377/90 (the MRL regulation) contains procedures for evaluating the safety of veterinary medicines.
- Inspections by the commission's food and veterinary office (FVO) are necessary to confirm compliance with the above requirements. Such an inspection mission is the basis for establishing confidence between the EU commission and the CA of the exporting country.
- Fishery products must be presented at a community border inspection post (BIP) to be submitted to an import control.

The first three elements relate to the procedures exporting countries must implement to fulfill the requirements of the EU market. This process is discussed in section 6.3, in the case of Pangasius export from Vietnam.

The European Union delegates the control of food safety to a CA in each country, who in turn ensures that exporting farms, vessels, and processors are producing safe food under a system equivalent to that in the European Union. EU legislation consists of directives and regulations. A directive is a number of guidelines that can be transformed by member states into national law. In the case of directives, there is some space for adaptation to the specific national situation. EU regulations, on the other hand, are literally taken over by member states.

An EU regulation relevant for the fish chain is the council regulation (EC) No. 2406/96 of November 26, 1996. This regulation lays down common marketing standards for fishery products. It includes requirements on freshness, size, and traceability of products from third countries (CBI, 2001) based on the principles of HACCP: (1) fish products are prepared or processed in certified plants and establishments. The certification process requires that the plant meets minimal requirements in terms of layout, design and construction, and hygiene and sanitation; (2) the industry takes responsibility in fish safety control and implements HACCP based in-plant quality control programs; (3) a regulatory competent authority is in charge of certifying fish plants and establishments, approving and monitoring HACCP-based in-plant quality control programs and certifying fish and fishery products before distribution; (4) where necessary, national surveillance programs of the harvesting areas should be in place to

control the threats of bio-toxins and other biological and chemical pollutants; and (5) an additional control is exercised by the importing party and involves an audit of the national control system of the exporting country to ensure that it meets the requirements of the importing country. This implementation should lead to the signing of mutual recognition agreements between trading countries (source: FAO, 2005).

Third countries are categorized as list I or list II. List I comprises countries and territories that have been approved to export to the European Union following an inspection by the Commission Services. List II comprises countries that have submitted satisfactory dossiers and prepare an inspection by the Commission Services. List II also includes some countries that have received inspections but will remain on list II, pending the receipt of satisfactory guarantees that certain observed deficiencies have been rectified. In addition, imports from third countries must be accompanied by health certificates, and must originate from approved establishments or factory vessels. Approval of establishments by the competent authorities of the third country is a result of compliance with the requirements equivalent to those laid down in the directive. For identification purposes, the exporting firms are given registration numbers. Thus, imports from the third countries carry an identification mark with the license number of the establishment so that the source of the fishery product is easily traced.

Practically, for fishery products, in order to assure consumer safety, only countries whose sanitary control systems have been approved by competent EU-authorities are allowed to export fishery products to the European Union. At the moment, Vietnam is on list I for the harmonized countries (see appendix 6.1) and is able to export to every country in the European Union. EU legislation strives for a quality assurance system that is based on the recognition that microbiological hazards exist at various points in the production and processing of fishery products but that, through a rational approach and by applying the necessary measures is possible to control the hazards. The system's main purpose is to avoid systematic detention, heavy sampling, and laboratory checks at the point of entry in the European Union. Consequently, a shift from traditional end-product inspection and certification to this preventive assurance approach is required. Further, the actual control must take place in the third countries instead of at the point of entry in the European Union. This requirement has various implications for developing countries such as implementing new regulations that will have to be updated regularly, organizing inspection services, improving production procedures.

Although the United States constitutes a minor export market¹³ at the moment, it is important to compare the EU rule with the US requirements as the later market may become more important in the future (see table 6.1).

Table 6.1 Comparison of fish import systems in the EU and the US

Exporter (s)	Importing country or region	
	European Union (EU)	United States (US)
Role of exporting government for exports to the importing country/region	EU certifies a CA in exporting country	Can voluntarily create an agreement with US
Role of exporters for exports to the importing country/region	Apply GMP/HACCP (own checks) to be certified by their own country's CA following physical inspections, documentation review and final product checks.	Apply SSOP/HACCP based program and make necessary documentation available to FDA through importer
Role of importing governments on the importing country/region	Run inspection system to ensure EU legal and technical requirements are met	Run inspection system to ensure US legal and technical requirements are met, but not mandatory as for US
Role of importers in the importing country/region	Has border inspection posts Check GMP/HACCP plans of exporting firms and make them available to FVO inspectors Notify authority of all imports	Has border inspection posts Check SSOP/HACCP plans of exporting firms and make them available to FDA inspectors Notify authority of all imports
Frequency of documentary and identity checks at the border in the importing country/region	All imports	All imports
Frequency of physical checks at the border in the importing country/region	Variable frequency depending on the status of the country of original and company' history	Variable frequency depending on the status of the country of original and company' history
Type of microbiological tests done when required in the importing country/region	At discretion of inspector but includes <i>L. monocytogenes</i> , <i>Salmonella</i> , Faecal coliforms, <i>E.coli</i> , <i>S.aureus</i> , <i>Vibrio</i> spp.	At discretion of inspector but includes <i>Salmonella</i> , Faecal coliforms, <i>E.coli</i> , <i>S.aureus</i> , <i>Vibrio</i> spp.
Type of chemical tests done when required in the importing country/region	At discretion of inspector but includes histamine, heavy metals, veterinary drugs	Includes histamine, heavy metals, veterinary drugs (refer to table 6.5)

Source: adapted from FAO, 2005.

¹³ The reason for this issue is a conflict regarding anti-dumping and the use of the name catfish. Since 2003, the vulnerability of rapid expansion in international markets was illustrated by the anti-dumping case brought against Vietnam in the United States by the Catfish Farmers of America (CFA) in response to the cheap import of *Pangasius* after the normalization of trade relations with Vietnam (Bush et al., 2008). Tariffs between 37% and 65% were placed on Vietnamese exporters-equivalent, it was argued, to the dumping rates. Imports of *Pangasius* to the United States fell by around 50%, at an estimated loss of US\$24 million (Tung et al. 2004). Processing companies responded to the loss of the US market by rapidly diversifying to other export markets in Europe and the ASEAN region. The success of the industry since the anti-dumping case has also led to changes in production practices to comply with international quality standards such as EU countries.

Table 6.1 shows minor differences between the border control systems used by EU and US countries. For example, both markets apply HACCP standards for exporters. Moreover, the type of chemical and microbiological tests is rather similar. NAFIQAVED (2007) revealed that the tests of substances and maximum residue limit (MRL) of Pangasius export to the EU and US markets are the same.

6.2.3 The role of the Food and Veterinary Office (FVO)

As a commission service, the FVO assures that the fishery products placed in EU markets meet hygienic and sanitation conditions at least equivalent to the requirements laid down in the EU legislation (Council Directive 91/494/EEC). It verifies the availability of a fishery legislative in the country, the competency of the CA, and the assurance that the third country is in compliance with the standards in the EU directive. The task of the FVO is not to evaluate the performance of processing plants, but to assess and report whether relevant authorities in third countries meet their responsibilities in ensuring that legislation is properly implemented in their territories. The FVO will conduct on-site inspections of fishery processors and the fish safety system administered by the third government periodically. During the inspection visits, the FVO will check the control system governing the production of fishery products intended for export to the European Union and the control of veterinary medicinal products that are used to treat fish diseases (EU Commission, 2007).

The findings of each inspection are published in an inspection report. The CA of the country visited is given the opportunity to comment on the report. The FVO makes recommendations to the country's competent authority to deal with any shortcomings revealed during the inspections. The competent authority is asked to present an action plan to the FVO on how it intends to address the shortcomings. Together with other commission services, the FVO evaluates this action plan and monitors its implementation through a number of follow-up activities.

FVO inspection missions are currently undertaken in all exporting countries and are the basis for establishing confidence between the EU Commission and the CA of the exporting country. All inspection visit reports are publicly available and published on the FVO Website. The mission of the FVO was carried out in Vietnam from September 27 to October 8, 2007. The object of this mission was to evaluate the control system governing the production of fishery products intended for export to the European Union. The result of this mission is discussed in section 6.3.2.

6.2.4 EU border control practices

As described by DG SANCO, all fishery products imported from third countries must be inspected by a border inspection post (BIP). One of the seven approved BIPs in the Netherlands is Eurofrigo in Rotterdam. Eurofrigo inspects imported containers with fish, meat, vegetables, fruit and plant products. With its long experience in handling imported products, Eurofrigo is able to carry out such inspections quickly and cost-effectively for its customers. We conducted a desk survey at this BIP to analyze how import regulations in Rotterdam influence quality assurance of Pangasius products from Vietnam.

The structure of the inspection service at the Eurofrigo port consists of two parts: the quality assurance office and the laboratories. The quality assurance office performs internal audits on documents. The laboratories deal with physical tests.

- The documentary check is carried out on all consignments. It involves checking the health certificate (see appendix 6.2) accompanying the fishery products. These include requirements of an approved country¹⁴, a published list with recognized companies¹⁵, a health certificate, and an analysis report that issued by the CA (NAFIQAVED). A Pangasius consignment passes the documentary check if all documentation is a properly filled out and issued by the EU-recognized CA in the country of origin (NAFIQAVED for Vietnam, see appendix 6.3).

- The identity check is also carried out on all consignments. It involves checking that the data on the certificate are consistent with the imported product. Also checked are the seal and health marks identifying the country and establishment of origin. Moreover, the name of the importer is also checked (table 6.2).

- In principle, a physical check is required for all consignments.¹⁶ However, as Pangasius products are fully harmonized with the import rules of the European Union, the physical check is carried out on a sample. The size of the sample varies according to the product and country of origin (see table 6.3). The

¹⁴ Approved country is a country whose sanitary control system has been approved by the EU's competent authorities and allowed to export fishery products to the EU.

¹⁵ The EU publishes a list of processing companies on list I countries that can export to every country in the EU. Each approved company has an EU code that can trace the products from the relevant companies

¹⁶ A consignment is defined as a quantity of products of the same type covered by one health certificate, conveyed by the same transport and from the same third country. A separate health certificate is required for each consignment and must be submitted by the importer or agent to the BIP.

Table 6.2 Consignment checks at EU borders

Consignments that do not arrive in containers	Check on some packages to ensure that the stamps, official marks, and health marks identifying the country and establishment of origin are present and conform to those on the certificate or document.
Consignments that arrive in containers with official seals	Documentary and identity checks for all consignments; some may not need to be opened in order to complete an identity check provided official seals have been used in the country of dispatch and the seal numbers are clearly recorded in official veterinary certification.
Consignments that arrive in containers with no official seals	If official seals have not been used, or there is doubt over whether the seal number was recorded by the certifying veterinarian, the container would need to be opened and a check made on the packages therein to ensure that the stamps, health marks and other marks identifying the country and establishment of origin are present and conform to those on the certificate or document.

Source: Council directive 97/78/EC.

purpose of the physical check is to ensure that the product still complies with the regulatory requirements. The detailed rules for physical checks on products exported to the EU were presented in the decision 94/360/EC.

Table 6.3 Summary of physical checks at BIPs

Category I – 20% of consignments of:

Fish products in hermetically sealed containers (stable at ambient temperature), fresh/frozen fish, dried/salted fishery products

Category II - 50% of consignments of:

Other fishery products other than those in Category I and bivalve molluscs

Category III – minimum 1% - maximum 10% of all consignments of:

No fish products in this category

Source: Decision 94/360/EC.

Pangasius products belong to category I. Laboratory staff check the veterinary specifications as mentioned in the health certificate provided by NAFIQAVED in Vietnam (Regulation 854/2004/EC). Once a physical check has been completed, the inspectors reseal the container with a BIP seal. But, if the consignment fails the physical checks for any reason, then the official inspector will destroy or send back the products. If the consignment is sent back to the

export country, other Community BIPs are notified by the EU RASFF (Rapid Alert System for Food and Feed) to prevent illegal re-entry of the consignment.

6.2.5 Rapid Alert Systems for Food and Feed

The Rapid Alert System for Food and Feed (RASFF) is a tool that the EU uses to enable the quick and effective exchange of information between member states. The legal basis of the RASFF is found in article 50 of regulation 178/2002/EC. It has become an indispensable tool for protecting and reassuring European consumers. If food safety problems are identified, information about the product and the country of origin are transmitted immediately throughout the European Union. Exporters with an EU approval code that appear in the RASFF system may be removed from the published list of EU-approved establishments.

The CA of the country of origin must make a full investigation and report back to the European Union to avoid recurrences. The European Union publishes a yearly report on RASFF, providing data on the number of notifications received during the year, as well as details on the origin of the notifications, the products and countries involved, and the identified risks. As of May 26, 2003, the European Union began posting a weekly internet report with information on all notifications from the RASFF (<http://europa.eu.int/comm/food/food/rapidalert>).

Prior to 2001, the main quality problems in fishery products exported to the European Union concerned mercury and cadmium of the cases in 1999 and 2000 (table 6.4). However, in 2001 and 2002, three new chemical agents appeared: Chloramphenicol, Nitrofurantoin, and Malachite green. Nitrofurantoin and Chloramphenicol are broad-spectrum antibiotics widely used to control and treat infections in fish farms (Dung, 2008). However, due to their toxic character, their use is prohibited in the European Union. Malachite green is a fungicidal dye with pharmacological activity whose use as a veterinary medicinal product for food-producing animals is not authorized in the community. The reason for this sudden and steep increase of these three veterinary drugs is due to rigorous testing regimes imposed in 2001 and 2002 on seafood imports from various Southeast Asian countries by the European Union (FAO, 2005).

The data from 1999-2006 show that cases of violation resulting from microbiological and antibiotic residues occurred in the EU market. As a result, the EU importers began to regularly test the antibiotic residues of final products to ensure the high level of human health and consumer protection. The antibiotic residues are mostly caused by using veterinary drugs and feed used for fish disease treatment. From the perspective of quality management, fish disease treatment is a focal issue of quality control at the farm level. Awareness about

fish disease and treatment results in the increase of production cost and prompts importing countries to ban products found with traces of banned chemicals or drugs by importing countries.

Table 6.4 The main reasons of fishery products rejected from 1999-2006 at the EU BIPs

Causes of fish rejection	1999	2000	2001	2002	2003	2004	2005	2006	Total
Microbiological	56	46	46	49	98	161	160	32	648
Micro organisms	-	-	-	-	27	20	18	5	70
V.parahaemoliticus	13	10	19	15	22	38	12	-	109
V.cholerae	9	8	9	6	5	11	13	1	62
Enterobacteria	6	2	4	6	6	-	13	-	37
S.aureus	7	-	-	-	1	1	1	-	10
Listeria	-	-	-	-	15	41	51	7	114
Total plate count	1	8	4	7	1	2	2	1	26
Salmonella	20	18	10	15	18	26	29	4	140
E.coli	-	-	-	-	3	22	21	14	60
Antibiotic residues	31	27	66	245	160	205	264	252	1250
Chloramphenicol	-	-	44	102	10	12	2	5	175
Nitrofurantoin	-	-	-	89	25	21	36	57	228
Malachite green	-	-	-	1	10	11	50	17	89
Mercury	14	11	11	19	18	45	46	71	235
Cadmium	12	7	5	12	52	43	43	27	201
Histamine	4	8	1	3	15	39	21	11	102
Polyaromatic Hydrocarbons	-	-	3	11	12	2	4	40	72
Food additive	1	1	2	9	5	18	4	3	43
Lead	-	-	-	3	10	1	1	1	16
Carbon monoxide	-	-	-	-	3	13	57	20	93
Total	87	73	112	294	258	366	424	284	1898

Source: EU RASFF report (2000 - 2007).

According to the latest RASFF report in 2007, there were fewer RASFF notifications for residues in fishery products than in the years before. However, Chloramphenicol, Nitrofurantoin and Metabolites, and Malachite green still represent the biggest portion of rejected fishery products imported from the Asian countries such as China, Thailand, and Vietnam (RASFF report 2007). As these veterinary drugs are also used for Pangasius disease treatment (refer to chapter 9), it is not surprising that in 2007, Vietnam had four RASFF notifications related to the presence of residues of these drugs in Pangasius. Four RASFFs is a small figure compared to 7,000 shipments (VASEP, 2008) of Pangasius export to the EU; however, the quality assurance system of testing fish quality of Vietnam still needs improvement.

6.2.6 Importers' requirements and their effect on other chain members

Importers may require additional standards dependent on the specific market niche they are targeting. Importers who sell to low-price supermarkets and market vendors place a strong emphasis on price, while importers who sell to bio-stores or up-market supermarkets require additional private quality standards (Trienekens and Zubier, 2008). Examples of these private quality standards are EUREP-GAP and organic standard.

*Eurep-GAP is a certification system developed in 2000 by the Euro-Retailer Produce Working Group (EUREP) to guarantee environment-friendly safety and high-quality products. The GAP acronym stands for Good Agricultural Practice. The practice pays major attention to food safety, human resource management, and environmental measurements and it targets primary producers. Eurep-GAP offers a series of standards covering GAP in the agro-food industry. The Eurep-GAP system was introduced and fully developed in the fruit and vegetable market, but was later expanded to other sectors like flowers and ornamentals, meat and fish (Van Plaggenhoef et al., 2003).

The Eurep-GAP standards are more rigid than the EU government demands (see box 6.1 for details of Eurep-GAP requirements). Eurep-GAP supports the use of HACCP and members are obliged to comply with EU legislation. Moreover, primary producers must show commitment to issues such as reduction of environmental damage and drug use, and efficient use of natural resources, health and safety for employees, and traceability efforts (Van Plaggenhoef, 2007). One disadvantage of Eurep-GAP is that it takes the legislation of the country where it is implemented as a starting point, and that there is still no uniform certification scheme. As a result, Eurep-GAP implementation can differ from country to country (Trienekens and Zuurbier, 2008). The complete checklist of all the criteria and extensive information about Eurep-GAP is available at www.eurepgap.org. At the moment, the first draft of the Pangasius Global-GAP¹⁷ standards was trial-audited in Vietnam in May 2008, and was submitted for a second round of public comments in 2009; it remains to be seen how it will be accepted on the ground in Vietnam (VASEP, 2009). However, Global-GAP Pangasius is almost entirely a paper exercise, which makes it difficult for small-scale farmers in the MRD to access due to the requirements of large certification schemes that exclude local knowledge from formulation of quality standards (expert interview, 2009).

¹⁷ GLOBAL-GAP (formerly known as EUREP-GAP) is an internationally used management system for Good Agricultural Practice (GAP).

Box 6.1 Typical Eurep-GAP requirements for fish

- Traceability of products up to the farm (a documented system is required)
- Record keeping of farm activities (to be stored for two years)
- Record keeping of brood stocks (e.g., quality certificates of fingerlings, nursery stock health certificates)
- Record-keeping of site history and site management (e.g., site characteristics, crop rotation)
- Record-keeping of feed usage, chemical usage, veterinary drugs usage (e.g., type, quantities, applications)
- Record-keeping of irrigation activities (quality and supply of water documents)
- Record-keeping of harvesting activities (documented records on operations)
- Waste and pollution management (types, quantities, recycling plan)
- Attention to worker health, safety, and welfare (e.g., first aid boxes, training records)
- Attention to environmental issues (e.g., dealing with biodiversity management)
- Internal audit (one internal audit against the Eurep-GAP standard every year, Eurep-GAP checklist).

***Organic standard**

The organic association Naturland has already developed a standard for organic aquaculture. Naturland e.V. is a German non-profit organization that was established in 1982 to promote certified organic food production. Its key activity is the development of standards and the certification of qualified products. To deliver organic quality to the customer, the whole chain must be monitored. This is the responsibility of Naturland. Organic labeling does offer a price premium that might cover the extra costs involved with the implementation of the extra quality management in the value chain. Currently, organic cod, salmon, and pangasius are sold on the German market. The prices of conventional and organic fish are respectively around 15-37 Euros (cod), 12.50-39 Euros (salmon), and 12-34 Euros (Pangasius) (www.eismann.de). There is a significant price premium for organic fish, which could create opportunities for investment. The organic standards are also more rigid than the EU government demands (see box 6.2). The standards require that primary producers following an organic production process: certified organic fingerlings, low stocking densities, certified organic feed, forbidden the use of chemicals, and set guidelines for the protection of nature and animals. In addition, the operations must sustain social standards.

Box 6.2 Typical organic requirements for fish

- Traceability of products up to the farm (a documented system is required)
- Record-keeping of farm activities (to be stored for two years)
- Record-keeping of brood stocks (e.g., organic quality certificates of fingerlings, at least two-thirds of their lives accordance with Naturland standards)
- Laboratory antibiotic fingerling analysis
- Record-keeping of site history and site management (e.g., site characteristics, crop rotation)
- Laboratory analysis of the pond (water and sediment)
- Record-keeping of organic feed usage (e.g., type, quantities, applications)
- No chemical or veterinary drugs usage
- Record-keeping of irrigation activities (quality and supply of water documents)
- Waste and pollution management (types, quantities, recycling plan)
- Settlement pond for water treatment
- Laboratory analysis of fish one or three weeks before harvest
- Attention to worker health, safety, and welfare (e.g., first-aid boxes; separate housing and toilet; mandatory contract, insurance, and organic training for all employees)
- Weekly report (feed usage, mortality, operations, etc.)
- Record-keeping of harvesting activities (documented records on operations)
- Internal audit (one internal audit against the organic standard every year, organic checklist).

At the present time, only two *Pangasius* farms have supplied close to 600 tonnes of organic *Pangasius* to the Germany market through an exclusive contract by a German seafood company. However, this niche market is not accessible to traditional smallholders due to high-quality requirements and huge investment costs (Niels, 2007).

In summary, compliance with HACCP (hygiene regulations) is mandatory for fish processing operators. Moreover, in practice, the retailers require the additional implementation of the private retail standards such as Eurep-GAP or organic. These private standards constitute major challenges for small-scale producers due to the requirements of many investments and high auditing costs.

6.3 Quality assurance regulations and systems for fish export in Vietnam

This section deals with the role of various actors involved in the *Pangasius* production chain for fish safety. It provides first a general overview of the export market requirements for quality assurance. Subsequently, the role of NAFIQAVED for fish exports to the European Union is discussed.

6.3.1 Vietnamese institutions for fish safety

In the beginning of 2007 Russia suspended its imports of Pangasius because of the inaccurate packaging and high-residue contents, and in addition, the United States and the European Union have intensified their alert systems. MARD recently announced that it will focus on control of antibiotic residues in raw material. A new agency will be established that is responsible for managing quality, hygiene, and food safety for the whole agriculture industry. MARD also ordered provincial authorities to avoid increasing volume and to focus on improving the quality of Pangasius products.

Pangasius products for export must be produced in accordance with importing countries' requirements and international standards such as Codex and White Paper of EU regarding safety of food for the entire production from farm to table. Development and implementation of Good Aquaculture Practices (GAP) and Hazard Analysis Critical Control Point (HACCP) are required in the fish supply chain. MOFI set up NAFIQAVED as the CA in Vietnam to enforce fishery product regulations and deal with RASFF notifications (e.g., pesticides, heavy metal, antibiotics, hormones, and other veterinary drugs or animal feed additives).

6.3.2 The role of National Fisheries Quality Assurance and Veterinary Directorate (NAFIQAVED) for fish quality issues

Under MOFI, NAFIQAVED is responsible for implementing quality management. They deal with local governments, provincial aquacultural departments, processing/export companies and other relevant institutions and organizations. Moreover, NAFIQAVED is responsible for the certification and supervision of processing plants for exports to the EU (FVO report, 2007).

NAFIQAVED inspects fish quality and promotes research and training activities so that exports fulfill EU requirements. NAFIQAVED collaborates with international agencies and authorities in importing countries to create confidence in fishery products and to upgrade the quality control systems. Following their belief that "quality is made, not inspected," the organization establishes and improves training programs for personnel performing activities that affects quality and safety in the production, harvesting, processing, and marketing of fishery products. These activities are managed by the Post Harvest Research, Standards and Training Unit. The training is mainly on farming techniques and fish health management. For example, roughly 300 training courses organized in

An Giang, Can Tho, and Dong Thap in 2007 with a total of 10,000 farmers participating (source: DARD, 2008). Whenever there is a change in the standard regulations of the importing countries, the unit is responsible for informing the relevant bodies. The quality manuals set by the processing firms are controlled and evaluated by this unit of the division. The unit also administered training programs to fish inspectors, quality controllers, and traders on implementation of the HACCP principles and Codes of Best Practices.

At the farm level, NAFIQAVED supervises and deals with violations of fish hygiene and safety monthly. NAFIAQVED has conducted a residue-monitoring program for certain harmful substances in Pangasius since 2003. Each month, NAFIQAVED randomly takes samples of Pangasius in culture areas such as An Giang, Can Tho, and Dong Thap provinces. If antibiotic residues are detected, the farm is required to take action. For example, two samples of Pangasius in CanTho were found to contain Chloramphenicol in February, 2009. NAFIQAVED supplies processing/export firms with the list of farms that violated the rules and publishes a monthly report on antibiotic residue testing (notifications of monthly and annually monitoring results are uploaded to the Website www.nafiqad.gov.vn). Next, NAFIQAVED conducts other tests in this region that include fish samples, feed samples, and veterinary drugs samples. If antibiotic residues are still discovered after a second test, NAFIQAVED urges the processing/export firms not to purchase fish from these farms, and the farms are fined.

Presently, the NAFIQAVED has a plan to implement a traceability system for Pangasius which will give each farm a code for product traceability (NAFIQAVED, 2009). The farms are required to keep records of all inputs such as fingerlings, feeds, veterinary drugs, and environmental treatment substances. The system will be available for fulfilment of the EU traceability directive to Pangasius products in the future.

Every year, NAFIQAVED prepares the aquaculture plan based on the results from previous years (in residue testing reports), test results from importing countries (in RASFF reports), and information on the usage of veterinary drugs (in the testing results of veterinary drug agents) from local authorities such as departments of fishery in the country are taken into account. The plan is approved by the MOFI at the beginning of each year and is submitted to the EU commission concerning the export of fishery products as along with a complete report on the functioning of its controlling authority and the infrastructure within which it operates.

Extensive pre-export testing for residues in Pangasius products is conducted by the NAFIQAVED. Currently, no specific food safety standards or import

requirements exist that would apply specifically to Pangasius from Vietnam; only requirements for fishery products in general exist (EU fish legislation). According to a NAFIQAVED expert (2008), the consignments meant to be exported to the European Union are tested for the criteria/ parameters described in table 6.5. These criteria are based on the regulation 854/2004/EC in chapter 2 of annex 3 for fishery products.

Table 6.5 Provisions of the National Legislation standards used for exports of fishery products to the EU

COMMUNITY LEGISLATION		NATIONAL LEGISLATION/ STANDARD	Testing bases
Regulation (EC) No 854/2004 of the European Parliament and of the council laying down specific rules for the organization of official controls on products of animal origin intended for human consumption.	Annex III		
Official controls of fishery products	Chapter II		
Organoleptic examinations	Chapter II.A	- Decision No.153/QD-CLTY of July 6, 2007 of NAFIQAVED Director Genral laying down temporary procedures for sampling of fishery consignments	Random checks were carried out to check compliance with the freshness criteria laid down in Community legislation. Where there is doubt as to the freshness of the products, the organoleptic examination must be repeated
Freshness indicators (TVB-N & TMA-N)	Chapter II.B	- Decision No.153/QD-CLTY of July 6, 2007 of NAFIQAVED Director Genral laying down temporary procedures for sampling of fishery consignments	Where the organoleptic examination reveals any doubt as to the freshness of the fishery products, samples may be taken and subjected to laboratory tests to determine the levels of TVB-N. The TVB-N levels and the methods of analysis to be used shall be those specified in Commission Decision 95/149/EC of March 8, 1995, fixing the total volatile basic nitrogen (TVB-N) limit values for certain categories of fishery products and specifying the analysis methods to be used

Table 6.5 (cont.)			
COMMUNITY LEGISLATION		NATIONAL LEGISLATION/ STANDARD	Testing bases
Histamine testing	Chapter II.C	- Decision No.153/QD-CLTY of July 6, 2007 of NAFIQAVED Director Genral laying down temporary procedures for sampling of fishery consignments	Random testing for histamine The level of histamine in certain fishery products must be within the following limits in nine samples taken from a batch: - the mean value must not exceed 100 ppm, - two samples may have a value exceeding 100 ppm but not more than 200 ppm, - no sample may have a value exceeding 200 ppm.
Testing for residues and contaminants	Chapter II.D	- Decision No.153/QD-CLTY of July 6, 2007 of NAFIQAVED Director	Mecury, Led, Cadmium Dioxins Polycyclic Aromatic Hydrocarbons (PAH)
Microbiological checks	Chapter II.E	- Decision No.153/QD-CLTY of July 6, 2007 of NAFIQAVED Director	Chloramphenicol, metabolites of Nitrofurans, Malachite green: zero tolerance
Parasites testing	Chapter II.F	- Decision No.153/QD-CLTY of July 6, 2007 of NAFIQAVED Director	Total plate count (CFU/g) <2,5.10 ³ Faecal Coliforms (CFU/g) <10 Samonella ND Staphylococcus aureus (CFU/g)<10 Vibrio spp ND
Poisonous fishery products	Chapter II.G	- Decision No.153/QD-CLTY of July 6, 2007 of NAFIQAVED Director	Will be carried out, depending on risky species

Source: NAFIQAVED report to EU, 2007.

In setting up these criteria, NAFIQAVED followed the Council Directive 91/493/EEC which records health conditions for the production and sale of fishery products. The directive prescribes criteria for organoleptic quality, parasites, chemical checks (TVB-N, histamine and chemical contaminants) and microbiological analysis, including sampling plans and methods of analysis. Regulation 854/2004/EC of the European Parliament and the council records specific rules for the organization of official controls on products of animal origin intended for human consumption. Table 6.5 shows how national regulations and standards implemented by NAFIQAVED comply with EU standards.

According to NAFIQAVED (2007), every batch¹⁸ of Pangasius intended for export to the EU is tested for these criteria listed in table 6.5. A minimum of two samples per batch is taken and analyzed in the regional NAFIQAVED laboratories. According to certification procedures, for every Pangasius batch, the NAFIQAVED inspector must verify the production records including the inspection record of raw materials used (see box 8 in appendix 7.1). The inspector provides verifying records of all information necessary to certify as official (source: NAFIQAVED response to the FVO mission report, 2007). The test results are then conveyed to the processing/export firms, as well as reported to the MOFI (NAFIQAVED report, 2007).

The evaluation report of the FVO mission (2007) concluded that the provisions implemented are considered equivalent to the EU legislation and particularly to Council Directive 91/493/EEC (health conditions for the production), Council Directive 92/48/EEC (hygiene rules on fishing vessels), Commission Decision 93/140/EEC (parasite checks) and Commission Decision 94/356/EC (company's own health checks). MOFI and MARD possess list of banned and restricted chemicals/antibiotics according to the EU regulation (see appendix 6.4 and 6.5 for details). However, veterinary medicinal products are freely available for purchase without prescription, and the labels for medicines do not contain all the relevant data (FVO final report, 2007). These incidents are the major causes of antibiotic residues in Pangasius products, making the control of proper veterinary drugs for Pangasius difficult (refer to chapter 9 and 6.2.1). Moreover, the FVO team observed that the records of medical treatment, kept on the Pangasius farms show inefficiencies regarding the use of veterinary drugs. These inefficiencies are typical for the Pangasius independent farmers who use veterinary drugs for fish disease treatment without proper record-recording. At the present, extensive additional pre-export testing by the authorities for Pangasius products increases confidence in the quality assurance system (NAFIQAVED, 2008). Chapter describes the role of processing/export firms in the quality assurance chain. Table 6.6 shows the response of NAFIQAVED for the comments of FVO.

¹⁸ Batch is a quantity fish of each farm and each farm have a batch code (refer to box 8 in appendix 7.1)

Table 6.6 Deficiency observed by the FVO and the response given by the NAFIQAVED

Comments of FVO	Response of NAFIQAVED
<p>Legislation</p> <p>The CA should ensure that the current standards applied to the export FP to the EU ensures full equivalence with community standards on hygiene (Regulations [EC] No 852/2004 and [EC] No. 853/2004).</p> <p>Official control of fishery products</p> <ul style="list-style-type: none"> - The CA should ensure that FPs intended for export to the EU are landed only at landing sites that are officially controlled in accordance with Regulation (EC) No. 854/2004 and provide public health guarantees at least equivalent to Regulations (EC) No. 852/2004. - The CA should ensure that fishing vessels and freezer vessels providing FPs to EU-approved establishments are officially controlled in accordance with Regulation (EC) No 854/2004 and provide public health guarantees at least equivalent to Regulation (EC) No. 852/2004. - In the context of the export of FP to the EU, the CA should ensure that official controls on FPs exported to the EU are carried out in order to provide standards at least equivalent to the ones listed in Regulation (EC) No. 854/2004, in particular: <ul style="list-style-type: none"> • Organoleptic checks (Regulation (EC) No 854/2004, annex III, chapter II, A); • Contaminants (Regulation (EC) No. 854/2004, annex III, chapter II, D, and Regulation (EC) No. 1881/2006) - In the context of the export of FPs to the EU, the CA should ensure that FP establishments approved for export to the EU, together with any establishment handling raw material of animal origin used in the manufacture of FP, comply with community requirements, as foreseen in Article 12, 2), a) of Regulation (EC) No. 854/2004. - The CA should ensure that only those establishments in compliance with community requirements are kept on the list for export to the EU, and approved only for their relevant activities, in accordance with Articles 3, a), and 12, 2) and 3) of Regulation (EC) No. 854/2004. 	<p>Some regulations and requirements not fully in compliance with Regulations (EC) No. 852/2004 and (EC) No. 853/2004 will be modified as follows:</p> <ul style="list-style-type: none"> - Checklists are modifying in accordance with revised EC and Vietnam regulations. The modified checklist will be disseminated for application in 2008. - In 2008, NAFIQAVED will provide more training for local competent authorities and strictly monitor their activities so that 100% of fishing ports, and landing sites (including the ones of middlemen or processing establishment) supplying for export to the EU will be inspected. - Capabilities of local CA will be strengthened so that they can carry out control of fishing vessels supplying raw materials to EU approved establishments in accordance with relevant EC regulation. - It will be regulated that if any suspicious on freshness of the product occurs during the fishing port inspection, the Competent Authority must take samples of the product to test TVBN and TMAN parameters. • Certain contaminants (such as PAH, Dioxin, PCBs) will be added in the sampling plan of post-harvested fishery products. - Establishment handling raw material (Middlemen) for supplying raw materials to EU approved establishments will be inspected in compliance with EU regulations. - Continuing to suspend the certification of consignment intended to export to the EU in case the establishment does not apply appropriate corrective actions, leading to be at C and D category. NAFIQAVED inspectors will give a deadline for corrective actions. In case the establishment does not meet the deadline, it will be removed from the list of EU-approved establishments.

Table 6.6 (cont.)

Comments of FVO	Response of NAFIQAVED
<p>Laboratories</p> <p>- The CA should ensure that laboratories responsible for official controls and monitoring for fishery products are reliable, and to this end are assessed and accredited (for all the analyses concerned) in accordance with standards providing guarantees at least equivalent to the requirements of Article 12 of Regulation (EC) No 882/ 2004, taking into account Article 18 of Regulation (EC) No 2076/2005 and carry out proficiency tests</p> <p>- The CA should ensure that laboratory methods and results of marine biotoxins analyses are in line with Regulation (EC) No 2074/2005, annex III, chapter III on lipophilic toxins detection methods</p>	<p>- In January 2008, all NAFIQAVED laboratories will be reassessed by VILAS for accredited parameters. Moreover, some new parameters (including <i>E. Coli</i> MPN/100g as recommended by the MT) have also been registered by NAFIQAVED laboratories for accreditation</p> <p>- In 2008, NAFIQAVED laboratories have planed to take part in international proficiency tests for some microbiological parameters (including <i>Salmonella</i> spp., and <i>E. Coli</i>), and organize internal proficiency tests for histamine, veterinary drugs (tetracycline compounds, MG/MLG), and others biotoxin parameters (ASP, PSP and lipophilic toxins) as recommended by the MT.</p> <p>- With the EU support, in November 2007 NAFIQAVED has organized, in coordination with APRIS II, the workshop on ASEAN Reference Laboratories (ARL) for fishery products. At the workshop, one NAFIQAVED laboratory was appointed as ARL for toxic phytoplankton and biotoxin. The project on building up and operating this ARL will be started by the end of 2008.</p> <p>- Laboratory methods of NAFIQAVED branches are in compliance with Regulation (EC) No. 2074/2005, annex 3, chapter 3 on lipophilic toxins detection methods. Following the MT's recommendation, NAFIQAVED laboratories changed report form in line with EU regulations.</p>
<p>Health Certification</p> <p>The CA should ensure that certifying officers have a satisfactory knowledge of the specific Community requirements for the export of FPs and are informed as to the rules to be followed for drawing up and issuing the certificates of Regulation (EC) No 2074/2005, in line with Directive 96/93/EC.</p>	<p>NAFIQAVED certifying officials have been trained and have a satisfactory knowledge of the specific Community requirements for the export of FPs. They are also aware of requirements of importing countries with which NAFIQAVED had signed MRAs.</p> <p>According to certification procedures, for every fishery consignment intended to export to the EU, NAFIQAVED inspector must verify whole production records including the inspection record of raw materials used for the consignment production, then the inspector provides verifying records of all that information to certifying official.</p>

Source: Final report of FVO mission to Vietnam, 2007.

6.4 Conclusions

The European Union set up a quality assurance system to protect their markets from unsafe fishery products and to harmonize a level playing field upon which all suppliers (domestic and foreign) face the same requirements. The exports of fishery products to the European Union must meet the EU regulations that determine the conditions for fish imported from third countries. The EU council directive 91/493/EEC urges all fish business to develop an HACCP system. The HACCP-based regulations of importing countries provide working procedures to determine the equivalence of processing conditions and to document the compliance. Vietnam is on list 1, implying that they are allowed to export to the European Union. The competent authority in Vietnam (NAFIQAVED) inspects the exports according to the EU rules and regulations. Despite this organization Vietnam had four RASFF notifications in 2007, which shows that the system still needs improvement. Quality assurance at the export level and in processing firms has met the quality requirements of the European Union. However, no tracking or tracing exists at the farm level. It is important to improve the quality assurance system at the farm level. Currently, some concerns exist in the niche market share (organic) and not yet operated (Eurep-GAP). Moreover, the NAFIQAVED is preparing the traceability system for the future when these systems will become more important.

