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Full Length Research Paper

Food safety regulatory requirements with potential effect on exports of aquaculture products from developing countries to the EU and US

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Aquaculture production presents unique sources of food safety hazards in addition to those common to fish and fishery products and general food stuffs. Hence, its products attract stricter controls in international trade especially in the markets within industrial countries like in the European Union (EU) and the United States (US). Environmental chemical and microbial contamination of fish culture containments, fish infection and disease, use of veterinary drugs, improper use of chemicals, use of genetically modified organisms (GMOs), and improper husbandry and hygiene practices are the major sources of food safety challenges in aquaculture. Most food safety legislations applied in major prime markets of fish like EU and US are aimed at regulating against these challenges, which means that developing countries that do not address these food safety issues may have their access to these markets blocked. Inspection and certification of aquaculture farms and application of Hazard Analysis and Critical Control Points (HACCP) and Good Aquaculture Practices (GAqPs) have been recommended as good approaches for limiting the introduction of potential food hazards in aquaculture products. These approaches are as well incorporated in international regulations and those applying to producers and traders in US and EU to prevent production and trade of unsafe food products. Already most food safety regulatory oversights applied in industrialised countries recognise the concept of equivalence, implying that developing countries that plan to export their products have to comply with the requirements in importing countries. This paper identifies international food safety and other regulatory requirements for production and trade of food from aquaculture and provides an analysis of legislations applied in the European Union (EU) and United States (US) markets that may impact on trade of food of aquaculture origin from developing countries.

Key words: Food safety legislations, aquaculture products, international trade, fish trade regulation, developing counties

INTRODUCTION

The continued growing demand for food fish and fishery products in global markets which cannot be met by products from capture fisheries due to declining stocks has resulted in the increase in aquaculture production worldwide (Josupeit et al., 2001). Approximately 40

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percent of fish produced from both capture fishery and aquaculture are traded across the borders with more than 50% of aquaculture coming from developing countries. This highlights the urgent need for agreed-upon criteria to allow trade to be harmonized between countries and also stresses how any disagreement can lead to negative impacts on exports of developing countries. Generally, food safety in aquaculture like other on-farm operations has in past received limited regulatory oversight (WHO, 1999). However, the recognition that hazards can occur at any stage in the production chain has resulted in many markets developing food safety policies that include the whole food chain from farm to table (Arvanitoyannis et al., 2005; 2006). Many regulatory instruments aimed at controlling food contamination during on-farm operations both for products of animal and plant origin exist in the United States (US) and the European Union (EU) and other industrialized countries.

In principle, it is desirable to have equivalency of national regulations to ensure there are similar levels of protection of consumers within and between trading countries. However, in the past, disagreements on the nature of regulations and standards applied by two potential trade partners have led to food safety- related trade barriers resulting in continuing disputes and legal challenges at the international level. The World Trade Organization (WTO) established the Sanitary and Phyto-sanitary Measures Agreement (SPS) to limit these kinds of disputes by requiring scientific rationale and specifically risk assessments to justify the establishment of standards that are more restrictive than for the exporting country. This is further discussed below. Whereas progress has been achieved in implementing food controls in fishery products, much is still needed both at regulatory and operational level in area of food safety management in aquaculture (Howgate et al., 1997; Reilly and Käferstein, 1997; WHO, 1999). Some of the regulatory systems that affect aquaculture are general in nature – general because they are aimed at controlling food safety in all farmed food animals. However, because of its (aquaculture) growing importance in international trade, some aquaculture-specific regulations are emerging to regulate the unique features of aquaculture practice especially by developed countries like in the EU and to some extent the US. Aquaculture is different from wild fish harvesting since the fish are produced under controlled conditions of containment with many feed and chemical inputs added in the production systems such as ponds. Under these conditions, there are unique risks for chemical and microbiological contamination of its products. In addition, once introduced during the fish rearing stage, the hazards may not be eliminated or reduced by the subsequent processes in the chain, and in fact some like the pathogenic micro-organisms may increase the risk of spread. The diverse nature of aquaculture products which span a wide dichotomy of plant and animal kingdom, ranging from aquatic plants such as seaweeds and algae, to vertebrate and non vertebrate animals like echinoderms, molluscs, shellfish, and fish, where each are exposed to different forms of hazards, pose another challenge to food safety management and regulation.

There is also the emerging potential for increasing production through biotechnology which has introduced debate on the safety of genetically modified organisms (GMOs). The novel nature of genetically engineered fish creates significant human health concerns such as allergenicity, toxicity and other unintended effects (Kimbrell and Letterman, 2005). The human health impacts of consuming genetically engineered animals include the possibility of novel genes triggering allergenic reactions to some people among others. There is also fear of increased toxicity to some people since the transgene cannot be “turned off” once it is inserted into the organism. Hence it could result into uncontrolled expression of an existing protein leading to high level of exposure of that protein that may create toxic results (Kimbrell and Letterman, 2005). The inter-relatedness of food safety, animal health and animal welfare, and environmental health issues pose challenges to the food safety control for food products of aquaculture origin. These challenges could serve to justify the need for food legislation that target aquaculture and related animal products.

The modern food legislations especially in Europe and the US have changed food safety management paradigm from routine inspection of food and analysis of end product samples, to proactive prevention programmes. These programmes spread in the entire continuum of the food value chain from primary production, all the way to the food service centres like restaurants. Some of the efforts to spread these programmes have led to the publication ISO 22000:2005 standard on food safety management systems. With ISO 22000:2005, food safety approach has taken a different dimension. There is increasing possibility of food safety programmes like HACCP that were originally considered for the industry and related post harvest operations now being extended to primary production (Arvanitoyannis, 2008). ISO 22000:2005 lays down the food safety management requirements for all types of establishments within the chain including: feed producers, primary producers, food manufacturers, transport and storage operators, subcontractors and retail and service outlets. This standard (ISO 22000) requires implementation of good practices and envisions each type of establishment to define practices that are appropriate to their situations. For aquaculture, these programmes could involve Good Aquaculture Practices (GAqP) as well as Hazard Analysis and Critical Control Point (HACCP) systems which emphasize maintenance of operational records and written standard operating procedures, as the norm has been for post harvest operations. The influence of the media and the agitation of consumer groups in Europe

and other potential markets concerned with food safety and environmental quality have increased requirements for stiffer regulation. And as this agitation continues, more regulatory controls by the authorities in developed country markets are anticipated. This means new requirements like ISO 22000:2005 could soon be mandatory to aquaculture producers. There has been increasing requirements for self regulation in developed country markets like Europe spearheaded by producers and supply chain players who created EurepGAP (now called Global Gap), and set retail industry food standards. However, food scares have also led to increase of government regulatory roles to control food safety, animal health and welfare and environmental issues in aquaculture (FAO, 2006). The emergence of the demand for organic food has introduced another set of voluntary standards increasing the need for oversight over farmers interested in penetrating markets for organically produced aquaculture products. This area is particularly vital to farmers in developing countries especially those in the sub-Saharan Africa region where great potential exists for exploiting organic aquaculture market. In addition, aquaculture food has also to meet all the food safety trade requirements for general foodstuffs.

These several types of regulatory measures in place for aquaculture are meant to improve safety of the aquaculture products. However, they also may negatively impact on trade between developing countries with the partners in industrialised world such as the EU and US, where it has always been presumed that production in some areas of developing countries occurs with minimal regard to food safety. These measures being applied to perishable products which make the majority of food from aquaculture; and more especially being imposed on producers in poor countries where there is shortage of necessary financial capital to install adequate food safety controls, generally pose a huge challenge to developing countries in their effort to exploit the enormous potential for aquaculture production. However, these challenges also provide an opportunity to developing countries to analyse these requirements and develop innovative and home-grown approaches to develop sustainable export revenue from aquaculture; and also ensure the health of their population. There is, therefore, the need to analyze all the international legal requirements to establish those with specific effect on production and trade of aquaculture products to guide countries, especially in the developing world, wishing to access markets in industrialized countries for their products.

METHODOLOGY FOR THE REVIEW

Library searches for relevant information were carried out, e-resources from the internet were accessed and a desk review of literature on international food safety legislation conducted to identify the international food safety regulations and standards related to food generally, fishery products and aquaculture products. The relevant provisions of food safety-related trade controls as provided for in the World Trade Organization's (WTO) Sanitary and Phyto-Sanitary (SPS) measures and Technical Barriers to Trade (TBT) agreements, Food safety requirements as provided by FAO/WHO Codex Alimentarius Commission, and other International recommendations, and EU and US food safety legislations were analyzed to identify contextual issues that could affect their application to international trade related to fishery and aquaculture products. Based on the analysis of various food safety-related requirements, guidance on approaches to the understanding of food safety legislation applied to aquaculture products was found necessary and was also provided. The WTO agreements and/or FAO/WHO guidelines and code of good hygiene practices regarding food safety were analysed to identify specific clauses and sections that affect all the food stuffs generally, food of animal origin, fishery products and those specific for aquaculture products. Likewise food safety laws in the US and the food safety regulations and standards enforced in the US and EU markets were synthesized for clauses or sections that impact on food of animal origin, fishery products, and those specific to food of aquaculture origin. Based on the synthesis of the information on International food safety trade requirements under the WTO agreements and the joint FAO/WHO guidelines, standards, recommendations and code of good hygiene practices, and the US and EU food safety regulation and standards; the linkage between the WTO and FAO food safety requirements was established and analyzed in the context of trade of aquaculture products from developing countries. Also a comparison between the EU and US food safety trade requirements for fish and aquaculture products was analyzed in the context of impact on trade of aquaculture products from the developing countries.

Approaches to Understanding of International Food Safety regulatory Systems for fishery and aquaculture products

At international level, food safety is controlled through the framework of WTO agreements - the relevant ones in this context being the WTO SPS and TBT agreements. These are agreements on food trade with implications on food safety matters. These agreements give recognition of international standards established by international bodies of competences [on food safety - the Joint FAO/WHO Codex Alimetarius Commission CAC); Animal Health – the World Animal Health Organization (WAHO) [or OIE] and Plant Health – the International Plant Protection Committee (IPPC)]. These bodies therefore serve as major regulatory references for trade on specific food safety and any other matters. In the European Union, there is a growing use of the term food safety legislation to mean all the food safety requirements for local and international trade (Lupin, 2000). In this context food safety legislation means the European Commission's (EC) food regulations, directives, decisions, recommendations, code of good practices, officially recognised food standards (voluntary and regulatory) , guidelines, and other food safety related conditions for trade. In the US, food safety generally, is controlled through the Acts of Congress and a number of regulations and administrative procedures and guidelines by US Department of Agriculture (USDA), Food and Drug Administration (FDA) and other federal and state government agencies. Fishery products, especially the imports, are among those that fall under the mandate of FDA.

As regards to fish and aquaculture safety, one has to be cautious about interpreting the regulations that affect the trade in these products especially in the EU market, since the situation has been evolving over several years. Changes in food safety legislation have been continuously introduced as result of food safety crises, emergence of new scientific knowledge about food hazards, or the introduction of new products in the market.

There are several pieces of legislation targeting the diverse aquatic species and associated hazards which are continuously reviewed. Although in many cases the older legislations are repealed in favour of newer ones, in some situations the old and new approaches may co-exist to a certain extent. For instance,

some of the EC Decisions and Directives which have effect on fish or aquaculture products in previous EU legislation were repealed by the new set regulations that have been introduced since 2002. Ordinarily the text of the new food safety regulations which apply to all food stuffs including fish and aquaculture products is the official food safety legislation. Some of the new regulations apply across a wide range of food stuffs. Therefore, in such cases the new regulations most probably will be elaborated and adapted to fish and aquaculture conditions by developing specific guidelines, code of practices, standards and procedures. More implementation procedures are expected to give effect or to articulate the specific provisions dealing with fish or aquaculture under the new food safety regulatory regime. Another feature of EU regulations is that food safety is not treated in isolation from other risk factors associated with fish production and trade. Some food safety regulations for production of food animals include animal health and welfare rules, protection of environment and social responsibility issues.

In the US the situation is a bit confusing. Although the HACCP system regulations for sanitary processing and importation of fish and fishery products is the official "food safety legislation" on matters of fish and aquaculture products, the regulations only apply from the fish processing level. They do not cover aquaculture at all, and therefore, there is nothing to cover the farm-to-table approach. Despite the lack of coverage of aquaculture in HACCP regulations, FDA's hazards and control guidance for fish and fishery products regarding end product testing covers residues in aquaculture and identifies hazards and their control procedures (US FDA, 2001); meaning in effect, that recommendations of HACCP rules could be used to reject or accept aquaculture imports into the US.

Food Safety regulation under the WTO and effect on aquaculture products

The regulatory framework under the World Trade Organization (WTO) affects food of aquaculture origin in the same way they affect products of other food stuffs, especially those of animal origin. From 1986 to 1994, the legal framework for regulating international trade was the General Agreement on Tariffs and Trade (GATT) which resulted from the Uruguay rounds of negotiations (Croome, 1995). Its successor, the WTO, was established on January 1, 1995. The WTO is responsible for the rules of trade and is in charge of monitoring the implementation of the trade rules by member countries. The main WTO agreements that have effect on food safety are the Sanitary and Phyto-Sanitary (SPS) measures and the Technical Barriers to Trade (TBT) agreements. The SPS agreement aims at ensuring that there are no unnecessary barriers to trade resulting from un-harmonised sanitary and hygiene conditions for food, which are the pre-cursor for introduction of food hazards.

The SPS agreement also recognizes the right of countries to protect human, animal and plant life/health through application of standards, provided that the standards are based on science, they are appropriate to the level of risks incurred, and they do not unjustifiably discriminate among different exporting countries. Complaints against a country's perceived discriminatory SPS measures can be brought to the dispute settlement body of WTO. SPS encourages countries to use international standards, guidelines and recommendations, and where they exist the FAO/WHO Codex Alimentarius Commission (CAC) standards are the recognized international food standards.

Although the CAC has functioned as part of the United Nations' Food and Agriculture Organization since 1962, its activities had been of little or more than occasional interest to the international food trade, until recent years. However, with the advent of the World Trade Organization (WTO) and establishment of regional trading blocs, the deliberations of Codex have become significantly more important to the international trade interests of governments (Mansour and Bennett, 2000). Increased interest in the elaboration of Codex standards, guidelines, and recommendations may be attributed to increased international awareness of two very practical functions of the Commission and its numerous committees. First, developing countries lacking both the expertise and financial resources to fully develop food regulatory structures adequate for the protection of public health and the free flow of goods within their own borders have become aware that the guidance and information needed to fill in these regulatory gaps is often made available in the Codex activities and deliberations of delegates from more industrialized nations. Second, both producer and consumer groups have become aware of the role that Codex has been given in the WTO Agreements as the means by which disputes over trade in food products may be resolved (Mansour and Bennett, 2000)

The CAC standards normally relate to food additives, veterinary drugs, pesticide residues, and other chemical and microbiological contaminants, methods of analysis and sampling and guidelines on hygiene practices. The standards, guidelines and recommendations of CAC are voluntary in the sense that, they can have legal value only when incorporated into national regulations. However, the WTO agreement gives these CAC standards a legal weight as they have been scientifically derived and approved by Member States. They can be taken as reference levels for trade in case of international disputes.

The WTO Agreement on technical barriers to trade (TBT) aims at ensuring that the manner in which standards are made is fair to all the parties in both the importing and exporting countries. The TBT was established with the recognition that technical regulations and standards are important, but they can vary from country to country and thus become an impediment to international trade. Therefore, it was meant to harmonize the technical regulations and standards between trading partners to remove trade obstacles that may be related to un harmonized standards, testing and certification procedures. If the standards are set arbitrarily, they could be used as an excuse for protectionism. The TBT Agreement ensures that regulations, standards, testing and certification procedures do not create unnecessary obstacles. The agreement sets out codes of good practice for the preparation, adoption and application of standards by government and non-governmental bodies as means of achievement of harmonized standards. The TBT agreement recognizes countries' rights to adopt the standards they consider appropriate for human, animal, and plant life/ health, and protection of environment and consumer interests. Countries are not prevented from taking measures necessary to ensure their standards are met. In order to prevent too much diversity, the agreement encourages countries to participate in development and to use international standards where these are appropriate, but it does not require them to change the level of protection already set by those standards as a result.

The agreement provides that, the procedures used to decide whether a product conforms with national standards have to be fair and equitable. It discourages any methods that would give domestically produced goods an unfair advantage. The TBT agreement, therefore, encourages countries to recognize each others' testing procedures provided they are established in accordance to international standards. Producers, manufacturers, and exporters need to find information on the latest standards operating in the prospective markets. To help ensure that this information is made available to everyone in need of it, countries are required to establish national enquiry points (WTO/WHO, 2002).

FAO/WHO and CAC Food Safety Requirements for Aquaculture Products

The important element of the SPS agreement is the recognition of the United Nations FAO/WHO CAC standards, guidelines and recommendation as the "International standards" regarding food safety (Josupeit et al., 2001). In case of any disagreements in

international trade, SPS agreement is, therefore, the main anchor for all standards, guidelines and code of good practices developed by CAC.

For the case of fish and aquaculture products, there are three basic CAC instruments that have legal recognition in international trade. The first one is of general nature and is called "Recommended International Code of Practices; General Principles of Food Hygiene" (FAO/WHO, 1997). This instrument includes the HACCP system and guidelines for its application, and is general to all food stuffs, including fish and aquaculture products. The second specific one is the "Code of Good Hygiene Practice for Products from Aquaculture' which is incorporated as section 6 of the 'Code of Practice for Fish and Fishery products' (FAO/WHO, 2003a). The code of practice is based on HACCP general principles and identifies main points within the aquaculture production chain where the food safety hazards are likely to be introduced, and gives technical guidelines for avoiding hazards. The third is the "Code of Good Animal Feeding" (FAO/WHO, 2004) which establishes a feed safety system for producing food animals that covers the entire feed chain, taking into account relevant aspects of animal health and environment in order to minimize the risk to consumer's health.

In addition, a number of CAC committees handle various issues related to food safety that have direct effect on aquaculture products. The deliberations of these committees contribute to setting of international food standards. They include: Committee on Food Hygiene, Committee on Pesticide Residues, Committee on Food additives, and Committee on Veterinary Drug Residues.

The food standards developed by the CAC committees facilitate/assist countries which do not have in place strong regulatory framework for food safety to control problems related to consumer safety and therefore could serve and has been serving, as a major source of reference materials for regulatory agencies in the developing countries. CAC established and provides a forum for discussion and consensus building. Regarding the residues and the residue testing programmes, discussions are derived from two fundamental considerations; consumers concerns regarding the quality of supply, and the requirements imposed for trade. Maximum residue limits are set by the respective CAC expert committees. For fish as food, regulatory initiatives tend to concentrate on residues of veterinary drugs, pesticides and microbial concerns among others (Lima dos Santos, 1996), - the responsible CAC committees being Joint FAO/WHO expert committee on Food Additives (JECFA), Joint FAO/WHO meeting on pesticide residues (JMPR) and Joint FAO/WHO expert meeting on Microbiological Risk assessment (JEMRA). Expert committees are not part of CAC but independent bodies established by FAO and WHO to provide scientific advice to CAC and member governments.In addition FAO and WHO have developed a number of guidelines to assist countries to comply with international requirements of food safety. The guidelines are not mandatory or covered under the SPS criteria and they are not CAC documents. However, they are increasingly taken as reference at national and international level, particularly regarding the aspects of fish and food safety issues (Lupin, 2000). For instance, FAO and WHO have jointly developed guidelines to improve food safety regulators' understanding and use of risk analysis in national food safety frameworks for use by officials at government level (FAO/WHO, 2006). Risk assessment, risk management and risk communication which are the three components of the risk analysis process have already been formalized and incorporated into food regulations of developed country markets like in the EU. The risk analysis approach has gained acceptance as the preferred way to assess the possible links between hazards in food chain and actual cause of ill health related to food safety, and taking into account a wide range of inputs to decision-making on appropriate control measures. When used to establish food standards and other control measures, risk analysis is considered effective by the markets since it fosters comprehensive scientific evaluation, wide stakeholder participation, transparency of the process, consistent treatment of different hazards and systematic decision making by risk managers. Application of risk analysis facilitates trade in foods and existence of those guidelines could help extension of risk analysis principles in primary production operations like aquaculture to enable their access to international markets.

Also FAO/WHO have developed the guidelines for strengthening of national food safety control system which identifies the main components of an effective national food control system. The components include; a national food control legislation that conforms to the principles of good food law for which a model was developed by FAO/WHO in 1976 and reviewed in 2003 (FAO/WHO, 2003); a legally empowered and capacitated competent authority to provide the necessary regulatory and managerial oversights to food safety in the country; an effective inspection service to ensure proper controls on practices of producers and traders; qualified laboratory testing services to check the integrity, quality and safety of produced and traded products; and, a system that ensures proper communication and exchange of information, and education and training of stake holders (FAO/WHO, 2003b).

Specifically concerning aquaculture products, there are several important guidelines developed by FAO and WHO. The first is the "Aquaculture Development - FAO Technical Guidelines for Responsible Fisheries" (FAO, 1997). This was based on the "Code of Conduct for Responsible Fisheries" adopted at FAO 32nd Conference in 1995, which includes one section (No. 9) on aquaculture development. Other FAO and WHO documents relevant to aquaculture products include: FAO Aquaculture Feed Manufacturing Practices - also covered in the Technical Guidelines for Responsible Fisheries (FAO, 2001); FAO/WHO/NACA recommendations of expert panel on food safety issues associated with products from aquaculture (WHO, 1999); and FAO /WHO recommendations of expert panel on Biotechnology and food safety (FAO/WHO, 1996) which is general to all food stuffs, but with relevance to aquaculture.

In the recent times aquaculture safety and certification has been a subject of on-going interest with focus mainly put at obtaining harmonized guidelines for application in production processes to facilitate standard measures in promoting food safety and facilitating smooth trade in the world. In 1999 WHO and FAO in collaboration with the Network of Aquaculture Centres in Asia – Pacific (NACA) organized an expert panel that resulted in the report on food safety issues in aquaculture (WHO, 1999). In 2006 these efforts were re-ignited by FAO/NACA and other donors in a series of meetings and events that culminated into the February 2008 expert panel on development of international guidelines for aquaculture certification (FAO/NACA/SCA/DFID, 2008). Final guidelines have since been issued (FAO, 2009). The guidelines set minimum substantive requirements and criteria for granting certificate of aquaculture system, practices or products. The minimum substantive requirements address food safety, social issues, environmental issues, animal health and welfare. For food safety, they include locating aquaculture facilities where the risk for food hazards is minimized; avoiding feed contamination and selection of appropriate feed and feed additives; use of veterinary drugs and chemicals in accordance with national regulations, control of animal diseases, use of water with appropriate quality for production of safe food; avoiding transfer through carry-over of potential hazards by the fry and fingerlings from other sources to farms; traceability and record keeping for farm activities that impact on food safety; maintenance of aquaculture facilities in good culture and hygienic conditions; implementing residue monitoring programmes; and workers training on good hygiene practices to ensure that they are aware of their roles and responsibility of protecting aquaculture products from contamination and deterioration (FAO, 2009).

Food Safety Regulation in the European Union applied to aquaculture products

EU Food hygiene legislation

Because of the many food safety incidents in Europe, the period after year 2000 has seen rigorous legislative activities in the European Community (EC), resulting in several pieces of legislation being formulated and others repealed to strengthen food safety controls in the European Union. One of the top priority areas was dealing with the several food hygiene Directives which according to the EC made the enforcement difficult due to their diversity (EC, 2000). Overall there were 17 Directives responsible for regulating the hygiene of food of animal origin. Of these, five were for meat products, four for fishery products, three for poultry products, and one each specific for pig meat, dairy and milk products, rabbit and game, wild game and general food hygiene (Arvanitoyannis et al., 2005). In July 2000, the European commission published a package of five (5) measures to update and consolidate the 17 Directives. The package was intended to introduce consistency and clarity for food controls throughout the food chain from "farm-to-fork". The texts of regulations were adopted on 29th April 2004 and published in the official Journal of the European Commission on 30th April 2004 after four years of negotiations. All the five pieces of hygiene legislation came into force on January 2006 (Table.1).

The new EU food hygiene legislation covers all food stuffs from farm-gate to retail. Special provisions, chapters or annexes apply to fishery and aquaculture products, most of them having been pulled from the old fishery-specific legislations. In summary the main features of the new "hygiene package" are: 1) All trading countries outside the EU need to have health and sanitary regulations that are at least equivalent to the ones required within EU; 2) They need to have competent authorities that can guarantee effective implementation of the relevant regulations through inspection, monitoring and certification systems; 3) Business operators need to apply specific sanitary and health practices in producing, handling, processing and packaging food products including fish and fishery products and a system of risk management based on HACCP is mandatory to all other food and feed business operators, but only recommended for those food businesses engaged in primary production such as farming and fishing; and 4) Most food controls applied to food for human consumption also apply to feed for food animals.

Of the regulations in the hygiene package, the farm-to-fork approach is more elaborately presented in the Regulation (EC) 852/2004) which embraces primary production for the first time (Arvanitoyannis et al., 2005). All primary producers have to be registered by the competent authority.

Primary producers (including aquaculture operators) need to follow good practice and manage their operations in accordance to food hygiene requirements set out in the annex of this regulation. Briefly, farm operators are required to put in place measures to control contamination arising from the air, soil, water, feed, fertilizers, veterinary drugs, pesticides, and to ensure proper storage, handling and disposal of waste; facilities used to store and handle feed and other products on-farm have to be kept clean, and to ensure that animal and pests do not contaminate products at the farm; farm operators must keep records relating to measures put in place to control hazards including records on nature and origin of feeds, veterinary drugs, and occurrence of disease; among others.

In practice, the requirements on primary producers amount to mainly following basic hygiene procedures. They need to ensure that hazards are acceptably controlled and respect other existing legislation on hygiene. The regulation does not make it mandatory for primary producers to comply with the HACCP principles but to institute Good Agriculture Practices (GAPs)-[GAqPs in case of aquaculture]. Implementation of HACCP could be done on voluntary basis to the extent possible as a tested means of reducing and eliminating hazards in production chain.

The implication of the Regulation (EC) 852/2004) to aquaculture producers is the need to observe hygiene and sanitation of fish farm premises, adopting Good Aquaculture Practices (GAqPs), implementing written standard sanitation operating procedures (SSOPs), complying with national policy, legal and certification requirements and the implementation of HACCP to the extent possible, especially for the large scale commercial producers. These requirements have for over a decade been emphasized and promoted by retail and wholesalers in Europe under the umbrella organization of EurepGAP (now GlobalGAP) as a voluntary standard for best farm practices. EurepGAP was established in 1996 as an initiative of European retailers and later the producers were involved – [EUroREtailer/Producer (EureP) Good Agricultural Practices (GAP)]. Since September 2007 EurePGAP changed its title and logo to GlobalGAP to reflect its expanding international role. The current specific form of (EurePGAP) standard for aquaculture is the "Control points and criteria for compliance to integrated aquaculture assurance" which was first launched in October 2004, and updated in June 2005 (EurepGAP, 2005). The standard gives whole package for good aquaculture practices covering food safety, environmental safety, workers and animal health and safety, and animal welfare rules.

EU non-hygiene food legislations with effect on food safety and trade of aquaculture product

Apart from the general package of food hygiene regulations, there are other EC regulations, directives, and decisions that address key food safety issues. Some of these apply to general food stuffs, food of animal origin, fishery products and others are specific to aquaculture. They include legislation related to animal health, food contaminants, Genetically Modified (GM) food, organic agriculture, pesticides, microbiology, feed hygiene, and food labelling among others.

EU regulations on aquaculture animal health with potential effect on aquaculture products trade

Prior to year 2005 the rules that were in force in the EU with regard to animal health conditions for aquaculture animals and their products and measures for the combat and control of fish and molluscan diseases were governed by Directives 91/67/EEC , 93/53/EEC and 95/70/EC. This legislation has recently been updated to take into account developments within the industry, acquired experience and scientific progress, and also to bring it into line with international standards and agreements. The European Commission (EC) Council Directive 2006/88/EC of 24 October 2006 was therefore established with intension to repeal and replace these directives from 1 August 2008. In summary, the Directive establishes: animal health requirements for the placing on the market, importation and transit of aquaculture animals and their products; minimum measures to prevent diseases in aquaculture animals and; minimum measures to be taken in response to suspected or established cases of certain diseases in these animals.

The animals concerned are fish, molluscs and crustaceans and their products, not including ornamental animals bred in an aquarium not intended for sale; and wild animals introduced directly into the food chain and animals intended for the production of fish meal, fish oils and similar products. Ornamental animals not in direct contact with natural waters or which live in treated water systems are only concerned by the rules on prevention and treatment of the diseases. The new legislation provides for

Table 1: EU food hygiene legislation

Legislation	Main feature of the controls introduced by the legislation	Description of the main provisions
Regulation 178/2002	Framework regulation establishing basic principles of good food law	Gives the objective (elements) of good food law as providing for: food safety and quality responsibility; protection of human life and health; protection of consumer's interests; protection of animals and environment ; promotion of fair practices in food trade; ensuring effective risk analysis; precautionary measures to protect health of consumers in times of scientific uncertainty; transparency and public consultation during the development of the law; and providing the public with information on food safety risks associated with food and the control measures taken.
	Traceability (Article 18) sets guidelines for establishment of a comprehensive system for traceability of products, recall and withdraw of defective products from the market	All food businesses to maintain documentation of suppliers and buyers (one-step-back, one-step-forward) for food and feed; Need to know the identity of buyers/suppliers (except for final consumers) and what item/batch has been bought or sold; Applies to any substance intended to be or expected to be incorporated into food or feed. Applies to all business operators at all stages of the value chain, including primary producers and transporters; Applies from importer to retail levels in case of products coming from third countries (Article 11) Exporters are not legally required to fulfil traceability requirements, except in case of special bi-lateral agreements for sensitive sectors, or where there is specific EC legal requirement; In practice, food businesses may require trading partners to provide traceability information for the whole value chain in third countries – but this is a matter of contractual obligation not EC regulation.
Regulation 852/2004	Sets general principles of food hygiene to be followed by all food business operators including primary producers	All the food producers in other categories and primary producers for commercial purposes included; Demands application of HACCP Exempts primary producers from HACCP requirements but encourages its application to the extent possible. Primary producers must ensure food is not contaminated with hazards. Primary producers to apply Good Agriculture practices - [GAqPs] in case of aquaculture and comply with basic hygiene rules; Demands registration and /approval of food business by competent authorities. Does not have an extra-territorial dimension and all imported food stuffs have to comply with EC hygiene standards in their production, processing and handling.
Regulation 853/2004	Sets specific hygiene rules for food of animal origin to be carried out by food businesses; Sets implication to third countries and gives general guide lines for approval of	In general, does not apply to primary producers, however it does apply in case of fisheries products; Sets a list of non - European countries from which imports products of animal origin are permitted; The guidelines for approval of third countries include: National legislation, quality of organization of competent authority, inspection,

Table 1 continuation

	imports from third countries; Sets rules on inspection and audits to be done in countries outside the EU that export to the EU; Gives special provisions for fisheries products.	general hygiene situation and experience in exporting. The special provisions for fisheries products (Section V111) include equipments and hygiene conditions on vessels, hygiene during and after landing, hygiene rules for fresh, frozen, processed fishery products, health standards to be matched by fishery business, and rules on wrapping, packaging, storage and transport.
Regulation 854/2004	Sets rules for Official controls of products of animal origin to be carried out by competent authorities, including those in third countries Sets rules for approval of establishments by competent authorities	Gives general provisions for audit of good hygiene practices and HACCP; Special provision for fishery products include: checks on hygiene conditions of landing sites and first points of sale; inspection of vessels, land based establishments, storage, and transport conditions; and Official controls of fishery products which include: organoleptic examinations, freshness indicators, histamine, residues and contaminants, and microbiological checks (where necessary) and parasite.
Regulation 882/2004	Lays out EC's duties in organization of official food and feed controls, includes rules on requirements and activities carried out by the competent authorities; Gives provisions for creation of third country list by EU and lays out rules to be followed by the competent authorities.	All third countries have to undergo a compulsory EU audit and obtain a veterinary certificate; EU inspections can be carried out in non-member countries; Controls by EU will be appropriate to the level of risk; The rules to be followed by the competent authorities include: Having an operational criteria, adequate staffing and equipment, auditing of GHP, GMP, and HACCP, effectiveness, impartiality, contingency plans, delegation to non-governmental and other bodies, transparency, sampling and analysis, pre-export checks from non-member countries, official laboratories, and criteria for certification.

authorisation of aquaculture production businesses and processing establishments by a competent authority

In order to obtain this authorisation, the aquaculture farms and establishments must keep a register that includes details of movements of animals and products, implement the appropriate good hygiene practices and, in the case of fish farms and mollusc farming areas, the Directive requires application of a risk-based animal health surveillance scheme. The Directive provides for a list of exotic and non-exotic diseases and a list of species sensitive to them. The diseases on this list have substantial economic repercussions or an adverse effect on the environment of wild aquatic animals. Exotic diseases are those that are not established in European community aquaculture and whose pathogen is not present in European community waters. These include the following diseases: epizootic haemopoietic necrosis, infection with Bonamia exitiosa, infection with Xenohaliotis californiensis, Taura syndrome, or even yellow head disease. Non-exotic diseases included on the list are: spring viraemia of carp, viral haemorrhagic septicaemia, infectious haemopoietic hecrosis, herpes infection, infectious salmon anaemia, infection with Marteilia refringens, infection with Bonamia ostreae, and white spot disease.

The territory of a State or a part thereof can be declared free of a non-exotic disease if no species sensitive to that disease is present there or if the State has had surveillance and detection measures in place for a sufficiently long period of time. Moreover, the State must also create buffer zones between its territory and the territory of neighbouring states that have not been declared disease-free areas. The European Community draws up, updates and publishes the list of disease-free states and areas. The legislation states animal health requirements for the placing on the market of aquaculture animals and products. It makes provision for general rules for the transport and traceability of animals (animal health certification). It also includes animal health conditions for animals and their products intended for breeding or restocking, with particular reference to whether their region of origin has disease-free status and the obligation in some cases for them to be kept in quarantine. Other specific conditions relate to animals and their products intended for human consumption, particularly their health status, and hygiene in processing and temporary storage establishments. Some rules relate to wild aquatic animals, which must normally spend a period of time in quarantine when they are reintroduced into disease-free areas, and ornamental animals. This Directive also provides for import of aquaculture animals and their products into the EU from third countries. Third countries or parts of third countries authorised to export into the EU must appear on a list drawn up by the EC. These countries or parts of countries are placed on the list once an evaluation has been carried out by the Commission to assess, among other things, the state of health of

aquatic animals there, the legislation of the country in question, and the organization of the relevant local authority and inspection services. EC experts can if necessary carry out on-the-spot inspections to complement the evaluation.

Consignments of imported animals or products must be accompanied by an animal health certificate attesting that the consignments meet Community requirements. The Directive provides for notification and minimum measures for control of diseases. When there is reason to suspect the presence of a disease listed by the EC or when increased mortality occurs in aquatic animals, the responsible authority in the EU Member State must immediately consult with professionals in the field with regard to the health of and trade in the aquatic animals. The affected country must notify the European Community, the other Member States and European Free Trade Association (EFTA) Member States of the presence of a listed exotic disease within 24 hours and of the presence of a listed non-exotic disease if the affected area has been declared free of this disease. The Directive makes provision for measures to be taken in response to the suspected presence of a listed disease, specifically the examination of samples by an authorised laboratory, a ban on movements of aquatic animals into and out of the infected farm and the carrying out of epizootic investigations.

In the event of confirmation of a listed exotic disease, a containment area must be set up around the infected farm, together with a ban on movements of animals. Furthermore, all dead animals, live animals exhibiting clinical signs of the disease and animals which have not reached commercial size and do not exhibit clinical signs of the disease must be removed and disposed of in an appropriate timeframe. The harvesting, catching and subsequent processing of animals may continue once treatment can take place in conditions that prevent the spread of the pathogen. The infected farm may be required to undergo an appropriate period of fallowing.

In the event of confirmation of a listed non-exotic disease in an area declared free of that disease, the affected Member State must either implement the same measures as for contamination with an exotic disease, or apply minimum measures of containment and restriction of movement, and remove and dispose of dead animals.

In the event of suspicion or confirmation of contamination of wild animals with a listed disease, the affected Member State must monitor the situation and implement the necessary measures to prevent the spread of the disease. If an emerging disease develops, the Member State must take the necessary steps to prevent the disease from spreading and inform the EC and the other Member States of the situation. Where necessary, the list of diseases will be amended as a result. Vaccinations are normally prohibited, unless they are part of an EC-approved control and eradication programme, are being used to control an emerging disease, or have been authorized by the EC where the epizootic situation requires it.

EU legislation on Organic Agriculture with effect on food safety and aquaculture products trade

On 28 June 2007 the Council of the EU approved a proposal for a new Regulation, Council Regulation (EC) No. 834/2007 of 28 June 2007 on organic production and labelling, which had been developed since 2005. One of the new features of the current EU legislation, which was missing in the previous versions of legislations dealing with organic agriculture, is the recognition of aquaculture as a potential sector for producing organic products. The new regulation if adequately implemented could particularly have positive impact on aquaculture producers especially in developing countries where significant contamination of soil, water sources and aquaculture inputs with chemical residues arising from fertilizers, agricultural chemicals, chemicals from manufacturing industries and the use of GM products like corn and soya bean in manufacture of feed; has not taken place. The new Regulation improves clarity for both organic farmers and consumers and sets out a complete set of objectives, principles and basic rules for organic production. Under the new regulation, producers of organic food in the EU will be obliged to use the EU organic logo. The EU logo is to be in all cases combined with an indication of origin. At least 95 percent of the agricultural ingredients of the final product will have to be organic for it to be labelled as such. All other final food products produced according to the rules may carry references to organic ingredients in the ingredient list only. The use of GMOs in organic production is completely forbidden. Products containing GMOs will not be able to be labelled as organic, except those containing up to 0.9 percent of GMO residues through accidental contamination. Imports of organic products would be allowed if they come with the same or equivalent guarantees from the country of origin.

The original basic organic agriculture production legislation was introduced on 24 June 1991. Regulation (EEC) No. 2092/91 laid down rules applicable to all EC output of organic crop products only. It regulated: the method of agricultural production, labelling, processing, inspection, marketing of organic products in the EC, and the import of organic products from non-member countries. In 1999, the EC Council adopted another Regulation (EC) No. 1804/1999 of 19 July 1999, which laid down EC rules for the production of organic livestock products and issues such as foodstuffs, disease prevention and veterinary treatments, animal welfare, husbandry practices and the management of manure.

Just like Regulation EEC No. 2092/91, the 1999 Regulation also excluded production using genetically modified organisms and products derived from them and allowed imports of organic products from non- European countries whose production criteria and control systems were recognized as equivalent by the EU.

The current new Regulation which came into force on 1st January 2009 repeals Regulation (EEC) No. 2092/91. The major changes introduced by the new legislation from the old ones are mainly structural but all the technical standards remain. There have been changes in the scope for instance where in addition to aquaculture, wine, seaweed and yeast are now also included in potential organic foods. Food and feed processing is also included meaning that control of organic food is extended beyond the farm. The criteria for substances affecting organic food has changed and labeling of organic food simplified.

The definition and objectives of organic agriculture has now been changed. The new definition alludes to a sustainable management system that respects natural cycles, enhances balance and health, ensures biodiversity, responsible use of energy and natural resources, results in high quality products, meets consumer's demand for wide varieties but ensures responsible processes. The implication is that traditional farming is not regarded as organic agriculture any more. In the new regulation EU organic agriculture logo is applied to both domestically produced and imported products as a simplified way of labelling. The regulation maintains that there must be a list of non-European countries within EC authorized to export to the EU with full compliance requirements respected. The control body for organic agriculture in non-EU country and producers must operate at levels equivalent to EU and a transaction certificate has to be issued to exporters.

EU Legislation on genetically modified organisms with effect on food safety and aquaculture product trade

Although potential is being realized in crops where over 60 million hectares are under cultivation, there has been no commercial development of an aquaculture industry for GMO fish or shellfish (Beardmore and Porter, 2003). There is extensive use of products of biotechnology, but the resulting genetic structure of aquaculture animals in use do not differ from the natural species. More than a

dozen of candidate GM fish species exist in the world and are being researched as potential for fish farming (Kimbrell and Letterman 2005). GMOs offer potential for increased aquaculture fish production to supplement supply from capture sources by culturing species with characteristics suitable for various environmental conditions and regions. With continued research in developing potential commercial species which is likely to result in faster maturing, disease resistant or products that offer characteristics common to species with high demand on market, GMOs are likely to be introduced in aquaculture in near than far future (Kimbrell and Letterman 2005). The GMO risk factors in aquaculture are mainly associated with public health, biodiversity and animal welfare among others which justify the need for regulatory measures (Macklean and Laight, 2000). For the EU market, the concerns have been fear of contaminating natural stocks in environment, and the safety of GMO products. The novel nature of genetically engineered fish creates significant human health concerns, such as allergenicity, toxicity and other unintended effects. The EU food regulations have been revolving around these concerns and mainly focus on restricting introduction of GMO animals for rearing in aquaculture, and possibility of exposure to risks from possible GMO contaminants through farm inputs like feeds. EU legislation that governs all aspects of genetically modified organisms are summarized in Table 2

EU legislation on food contaminants that have effect on aquaculture product trade

EC Council Directive 96/22/EC of 29th April 1996 concerning the prohibition of certain substances for use in stock farming and EC Directive 96/23/EC on measures to monitor certain substances and residues in live animals and animal products on farm are key requirements that affect safety of farm animals including those in aquaculture. The key feature of the two legislations is the determination of compounds or chemical substances that are unauthorized for use in animal production operations which also applies to aquaculture as category A, where no residue traces are allowed in the final products; and those authorized for use in production of food animals, but for which residue levels have to be monitored and controlled (veterinary drugs) as category B1 compounds; and the pesticides and environmental contaminants for which residues have to be monitored as category B2 compounds (Table 3). The maximum residue levels for category B1 compounds are included in Regulation (EEC) No.2377/90 that fixes the Maximum Residue Limits (MRL) for substances of pharmacological use, while B2 compounds are covered by Reg. EC No. 396/2006 (pesticides) and Regulation (EC) No. 1881/2006 (contaminants) which repeals Reg. (EC) 466/2001 that sets maximum levels for certain contaminants including mercury, lead and cadmium in foodstuffs. Regulation (EC) No. 2073/2005 gives the microbiological criteria for food, and therefore has relevance to contaminants in aquaculture as well. The summary of the pieces of legislation related to food contaminants with direct link with aquaculture products as they do with other foodstuffs is presented in table 4.

EU legislation on feed hygiene with effect on aquaculture product trade

There is considerable food safety risk associated with feeds and their sources which potentially affect the final products of farmed animals such as fish that is produced from aquaculture. The EU has taken measures to control the effect of this risk by developing legislations that control potential contamination from feeds and feeding of farmed animals.

Feed hygiene in the EU is currently regulated by Regulation (EC) No. 183/2005 of the European parliament and of council of 12th January 2005. According to the regulation, primary responsibility of feed safety for farmed food animals including aquaculture rests with the feed business operator. The regulation introduced the focus of ensuring feed safety through the entire food chain from primary production up to and including feeding of food producing animals. Feed business operators have to introduce HACCP principles in the feed processing operations and application of good hygiene practices is necessary to reinforce feed business operators responsibility. Microbiological criteria for food are also applied to feed hence the requirements under EC Regulation No.2073/2005 which gives the microbiological criteria for all food have specific effect on feed as well. Same standards applying to feed produced in the EU also apply to imported feed. In order to enhance traceability, the regulation requires all feed establishments to be registered with the responsible agency of government. Because of diversity of feed types and forms, the regulation calls for integrated approach to ensure feed safety especially during primary production of feed. Definition of primary production includes simple physical treatment such as cleaning, packaging, storage, and natural drying among others. It requires that food hazards present at all stages including primary production of feed be identified and adequately controlled. Regulation 183/2005 affects firms that produce feed and those that place feed on the market as well. HACCP in primary production being a midterm objective of EC is encouraged though not yet an obligation and good practice and use of appropriate hygiene requirements are encouraged in animal feed production, as the case is for primary production of food. Feed business operators have to ensure that all production, processing and distribution chain activities for feed are done in accordance with the EU requirements and national law. Farmers have to adopt procedures that keep hazards out of contamination with feed and animals and animal products. Regulation 183/2005 sets out requirements for primary production, transportation, storage and mixing of feed. It also sets out requirements to be observed by feed business operators at other stages other than primary production such as requirements for equipment and facilities for use, production and quality control personnel, storage and transport among others. The regulation also sets good animal feeding practices.

EU food safety and related legislations specific to fish and aquaculture with potential effect on trade

Fish including aquaculture products being among the major food imports of the EU, the EC has issued legislation that are targeted specifically to these products to protect consumers against potential hazards associated with fish. Decision 2003/858/EC lays down conditions and certification requirements for import of live fish, eggs or their gametes for farming and live fish of aquaculture origin intended for consumption. It is concerned with control procedures necessary to avoid spread of fish health pathogens. This Decision requires fish imported from third countries into the EU for further processing to meet the requirements of Directive 91/493/EEC on public health certification [repealed and now replaced by (EC) Council Directive 2006/88/EC of 24 October 2006]. It also states requirements for packaging, labelling and animal health certificate, and requires place of origin to be free of disease listed in Directive 91/67/EC on fish disease on quarantine in EU [also replaced by (EC) Council Directive 2006/88/EC of 24 October 2006]. Territories where live fish is authorized for import to EU (24 countries listed; 50% only allowed for import of carp) are listed. EC Regulation No.2065/2001 gives the information needed to accompany aquaculture and fishery products destined to markets in the EU for traceability purposes. This legislation requires labels on package of fish/aquaculture products to include information on trade names of species, production methods (capture or aquaculture), and country

Table 2: EU Legislation on Genetically Modified Organisms

Legislation	Main focus	Detail
Directive 2001/18	Concerns the deliberate release into the environment of genetically modified organisms	Main legislation which governs experimental releases and placement on the market. Gives conditions in which permission for commercial releases of transgenic organisms into the environment could be given, including limiting the life of permits and requiring monitoring of the impact of the organisms on the environment. Provides a step by step approval process on a case by case assessment of the risks to human health and the environment. (Note) After October 2002, the Directive requires that Member States should ensure labelling of GMOs as or in products. Foods produced from GMOs but no longer containing GMO DNA or protein do not have to be labelled if they are "substantially equivalent
Directive 98/81	Contained use of genetically modified micro-organisms	Regulates the contained use of genetically modified micro-organisms for research and industrial purposes.
Regulation 258/97	Novel Foods and Novel Food Ingredients governing the marketing of GM foods.	Lays out the rules for authorisation and labelling of novel foods including products containing, consisting or produced using GMOs. Requires that all food in which there are detectable levels of genetically modified DNA or protein must go through the full authorisation procedure before being placed on the market. Requires mandatory labelling to indicate the presence of GMOs.
Regulation 1139/98	Labelling of ingredients from GM soya and GM maize	Concerns the labelling of food or food ingredients from one GM soya and one GM maize variety which were authorised under Directive 90/220, before Regulation 258/97 was in place.
Regulation 50/2000	Lays down the requirements for labelling of food and food ingredients containing additives and flavourings from GM sources.	
Regulation 49/2000	Introduces a 1% threshold for the adventitious presence of DNA or protein from GM material in conventional food.	
Regulation 1830/2003	Concerns the traceability and labelling of GMOs and the traceability of food and feed products produced from GMOs.	Aims to ensure a high level of protection of human life and health, animal health and welfare, the environment and consumers' interests in relation to genetically modified food and feed, whilst maintaining the effective functioning of the internal market; Lays down Community procedures for the authorisation and supervision of genetically modified food and feed; Lays down provisions for the labelling of genetically modified food and feed; Lays down procedures on traceability and labelling of GMOs and products produced from GMOs; Extends the labelling requirements to all food and food ingredients produced from GMOs regardless of the detectable presence of DNA or protein with in the final food product; Requires business to transmit and retain information about

Table 2 continuation

		products that contain or are produced from GMOs at all stages of being placed on the market; Covers the labelling provisions to all genetically modified food or feed which consist of, contain or are produced from GMOs. It would not matter whether modified DNA or protein was detectable in the food or feed.
Regulation 1830/2003	Concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms.	
Regulation 1829/2003	On genetically modified food and feed	Covers the labelling provisions to all genetically modified food or feed which consist of, contain or are produced from GMOs. It would not matter whether modified DNA or protein was detectable in the food or feed. There will be a 0.9% threshold for the accidental presence of GM material, below which the labelling of food or feed is not required to declare the presence of GMO's. There will be a 0.5% threshold for the unavoidable presence of GM material not approved for use in the EU, provided it has received a favourable opinion from the EU Scientific Committee.
Regulation 1946/2003	Concerns trans-boundary movements of genetically modified organisms	The Regulation transposes the Cartagena Protocol on Bio-safety into EC law; Requires Member States to take the necessary and appropriate legal, administrative and other measures to implement its obligations under the Protocol; The Regulation covers the procedures necessary for the trans-boundary movement of GMOs, including notification of parties of import, information to the BCH and identification and accompanying documentation standards.
Recommendation 2003/556/EC	Guidelines for the development of national strategies and best practices to ensure the coexistence of genetically Modified crops with conventional and organic farming.	The main objectives behind the Recommendation were: No form of agriculture be it conventional, organic or agriculture using genetically modified organisms (GMOs), should be excluded in the European Union; The European Commission considers that measures for coexistence should be developed and implemented by the Member States; Introduced the concept of coexistence - that in principle farmers should be able to cultivate the types of agricultural crops they choose – recognising that European farms are extremely diverse; that decisions must be science-based and management measures for coexistence should reflect the best available scientific evidence on the probability and sources of admixture between GM and non-GM crops; Proportionality - measures for coexistence should be efficient, cost-effective and proportionate and; Defined Adventitious presence as: in the context of transgenic crops, as the term that describes the inadvertent presence of transgenic seeds or other material in conventional and organic crops. In addition, the regulation required member States to look at existing liability regimes and explore the possibility of setting up new specific schemes.

Table 3. Groups and categories of substances controlled in food animals as set by Directive 96/23/EC

Group of substance	Category	Substances
Group A	1. Substances having a anabolic effect and unauthorized substances	(1) Stilbenes, stilbene derivatives, and their salts and esters (2) Antithyroid agents (3) Steroids (4) Resorcylic acid lactones including zeranol (5) Beta-agonists (6) Compounds included in Annex IV to Council Regulation (EEC) No 2377/90 of 26 June 1990 (Chloramphenicol, Nitrofurans, Nitroimidazoles)
GROUP B1	*2*. Veterinary drugs and contaminants	(1) Antibacterial substances, including sulphonomides, quinolones (2) Other veterinary drugs (a) Anthelmintics (b) Anticoccidials, including nitroimidazoles (c) Carbamates and pyrethroids (d) Sedatives (e) Non-steroidal anti-inflammatory drugs (NSAIDs) (f) Other pharmacologically active substances
GROUP B2	3. Other substances and environmental contaminants	(a) Organochlorine compounds including PcBs (b) Organophosphorus compounds (d) Chemical elements (d) Mycotoxins (e) Dyes (f) Others

of origin. Directive 91/493/EEC and amendments give conditions for production and placement on markets of fishery products for human consumption. Most of the provisions of these legislations are now incorporated in the new ones. For instance much of 91/493/EEC is now covered in the new package of the food hygiene regulations of 2004 and much of Decision 2003/858/EC has been incorporated in 2006/88/EC.

Food safety controls and import conditions for fish/aquaculture products in the EU

In a European Commission's guidance document on the new food regulations published on 29th June 2005, certain key questions related to import requirements and new regulations on food hygiene were clarified (EC, 2005). Chapter 7 of the document discusses import procedures for products of animal origin. The products of animal origin must be presented at a European Community border inspection post to be subjected to an import control check. Consignments are approved if the products are derived from approved countries. The obligation of the food business operator in the EU wishing to import products of animal origin from the third country is to ensure that: the food is coming from a country that appears on the community approved list, the food is coming from an approved establishment, the food is accompanied by health certificate issued by representative of the competent authority in the third country, and the food is produced in accordance to the set of hygiene regulation and animal health directive 2002/99/EC.

The competent authority in exporting country is obliged to offer guarantees as to compliance or equivalence to EU requirements for official controls to food products by ensuring that: their control services comply with the operational criteria laid down in the (EC) Regulation No. 882/2004, the establishments that are authorized to export to the EU comply and continue to comply with EC requirements and the list of such establishments kept up-to-date and communicated to the European Commission in accordance with article 12 paragraph 2 of Regulation (EC) No. 854/2004), and ensure that the certification requirements are satisfied. Detailed rules with regard to certification are laid down in (EC) Directive 96/93/EC on certification of animals and animal products (OJ No. L 13 16.1.1997. p.28). Further details are laid down in Annex VI of Regulation (EC) No. 854/2004 (e.g. Certificate must be issued before consignment to which it relates leaves the control of competent authority of third country of dispatch).

The EC's Directorate General for Health and Consumer Protection (DG SANCO) is responsible for food safety in the EU. The import rules for fishery products and shellfish (bivalve molluscs) seek to guarantee that the imports fulfil the same high standards as products from the EU-member states with respect to hygiene and consumer safety, and if relevant also to animal health status. According to EC, spot checks on end product alone cannot provide the same level of safety, quality and transparency to the consumers. To fully implement the principle of quality management and process-oriented controls throughout the food chain, from fishing vessels or aquaculture farm to the consumer table, the Food and Veterinary Office (FVO) of the EC regularly undertakes inspection missions in exporting countries.

Imports of fishery products into the EU are the subject of official certification, which is based on the recognition of Competent Authority (CA) of non-EU country by the EC. This formal recognition of reliability of the CA is a pre-requisite for the country to be eligible and authorized to export in the EU. Public authorities with necessary legal powers and resources must ensure credible inspection and control throughout the production chain, which covers all relevant aspects of hygiene, public health and in case of aquaculture products also animal health

All bilateral negotiations and other relevant dialogue concerning imports of fishery products (where fish in this refers to all aquatic animal food products) are undertaken by national CA. All other interested parties and private businesses wishing to export to the

Table 4: EU legislation on Food Contaminants

Legislation	Focus	Details
Directive 96/22/EC	Concerns the prohibition on the use in stock-farming of certain substances having a hormonal or thyrostatic action and of ß-agonists,	Prohibits placing on market of stilbenes stilbene derivatives, their salts and esters and thyrostatic substance for administering to animals of all species; Prohibits placing on market of beta- agonists for administering to animals the fresh products of which are intended for human consumption purposes; Sets prohibitions and other provisions concerning use of veterinary medicinal products, hormonal products, beta-agonists among others.
Directive 96/23/EC (and amendments)	Sets rules for controlling the residue levels of un-intentional (environmental) or intentional (veterinary drugs) residues in farmed animals – (relevant to aquaculture production)	Requires countries to monitor production process for food animals and to develop and implement annual residue monitoring plans; Provides for co-responsibility between competent authority and farm operators to ensure monitoring of chemical residues; Requires observance of drug withdraw periods; Provides categories of chemical substances to be monitored (table 3); Gives sampling methods for residue analysis; States the required sampling frequencies and sampling levels; Gives a list of EC reference laboratories approved contaminants; Prohibits trade in food with residues above MRLs.
Regulation 2377/90	Lays EC procedures for the establishment of Maximum Residue Limits of veterinary medicinal products in food stuffs of animal origin	Lists the pharmacological substances used in food animals and fixes their MRLs
Regulation 1881/2006	Sets maximum residue levels (MRLs) for heavy metals in a number of species of fish and shell fish, repeals Reg. (EC) No. 466/2001	Set MRLs for meat of fish for mercury, lead and cadmium at 0.05, 0.2 and 0.05mg/kg of wet weight, respectively, raising the residue limit for mercury from 0.5 mg/kg of weight earlier fixed by Reg. (EC) No. 466/2001
Regulation 396/2005	Sets maximum residue levels of pesticides in food and feed of plant and animal origin	Establishes maximum residue levels of pesticide residues permitted in animal or vegetable products intended for human consumption, and sets general limits that apply to food products where no specific MRLs have been set at 0.01mg/kg
Regulation 2073/2005	Gives the Microbiological criteria for all food stuffs	Re-instates the microbiology criteria in repealed directives including for fish; Gives conditions to ensure that microorganisms, their metabolites and toxins do not enter food; and gives criteria for sampling and analysis of microbiological test samples [applied to all stages in the chains for animal feed and food for human consumption

EU have to contact their CA and communicate with the EC via this channel. The specific key element of the import rules is that the country of origin of fishery product must be on a positive list of eligible countries for the relevant product. The EC has changed the system for controlling supply of fishery products and bivalve molluscs to the European Community by non-member countries to

bring it in line with the new rules on hygiene and official controls adopted in 2004. Originally, through Decision 97/296/EC, the EC had specified the eligible countries for exporting the fishery products in the EC in list 1 (countries eligible to export to any country in the Community), or in list 2 (countries to export to specific countries where bilateral arrangements exist). This has since been repealed. In future, only countries covered by a specific EC Decision will be eligible to supply fishery products and bivalve molluscs to EU. The list of non member countries and territories from which fishery and bivalve molluscs for human consumption may be imported are annexed to Decision 2006/766/EC of November 6, 2006.

The eligibility criteria are: 1) Exporting countries must have a CA which is responsible for official controls throughout the production chain. The CA must be empowered, structured and resourced to implement effective inspection and guarantee credible certification of relevant hygiene conditions. 2) Live fish, their eggs, and gametes intended for breeding and bivalve molluscs must fulfil the relevant animal health standards. This requires that the veterinary services must ensure effective enforcement of all necessary health controls and monitoring programmes, 3) the national authorities must also guarantee that the relevant hygiene and public health requirements are met. The EU hygiene legislation contains specific requirements on structure of establishments and operational processes, freezing and storage. These provisions are aimed at ensuring high standards and preventing any contamination of the product during processing, 4) Specific conditions apply for imports of live or processed bivalve molluscs (e.g. mussels and clams), echinoderms (e.g. sea urchins) or marine gastropods (e.g. sea snails and conchs). These imports are only permitted if they come from approved and listed production areas. The national authorities of exporting countries are required to give guarantees on the classification of these products and close monitoring of the production zones to exclude contamination with certain marine bio-toxins causing shell fish poisoning, 5) In case of aquaculture products, a control and monitoring plan for heavy metals, other chemical contaminants like PCBs, residues of pesticides and veterinary drugs must be in place to verify compliance with EU requirements. 6) A suitable control and monitoring plan must be designed by the CA and submitted to the EC for initial approval and yearly renewal. The EC Council Decision 2004/432/EC on approval of residue monitoring plans (RMP) submitted by non-EU member countries in accordance with Directive 96/23/EC annexed a list of all countries for which residue monitoring plans for animals and primary animal products were approved. This list is periodically reviewed, and through a council decision, non-complying countries are deleted from the list while new countries and their animals and animal products that meet the requirements are introduced. The current positive list for non-EU member countries that meet the requirements for residue monitoring plans is annexed to the EC Council Decision 2010/327/EU, which amended the Annex to Decision 2004/432/EC. The countries or products not appearing on the list are in effect not approved for export to EU. 7) Imports are only authorized from approved vessels and establishments (e.g. farms, processing plants, freezer or factory vessels or cold stores) which have been inspected by the CA of exporting country and found to meet EU requirements. The CA provides necessary guarantees and is obliged to carry out regular inspections and take corrective actions if necessary. A list of such approved establishments is maintained by EC and it is published on its website, 8) Inspections by the DG SANCO's Food and Veterinary Office (FVO) are done regularly and are meant to confirm compliance with the requirements. The inspection missions are the basis for establishing confidence between EU commission and the CA of the exporting country.

Imports of fishery products from non-EU countries must enter the EU via an approved border inspection post under the authority of an official veterinarian. Each consignment is subject to a systematic documentary check, identity check, and as appropriate, a physical check. The frequency of the checks depends on the risk profile of the product and also on the results of the previous checks. Consignments which are found not to be compliant with EU legislation are either destroyed or under certain conditions, re-dispatched in 60 days (http:/europa.eu.int/comm./food/animalproducts/ Accessed 02 June 2007)

Formal steps for approval of fishery/aquaculture imports to the EU

The EU has designated a procedure for evaluation of eligibility of non- European countries wishing to export fishery products to the EU: 1) First, the national authority of the third country must submit a formal request to the Directorate General for Health and Consumer Protection (DG-SANCO) of the European Commission (EC) to export fish, fishery products, or bivalve molluscs to the EU. The request should contain confirmation that the authority can fulfil all relevant legal provision to satisfy EU requirements; 2) The Director-General for Health and Consumer Protection sends out a questionnaire which should be completed and returned. Information on relevant legislation, competent authorities, hygiene and many other elements are requested; 3) For aquaculture products, a residue monitoring plan (RMP) of the exporting country must also be submitted and approved at this stage in accordance to relevant legislations. The basic legislations for controlling residues of contaminants in the EU: Directive 96/23/EC, which lays out requirements that must be met in relation to planning and execution of national residue control plans for live animals and products of animal origin; Directive 96/22/EC as amended by 2003/74/EC concerning the prohibition on use in stock farming of certain substances having hormonal or thyrostatic action and beta-agonists; EC Decision 97/74/EC which fixes the levels and frequencies of sampling provided for by Directive 96/23/EC for monitoring of certain substances and residues in certain animal products aquaculture inclusive; and EC Decision 98/179/EC that lays down detailed rules on official sampling for monitoring certain substances and residues in live animals and animal products, among others; have to be complied with. The RMP and other required information have to be submitted to Food and Veterinary Office (FVO) of DG SANCO on 31st March every year. When the initial RMP is being submitted and request to export to Europe is being made, the exporting country's relevant legislation and the profile of organization of Competent Authority (CA) in monitoring and surveillance of residues among other information is submitted together with RMP. It is on the basis of the provided information and the RMP that a decision to authorize export to the EU under prescribed conditions is given. Subsequent to the decision, RMP for coming year and the reports of previous monitoring have to be submitted yearly to FVO. The substances to be monitored are in two categories: those that are essential and therefore must be monitored by every country and those that are highly desirable which should be selected for monitoring basing on the environmental and farming conditions. An EU format for RMP and sampling procedures must be adopted for the submission to be accepted. 4) After evaluation of the paper submission, an inspection by the FVO may be carried out to assess the situation on the spot. Such an inspection is mandatory for high risk products like shell fish, 5) Based on the results of the evaluation/inspection, and guarantees given by the exporting country, DG SANCO proposes the listing of the country, the specific conditions under which imports from that country will be authorized, and the list of approved establishments in the country. These are then discussed with the representatives of EU Member States; 6) if the Member States have favourable opinion on the proposal, the EC adopts specific import conditions. Lists of eligible establishments can be amended at the request of exporting country and are made available to the public on internet (http:/forum.europa.eu.int/irc/sanco/vets/info/data, SANCO, 2005 accessed 02 June 2007)

Food safety legislations in the United States with effect on aquaculture product trade

The US Food and Drug Administration (FDA) is mandated to enforce the Food, Drug and Cosmetic Act (1938) which also covers fishery and aquaculture products. The agency is responsible for food safety of all food stuffs except for meat, poultry and eggs. The responsibility for ensuring the safety and regulation of all raw beef, pork, lamb, chicken, and turkey as well as processed meat and poultry products, including hams, sausages, soups, stews, pizzas, and any frozen dinners falls to the Food Safety and Inspection Services (FSIS) – a public agency under the US Department of Agriculture (USDA).

The US government has instituted several laws and procedures to ensure food safety. In addition to strict regulations on safety and wholesomeness of food, products are safeguarded through pre-market clearances, mandatory production practices, and random ongoing sampling which include border point sampling and food import surveillance. The food safety standards that apply to domestically produced food also apply to imported foods (USDA, 2001). The US Food Safety Act (1990) and Regulations specified certain safety standards for processing and sale of food. The US Food Quality Protection Act (FQPA) (1996) is one of the most significant pieces of legislation enforced by the US Environmental Protection Agency (EPA) that impact on food safety. It includes food safety protection provisions and regarding how pesticides are regulated, and aims to improving environmental and public protection. The Consumer Product Safety Act (1972) regards a consumer product safety standard as one that consists of one or more of any of the following: requirements expressed in terms of performance, requirements that consumer products be marked with or accompanied by clear and adequate warnings or instructions, or requirements respecting the form of warnings or instructions. Any requirement of such a standard is one considered reasonably necessary to prevent or reduce an unreasonable risk of injury associated with that product. The Act also requires products not meeting the standard requirement to be removed from market and for manufacturers to issue certificates that their products are produced using the required standards. The certificate accompanies the product and is furnished to the distributor or retailer to whom the product is delivered.

The Presidential National Food Safety Initiative established in 1997 (USFDA/USDA/U EPA and CDCP, 1997) increased efforts of US government to reduce food-borne illnesses from farm to fork. The initiative resulted into strategic planning for food safety efforts with a national food safety strategic plan released by the national council on food safety (USDA, 2001). The national food safety strategic plan has led to improvements in US food surveillance systems, and coordination among federal, state and local health authorities, improving risk assessment capabilities, increased inspection, expanded research and consumer education. A strong science base drives all the food safety efforts. The science base has led to processors of seafood, meat and poultry, juice and others to adopt HACCP to reduce food-borne illness.

The events of September 11, 2001 and the recent food safety incidents have led to the changes geared towards strengthening of regulatory and administrative controls for food in order to improve control and traceability of product flow in the US. The Public Health Security and Bioterrorism Preparedness and Response Act (2002) or simply Bioterrorism Act (BTA), gave comprehensive determination of what biological agents and toxins may be, and the restrictions to trade in products with potential of containing biological agents and toxins. In addition, the Act requires all local and foreign manufacturers, processors, packers and handlers of food consumed in the US to be registered with the US FDA and to obtain persons resident in US to serve as their agents. Also the Act provides for detention of food when there is credible evidence that it contains food hazards. The act further requires maintenance of records both by local and foreign food manufacturers and processors and provides for mandatory prior notice of food shipment (Weick, 2006). As a result of BTA, enforcement of food legislations have been increased by strengthened food import regulations (Table 5).

Some product categories already faced more restrictive import requirements prior to the BTA and, therefore, the BTA did not lead to a stronger import requirements for these products. Depending on the category, these requirements consist of registration of the food facility and specific product information that had to be filed with the arrival at the port (alcohol beverages, fruits and vegetables, dairy products) or having a food safety system in place (HACCP) in the production facility (seafood, live fish), or import permits issued for the firm and kept valid for up to 5 years (fruits and vegetables) (Weick, 2006)

The US Farm Security and Rural Investment Act of 2002, requires the “Country of Origin Labelling” (COOL) on all beef, lamb, pork, fish, perishable commodities, and peanuts. Voluntary guidelines were established in 2002 and became mandatory for fish and fishery products in April 2005 when their implementation took effect (Thompson et al., 2005). However implementation of all covered commodities except wild and farm-raised fish and shellfish was delayed until September 30, 2008.

Food safety controls and import conditions for fish/aquaculture products in the US

Under the Federal Food and Drug and Cosmetic Act (FFDCA), FDA is the responsible agency for safety of domestic and imported seafood to consumers. For domestic aquaculture, FDA is mandated by FFDCA to review the requests to market new products used in aquaculture, with aquaculture drugs seemingly being main focal concern of FDA. Under this role FDA approves certain drugs used in aquaculture and has in its definition of “drug” included genetic material-treated fish and genetically engineered fish. To be approved, the sponsor of the drug must demonstrate that the drug is safe and efficacious among others.

The FDA over the years has adopted a food safety program based on preventive controls designed to identify hazards during the seafood production process.

The approach requires seafood processors to identify harmful microbiological, chemical and physical hazards that are reasonably likely to occur, including food safety hazards that may occur as a result of natural toxins, microbiological contamination, pesticides and drug residues. The US Code of Federal Regulations (CFR) provides rules that govern operations of food safety. The relevant code for control of fish imports is 21 CFR section 123 “Procedures for the safe and sanitary processing and importing fish and fishery products” which sets forth specific regulations for sanitary processing and importation of fish and fishery products. In 1994 FDA proposed regulations that would establish HACCP system for seafood industry. On December, 18th 1995, a new US regulation of inspection for food safety in seafood and aquaculture industry was adopted by FDA. The new system was proposed in the final rule “Regulations for HACCP of seafood and aquaculture”. The regulations were issues by FDA on the same day in the federal register (Vol. 60 No. 242). The system was named “HACCP” for proven concept of Hazard Analysis and Critical Control Point programmes designed to prevent and control food safety problems. Justification for the programme was based on continuing concerns for food-borne illnesses, public expectations, industry requests, and market trends in both domestic and international settings. The final rule on seafood HACCP became mandatory in December 1997.

These regulations apply to domestically produced products and imports. They require that processors of fish and fishery products operate preventative control systems that incorporate seven principles of HACCP. This involves processors producing HACCP

Table 5: Changes in the import requirements for specific food categories due to US Bioterrorism Act (2002) (BTA)

Product Group	Basic Legislation	Provisions in place before BTA	Stronger provisions in BTA
Food Categories not covered by (BTA under USDA Authority)			
Meat, poultry and eggs	Federal meat inspection Act Poultry products inspection Act Egg products inspection Act	Equivalence of food safety system, inspection and approval of foreign facility, firm-related import permit, and inspection at port of entry	Not applicable
Food categories covered by the BTA (under FDA authority)			
Low acid canned products	Food, Drug and Cosmetic Act Low-Acid canned food program	Registration of food facility Providing of processing information	*
Alcohol beverages	FD&C Act Federal Alcohol Administration Act	Firm related import permit	**
Fresh fruits and vegetables	Food, Drug and Cosmetic Act	Inspection certificate Firm related import permit	**
Diary products	Food, Drug and Cosmetic Act	Firm related import permit Quota system	**
Seafood and live fish	Food, Drug and Cosmetic Act Procedure for the safe and sanitary processing and importing of fish and fishery products	HACCP must be in place and verified by foreign government inspection authority or equivalence or compliance agreement with the US	**
Other food item (e.g. pasta)	Food, Drug and Cosmetic Act	No Specific requirements	***

Key
BTA – Bioterrorism Act
FDA – Food and Drug Administration
USDA – US Department of Agriculture
Note – For Alcohol beverages, the Bureau of Alcohol, Tobacco and Firearms is administering the Federal Alcohol Administration Act
* indicates no or only minor changes due to BTA provisions
** indicates stronger provisions in the BTA in terms of registration, prior notice, record keeping and detention
***Indicates stronger provisions in the BTA with respect to all four provisions
SOURCE: Weick, 2006

plans and making them available for "official review and copying at reasonable times." The essence of the regulations is that purchaser/importer of the products should be able to demonstrate to the authorities that the products have been produced in safe and acceptable manner. This implies the producers are using a quality assurance system that incorporates HACCP, standard sanitary procedures and good manufacturing practices. The sanitary procedures which are needed to ensure that products meet requirements for production are often referred to as Standard Sanitation Operating procedures (SSOPs). The US FDA's Center for Food Safety and Applied Nutrition (CFSAN) has since issued fish and fishery products hazards and control guidance to assist processors identify hazards associated with products and help consumers understand commercial seafood safety issues (US FDA, 2001). The guidelines relate to FDA final regulation 21 CFR 123 which require fish processors to develop and implement HACCP in their operations. The fish and fishery products hazards and controls guidance specifies that aquaculture drugs are reasonably likely to pose hazards. It provides guidelines for controlling hazards in aquaculture especially regarding control of veterinary drug residue, lists potential chemical products likely to result in food hazards in aquaculture and fishery production chain and sets the action levels (MRLs) for each of the contaminants.

Apart from control of hazards by the processors, according CFR 123, US importers of aquaculture products are expected to inspect and approve HACCP plans and other documents of foreign processors. Apparently, there appears no obligation for the importer to inspect the facilities of aquaculture operator in exporting country but the importer could rely on the documentation about the sources of the products available in the facilities of the processor or exporter.

Formal procedure for import of fish/aquaculture products to the US

The FDA considers any fishery products [including those from aquaculture] produced in absence of an appropriate HACCP programme to be adulterated. Processors or importers of such products are subject to regulatory actions and penalties. While prior to the HACCP rules importers used to be responsible for compliance with FDA regulations that prevent the entry and

commerce of adulterated foods and the previous practice depended solely on regulatory surveillance, the current mandatory HACCP regulations include requirements for importers to become more proactive in ensuring the safety of imported seafood and aquaculture products. In addition to traditional import surveillance and periodic inspections, the FDA now requires certain HACCP controls and they apply to the following categories: 1) US owners or consignees at the time of entry into the US or the US agent or representative of owner at the time of entry must comply. Foreign processors and producers are influenced indirectly through requirements for US importer to ensure their suppliers comply with HACCP programmes; 2) Processors – firms either in the US or in foreign country engaged in handling, storing, preparing, heading, eviscerating, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labelling, dockside unloading, or holding fish and fishery products, must comply; 3) All fresh or salt water fish, crustaceans, all molluscs, alligators, frogs, aquatic turtles, jellyfish, sea cucumbers, sea urchins, other aquatic animal life except mammals and birds; if intended for human consumption are all involved in HACCP controls; 4) If the importer also performs some processing, a HACCP programme must also be considered to address this activity as required for all domestic and foreign processors. However, if the importers are not involved in processing they are not required to have HACCP programmes for the products in question, but they must help to ensure foreign processors' compliance. Foreign processors must implement and maintain HACCP plans required by the US processors. The burden for compliance and/or proof is shared by the US importer and foreign processor.

The mandatory HACCP regulation specifies two options for importer compliance. The first one is that of imports involving products from a country with an established and recognized Memorandum of Understanding (MoU) with the USFDA. If an appropriate MoU exists, the importer does not need to take further action. However, it is the importers' responsibility to keep appraised of the changes in the status of HACCP-related MoUs. The second one is that involving imports with a country where no such MOU exists. In absence of the MoUs, the importer must have and implement "verification" procedures. The FDA regulation specifies that these procedures must include two parts. One, the product specifications which ensure that the involved products are not injurious to health and have been processed under sanitary conditions, secondly, affirmative steps or options that ensure that the involved products are produced under controls that meet the requirements for the HACCP regulation for processors must be put in place. The options for affirmative steps include: obtaining the foreign processors' HACCP and sanitation records as related to specific lot of imported fish or fishery product; obtaining lot-by-lot certification from an appropriate government inspection authority; regularly inspecting the foreign processors facilities; maintaining on file a copy of foreign processors' HACCP plan, and written guarantee from processor ensuring performance; periodically testing the imported products and maintaining on file copy of written guarantee from processor and; other appropriate verification measures that provide equivalent level of compliance. It should be therefore noted that although the procedures do not specifically require aquaculture producers to provide the necessary written guarantees, such information could be demanded by the importer, third party or competent authority during inspection. In case aquaculture products are processed by the exporter, it is to the discretion of the inspector to demand information on the aquaculture pre-harvest chain as part of the "other written guarantees".

Comparison and linkage between FAO/WHO, EU and US food safety requirements applied to aquaculture and effect on trade with developing countries

Generally, most of the EU and US regulations are already covered by the FAO/WHO Codex Alimentalius Commission (CAC) code of good hygiene practices, standards, guidelines, and recommendations. Regarding the common features, the FAO/WHO guidelines, the EU and to some extent the US regulations recommend, but they do not require mandatory implementation of HACCP in aquaculture as a means to reduce the possibility of food hazards that exit in aquaculture chain contaminating the fish products on the farm. The FAO/WHO HACCP recommendations for aquaculture are contained in expert panel report on food safety issues associated with products from aquaculture (WHO, 1999) and code of good hygiene practices for aquaculture products (FAO/WHO, 2003a) which suggest mandatory application of HACCP only in industrialized or commercial aquaculture. For small scale fish farmers, it is advised that food safety awareness, sensitization and training through extension services covering application of Good Aquaculture Practices (GAqPs) and observing basic hygiene rules should be undertaken to improve safety of products coming from this category of aquaculture producers. For the EU market, HACCP in aquaculture is recommended through Regulation (EC) No. 852/2004 on hygiene of food stuffs which includes primary production. The regulation does not require mandatory implementation of HACCP in primary production, but recommends and encourages primary producers to apply HACCP to the extent possible at the farm. In practice HACCP is not mandatory to the domestic primary producers in the US. But there is voluntary implementation of HACCP in most US commercial aquaculture farms. Although it is not specifically stated in the US FDA HACCP regulations that implementation of HACCP in aquaculture is mandatory to foreign aquaculture suppliers, it could however be implied, since FDA regulations require importers to take affirmative steps and any "other guarantees" to ensure the safety of the products they import. Affirmative action and "any other guarantees" could extend to taking inspection of the foreign exporting firms to check the safety controls that may include hazard control procedures employed for aquaculture products. US FDA hazard control guidelines include control of use of aquaculture drugs in seafood production. FDA enforces the MRLs for aquaculture drugs as well as other contaminants like pesticides, PCBs and heavy metals, as means to verify performance of hazard control procedures used in the production of the food products. Products of farms that do not meet the FDA Action level (or MRLs) requirements for food contaminants could have their products detained at the US border of entry. Therefore, implementation of HACCP may not be a choice but a necessity since meeting the MRL requirement without HACCP is matter of luck, and no commercial operator would wish to subject his/her business to luck.

Both the EU and US markets require exporting countries to produce products under similar or equivalent conditions as those pertaining to their markets. Another common feature in both markets is the enforcement of MRLs for certain residues as required in Directive 96/23/EC, Regulation 1881/2006 and regulation 396/2005 in the EU, and the FDA guidance and hazard control for fish and fishery products (FDA 2001), and Bioterrorism Act (2002) for the US. Both markets emphasize the concept of traceability. In the EU general traceability requirements are laid down in regulation 178/2002, while traceability regarding the hygiene of food animals on farm is contained in regulation 852/2004 and other pieces of legislation addressing other commodities like feed. For culture products, there are other traceability issues related to the public and fish health covered in decision 2003/858/EC and 2006/88/EC. In the case of the US, traceability is covered under the Farm Security and Rural Investments Act 2002, which introduced the Country of Origin labelling (COOL), and Bioterrorism Act of 2002 that requires local and foreign producers to keep records.

The EU and US markets regulations differ mainly on who bears responsibility for food safety regarding fish or aquaculture imports. Whereas the EU regulations place legal responsibility of producing safe products to food producers, including foreign producers (as well as primary producers – in this case aquaculture operators), in the US, this responsibility is shared between the importer and

foreign processor, without a direct obligation to the primary producer. The EU regulations also hold the competent authority (CA) in the exporting country accountable for the safety of the products supplied by the producers under its (CA) jurisdiction. The regulations require the CA to be proactive and monitor the production chains and guarantee to the market the safety of products produced by business operators. This is however different with the US regulations. Although the CA could certify consignments of the export products as proof of products being produced in accordance to HACCP requirements, the US regulations do not hold the CA accountable for any defects associated with the products or practice.

The EU has the most comprehensive food safety regulatory regimes as compared to the US. There are specific legislations in EU for different categories of food, segregated into those for general food stuff, food of animal origin, fish and fishery products and some are specific to aquaculture, which are continuously reviewed as more information on risks and production conditions is unveiled. Also some EU legislation target specific products, species or regions. On the other hand, the US regulations are brief and generalized, and tend to combine both capture fishery and aquaculture products. Although some other US legislation do provide a framework for regulating fish and aquaculture as they do for other commodities, the requirements for fishery and aquaculture products are harmonized in one piece of legislation (Regulations for HACCP inspection of seafood and aquaculture). Countries that wish to export to the EU may face challenges of analyzing the requirements of several legislations that apply to various specific products, and keeping in pace with the several frequent amendments on the legislations, which makes the US legislation when compared to EU less stringent to producers and importers in developing countries. Also MRLs (Action Levels) for most chemical contaminants of food are low in EU than in the US.

CONCLUSION

The paper is targeted to provide an insight to international legislation relating to safety of fish from aquaculture. It is also anticipated to provide a synthesised single-source of information for harmonising aquaculture production activities with cross-border trade requirements and, the analysis of conditions for importing aquaculture products into the EU and US markets. Overall, the WTO SPS agreement is the main legislation describing conditions for managing safety and other related requirements for food trade across the border. WTO SPS gives FAO/WHO Codex Alimentarius Commission standards, guidelines and code of good practices de facto legal mandates for resolving trade related disputes regarding food safety for all food stuffs, and it as well applies to food from aquaculture in a similar manner.

Of the two markets, the EU has the most stringent and diverse food safety regulatory regimes for aquaculture products as compared to the US. Also the Maximum residue limits for fish and aquaculture products is high in the EU as compared to the US. Although the EU food safety and related legislation are several and diverse, the diversity, comprehensiveness and dynamic nature provides the advantage of elaboration which in a way facilitates better understanding of precise requirements that is vital in planning compliance. Likewise, although the generalized nature of the US regulations could make understanding of the precise requirements rather difficult and it is prone to regulatory abuse by authorities who may use it discriminately stop imports from unfavourable countries; it has got the advantage of providing flexibility during enforcement. This too would make the US market regulatory requirements for aquaculture and fishery products less stringent especially to developing countries that do not have human and technological resources for interpreting and complying with continually changing, diverse and specific requirements for different species, products and regions as required by EU market. However caution should be taken in drawing conclusion to imply that the US market is less restrictive and therefore could likely to be more accessible to aquaculture products especially from developing countries as compared to EU. This analysis left out other important factors among others; price, proximity and transportation which are also equally important in determining the preferred market of access by producers and traders in developing countries. Since most of FAO/WHO Codex standards and guidelines already measure up to most of the requirements of EU and US markets, they may be adopted directly by developing countries that do not have resources to develop their own regulatory system as an initial step to complying with requirements of markets in developed countries like in EU and the US. For aquaculture, some of the food safety regulations are linked to animal health, animal welfare, and environment. This implies that a country wishing to export aquaculture products would require not only to focus on food safety requirements in isolation, but also to integrate other regulations on animal health and welfare, and environmental safety in order to be able to meet the import conditions of EU or US markets.

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