Exponent®

Center for Chemical Regulation and Food Safety

Catfish Risk Profile

Executive Summary

The Catfish Farmers of America asked Exponent to evaluate the risks associated with consumption of catfish as part of their program to ensure that American consumers purchase safe food. Given the growing share of imports, it is increasingly difficult for consumers to know the source of the catfish they consume. This is especially an issue for catfish eaten away from the home, such as in restaurants and other food service establishments, which are not required to disclose the country of origin and may not know themselves where the catfish were raised. The United States Food and Drug Administration (FDA) import inspections regularly find contamination with *Salmonella* and drug residues in these imported products in the 2% of foods that are inspected at the port of entry. Other microbiological and chemical contaminants have also been identified on many imported products.

Based on its review of the current practices in catfish aquaculture and processing, Exponent concludes the following:

- For food safety considerations, freshwater aquaculture should have an inspection system that differs from other seafood systems, because their hazards, sources, and interventions differ significantly from those applicable to wild caught, marine seafood species.

- Since consumers cannot differentiate among the various catfish species and there is evidence that imported fish of the *Siluriformes* Order can and are being labelled as catfish, when establishing food safety control systems the taxonomic definition of catfish that includes all species within the *Siluriformes* Order of finfish will provide the greatest level of consumer protection by including products with similar characteristics and potential hazards.

Public Health Effects and Hazard Exposure

- The major hazards of concern for aquaculture fish include pathogenic microorganisms, antimicrobial/drug residues, and environmental chemicals. Chemical and antimicrobial residue contaminants pose potential long-term threats to public health. Chemical contaminants can accumulate in the body for years. Antimicrobials are used to treat diseases or maintain health of the fish, particularly in contaminated water and crowded ponds/cages. Some of the illegal antimicrobials are considered carcinogens. The use and resulting presence of these antibiotics can cause microorganisms to gradually become resistant to the antibiotics and their ability to treat human infections is thereby decreased. Pathogenic microorganisms, in contrast, are short-term threats because they can cause illness after ingestion of a single contaminated serving.

- FDA's surveillance testing of imported catfish showed the frequent presence in the fillets of illegal drugs and chemicals that were given to the live fish. The antimicrobials commonly present in imported catfish include malachite green and gentian violet, both considered to be human carcinogens, and fluoroquinolones, a class of antibiotics that authorities worldwide consider at risk of losing its effectiveness for treating human illnesses. All are illegal for use in aquaculture in the US and, therefore, their presence in a food is deemed an adulteration by FDA. A food adulterant is any poisonous or deleterious substance intentionally or unintentionally added to the food which may render the food harmful to health.

- FDA has not found an illegal drug in domestic aquaculture seafood. Antimicrobial use in the United States (US) follows FDA's requirements for choice of antimicrobial, dose level and withdrawal periods and does not pose a public health threat from residues. Proper use does not promote development of antibiotic resistant microorganisms.

- *Salmonella* is the most important microbiological pathogen associated with catfish and the second most common violation found in imported fishery and seafood products. This bacterial pathogen is carried by many animals and arises primarily from environmental contamination. When present on catfish products, it has the potential to grow if the fish are not kept at proper temperatures and to be disseminated by cross-contamination to other foods during meal preparation. This microbial hazard has been detected on both domestic and imported products; however, comparative surveys found it more frequently on imported products.

Problems and Solutions

- The illegal antimicrobials are added by the growers and their use can be stopped by effective enforcement. The presence of environmental chemicals in the catfish fillets can be greatly reduced by the use of clean water and uncontaminated feeds.

- *Salmonella* have a natural presence in the environment and processing facilities. Their presence on the catfish fillets can greatly reduced by control of wildlife in the pond areas and by an effective sanitation and testing program in the processing facilities.

- Because there are no technological treatments during processing that eliminate the chemical or microbiological hazards, the greatest reduction in consumer exposure will come from an emphasis on prevention of contamination across the entire catfish production, processing, and distribution chain.

- United States Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) inspection program directs greater regulatory resources toward their regulated foods than FDA and National Oceanic and Atmospheric Administration (NOAA) to define performance standards for microbial hazards, conduct baseline testing to determine the current presence of contaminants in the foods across an industry, test production in individual facilities, and evaluate each establishment's progress toward achieving acceptable performance levels.

- The Global Food Safety Initiative is a world-wide program promoted by retailers to require food producers to meet stringent requirements for controlling production and achieving a high level of safety. This non-governmental program will place additional constraints on the marketing of products that cannot meet these standards. All safety standards would need to incorporate applicable governmental requirements for acceptance of these products by US retailers.

- Safety cannot be inspected into a product by the government at a domestic processing establishment or at the port of entry. Rather, effective regulatory and private sector control must extend back to the growing operations to prevent the hazards from being in the final product.

1 Risk Profile

The Catfish Farmers of America asked Exponent to evaluate the risks associated with consumption of catfish as part of their program to ensure that American consumers purchase safe food. This risk profile was developed to summarize the available information relating to the potential risks from consuming catfish to provide a basis for making informed decisions. A risk profile is an internationally recognized tool that describes a specific issue within a food safety context. The risk profile summarizes the existing scientific information and helps risk managers prioritize the various issues.

It is a document that may include the following:

- Brief description of the situation;
- Commodity involved;
- Pathway by which consumers become exposed to a hazard(s);
- Risk mitigation practices relevant to the issue;
- Distribution of risks among different segments of the population;
- Perceptions of the risk;
- Characteristics that might affect risk management options; and
- International agreements that affect the risk issue.

A risk profile is initiated by risk managers to collect and assemble information for use as the basis for further action that will lead to the effective management of the specified risk (WHO, 2000; Food and Agricultural Organization/World Health Organization (FAO/WHO), 2006). These actions may be a change in the food process or regulations, further research and data collection, commission of a quantitative risk assessment, or the acceptance of the current status (insignificant hazard).

Exponent determined that the best approach to identify potential hazards and control mechanisms would be to conduct a risk profile of the scientific information on imported and domestic catfish. In order to perform this risk profile, Exponent assessed published and unpublished scientific data on production and characteristics of domestic and imported catfish and identified the potential health risk to United States (US) consumers. Three groups of hazards associated were recognized with these products including: environmental chemicals, antimicrobial residues and pathogenic microorganisms.

2 Background

Farmed catfish is a US success story, as production of this traditional American food reached 466 million pounds in 2009 (NASS, 2010). Aquaculture production is centered in Louisiana, Arkansas, Mississippi and Alabama, where 93% of domestic catfish originate. Products are marketed either fresh or frozen, as fillets, strips, steaks and nuggets. Some products are breaded or marinated. In February 2010, 22.6 million pounds were produced in the US; 8.1 million pounds (36%) were marketed fresh and 14.5 million pounds (64%) were frozen. Imports of all catfish were 10.4 million pounds in February 2010, up 60% from February 2009 (NASS, 2010).

Imports currently represent 31.5% of the total US catfish market. Major exporters of catfish to the US include: Vietnam (52.2%), China (29.7%), Thailand (12.3%) and other countries (5.7%). Imports of *Ictalurus* channel catfish, primarily from China, were 2.2 million pounds, the rest of the imports are *Pangasiidae* species (NASS, 2010).

The USDA Agricultural Marketing Service requires that fish in the retail market be labelled with the country of origin; restaurants and other food service providers are not required to follow this requirement. Recent lessons from other commodities have demonstrated that a foodborne illness outbreak associated with consumption of catfish will have impact on both domestic and imported catfish sales. It is critical to growers, processors, and purveyors that the most significant hazards are identified and controlled, to ensure that catfish is safe for consumption.

The US Food & Drug Administration has had regulatory authority over this industry, under the Federal Food Drug & Cosmetic Act, and has enforced comprehensive seafood HACCP regulations and programs that include catfish (21 CFR Part 123 —Mandatory Seafood HACCP Regulations). NOAA National Marine Fisheries Service provides a voluntary inspection and grading system in partnership with FDA. As imports of channel catfish and related species grew, however, concerns have been expressed about the safety of these products. As described in subsequent sections of this risk profile, about 2% of the imports are inspected or tested by

FDA (General Accounting Office (GAO), 2009). FDA import inspections, from 1998 to 2004, have consistently shown that fish and seafood products have one of the highest rates of violations and import refusals (USDA, 2008a). Within fish and seafood products, 27% of the refusals were for microbial pathogens, 3% for chemicals, 53% for others (mostly decomposition and filth) and 14% for misbranding. *Salmonella* was the most frequent microbial pathogen (67.6%) and *Listeria monocytogenes* the second (21.6%).

A GAO report on seafood safety (GAO, 2001) titled *Federal Oversight of Seafood Does Not Sufficiently Protect Consumers*, made several critical distinctions between the risks from various seafoods. It is necessary to differentiate among these various classes, which include: wild caught versus aquaculture seafood, fresh water versus salt water aquaculture, and aquaculture fresh water finfish versus shell fish. Similarities in hazards and human risks exist among all pond raised finfish (catfish, tilapia and trout) and shellfish (shrimp), accordingly FDA has placed aquaculture on its priority lists as a distinct subset of high priority seafood products and increased its efforts to enforce the Seafood HACCP program upon this industry (FDA, 2008). In response to rejections at the port of entry, the FDA (2008, 2010) has put Chinese farm-raised catfish on import alert, so that no products may enter the US without specific evidence for the absence of hazards in that shipment.

Increasing concerns for threats to public health from catfish and fish marketed as catfish resulted in the 2008 Farm Bill (Food, Conservation, and Energy Act of 2008, Section 11016) directing transfer of catfish inspection to the USDA, Food Safety and Inspection Service (FSIS) because of its intensive regulatory and inspection program in order to enhance catfish's safety to the public. The Act further stated "It is the intent of Congress that catfish be subject to continuous inspection and that imported catfish inspection programs be found to be equivalent under USDA regulations before foreign catfish may be imported into the United States." The requirement for equivalent inspection programs is the same safety standard that FSIS applies in permitting the importation of other meat and meat products into the US. Because FSIS has not published final regulations for their regulatory program, this transfer has not yet occurred.

3 Catfish Taxonomy and Issues

The US Government's Interagency Taxonomic Information System (ITIS) follows the scientific nomenclature system and defines the Order called *Siluriformes*, which the ITIS refers to as "catfishes and silures" (Figure 1) (http://www.itis.gov/info.html). Within this Order are 36 Families, including the Family of *Ictaluridae*. This family contains the native North American catfish (*Ictalurus punctatus*, which is harvested domestically and has been imported into China for aquaculture) and the Family of *Pangasiidae* (which include the fish imported from Southeast Asia). These *Pangasiidae* fish are properly labeled as basa, tra, swai or sutchi. There are over 3,000 species of *Siluriformes* in the world and more than 100 species are used for human consumption.

The *Pangasiidae* fish are frequently imported into the US and sold as catfish; consumers are not readily able to differentiate between the *Ictaluridae* and *Pangasiidae* species. To properly inform and ensure consumers that they were purchasing or ordering the intended fish, the 2002 Farm Bill limited the common name, "catfish," to the *Ictaluridae* species.

Because of concerns about the safety of the *Siluriformes*, the 2008 Farm Bill amended the Federal Meat Inspection Act (FMIA) to require the USDA Secretary to define catfish for the purposes of FMIA, and to promulgate rules for a catfish inspection program by the USDA Food Safety and Inspection Service (FSIS). The term "catfish" is used in the Farm Bill and the Conferees Report accompanying the 2008 Farm Bill stated that the "Secretary [of the USDA] has underlying authority… to amend the definition of amenable species as he considers necessary and appropriate." The 2008 Farm Bill additionally defines the intended regulations to include "farm raised catfish" and "additional species of fish and shellfish" indicating the intent to include fish of similar characteristics and safety concerns.

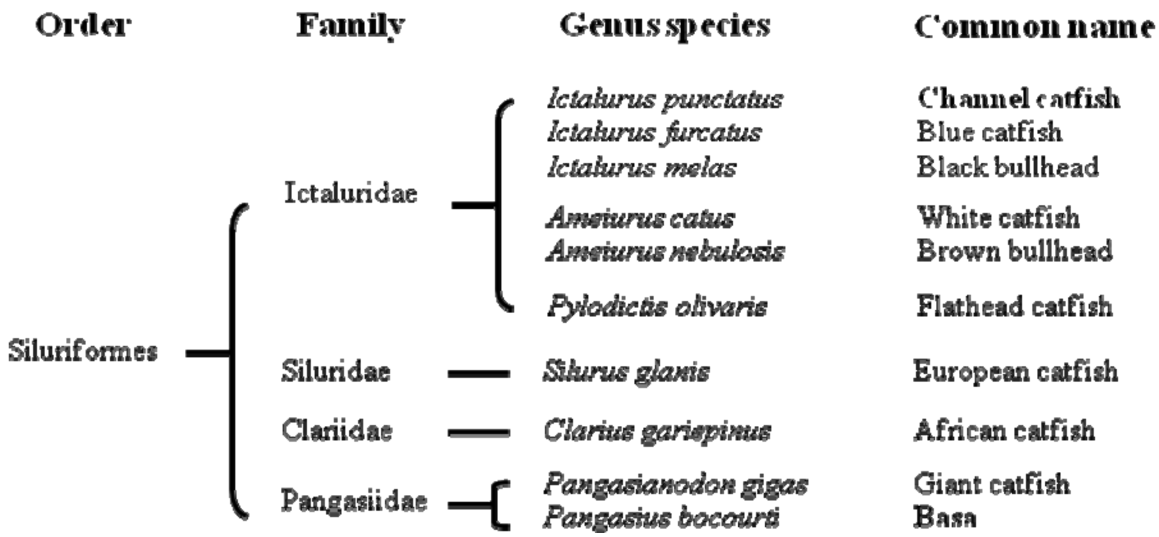

Figure 1 Taxonomy of Catfish showing 4 of the 36 Families

The scope of use of a common name is governed by usage and other non-scientific criterion. Because of the interchange ability of these species in the marketplace, it is necessary for regulatory control to cover all species raised, processed and marketed in similar ways in order to protect the public.

4 Product Pathway Description

The production and processing of catfish are similar in the US and Asia. Differences include: water and feed sources, antimicrobial use, and stringency of process controls. The production and processing steps are summarized on Figure 2.

4.1 Domestic Catfish

Domestic catfish are produced using controlled aquaculture conditions and are harvested year round. Production begins with fertilized eggs. After hatching in tanks and initial growth, sac fry are transferred to a nursery pond. At four to six inches, the fingerlings are transferred again to raised-embankment, rectangular grow out ponds having surface areas of 10 to 20 acres. Ponds are built over clay-rich soil and filled with ground water, which minimizes ground infiltration and contamination, respectively. Feed consists of plant protein pellets made from soybeans, corn, wheat, and supplements, and are produced under feed safety and labeling programs that minimize contaminants such as dioxin, heavy metals, and organochlorine pesticides.

US farm-raised catfish are harvested with nets when fish reach 18 to 36 months and average one to two pounds live weight. Only FDA approved antimicrobial agents are employed during the growing of these fish. These market fish are transferred into baskets and placed into aerated tank trucks for transport to processing plants that are located within a relatively short geographical distance from the ponds. At the processing facility, live fish are electrically stunned, sorted, de-headed, eviscerated, skinned, filleted, spray-washed, then conveyed to a chill tank. Over 50% of the processed fish are frozen, much of which is breaded and sold as a (raw) ready-to-cook food (NASS, 2010). Newer technologies used by the industry include injection and vacuum marinating with phosphates, spices, and flavorings, which infiltrates these agents into the core of fillets. Catfish are sold to both retail (consumer) and food service industries (institutional) markets.

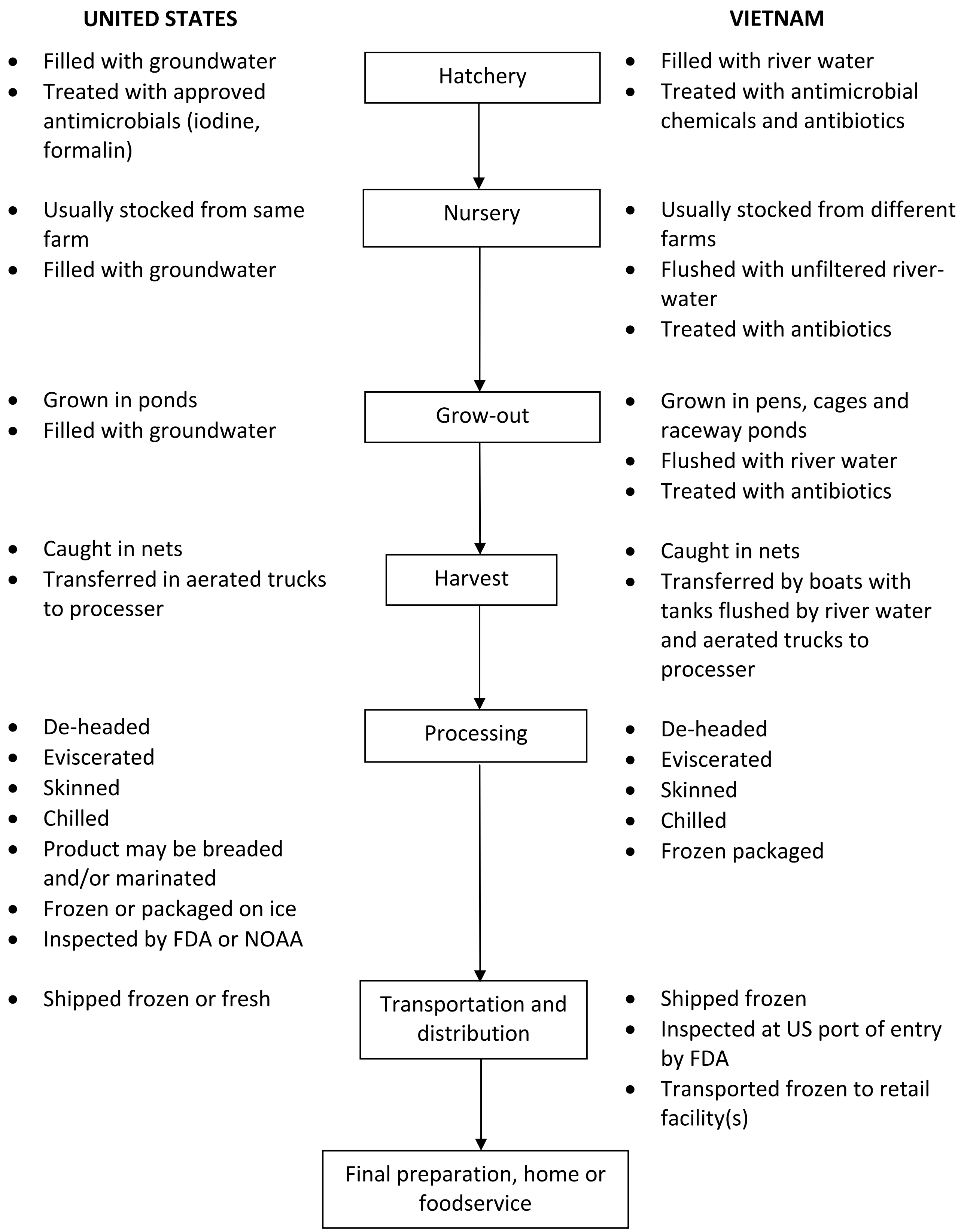

Figure 2 Comparison of US and Vietnamese product pathways

4.2 Imported

Imported fish, such as those from Vietnam and China, are produced in less controlled environment with many more opportunities for microbiological and chemical contamination of the water in which the catfish are grown. Pond culture is the most prevalent catfish farming system in China, accounting for approximately 71% of inland aquaculture (FAO, 2010a). The majority of pond agriculture is centered in the Yangtze and Pearl River basins. Vietnamese catfish are produced in freshwater areas of the Mekong River Delta using pond, cage and fence culture methods (FAO, 2010b). The use of ponds is gaining in popularity with farmers, while cage and fence culturing have diminished.

Vietnamese catfish farms in the Mekong Delta are typically less than 5 hectors (ha) in size with 10-17 ponds per farm and can be categorized as small farmer owned and operated but intensively farmed systems (Phan et al., 2009). Cage and fence aquaculture grow the fish directly in the river, which may contain uncontrolled contaminants and sewage and would not meet US standards. With pond cultures, water is obtained, by the majority of farms, directly from the river, with few using either screens or sedimentation ponds prior to supplying water to rearing ponds (Phan et al., 2009). The ponds are continually filled and flushed with river water. In all of these practices, little control is possible over water quality and the presence of contaminants. During the first two months after stocking, water exchange is infrequent. Subsequently, water exchange frequency increases to up to two times per day. Most catfish farms discharge water directly back into the main river with no screening of the water prior to release (Phan et al., 2009). Phan et al. (2009) reported there is no communication or coordination between adjacent farms in regard to the intake and discharge of water allowing cross-contamination from one farm to downstream farms.

Seedlings are reared in nursery facilities to an average of 8.6 cm then they are purchased by grow out farmers for stocking. For processing, fish are harvested after a 6 to7 month growing period at 0.6 to 1.5 kg (1.3 to 3.3 lbs) in weight. The ponds are drained of 60-80% of their water and the fish are harvested with nets (Phan et al., 2009). Fish are frequently transported to the processing plant by boats that have tanks/cages filled and flushed with river water. The fish are processed into fillets and are either block frozen or individually frozen for shipment abroad. Feeds can be produced locally, not in controlled circumstances, using fish meal and other animal materials, potentially containing contaminants and unapproved antimicrobials.

At present, all production facilities that export to the US should have Hazard Analysis, Critical Control Point (HACCP) plans that ensure that the catfish will meet food safety standards which are equivalent to those for domestic catfish under FDA Seafood HACCP programs. Currently surveillance is only episodic and the available data suggest that there are important differences between US domestic and imported catfish.

5 Hazards

A hazard is any agent, either physical, chemical, or biological (microbial), that can cause illness. Fish incorporate desirable and undesirable components from the water and feed and integrate both nutrients and contaminants (hazards) onto their bodies. Some of the hazards can become a threat to public health. These components can be grouped as environmental chemicals (heavy metals, pesticides and other toxins), drugs that were administered to the fish and drug residues that remain in their tissues, and pathogenic microorganisms from the pond environment and processing facility. Many chemical contaminants accumulate in the body and do not immediately produce an illness which can be identified although there are a wide variety of illnesses that may occur with prolonged exposures. Their presence on a food, if identified at levels that may cause harm or that exceeds regulatory limits, is considered adulteration by federal and state regulatory agencies, making the product illegal to enter into commerce.

5.1 Environmental Chemicals

Environmental chemicals in catfish meat reflect the presence of these hazards that originate from water, soil used in pond construction, or fish feed (Figure 3). Some environmental chemicals, such as dioxins, Dichlorodiphenyltrichloroethane (DDTs) and Polychlorobiphenals (PCBs), accumulate and persist in the fatty tissues of the fish. US catfish ponds are typically built on farm land and filled with ground (well) water. These chemicals are present worldwide, but in the US only trace amounts are present in the fish. However, Asian fish may be raised in cages directly in the rivers in the Mekong River Delta. Ponds are often adjacent to rivers and filled with water taken directly from the river. Ponds have also been located near dumpsites containing chemical contaminants and can be polluted by runoff from these dumpsites (Minh, 2006). There are also differences between US and Asian production in the controls over the contamination of the fish feeds with Asian feeds containing fishmeal and other animal materials that are often uncontrolled for contaminants. US catfish feeds are based on plant products and much less likely to contain these contaminants.

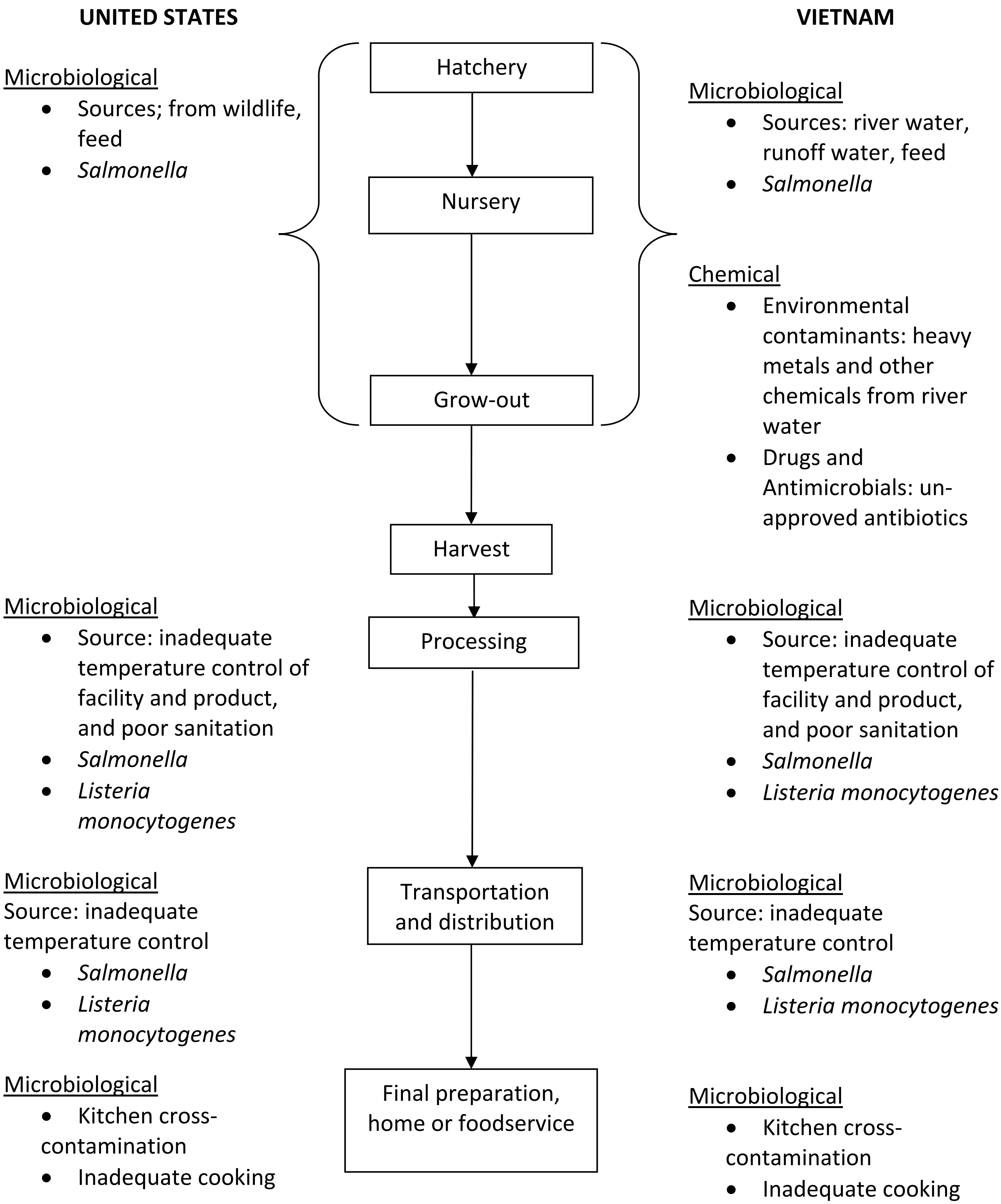

Figure 3 Hazard comparison of US and Vietnamese catfish

Surveys of persistent organic pollutants (DDTs and PCBs) in catfish taken from river cages, ponds near municipal dumpsites and sediment in the Mekong River area of Vietnam found widespread occurrence of these compounds although not generally at high levels (Minh et al., 2005, 2006). Catfish raised near the municipal dumpsites were significantly higher suggesting contamination of these ponds from surface runoff. Levels in some sediment from the river exceeded Canadian Environmental Quality Guidelines. The arsenic content of ground water in the Mekong River Delta frequently exceeded WHO drinking water guidelines and were correlated to arsenic levels in human hair and urine (Agusa et al., 2009).

Contamination by polybrominated diphenyl ethers (PBDEs) and persistent organochlorines in samples from 20 Mekong River Delta catfish, 5 pond-raised fish, and 5 commercial fish feeds were present at detectable but low levels in all samples (Minh et al., 2006). Contamination was again greater in fish raised near the municipal dumping sites compared to river-raised fish, suggesting surface runoff contamination. The pattern of the different organochlorines reflected the patterns in the feeds indicating feed was a significant source. Concentrations in the river catfish were below Canadian standards; however, samples from the fish in some ponds exceeded the standards. These ponds near dump sites would constitute a small proportion of catfish production and would tend to be locally consumed. Orban et al. (2008) evaluated the levels of mercury, organochlorine pesticides and polychlorinated biphenyls in Vietnamese sutchi catfish (*Pangasius* sp.) in Italian retail markets and concluded all were sufficiently low to be at a 'good' safety status. Organochlorine pesticides and their metabolites were found at parts per trillion levels in the Pearl River Estuary in China and at similar levels in Vietnam (Yu et al., 2008).

The US Environmental Protection Agency (EPA) approves the use of pesticides and establishes tolerances for residues on foods (FDA, 2009c). Except for products under FSIS's responsibility, FDA is charged with enforcing tolerances in imported and domestic foods shipped in interstate commerce. FDA with cooperation from state agencies conducts a program of selective pesticide monitoring. This program is primarily a surveillance program, but is not statistically based and random with emphasis on certain commodities and places of origin with a history of violations.

Catfish is not a product given special attention in pesticide monitoring. In 2007, the FDA program sampled and tested 45 domestic fish/shellfish/other aquatic products, including 4 aquaculture seafoods. Only one fish/shellfish had detectable residues. For imports, 233 products were sampled, including 49 aquaculture seafoods. Seven of these aquaculture products had detectable residues, but only one fish/shellfish product had violative levels (i.e., residues exceeding the tolerance level). No samples were taken from Vietnamese seafood. For the entire fish/shellfish/other aquatic products category, 15.6% of domestic samples and 13.3% of the imported samples had detectable residues.

The USDA Agricultural Marketing Program (USDA, 2009b) conducts the Pesticide Data Program (PDP). With cooperation from state and other federal agencies, PDP manages the collection, analysis, and reporting of pesticide residues in foods with an emphasis on foods consumed by infants and children. In 2008, farm-raised or wild, and domestic or imported catfish samples were collected from retail, distribution centers or other markets and tested for 200 parent pesticides, metabolites, degradates and isomers. From the 552 catfish samples, 44 different pesticide residues were detected. Most of the residues were present in a small percentage of samples with the exception of DDD, DDE and Diphenylamine (DPA) which were found in 235, 467 and 133 samples, respectively. The majority of the residues were most likely attributable to environmental exposure and not deliberate application. The FDA has Action Levels (AL) for these contaminants. One pesticide detected, diuron, has a tolerance in farm-raised finfish as an aquatic herbicide. Where action levels are established, all of the detected residues were below the AL (including DDD and DDE). Nineteen percent of the samples in the survey were from imported catfish; however, the test results were not separated into domestic/imported samples. The Pesticide Data Program also tested ground (well) water in 136 US sites where only low levels of detectable residues in parts per trillion were found.

In summary, trace levels of pesticides were detected in EPA and FDA surveys in catfish. However, they were below established tolerances and/or action levels which EPA as set to have “reasonable certainty of no harm.”

5.2 Antimicrobials

Antimicrobial residues in foods are an emerging worldwide issue. Concerns focus on the direct consumption of antimicrobial residues used illegally in agriculture; some of these are considered carcinogenic. Furthermore, inappropriate antibiotic use may cause harmful microorganisms to become resistant, which threatens treatment of human infections. Antimicrobials are used in aquaculture to control diseases and include antibiotics, antifungals and other drugs. This becomes increasingly necessary when fish are grown in contaminated waters or in crowded conditions. Antimicrobial residues in meat products, including in seafood from antimicrobial use in aquaculture, is an issue of increasing worldwide concern and was the subject of a recent Codex Alimentarius working group (Codex Alimentarius, 2009). The concerns are about the human consumption of the residual antibiotics and about pathogenic microorganisms becoming resistant to these antibiotics resulting from adapting to the widespread exposure to antibiotics (Sapkota et al., 2008). The widespread prophylactic use of antibiotics, usually administered in the feeds to forestall bacterial infections and promote animal growth, is receiving particular scrutiny. Treatment of human infections becomes more difficult as the antibiotics lose their effectiveness. There is an increasing consensus that the environmental levels of antibiotics should be reduced and that different antibiotics be used for veterinary and for human treatments. In aquaculture, the close confinement of fish in ponds or cages and the sanitary shortcomings of these environments have resulted in the use of a wide variety of antimicrobials in large amounts, including non-biodegradable antimicrobials used in human medicine (Serrano, 2005; Cabello, 2006). The handling of antimicrobials in the fish food can also create industrial hygiene problems and the residual antimicrobials in the fish meat and products can cause reactions by consumers.

The FDA maintains a list of approved aquaculture drugs, specifying species, conditions of use and withdrawal times (FDA, 2009d). Currently approved and used antibacterial drugs for catfish are florfenicol, sulfadimethoxine/ormethoprim, oxytetracycline and tricaine methanesulfonate. Formalin solutions may be used to control protozoa and tremetodes. Antimicrobial use in the US follows FDA’s requirements for choice of antimicrobial, dose level and withdrawal periods. FDA has not found an illegal drug in samples from domestic aquacultured seafood (Jones, personnel comm., 2010a).

Visiting US observers have noted frequent use of unapproved antimicrobials and unauthorized dosages in Asian countries (Engle, personnel comm., 2010). Dr. Lumpkin, FDA Deputy Commissioner, testified before the US Senate in 2007 and stated that:

> "As the aquaculture industry continues to grow in developing economies, concerns regarding the use of unapproved animal drugs and unsafe chemicals in aquaculture operations have increased substantially. The use of unapproved antibiotics or chemicals in aquaculture raises significant public health concerns. There is clear scientific evidence that the use of antibiotics, and other drugs and chemicals, such as malachite green, nitrofurans, fluoroquinolones, and gentian violet, during the various stages of aquaculture can result in the presence of residues of the parent compound or its metabolites that are found in the edible portion of the aquacultured seafood and can be potentially harmful to human health. Also, the use in aquaculture of unapproved antibiotics may significantly increase antimicrobial resistance to those antibiotics in human pathogens of public health concern" (Lumpkin, 2007).

Dr. Lumpkin testified that FDA monitoring during 2006-2007 found 25% of the farm-raised seafood imported from China contained drug residues. The fish contained malachite green at levels ranging from 2.1 to 122 ppb, gentian violet (2.5 to 26.9 ppb) and fluoroquinolones (1.9 to 6.5 ppb). FDA recognized that these levels were often at or near the minimum level of detection and did not seek a recall; however, Lumpkin stated that FDA was *"very concerned, however, about long term exposure as well as the possible development of antibiotic resistance"* [italics added] (Lumpkin, 2007).

FDA's testing of imported products in 2006 and 2007 found 12 of 98 samples from Vietnam and 88 of 517 samples from China contained unapproved new animal drugs. These drugs were crystal violet, malachite green and fluoroquinolones. All are not approved for use in aquacultured animals and are not GRAS (generally recognized as safe) under any conditions of intended use that may reasonably be expected to result in their becoming a component of food. In 2010, FDA issued an Import Alert (FDA, 2010 Import alert #16-131) for aquacultured fish, including catfish and basa, from China because of the presence of these drugs. This means that FDA inspectors automatically detain catfish, basa and other pangasius shipments unless the lots are from specifically identified firms or tested for these three antimicrobial residues. Inspection of imported catfish by FDA between April 2009 and March 2010 found 6 shipments from China that had drug adulterations (FDA, 2010). Parallel data on shrimp from October 2008 to October 2009 found 6.0% of imported shrimp contained chemotherapeutic agents, including chloramphenicol, nitrofurans and fluoroquinolones, in products from Vietnam, whereas domestic shrimp contained no residues (FDA, 2009a; Jones, personnel comm., 2010b).

The State of Alabama tested imported catfish and basa for antimicrobial residues in 2007 (Alabama, personal comm., 2010). They found 14 of 20 catfish from China contained fluoroquinolones and 5 of 13 basa from Southeast (SE) Asia were positive for antimicrobials.

The FDA-CVM Supplemental Policy 1240.4200 lists antimicrobials which residues were found in imported fish to be of “high enforcement priority” in the US and on the “forbidden list” of drugs. The US government’s policy is zero tolerance for these compounds.

The scientific literature contains other recent peer-reviewed reports of antibiotic residues or antibiotic resistant microbial pathogens in catfish and other aquaculture species. Zhao et al. (2003) reported antimicrobial resistant strains of *Salmonella* in two catfish from SE Asia and Thailand and four resistant *Salmonella* were isolated from shrimp and snails from Vietnam. Broughton and Walker (2009) sampled 35 catfish from China and found two positive for *Salmonella*. Both of these *Salmonella* isolates were resistant to erythromycin and penicillin.

Malachite green and gentian violet are both triphenylmethane dyes that have been applied extensively in other countries in aquaculture operations. They are used as therapeutic agents against external parasites and fungal infections of fish skin, gills and fish eggs. They are readily absorbed into fish tissue from the water and metabolized to a leuco moiety that accumulates in the muscle tissue. This moiety is eliminated slowly from the fish (half life of leucomalachite green is approximately 40 days). Application of these compounds to farmed fish at any stage could result in residues in the consumer product. Both of these compounds are considered to be potentially carcinogenic and mutagenic. Gentian violet has been linked to human bladder cancer and induces renal, hepatic and lung tumors in mice. Neither of these compounds has been approved by FDA for any use in animal feeds for any food-producing animal.

Fluoroquinolones are recognized as an essential class of antibiotics for treating serious infections in humans and for animal health by both FDA and WHO. Non-human use and the potential for development of resistant microbial pathogens is a major concern for these antibiotics. In 1997, FDA prohibited the extra-label use of fluoroquinolones in food producing animals (62 Fed. Reg. 27944) because of the evidence that widespread application in food animals promotes the evolution of drug-resistant pathogens which will be transmitted to humans via the food chain. This would have serious consequences for human health including increased duration of illness, treatment failure, and loss of therapeutic options. Fluoroquinolones have never been approved for use in any aquatic species in the US.

In summary, the public health community is in agreement that it is undesirable to be exposed to avoidable antimicrobials, even the low residue levels present in aquaculture fish. However, the indirect, although more consequential result of indiscriminate use of antimicrobials, is in the rising frequency of antibiotic resistant strains of microorganisms. These pathogens can establish a general environmental presence and reach humans by many routes. When individuals are infected with resistant strains, if warranted, disease management using antibiotics becomes more challenging or potentially ineffective. Governments worldwide are working to reduce the indiscriminate use of antibiotics, particularly those of high value in human therapy.

5.3 Pathogenic Microorganisms

Catfish muscle, similar to internal tissues of all healthy animals, is considered sterile in live, healthy fish, but becomes contaminated from numerous sources during harvest, slaughter, dressing, processing and packaging. The pond environment is recognized as a source for bacteria, especially *Salmonella* and *Vibrio.* The intestinal tract of animals, including birds, reptiles, farm animals and humans, is a primary habitat of *Salmonella* which can lead directly or indirectly to contamination of farm-raised fish (Pal and Marshall, 2008). Poor water quality, farm runoff, feeds, insanitary processing conditions, and poor distribution/handling/preparation practices can be part of the contamination pathway. Processing facilities can harbour *Salmonella* and *Listeria monocytogenes* and workers can carry *Staphylococcus aureus*, Hepatitis A virus and Noroviruses.

Microbiological pathogens were found on catfish in a variety of studies, including:

- Microbial analyses of 220 US catfish fillets sampled in 1994-1995 found *Shigella* on 1.8% of the samples and *L. monocytogenes* on 5.9%, but no *E. coli* O157:H7 (McCaskey et al., 1998).

- Fernandes et al. (1997a) found low levels of *S. aureus* ($\leq 10^3$ CFU/g) on US catfish fillets. The same group (Fernandes et al., 1997b) did not find any *E. coli* O157:H7 but did find *Vibrio cholerae* in 33 of 120 fillets, all from samples taken during the summer and fall months.

- Recently, a total of 272 fillets from US local and internet markets were found to be contaminated with *L. monocytogenes*, but no fillets were contaminated with *Salmonella* or *E. coli* O157:H7 (Pao et al., 2008). The authors did not indicate whether any of these catfish were imported.

5.3.1 Salmonella

Despite the negative findings in the Pao et al. (2008) survey cited above, *Salmonella* has a history of contamination in aquaculture products (International Commission on Microbiological Specifications for Foods (ICMSF), 1996). USDA (2008a) reported the presence of *Salmonella* was the second most common violation found in imported fishery and seafood products. Reports include:

- Andrews et al. (1977) and Wyatt et al. (1979) found that *Salmonella* levels in the ponds were enhanced by high stocking densities and warm water temperatures. Cross-contamination from skin and viscera in the processing plant resulted in highly variable contamination of fillets; good sanitation and processing practices greatly reduced the frequency and levels of contamination of the fillets.

- McCaskey et al. (1998) found *Salmonella* present on 2.3% of the US catfish fillets.

- An FDA survey from 1990 to 1998 (Heinitz et al., 2000) reported an overall incidence of *Salmonella* in imported seafood was 7.2% compared to 1.3% in domestic seafood. For finfish, the incidence rate for domestic fish was 1.3% and for imported fish was 12.2%. At that time, Vietnam had the highest country rate of 32% of all seafood contaminated. Another FDA study in 1998 (National Aquaculture Assoc., 2000) tested 405 samples of imported and domestic raw seafood and found 11 (2.7%) positive for *Salmonella*. Four of 40 catfish samples (10%) were positive at levels from 0.004 to 0.24 MPN/g. All 40 catfish were domestic (39 aquacultured and 1 wild caught fish).

- Recently, Pal and Marshall (2009) found that 21% of the domestic channel catfish and 41% of the Vietnamese basa were positive for *Salmonella*.

5.3.2 Listeria monocytogenes

This bacterial pathogen has received little attention with seafood products, in contrast to the red meat, poultry and other foods. *Listeria monocytogenes* has widespread occurrence in the environment but is of high concern in wet, cool food processing facilities where the pathogen can become endemic and continually contaminate food for months (ICMSF, 1996). Reports of *L. monocytogenes* with catfish include:

- Raw channel catfish fillets from three US processing plants were followed for a year (Chou et al., 2006). Overall, 37% of the fillets were *L. monocytogenes* positive and serotyping confirmed that some isolates were persistently found in processing facilities suggesting that either current sanitation procedures are inadequate or the isolates are persistent in the pond environment.
- *Listeria monocytogenes* was also found on:
    - 5.9% of 220 US catfish in an early study by McCaskey (1998);
    - 23.5% of the 272 catfish fillets purchased from 9 local and 9 Internet retail markets in the US (Pao et al., 2008); and
    - 76.7% of chilled fresh fillets and 43.3% on unchilled fillets suggesting contamination originates from the processing environment (US facilities) (Chen et al., 2010).

In summary, the Pal and Marshall (2009) study provides the best indication of *Salmonella* contamination in catfish fillets; imports from Vietnam were twice as likely to be contaminated as domestic catfish. Contamination of US fillets with *L. monocytogenes* was high and indicates a need to improve sanitation in processing facilities. No data were found for *L. monocytogenes* on imported catfish; however, it is likely to be comparable to US product as the microorganism thrives in wet, cool environments of processing plants.

5.4 Outbreak and Costs of Illnesses

One catfish-associated outbreak was caused by *Salmonella* serovar Hadar (Center for Science in the Public Interest (CSPI), 2010). There were 10 cases from a restaurant in New Jersey in 1991, showing that catfish can be a vehicle for foodborne illness. However, epidemiological investigations are able to determine the source for only a small fraction of the cases of foodborne illness, particularly for foods produced in relatively small quantities, and no estimates are available for foodborne illnesses attributed to catfish. Because catfish are usually cooked to sufficient temperatures to kill microbial pathogens, the likely pathways are cross-contamination from the raw fish to another food or eating utensil. FSIS has similar concerns for *Salmonella* and *Campylobacter* and, consequently, has an active program to drive these contamination levels down on raw poultry even though poultry is usually cooked thoroughly before consumption.

The costs to industry, government and consumers from the expenses of regulatory programs may appear significant; however, the costs of foodborne illnesses in the US are also high, even though not easily recognized and tabulated. Salmonellosis is the second most frequent foodborne bacterial illness. It is typically 3-5 days of severe gastrointestinal distress with vomiting, diarrhea and fever; the long term sequelae of reactive arthritis can occur although less frequently. Listeriosis is a rare and sporadic disease with a lengthy incubation time making it difficult for epidemiologists to trace and identify its food source. Listeriosis occurs in immunocompromised individuals and causes severe systemic infections. Hospitalization rates are 50% and deaths occur in up to 20% of the cases.

For *Salmonella*, of the 1.4 million cases estimated to occur each year, only 172,000 see their physician (12.4%) (USDA, 2009a). Of these, 14,400 are hospitalized and survive (1.04%) and 415 die (0.03%). The estimated cost for a physician visit in 2008 was $516, hospitalization was $11,072 and death was $5.6 million. The average cost per case was $1894 and total cost per year in the US was $2.6 billion. The Produce Safety Project (PSP) at Georgetown University has also estimated the costs of foodborne illnesses in the US (PSP, 2009). They estimated the total cost per case of *Salmonella* to be $9,146 and *L. monocytogenes* to be $1.7 million. The total costs per year are $14 billion (1.6 million cases/yr) and $8.8 billion (5205 cases/yr), respectively. Even with the difficulties in appropriately evaluating the costs of illnesses, particularly when deaths result, it is evident that efforts/funds spent by the food industry to prevent contamination and by regulatory agencies to enforce food standards have a high return on their value.

Even though catfish are not a ready-to-eat food, both *Salmonella* and *L. monocytogenes* appear frequently in both domestic and imported catfish. *Salmonella* is a contaminant in the environment which is transferred to the fillets during processing. *Salmonella* can also become established in the processing facility. *Listeria monocytogenes* characteristically becomes established in niches in wet and cool food processing facilities where it is very difficult to eliminate. The frequencies of these two microbial pathogens on catfish fillets found in by Chou et al (2006), Pao et al. (2008), Pal and Marshall (2009) and Chen et al. (2010) show that improvements in SSOPs and GMPs are urgently needed.

6 Interventions

Interventions or mitigations are changes that can be introduced into the production and processing chain to reduce the level or frequency of the hazards (Figure 4). These interventions must be at the appropriate place to prevent or minimize contamination; if the hazard is microbial, one must prevent growth or eliminate (kill) the contaminant. Interventions must be implemented, validated, and verified within an integrated food safety system.

6.1 On Farm

Many hazards enter the aquaculture chain from contamination at the pond. A Good Aquaculture Practices (GAqP) program will minimize hazard occurrence and levels. Pond construction should be distant from local sources of pollution, the site should not contain environmental residues or contaminants, good quality water should be available, and the facility should minimize as much as possible contamination by wild and domesticated animals as well as maintain hygiene standards for workers. Direct contact of catfish with river waters should be avoided because of their likelihood of containing contaminants and lack of control over all of these hazards.

The fish feed can be the source of chemicals, antimicrobials and pathogens. It should only come from a reliable and verified source. Catfish meals used in the US are based upon soybean corn and wheat. In SE Asia some foods are made with fish meal or other animal-derived ingredients which increases the potential for contamination from dioxins, organochlorides, DDTs and microbial pathogens.

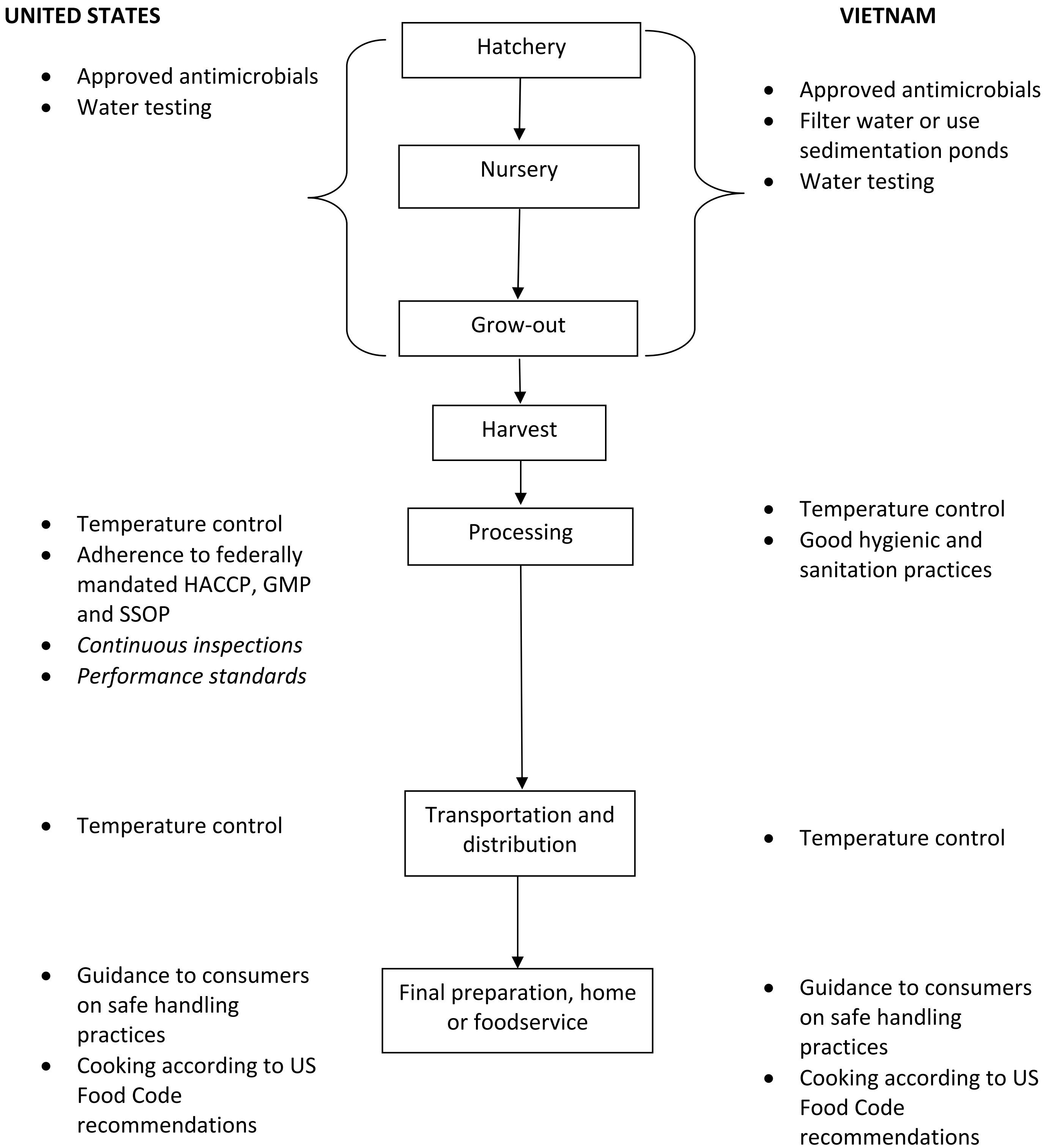

Figure 4 Comparison of interventions for US and Vietnamese catfish

Text in italics represents changes introduced by the 2008 Farm Bill

6.2 Processing

Environmental monitoring, Good Manufacturing Practices (GMP), Hazard Analysis, Critical Control Points (HACCP) system and Sanitation Standard Operating Procedures (SSOP) represent the key elements of the in-plant food safety system. Fish processing needs to be conducted in facilities having good sanitary design and construction and with equipment that can be cleaned and operating under a validated and verified HACCP plan. The prerequisites for a HACCP plan include an environmental testing program for control microorganisms, SSOPs and other GMPs. The microbial testing program should focus on *Salmonella* which can enter the plant with the fish or from within the facility and on *L. monocytogenes* which can become established in niches within the facility and is extremely difficult to eradicate.

If further processed products are being made, there should be Certificates of Analyses for the breading ingredients, marinates and spices used. A verification program should be in place to ensure these do not become sources of microbial pathogens.

The HACCP program should monitor temperatures of the facility and refrigerated storage rooms to ensure proper temperature control. Freezers and frozen storage rooms should also be monitored, freezers can be sources of *L. monocytogenes* if the sanitation during the defrost cycles is not adequate. Both FDA's Seafood HACCP and FSIS's regulations require HACCP programs.

The Global Food Safety Initiative (GFSI) is a voluntary program that major retailers worldwide (Wegmans, Whole Foods, Migros, Wal-Mart, Ahold, Carrefour, Metro) are asking their suppliers to be certified under. Objectives are to create a global standard recognized by all producers and retailers that would replace the numerous audits which have proven to be too superficial and inadequate to prevent major outbreaks. The GFSI benchmarks and harmonizes about 6 schemes, which conduct in depth audits and issue certifications of compliance that is recognized by all. These schemes include the British Retail Consortium (BRC), Safe Quality Foods (SQF), IFS (International Food Standards), Global Good Agricultural Practices (GAPs), International Standards Organization (ISO), and Dutch HACCP. The GFSI program has recently announced the establishing of a Global Aquaculture Alliance Best Aquaculture Practices certification scheme (GFSI, 2010). In addition to areas covered by traditional HACCP plans, these schemes evaluate management's commitment to safety, the corporate safety system, facilities, processing, and personnel (conduct and training). Achieving and maintaining certification under these schemes requires a more comprehensive safety program than is required under current HACCP systems.

The food safety legislation currently in the US Congress will require food processors under jurisdiction of FDA or FSIS to meet more stringent requirements similar to those under the GFSI program. Although the relationship between the US regulatory program and the non-government GFSI Schemes has not been specified, a company exporting to the US would also be required to have enhanced standards under some recognized protocol from the US, home country or GFSI.

6.3 Regulatory Controls as an Intervention

This section summarizes some of the relevant characteristics and differences between FDA, NOAA and FSIS inspection systems (Table 1). FDA has regulatory authority for most non-meat foods, as well as over animal feeds and animal drugs. The Department of Commerce, NOAA Seafood Inspection Program has a voluntary fee-for-service seafood inspection and grading program for the US, which functions under a memorandum of understanding in collaboration with FDA (http://www.seafood.nmfs.noaa.gov/Standards_for_Grades.htm). FSIS has regulatory authority for meat, poultry, and processed egg products.

Table 1 Comparison of FDA-NOAA and FSIS inspection systems

Inspection Element	Current system for aquaculture		FSIS
	FDA	NOAA (voluntary)	(current system for meats and poultry)
Prerequisites for granting inspection authority and permission to operate	Facility registration	List of Approved Establishments Voluntary services include: Establish sanitation inspection, System and process audits, Product inspection and grading, Product lot inspection, Laboratory analyses, Training, Consultation and Export certification	File formal application Facilities meet regulation's performance standards Obtain approval for labels/brands Obtain approval for water source Obtain approval for sewage system Provide written SSOP Provide written HACCP plan
Customary point in food chain where jurisdiction begins and ends.	Start: Catch or production End: Food service or retail	Catch, production or retail	Start: Ante-mortem inspection at slaughter facility End: Limited retail authority
Premarket requirements	Approved drugs and ingredients Mandatory HACCP	Follows FDA with HACCP, GMP and SSOP	Approved labels Approved Ingredients and processes Approved HACCP plan
Inspections	Periodic. Less than once per year	As requested for services listed above	Continuous Slaughter – every carcass

			Processing - daily Pre-operation sanitation verification Review HACCP plan and execution Daily *Salmonella* testing by agency Frequency of inspections depend on process controls and plant size and history
Sample testing	Takes samples for lab test at inspector's discretion	As requested	Collects samples for testing by FSIS labs on regular basis
Microbiological performance standards	No *Salmonella* and *L. monocytogenes* on ready-to-eat foods. No *Salmonella* in raw imported shrimp.	Follows FDA	Microbial performance standards—*Salmonella*, *E. coli* O157:H7, *Campylobacter*, *L. monocytogenes* (e.g., less than a specified percentage of samples positive) Zero-tolerance on Ready-to-eat foods Implements pathogen reduction programs Conduct baseline studies on products
Hazard surveillance	Surveys for chemical residues	Laboratory analyses as requested	Surveys for chemical residues Baseline studies for microbiological hazards

Imports	Inspection at point of entry Visual, filth, labeling Retention lists Foreign establishment inspections	Inspects foreign processors if requested Inspect product in US and issue certification if requested	Pre-market determination that exporting country has equivalent inspection system FSIS inspects country's system (1-2 wk audit) Approves specific companies and products for importing Import re-inspection

6.3.1 FDA and NOAA

FDA has current regulatory authority over domestic and imported seafoods. The agency's authority covers the entire production chain including feed, veterinary drugs, farms, processors and the distribution chain. Because of the large number of companies and facilities under its purview and a limited number of inspectors, FDA cooperates with NOAA, state and local agencies who conduct many inspections. In addition, FDA relies on education and voluntary compliance by the industry to achieve many of its public health objectives. FDA's Center for Veterinary Medicine establishes standards for animal feeds and determines allowable drug use which would presumable continue for catfish as it does for other animal products under the Federal Meat Inspection Act. The Office of Regulatory Affairs conducts inspections of both domestic and, in cooperation with the Customs Service, imported foods. The Center for Food Safety and Applied Nutrition establishes seafood policy and regulations.

FDA initiated its Seafood HACCP program in 1998 to enhance its Domestic Seafood Products Compliance Program (CP7303.842) and Imported Seafood Products Compliance Program (CP7303.844). Traditionally, imports were controlled by reviewing customs entries, conducting exams at import sites, collecting samples for laboratory analysis, and placing products and processors with a history of problems on automatic detention without physical examination. These exams are primarily directed toward determining whether the product is misbranded, decomposed or contains substances that would cause the product to be adulterated. FDA's lack of unique identifiers for firms exporting food products may allow contaminated products to evade FDA's review and limits its ability to assess penalties on importers who introduce violative products (GAO, 2010). FDA is testing a new computer screening system, the Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting, to better prioritize and identify import lots for additional inspection.

The Seafood HACCP Program requires the importer and foreign processor comply with the US HACCP regulations (21 CFR Sec. 123.12). Importers are required to take affirmative steps and verify that their processors comply with the regulation. By FY 2005, domestic seafood firms were at 91% compliance with the Seafood HACCP requirements (Official Action Indicated (OAI) status) as a result of efforts by the industry and inspections by FDA and the States (FDA, 2009b). FDA could inspect only a small percentage of importers and acknowledged that "importers, as a whole, still have much progress left to make. Low rate of inspection is a likely contributing factor" and from the import examinations "the specific HACCP deficiency cannot be identified without more information." FDA has sent inspection teams to foreign countries to evaluate the seafood HACCP programs of selected processors and to develop contacts and relationships with the foreign Competent Authorities to improve their understanding of US requirements. FDA conducted 31 foreign catfish inspections between 2000 and 2008. FDA admitted: "unfortunately, there is no equivalent substitute for FDA's domestic seafood processing surveillance program which provides regular, consistent feedback on the adequacy of HACCP systems" and for imports "in FY 2005, the percentage of success for five program elements lagged significantly behind those of domestic processors." FDA conducted 2770 microbiological analyses of imported fish and fishery products under the Enhanced Aquaculture and Seafood Inspection program during 2004 to 2006 (FDA, 2008).

NOAA National Marine fisheries Service's (NMFS) Seafood Inspection Program is a voluntary program which is "responsible for the development and advancement of commercial grade standards for fishery products, better health and sanitation standards in the industry, and for furnishing inspection, evaluation, analytical, grading and certification services to interested parties (http://www.seafood.nmfs.noaa.gov/). The NMFS Seafood Inspection Program's major purpose is to encourage and assist the industry in improving the quality, wholesomeness, safety, proper labelling, and marketability of fish and fishery products for the benefit of the consumer" (50 CFR 260). The services provided by NOAA include facility sanitation inspections, system and process audits, product inspection and grading, product lot inspection, laboratory analyses, training, consultation, and export certification. These services can be provided nationwide, in U.S. territories, and in foreign countries.

NOAA and FDA had signed a Memorandum of Understanding (MOU) describing their common interests in sharing the inspection of fish and fishery products and establishments (NOAA/FDA, 2009). The MOU recognizes NOAA's services contribute to consumer protection by helping establishments fulfil their responsibility to ensure that fish and fishery products are safe and meet applicable FDA requirements. The MOU states that the FDA is the Competent Authority for safety of fish and fishery products and determinations by NOAA do not change or diminish FDA's authority. NOAA maintains a list of Approved Establishments that have voluntarily contracted with NOAA for inspection services and have been sanitarily inspected, approved and certified as being capable of producing safe, wholesome products and verified to be in compliance with FDA's GMP and Seafood HACCP regulations. FDA and NOAA can share information on inspections and enforcement actions, have joint inspections, and maintain close working relations with each other, including in the field.

6.3.2 USDA FSIS

The 2008 Farm Bill (Section 11016(b)) provided that catfish is an amenable species under the Federal Meat and Poultry Inspection Act and would be transferred to FSIS control when final regulations are in effect. This transfer of jurisdiction will require that FSIS inspect and monitor catfish as it currently performs for all domestic meat and poultry sold in interstate and foreign commerce to ensure compliance with mandatory US food safety standards and inspection legislation. An appropriate program for inspection of catfish processors would be developed by FSIS. Meat processing facilities that qualify for inspection have daily inspection and continual surveillance during slaughter by federal inspectors or state inspectors if they have a cooperative agreement with the FSIS. Currently, 27 states have cooperative agreements with FSIS. Products inspected by state regulators may only be sold in intrastate commerce. USDA must review and approve all processes, ingredients and labeling information on inspected products prior to release into commerce. In addition, the catfish inspection program mandated by the 2008 Farm Bill extends FSIS control by requiring FSIS to include how catfish are raised and transported to the processor.

In 2000, FSIS completed implementation of the Pathogen Reduction/HACCP Systems rule. The Pathogen Reduction/HACCP rule requires;

- All meat and poultry plants to develop and implement written standard operating procedures for sanitation (SSOPs);
- All meat and poultry slaughter plants to conduct microbial testing for generic *E. coli* to verify the adequacy of their process controls for the prevention of fecal contamination;
- All meat and poultry plants to develop and implement a system of preventive controls, known as HACCP, to improve the safety of their products; and
- Sets pathogen reduction performance standards for *Salmonella* that slaughter plants and plants producing raw ground products must meet.

The Pathogen Reduction/HACCP rule applies to over 6,500 federally inspected and 2,300 State-inspected slaughter and processing plants in the United States and the requirements must be met by countries that export meat and poultry products to the United States.

The regulatory program of FSIS has included national baseline microbiological surveys for the meat and poultry products that it regulates. These surveys are designed to obtain a sufficient number of representative samples to characterize the prevalence and quantitative levels of the microorganisms on the products and support the development of FSIS's regulatory programs. Targeted baseline surveys are conducted for specific pathogen-product combinations of concern. Examples of baseline programs FSIS has done were for *Salmonella* on raw poultry and *E. coli* O157:H7 in ground beef. FSIS under their National Residue Program conducts tests for chemical contaminants, including antibiotics, other drugs, pesticides and environmental chemicals in domestic and imported meat products destined for human consumption, to verify that tolerances or action levels are not violated (USDA, 2009c). It is reasonable to assume that FSIS will initiate similar surveys for catfish when it establishes its regulatory program.

Since the implementation of the HACCP rule, FSIS has compiled microbial prevalence data across eight classes of raw meat and poultry products as part of its verification program (USDA, 2010). In 2009, this program analyzed 29,116 samples for *Salmonella* using a risk-based algorithm to target establishments demonstrating variable or poor process control. FSIS established this program with the belief that the prevalence of *Salmonella* on raw meats is related to the rate of foodborne illness.

For imported meat and poultry, FSIS is also responsible for assuring that these products are safe, wholesome, unadulterated, and properly labeled and packaged. The US makes determinations of equivalence by evaluating whether foreign food regulatory systems attain the appropriate level of protection provided by our domestic system. Thus, while foreign food regulatory systems need not be identical to the US system, they must employ equivalent sanitary measures and additive/residue requirements that provide the same level of protection against food hazards as is achieved domestically. The inspection system must ensure that only drugs permitted in the US are used in the production of products exported to the US. A foreign plant cannot export to the US until FSIS certifies that the country has an equivalent inspection system.

FSIS evaluates foreign food regulatory systems for equivalence through document reviews, on-site audits, and re-inspection and testing of products at the time of importation. Export requirements and a plant listing for qualified facilities in foreign countries are listed on the FSIS Regulations & Policies website (USDA, 2009d). FSIS is scrupulous in granting permission to import meat products into the US. There are only 34 countries eligible to export meat products to the US as of December 11, 2009; just 11 countries can export raw beef. Costa Rica, for example, received an 11 day audit by FSIS in 2008 of their Central Competent Authority, local offices, laboratories, and meat slaughter and processing plants in order to maintain their export eligibility. Only two facilities are approved for exporting products to the US. Neither China nor Vietnam is certified to ship FSIS-regulated, raw, non-processed products from any meat animal to the US.

6.4 International

Experts from many countries working under WHO/FAO Codex Alimentarius have established guidance for the safe production of aquaculture and fish products (CAC/RCP 52-2003) http://www.codexalimentarius.net/download/standards/10273/CXP_052e.pdf. Hazards that are listed in the guidance for incoming fish include, in part, chemicals (e.g., pesticides, heavy metals), pathogenic bacteria (e.g., *Salmonella, Shigella, E. coli, and Vibrio*) and viruses (e.g., Norwalk). Hazards introduced post harvest and in further processing include *L. monocytogenes* and *Staphylococcus aureus*.

Because of the serious threat of drug residues to human health, Codex Alimentarius has also established a Code of Practice to Minimize and Contain Antimicrobial Resistance (CAC/RCP 61-2005) http://www.codexalimentarius.net/download/standards/10213/CXP_061e.pdf and in 2009 they wrote Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programme Associated with the Use of Veterinary Drugs in Food Producing Animals (CAC/GL 71-2009) http://www.codexalimentarius.net/download/standards/11252/CXG_071e.pdf. This document's opening statement is "Modern food production systems should be designed and managed to ensure that the exposure of food producing animals to veterinary drugs does not pose a risk to human health."

The concerns about misuse of veterinary drugs and the creation of antibiotic resistant pathogens are the subject of current working groups under Codex. The Codex Committee on Residues of Veterinary Drugs in Foods will meet in August in the US and the *Ad hoc* Codex Intergovernmental Task Force on Antimicrobial Resistance will convene in October in Korea. Both groups are further developing science-based and internationally recognized guidelines for drug usage (http://www.codexalimentarius.net/web/current.jsp?lang=en).

6.5 Final Food Preparation

Cooking is the final hazard control measure to ensure safety of catfish. *Salmonella* and *Listeria monocytogenes* are inactivated when the internal temperature of the product reaches above 155°F. Unfortunately this step is primarily under the control of consumers or the person preparing food for consumers. Extensive experience with ground beef and *E. coli* O157:H7 has demonstrated that consumers are unable to ensure that products are cooked to the necessary temperatures. Therefore, it is better to ensure that harmful microorganisms are not present on the raw fish whenever possible. However, cross contamination of microorganisms from raw product to cutting boards and food preparation utensils and then to other foods is a major food safety concern. Accordingly, one of the four recommendations to consumers for safe handling of foods from the Partnership for Food Safety Education's Fight Bac! Program is 'Separate -- Don't cross contaminate' (http://www.fightbac.org/).

Generally, cooking will not reduce levels of chemicals, although some pesticides are heat sensitive or may be removed with fat separation. Therefore, preventing contamination of the catfish is the only effective control.

7 Conclusions

7.1 General

For food safety considerations, freshwater aquaculture should be evaluated as a unique food production system that differs from other seafood systems, because hazards, their sources, and interventions differ significantly from deep water marine seafood species.

In establishing food safety control systems, the broader interpretation of catfish - to include all *Siluriformes* finfish – will provide the greatest level of consumer protection because in segments of the US market these fish occupy the same product niche and the different species are frequently interchanged.

7.2 Public Health Effects and Hazard Exposure

Published literature and federal oversight reports show that imported catfish pose several elevated risks to US consumers than domestic catfish and that the current FDA/NOAA catfish inspection system does not provide sufficient protection. Compared to US products, imported catfish has more frequent exposures to illegal antimicrobial residues and foodborne pathogens, especially, *Salmonella*.

Antimicrobial use in the US product follows FDA's requirements for choice of antimicrobial, dose level and withdrawal periods and does not pose a public health threat from residues. Proper use does not promote development of antimicrobial resistant microorganisms. FDA's sampling shows the high frequency of illegal antimicrobials in imported catfish that present a major long-term public health risk to US consumers. Antimicrobials habitually present include malachite green and gentian violet, both carcinogens, and fluoroquinolones, a class of antibiotics that authorities worldwide consider at risk of losing its effectiveness.

The most significant acute hazard associated with catfish is *Salmonella* arising from environmental contamination. If present on fish, it has the potential to grow if not kept at proper temperatures and to become disseminated by cross-contamination. Although this microbial hazard has been detected on both domestic and imported products; comparative surveys find it more frequently on imported products.

The presence of *L. monocytogenes* is an emerging concern and processors will need to improve their sanitation and other control measures to eliminate this pathogen from processing facilities. There is no information on the presence of *L. monocytogenes* in imported catfish, but the processing conditions are very favourable to its occurrence. It is also likely to be more prevalent on imported catfish.

7.3 Interventions

Hazard controls must focus on prevention across the entire production, processing, and distribution chain, since there are no methods to reduce contamination for either chemical or microbiological hazards after it occurs. This includes an integrated food safety system consisting of HACCP programs, SSOP, GAqP, GMP and environmental monitoring. Producers and processors should verify their compliance with performance standards.

The trend to require meeting GFSI standards with its emphasis on complete management control will continue to place pressure on producers and processors to strengthen their food safety systems.

FSIS's inspection program focuses greater regulatory resources than FDA to define performance standards for microbial hazards, to conduct active hazard surveillance and to evaluate each establishment's progress toward achieving acceptable performance levels.

Safety cannot be inspected into a product by the government at a domestic processing establishment or at the port of entry. Rather, regulatory and private sector control should extend to growing operations to prevent the hazards from being in the final product.

Exponent reserves the right to modify these conclusions in new information is presented.

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