Food safety management of imported fishery products in Thailand: antibiotic standards and case study of enrofloxacin contamination in imported Pangasius catfish

Jansomboon, W., Boontanon, S. K., Boontanon, N., Polprasert, C. and Liamlaem, W.

1Department of Civil and Environmental Engineering, Faculty of Engineering, Mahidol University, 25/25 Phuttamonthon 4 Road, Salaya, Nakhon Pathom 73170, Thailand
2Faculty of Environment and Resource Studies, Mahidol University, Salaya, Nakhon Pathom 73170, Thailand
3Department of Civil Engineering, Faculty of Engineering, Thammasat University, Khlong Luang, Pathum Thani 12120, Thailand

Abstract

The aim of this study was to assess food safety management of fishery products imported into Thailand and identify lessons learned and key challenges based on observation, in-depth interviews, and data review from involved Thai government authorities. In addition, enrofloxacin antibiotic residues in imported Pangasius catfish were also investigated and analyzed by extraction process and liquid chromatography coupled with tandem mass spectrometry. Results revealed that there were many key challenges that involved government authorities of Thailand, and stakeholders must pay serious attention to the need for improvement. The key challenges suggested in this study were that the specific import documents of Thailand should be revised; many on-site test kits should be developed for real-life application so as to reduce cost and time; and food regulations should be updated and clarified, especially in terms of antibiotic contamination in food, for more efficient management. Moreover, no efficient traceability system is currently established in Thailand, resulting in difficult operation and management of a practical food monitoring system. Consequently, if no new measures or appropriate management procedures are developed to cope with these issues, it is possible that fishery products contaminated with various concentration levels of hazardous substances might be increasingly imported into Thailand in the future. The results showed that 14 out of 90 imported Pangasius catfish samples collected from around Thailand were contaminated with Enrofloxacin in the concentration range of 6.4–11.3 µg/kg, indicating that some contaminated fishery products were widespread in domestic markets, and legally so due to lack of regulation.

Keywords

Antibiotics
Enrofloxacin
Fishery products
Food safety
Pangasius
Thailand

Introduction

Nowadays, one of the foundations of sustainable development in modern society, food security, has been playing an increasing role, particularly given the growth of the population around the world (Kang et al., 2009; Ahmad et al., 2014). Not only production, but food distribution and processing are also issues which are of increasing importance to food security. New management and methodologies have been established for optimization approaches (Garcia-Flores et al., 2015). Many countries have paid more attention to food safety management and have established measures as a tool for solving problems and coping with unusual situations. For instance, the Food Safety Commission of Japan was established to respond to food-borne accidents and emergencies (Food Safety Commission of Japan, 2012), and a traceability system has been efficiently used to investigate contaminated products in the European Union (European Commission – Directorate General for Health and Food Safety, 2007b; Department for Environment, Food and Rural Affairs and HM Revenue and Customs of UK, 2012; Finnish Food Safety Authority Evira, 2014). The EU’s successful import system served as the model for the development of Canada’s import system (Canadian Food Inspection Agency, 2013).

Fishery products are imported into Thailand from several Southeast Asian countries, with Pangasius catfish products constituting the highest percentage of imported freshwater fish products in 2012 (Fisheries Foreign Affairs Division, 2013). To maintain a high level of fishery production, some chemicals
have to be used for aquaculture. Antibiotics are one of the pharmaceutical classes widely used as veterinary drugs for growth promotion and disease prevention in aquatic animals (Kümmerer, 2009); specifically, enrofloxacin (ENR) is one of the quinolone antibiotics which has been popular for use in catfish culture (Rico et al., 2013), such as at Pangasius catfish farms in the Mekong Delta (Chau et al., 2013). However, extensive use (or overuse) of antibiotics is the primary factor in the increase of antimicrobial drug resistance in foodborne pathogens (Polk et al., 2004; Hu et al., 2007). The development of drug resistance could also be due to the use of low-quality antibiotic products which do not meet the content standard, and consequently difficulty maintaining an appropriate therapeutic level during treatment (Farah et al., 2016), as well as using antibiotics to treat some diseases in a manner that could be described as careless or irresponsible. Lack of knowledge and poor management are among the causes of antibiotic contamination in aquatic animals and the environment (European Commission – Food and Veterinary Office, 2009; Currie et al., 2011).

Reports of antibiotic contamination in imported fishery products in Thailand have never been published (Food and Drug Inspection Office, 2013). However, they are available in some other countries. For example, prohibited antibiotics were recently found in frozen Pangasius catfish fillets imported into the European Union (EU) (European Commission – Rapid Alert System for Food and Feed, 2015). The reason why antibiotic contamination of imported fishery products in Thailand has never been reported is presumably that no one is aware of the presence of antibiotic residues or interested in this issue because of a lack of official regulations (Food Control Division, 2007).

To better understand the current situation in Thailand regarding food safety of imported fishery products, an assessment of food safety management of imported fishery products was conducted. A primary aim of this study was to identify key challenges and lessons to be learned concerning food safety management of imported fishery products. Antibiotic contamination of imported Pangasius catfish was also examined using liquid chromatography coupled with tandem mass spectrometry (LC-MS/MS technique), with enrofloxacin chosen as the antibiotic of interest.

Materials and Methods

Data collection

Primary and secondary data were collected to analyze the current situation of Thailand’s import system of fishery products. Primary data were the deep data that were not appeared on any documents or internet. In this study, primary data included observations and in-depth interviews, as well as information concerning the role and responsibilities of the Fish Trade Inspection Section Office and the Food and Drug Inspection Office. Import and export statistics were collected from involved Thai government authorities, i.e. the Fish Trade Inspection Section Office (Fishery Patrol, Department of Fisheries, Ministry of Agriculture and Cooperatives), Bangkok Port Customs Bureau, Laem Chabang Port Customs Bureau, Ladkrabang Cargo Control Customs Bureau (all under the Customs Department, Ministry of Finance), and the Food and Drug Inspection Office (Food and Drug Administration, Ministry of Public Health). Secondary data were the data which had been collected and published on media or documents by relevant government authorities. In this case, secondary data, which consisted of statistical reports on Pangasius catfish imports in 2010–2013, and Thailand’s import and export of freshwater fish with ASEAN countries, were in turn collected from available information published by those relevant government authorities.

This research specifically focused on the traceability system implemented by Thailand’s Food and Drug Administration, which is the major authority responsible for import licensing in relation to food quality. The established import system of the EU served as a benchmark for comparison because of its success. Through this process, key challenges of the import system for fishery products for Thailand were eventually identified.

Sample collection

Pangasius catfish was chosen as a case study because it is imported into Thailand in significant quantities (Fish Trade Inspection Section Office, 2014). To determine which places in Thailand the contaminated Pangasius catfish products imported from other countries were distributed to, 90 samples of imported Pangasius catfish products were purchased from shops, convenience stores, department stores and shopping malls located in 63 provinces around Thailand during the period from April to July 2014, as represented in Figure. 1. Thirty fish samples were collected from the Bangkok area and perimeter (5 provinces in total), and 60 fish samples were collected from 58 provinces around Thailand. Many people live in the greater Bangkok area, and many supermarkets, stores and department stores are located there. Additionally, this area is not far from the ports through which the fish products
were imported. Therefore, more fish samples were collected from this area than other regions. To ensure that all *Pangasius* catfish samples were imported products, specific data were recorded based on information from the packaging labels. Fish samples were packed with ice in a strong plastic box prior to transportation, and then kept in a freezer (−20°C) after arriving at the laboratory.

**Antibiotic determination**

Enrofloxacin was selected for studying antibiotic contamination due to its widespread use in catfish aquaculture (Rico *et al*., 2013). Fish samples were extracted based on an antibiotic extraction method from fish tissue adapted from Dasenaki and Thomaidis (2010). The samples were homogenized and extracted by acetonitrile, methanol and a small amount of formic acid. Vortex shaking, ultrasonic extraction and centrifugation were then applied sequentially to obtain the supernatant, which was evaporated to dryness under a nitrogen steam at 40°C. After that, the residue was reconstituted in 0.40 mL of 0.2% aqueous formic acid. Finally, the concentrated liquid was analyzed by liquid chromatography coupled with tandem mass spectrometry (LC-MS/MS). All samples were analyzed immediately after the extraction steps. The mobile phase of component A was methanol with 10 mM formic acid, while the mobile phase of component B was ultrapure water with 10 mM formic acid. A C18 HPLC column was used for enrofloxacin separation. Instrumental calibration was carried out to detect enrofloxacin at seven concentration points of the solution in a range of 0–200 µg/L. The results of linearity, method detection limit (MDL) and recovery percentages of enrofloxacin are summarized in Table 1.

<table>
<thead>
<tr>
<th>Antibiotic</th>
<th>Calibration curve</th>
<th>MDL (µg/kg) for 1 g of sample</th>
<th>Recovery (RSD, %)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrofloxacin</td>
<td>Y = 0.91X + 0.028</td>
<td>0.0974</td>
<td>1.04</td>
</tr>
</tbody>
</table>

* X = Antibiotic concentration (µg/kg); Y = Intensity.
* Method detection limit.
* % Relative standard deviation for n = 5.

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**Results and Discussion**

**Overview of Thailand’s import system for fishery products, and key challenges**

Dealers who intend to import fishery products from any country into Thailand have to wholly understand the procedures which are outlined under the regulations of the Fisheries Act, B.E. 2490 (1947), Animal Epidemic Act, B.E. 2499 (1956), Food Act, B.E. 2522 (1979), Wildlife Preservation and Protection Act, B.E. 2535 (1992), and Customs Act, B.E. 2469 (1926). Briefly, importers are required to submit detailed documents about the transaction to the appropriate government agencies: the Customs Department, Food and Drug Inspection Office, and the Fish Trade Inspection Section Office. Once the target products are transported to the port, documents and imported products are then checked by the related government agencies, verifying that all imports are in accordance with regulations. If no problems are discovered, products will be released for distribution in the domestic market. On the other hand, any illegal products which cannot be matched as specified in the import documents or are found to contain contaminants will be impounded, and the importers will be penalized accordingly under the regulations (Fish Trade Inspection Section Office, 2009; Bangkok Port Customs Bureau, 2013; Chonburi Fish Trade Inspection Section Office, 2013; Fish Trade Inspection Section Office, 2013; Food and Drug Inspection Office, 2013).

Although there are several regulations which serve to support the import system in Thailand, some steps or points must be improved in order to raise the efficiency of the system. Table 2 shows a summary of key challenges for the import system for fishery products in Thailand. They focus on the importation...
phase, consisting of two major steps: pre-import, and date of import and contaminants inspection.

Firstly, import documents generally lack specificity and strictness, and some conditions are not considered by authorities when granting import permission. For example, Pangasius catfish products are not required to be imported from a Thai-approved establishment or country. This means that Pangasius catfish reared in an area which the government or involved authorities cannot adequately pay attention to might enter the marketplace in Thailand. Hence, to improve the process, detailed information on Pangasius catfish products regarding the place of origin, together with other documents related to specific conditions and concerns, are needed for consideration before an import permit is issued (Fish Trade Inspection Section Office, 2009; Food and Drug Inspection Office, 2013).

Next, there is a shortage of on-site test kits. Presently, only formaldehyde is determined by an on-site test kit. Determination of other toxic substances is carried out in the laboratory, a process which usually is time-consuming and incurs considerable cost due to various procedures. The use of test kits could decrease the length of time required for determination of harmful substances from many days to minutes. For example, currently the test results for formaldehyde contamination can be obtained in approximately 30 mins by using an on-site test kit, while the results for heavy metal contamination and documentation procedures from the laboratory may take more than 15 days. Importers might incur additional expenses due to this delay, as they may be required to store the rest of their products while awaiting the test result. For this reason, new on-site methods or test kits should be applied in the import system so as to benefit both consumers and importers (Fish Trade Inspection Section Office, 2009; Food and Drug Inspection Office, 2013).

Finally, some toxic substances are not regularly monitored in imported fishery products, especially antibiotics. Such chemicals are typically used in aquaculture production for a variety of purposes, and can remain in products due to improper management. Lists of harmful substance standards have not been appropriately updated in Thailand’s regulations. Consequently, no one knows the exact situation concerning some chemicals and drugs because a complete determination of toxic substances has never been carried out. Therefore, lists of hazardous substances and management guidelines should be updated and implemented (Food and Drug Inspection Office, 2013).

Differences between the import systems of Thailand and the European Union (EU) regarding management of antibiotic contamination

The import systems of the European Union (EU) and Thailand differ in some respects. An important issue which is not equally managed is antibiotic contamination. Because fishery products imported into the EU are subject to many strict conditions, e.g. they must originate from EU-approved sources, the products are randomly checked for antibiotics regularly (European Commission – Directorate General for Health and Food Safety, 2007a). In the case of Thailand, antibiotics are seldom monitored in keeping with the monitoring plan of the Food and Drug Inspection Office, but even less often when the products are arrived at ports and after the products have already been distributed in the domestic market (Fish Trade Inspection Section Office, 2013; Food and Drug Inspection Office, 2013). Due to different regulations, the monitoring of antibiotic contamination implemented by the Thai government is not equivalent to that of the EU. Based on the existing regulations, few antibiotic types are monitored in Thailand, while large numbers of antibiotic types are monitored in the EU, as shown in Table 3. Furthermore, in comparing Thai standards and EU standards, one finds more details for each antibiotic in the EU standards (Food Control Division 2006; Food Control Division, 2007; European Commission, 2009). For example, the Thai standard for flumequine was only established for trout instead of all fishery products, while the EU has carefully set and distinguished acceptable levels of this antibiotic in various parts of fishery products such as muscle, fat, liver and kidney. Consequently, if flumequine is found in imported fish such as Pangasius catfish in Thailand, it could be accepted although it might be illegal according to EU standards. The fact that few antibiotics are specified in Thailand’s standards is a cause of careless monitoring of antibiotic contamination by involved government authorities, so reports of antibiotic contamination in fishery products imported into Thailand are extremely rare (Food and Drug Inspection Office, 2013).

<table>
<thead>
<tr>
<th>Importation phases</th>
<th>Key challenges</th>
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<tbody>
<tr>
<td>Pre-import</td>
<td>The specific import documents of Thailand should be revised.</td>
</tr>
<tr>
<td>Date of import and contaminants inspection</td>
<td>Many on-site test kits should be developed to reduce cost and time. Some harmful substances are not monitored. Food regulations should be updated and clarified. Effective traceability system should be developed.</td>
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</table>
Monitoring of imported fishery products in domestic markets

Thailand’s domestic food security is controlled by the Ministry of Public Health, in accordance with the Food Act, B.E. 2522 (1979), via ministerial regulations and notifications to the public. Antibiotic standards in food have been specified in the Notification of the Ministry of Public Health (No. 299) B.E. 2549 (2006) – Re: The standards of food contaminated with some chemicals (edition 2), and Notification of the Ministry of Public Health (No. 303) B.E. 2550 (2007) – Re: Veterinary drugs residues in foods. In some cases, imported fishery products can be freely distributed in domestic markets, while few of those products are subjected to toxic substance determination in the laboratory (Food and Drug Inspection Office, 2013). Accordingly, if test results reveal the presence of toxic substances such as antibiotic residues remaining in samples, indicating that the products are unsafe to consume, the public will be at risk of exposure to hazardous substance contamination. Moreover, the products can hardly be recalled because they have already been widely distributed in the marketplace.

Figure 2 shows the monitoring system and management for Thailand and the EU in cases where contamination is found in fishery products. The Rapid Alert System for Food and Feed (RASFF) has been established by the EU to be applied in the management of a food-alert situation (European Commission – Rapid Alert System for Food and Feed, 2012). In case of the EU, when contamination or another problem is detected in imported fishery products, the situation will be carefully considered. At that time, an alert and relevant information will be publicized to EU consumers. Entrepreneurs and importers will also be informed by an EU committee if they need to take suitable action according to RASFF principles, such as stopping product distribution, withdrawing or recalling unsafe products from the market (if necessary) by using trace information, or destroying all such products. A traceability system is a useful...
In such a system, the risk can be traced forwards and backwards along the food chain. Consequently, the cause of contamination or other problems can be quickly discovered and health risks minimized. Finally, punishment under EU regulations might be imposed on entrepreneurs or importers: for example, limiting the amount of fishery products allowed for future imports (European Commission, 2002; European Commission – Directorate General for Health and Food Safety, 2007a).

In the case of Thailand, food monitoring authority does not reside in a single government authority or monitoring system (Food and Drug Administration – Food Alert System of Thailand, 2009). Several monitoring systems exist, established by several parties. One is the Food Alert System of Thailand (FAST), established in 2007 (in cooperation with the EU-Thailand Economic Co-operation Small Projects Facility) by the Food and Drug Administration, which is an entity in charge of food monitoring in Thailand (Food and Drug Administration – Food Alert System of Thailand, 2009; Benjapong, 2013). However, FAST has been considerably less effective than RASFF in the EU because the traceability system is impractical and yields few results. Lack of product information and the absence of trace numbers on the products makes forward and backward tracing impossible. Furthermore, the principles of a food monitoring system and of risk management are not clearly defined in the Food Act, B.E. 2522 (1979), creating a loophole which makes implementation of a food monitoring and risk management system very difficult. For example, in some situations unsafe fishery products should be withdrawn as quickly as possible by importers under an order of the Food and Drug Administration, but enforcement of such regulations is difficult in practice, and the products could remain in the marketplace because they lack trace numbers or other pertinent information (Food and Drug Administration – Food Alert System of Thailand, 2009).

Suggestions regarding food safety management and the traceability system

When a potentially hazardous situation arises, such as the discovery of contaminated food products in a market or shop, the causes or origin of the problem should be determined as soon as possible in order to restrict further distribution of the contaminated items. In such a situation, specific information concerning those foods is very important. Problem analysis can be carried out by examining information such as production source, processing steps, transportation and distribution. If this information is clearly listed on the product package, the problem can be solved quickly and the situation rectified. In many Western countries, certain technologies have been applied for data maintenance, using patterns of numbers or symbols on the product package (European Commission – Directorate General for Health and Food Safety, 2007a, 2007b; Department for Environment, Food and Rural Affairs and HM Revenue and Customs of UK, 2012; Finnish Food Safety Authority Evira, 2014).

An example of a traceability system proposed in this paper, adapted from Bechini et al. (2008), is shown in Figure 3. When it is found that a contaminated product has been distributed in the domestic market, if the product has been tagged with essential information as part of a tracing system by producers or distributors, the problem can be rapidly contained. Information identifying the producer, original source, distributor, food or product composition, etc., would be useful for inspectors investigating the starting point of the problem by considering forward and backward information. Because the traceability system shows the connection of all processes, some defensive measures (if needed) such as product recall can be implemented quickly and accurately (black hands and black fish in Figure 3). However, food or food products which are not affected by those processes can still be distributed and sold in markets (white hands and white fish in Figure 3). Moreover, government agencies involved with food safety can establish and manage a food safety system, the laws and regulations of which can be made explicitly and
precisely known to all stakeholders.

No efficient traceability system currently exists in Thailand. Consequently, in case of any food safety issues, the execution and management of a proposed solution may encounter many obstacles.

The case study: antibiotic contamination in imported Pangasius catfish

Pangasius catfish, one of the major freshwater fish species raised widely in Mekong River aquaculture, are now a significant product in the global whitefish trade; they are greatly valued by consumers for their tasty white flesh, lack of bones, high nutritional value, absence of the smell of sediment and seaweed in the product, and affordable price (United Nations – FAO Fisheries and Aquaculture Department, 2010; Vietnam Association of Seafood Exporters and Products, 2012). Pangasius catfish products have been imported into Thailand in significant amounts over the last few years when compared with other imported freshwater fishery products. Almost all Pangasius catfish are imported from ASEAN countries (Fish Trade Inspection Section Office, 2014). Generally, they are frozen in sealed packages and then transported by cargo ships at temperatures under −20°C (Chonburi Fish Trade Inspection Office, 2013). Laem Chabang Port Customs Bureau and Bangkok Port Customs Bureau are the major checkpoints for Pangasius fish product imports (Fish Trade Inspection Section Office, 2014).

Ninety samples of imported Pangasius catfish products collected around Thailand for enrofloxacin determination were analyzed by LC-MS/MS technique (Jansomboon et al., 2016). The results revealed that 14 samples, representing 15.6% of all target samples, were contaminated with enrofloxacin in a concentration range of 6.4–11.3 µg/kg, which is lower than the European Union (EU) standard (100 µg/kg) (European Commission, 2009).

Enrofloxacin concentration levels found in this study were quite low or zero in some fish samples. However, the continuous use of antibiotics may promote the development of antibiotic resistance genes in bacteria (Rico et al., 2012). Additionally, using antibiotic products that are not legal, or not following the standard, could affect disease treatment (Farah et al., 2016). In some cases, it was found that the antibiotic used in fish farmed in cages was also detected in wild fish around that farm (Varol and Raşit Sünbül, 2017), indicating that inappropriate antibiotic use could be a major cause of the occurrence of antibiotic resistance in the environment.

Although contamination with enrofloxacin or other antibiotics has never been reported in imported Pangasius catfish products in Thailand, many studies have indicated that antibiotics still remained in aquatic food products and some aquatic animals. For example, Guidi et al. (2017) determined the antibiotic contamination in 193 fish samples collected from Brazilian fish farms. The results showed that enrofloxacin remained in 29, or 15%, of the total samples, and one of them contained enrofloxacin at a concentration higher than 50 µg/kg. In another report, 37 antibiotics were investigated in biota samples from a reservoir in Turkey (Varol and Sünbül, 2017). They found that only sulfamethoxine remained in those samples, with a maximum concentration level of 4.4 µg/kg. In a study by Won et al. (2011), sulfamethoxazole was found in a common eel sample at a concentration of 5,104 µg/kg, which was far higher than the EU standard (100 µg/kg). Many other studies have shown evidence that enrofloxacin and other antibiotics have been used in aquaculture and that some residues can remain in aquatic animals and the environment.

According to existing Thai antibiotic standards, one could say that most of the contaminated products were not illegal products. However, a product which has a level of enrofloxacin of more than 100 µg/kg should presumably be considered an illegal product, since this concentration exceeds the EU standard, but it could very well be legal in Thailand due to the lack of clear standards and lax regulations. The present study provides good evidence that some imported fishery products have been contaminated with antibiotics. As a result, monitoring of antibiotic contamination in imported fishery products in Thailand needs to be continuously practiced. In the meantime, antibiotic standards and accompanying regulations should be developed and made clear.

Conclusion

This study has shown that there exist many key challenges to which government authorities of Thailand and stakeholders must pay serious attention in order to improve the system. The specific import standards of Thailand are less strict than those established in the EU, and should be upgraded; on-site test kits for antibiotic detection should be further developed in order to reduce costs and save time; and food regulations should be updated and clarified, especially in terms of antibiotic contamination in food. There is currently no efficient traceability system established in Thailand, which causes difficulty in operation and management. If there continues to be a lack of new measures or management to cope with such issues, it is possible that fishery products
contaminated with unsafe levels of hazardous substances may be increasingly imported into Thailand in the future. In the case study, 14 out of 90 imported Pangasius catfish samples collected around Thailand contained detectable levels of Enrofloxacin which the discovery nonetheless provided evidence that some imported fishery products were contaminated with antibiotics but were still legal due to lack of regulation. It is possible that contaminated Pangasius catfish are widespread in the domestic market. Therefore, monitoring of enrofloxacin as well as other antibiotics and toxic substances in imported Pangasius catfish needs to be continuously practiced in Thailand, and in other countries as well.

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