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Drug Residue Issues of China Aquatic Product Exports to USA Based on FDA Import Refusals 2002-2012

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Abstract. This paper analyzes panel data on aquatic product exports from China to the USA from 2002 to 2012. The results show that US import refusals are mainly caused by drug residues. By combining literature research with analysis of the problems of drug residues in China's exported aquatic products, this paper reveals five major residue sources and three specific causes of drug residues in aquatic products. Finally this paper puts forward relevant proposals to help to improve China's export of aquatic products to ensure high quality and safety levels, increase international competitiveness, and reduce import refusals caused by drug residues.

Keywords: Aquatic Product Exports, Drug Residue, Pollutant Source, Import Refusals

1. Introduction

Since 1989, China has taken first place in both aquaculture production and exports continuously for over 20 years. Additionally, China's aquaculture production represents a quarter of global seafood production. Since 2009, China has become the largest exporter to the US, and China's aquaculture exports account for about 30% of all its agricultural exports. After joining the World Trade Organization, China has been affected by non-tariff barriers in the international market, including some problem areas such as quality, additives,

labels, certification and, especially, veterinary drug residue issues [1]. Therefore, it is necessary to understand aquaculture quality problems -- mainly the drug residues -- and to solve them efficiently and effectively.

A large proportion of aquaculture refusals in the last ten years, up to 25%, came from drug residues during 8 months between 2006 and 2007. Veterinary drug residues accounted for 14% of FDA refusals of imported seafood products from China between 2007 and 2008. The concern is that drug residues promote drug resistance in aquaculture production systems [2].

The domestic literature focuses on three elements of the aquaculture drug residue issue:

(1) Commercial trade influenced by drug residue and drug residue standards. For example, Li Kainian (2007) indicated that foreign countries have strict demands on aquaculture drug residues. An example was given that drug residues in aquaculture seriously restrict China's seafood exports [3]. Guo Liuchao, et al. (2009) analyzed how drug residues influenced China's seafood exports and pointed out that refusal of China's aquaculture exports is related to how each country implements trade barriers and standards for the aquaculture industry [4].

(2) Analysis of the causes of and harm from drug residues, and their control. For instance, Guo Shaozhong, et al. (2007) mainly analyzed the pollution sources (prohibited drugs) and causes (use of prohibited drugs) related to refusals of exported sea eels. He also proposed some measures for reducing drug residues in eels, such as establishing an eel traceability system [5]. Xie Wenwen, et al. (2013) presented reasons why formaldehyde residue might be found in seafood (e.g. it is generated in natural metabolic processes) and also proposed three measures for precluding man-made pollution of seafood formaldehyde in order to control the formaldehyde residue [5]. Jin Chunguang (2013) listed five categories of harm from aquaculture drug residues (like drug resistance and toxic reaction) and made suggestions for controlling aquaculture drug residues including enhancing management and government intervention[7].

(3) Drug residue detection methods and technologies. As one example, Wei Bojuan (2011) described multiple detection methods for quinolone residues in seafood [8].

In view of current studies, this paper concentrates on drug residue issues specifically, identifies the common pollution sources and causes of drug residue problems, and puts forward recommendations for amelioration of the problem.

This paper analyzes data from US FDA1 (Food and Drug Administration) refusals of imports of aquaculture exports from China, which were issued from January, 2002 to December, 2012. The data set contained 2,438 refusal cases which, excluding 29 "unknown" product category cases and two cases from Hong Kong, provided a total of 2,407 observations of FDA refusals of aquaculture exports from the People's Republic of China.

2. Drug residue issues and causes: analysis of China's aquaculture exports

2.1. Drug residue issue status quo

Reasons for aquaculture products being detained are divided into seven categories:

1. Drug residue (903 cases)
2. Non-conformant quality requirement (796 cases)
3. Unsafe additive contained (447 cases)
4. Microbial contamination (372 cases)
5. Failed package label (245 cases)
6. Producing and processing environment unsanitary (97 cases)
7. Incomplete corporate information (78 cases)

As Figure 1 shows, the first three categories account for 73% of cases, in which drug residues account for 30.7%, non-conformant quality requirement for 27.1% and unsafe additive contained for 15.2%.

1 http://www.accessdata.fda.gov/scripts/importrefusals/ir_months.cfm?LType=P

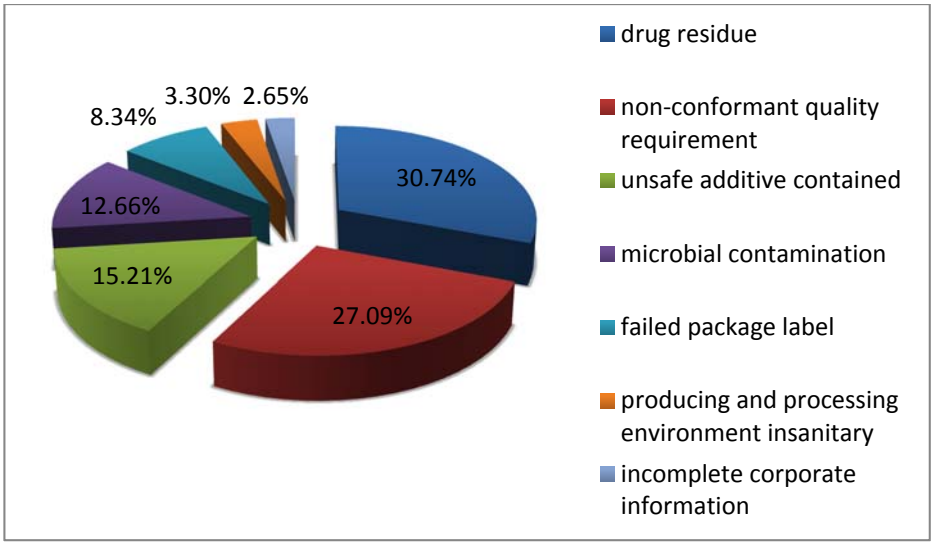

Fig. 1: Causes proportion of China's aquaculture detained by FDA

Referring to both the domestic literature and data on China's seafood exports detained by FDA, there are four issues characterizing "safety" of exported seafood:

1. The international situation

2. Government supervision and management

3. Aquatic food production and distribution, including aquaculture drug residues, quality, additives, and microbial residues

4. Label identification of aquatic product production

Over the years there have been a few significant quality or safety events affecting China's exported aquaculture products. The main reason was drug residues, as shown in Table 1.

Tab. 1: Quality safety events of China's exported aquaculture

Year	Import country	Events	Influences
1997	EU	Shellfish toxins were detected repeatedly in exported shellfish products and heavy metal content was out of limits.	EU prohibits importing China's shellfish products; some European importers also thought that Chinese shellfish products were both poor quality and low price [9].
	Japan	Eel oxolinic acid event	Refused to import Chinese eels
1999	Korea	472 tons of unqualified imported aquatic products were refused.	The main reasons were lack of freshness, poor in color, artificial watering, excessively ice-packed, pigment used, etc.
2002	EU	Chloromycetin detected in shrimp and frozen shrimp products was out of limits.	EU passed a resolution "protection measures taken about products of animal origin imported from China" and decided to suspend importing all Chinese animal

			origin products for human consumption and animal feed. This lead to a loss about 500 million US dollars of Chinese exported aquatic products to EU [10]. In 2004, EU lifted this order conditionally [11] 176.
	US	Early warning was implemented on shrimp products.	The export value of frozen lobsters decreased from 1.2039 million US dollars in 1996 down to 0.567million US dollars in 2002[12] 49.
	Japan	Sulfa drug residues were detected in eels.	Japan observed for 48 hours China-made eels after entering Japan and checked 11 different drug residues randomly [12] 49.
2003	US	A carcinogenic drug (furazolidone) was detected in China's aquaculture products [11] 176.	
	Japan	The antibiotic enrofloxacin was detected in frozen eels.	Early warning was implemented and 8210 kilograms of frozen eels were recalled [13] 58.
2004	Korea	381 tons of aquatic products were detected as out of standard.	All aquatic products were returned or abandoned [14].
2005	Japan	Malachite green residue was detected in eel products.	A ban was issued that prohibited importing grilled eel products 13] 58.
	Korea	Malachite green was detected in live perches.	All live perches were returned and disposed [3].
2006	Japan	Nitrofuran metabolites were detected out of limits in frozen grilled eels.	All eel products were returned and lost a value of 546 thousand US dollars [12] 50.
		Endosulfan was detected out of limits in live eels.	Thousands of tons of live eels were returned and some other seafood export companies were also implicated [3] 55.
	US, Canada	Some banned drugs were detected in aquatic products, including chloramphenicol, malachite green, nitrofurans, etc.	FDA examined China's aquaculture drug residues monitoring system [12] 50.
2007	US	Fluoroquinolone drug residues were detected in channel catfish.	Stop selling all channel catfish products imported from China.
		Illegal antibiotic, veterinary drugs and chemical pollution detected from seafood products were out limits.	Shrimp, eel, catfish, minnows and other imports were prohibited.

Table 1 shows that there exist serious problems in the quality and safety of China's exported aquatic products. Especially, an increasing number of quality/safety events were generated by drug residues, mainly including shellfish toxins, heavy metals, oxolinic acid, chloramphenicol, sulfonamides,

enrofloxacin, malachite green, nitrofurans, endosulfan, fluoroquinolone and others. Depending on the degree of media attention concentrated on China's aquatic products' quality and safety, the negative impacts derived from quality/safety events have often been exaggerated in the view of the public. Therefore, this paper mainly focuses on analyzing the causes and reason for drug residue problems.

2.2. Detailed problems of drug residues

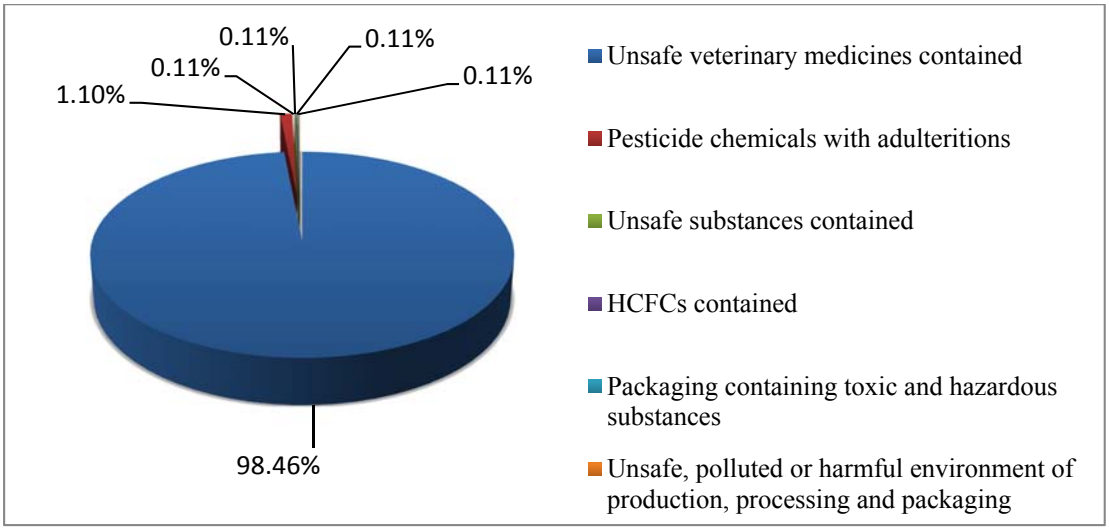

Fig. 2: Monthly distributions of drug residues detailed problems from 2002 to 2012

As seen in Figure 2, the largest drug problem by far is due to unsafe veterinary medicine contained in the product. FDA explains it as "suspecting a kind of unsafe new veterinary medicines (conversion products)." The second serious problem is products containing pesticide chemicals with adulterations. FDA explains it as "suspecting pesticide chemicals doping contained", for example, BHC (HCH).

2.3. Causes analysis of drug residue problems

From a global standpoint, China has the most serious problem in aquatic products drug residue quality/safety. Drug residues are mainly caused by irrational use of disease-treating medicines and feed additives during the aquaculture process.

2.3.1. Pollution sources of drug residue problems

According to the contents above, the pollution sources of drug residues are

oxolinic acid, chloramphenicol, nitrofurans drugs, sulfa drugs, antibiotics enrofloxacin, fluoroquinolone drugs, malachite green, heavy metals, histamine, shellfish toxins and so on.

(1)Drugs

Aquatic drugs can be classified by their function. Generally they are divided into water disinfectant, oral antimicrobials, parasiticides, herbal medicines, biological products, water conditioners and so on.

Banned drugs or banned drug ingredients include all banned drugs in China and US, like chloramphenicol, nitrofurazone, clenbuterol, furazolidone, diethylstilbestrol, other nitroimidazoles. They also include the drugs that China allows but the US prohibits, like sulfonamides, fluoroquinolones, isopropyl metronidazole, dimetridazole, and glycopeptide antibiotics.

Drugs that China allows can be divided into drugs with toxicity and withdrawal period, and drugs for preventing and treating diseases. The former category includes sulfa drugs that are used to treat some diseases caused by protozoa. The withdrawal period of sulfadiazine is 500 days; the withdrawal period of sulfamethoxazole carp, tilapia, etc. is more than 10 days; and the withdrawal period of shrimp is more than 15 days. The latter category includes the kinds of drugs that are used generally, efficiently and in low toxicity, like fluoroquinolones. This category of drugs is widely used for preventing and treating all kinds of aquatic animal diseases.

(2) Chemical substances of environment or inputs

The dyes, like malachite green and crystal violet, have many undesirable characteristics, not only in terms of high content of toxins and residues, but also with respect to carcinogenic, teratogenic, and mutagenic features. Many countries, including China, ban the use of these chemical substances in aquaculture.

Each country has a limit for heavy metals in aquaculture inputs (mercury, lead, chromium, etc.). For instance, China requires that the content of chromium in fish and shellfish products cannot be higher than 2.0 mg/kg.

China also stipulates a limit of BHC, DDT and some other pesticides. For example, the content of BHC in aquaculture water cannot be higher than 2.0 mg/kg.

(3) Hazardous substances of aquatic animals

Fish with green skin and red meat often have a high content of histamine, including certain kinds of mackerel, tuna, and herring. It is harmful for human health to ingest excessive histamine. Stale and rotten fishes (with green peel and red meat) contain excessive histamine. Eating this kind of fish will lead to

histamine poisoning.

Parasites are harmful to human health because some seafoods will harbor them when these products are not cooked, are cooked incompletely, or are not frozen properly. Nematodes, roundworms, tapeworms and flukes have close links to seafood. Some products can become cross-infected because these products are touched by humans who are infected; for example, capelin and its eggs, and codfish may contain parasites.

(4) Natural toxins

It is common for aquatic organisms to concentrate hazardous substances found in water, like heavy metals, pesticides, and organic pollutants, in addition to bacteria, viruses and biological toxins [11] 176. Fish and shellfish will accumulate and produce some toxins after they ingest certain aquatic organisms through the food chain [15] 159. An example is the shellfish toxins that are bioconcentrated from the algae implicated in red tides.

(5) Pathogens (bacterial and viral)

Some pathogens cause diseases (such as Vibrio cholera) or produce toxins (such as Staphylococcus aureus and Bacillus cereus). For instance, when

S. aureus populations reach numbers of 100,000 - 1,000,000 per gram, the toxins produced can lead to poisoning.

Food processing staff infected with viruses, or polluted water containing certain species of virus can cause some diseases that affect aquatic products, such as hepatitis A virus, norwalk virus, and norovirus[16].

2.3.2. Causes of drug residue problems

(1) Lack of government regulation and monitoring

Firstly, counterfeit pharmaceutical products can proliferate in uncontrolled and illegal drug markets.

Secondly, government regulation may be insufficient to prevent employees from using medicines improperly.

Thirdly, aquaculture employees usually have insufficient training in the legal and regulatory issues involving aquatic products. Most of them are trained as farmers and do not have adequate knowledge for proper use of drugs in production. In addition, there are very few technical experts who directly provide this service for these farmers because the government's public service establishment is not sufficiently funded and staffed. Furthermore, rapid expansion in the scale of aquaculture production often quickly exceeds the capabilities provided to meet these development needs completely, and harmful alternatives are often resorted to under these conditions.

(2) Aquaculture environment

The basic environmental facilities for aquatic production and processing are relatively undeveloped in China. Environmental pollution, industrial pollution, water pollution caused by solid waste emissions, and serious eutrophication is widespread. Those conditions lead to problems with microorganism residues, heavy metal concentration, and other toxic substances in aquaculture[19] 40.

Excessive pesticides collect in rivers, lakes and the sea due to runoff and erosion [15] 158. This water often contains components of aquatic pesticides and banned drugs even without their intentional use in aquaculture, such as BHC, DDT, and so on. Offshore oil spills can also cause serious water pollution [17] 17.

(3) Manual operation

Aquatic production employees often use drugs improperly because they lack awareness of quality, safety, and legal issues. They may not comply with withdrawal period provisions for drugs or they may use domestic or imported drugs that are banned (such as chemicals and dyes). Using feeds or drugs containing prohibited drugs or ingredients, using illegal drugs and using drugs in improper ways all serve to bring about drug residue and chemical pollution problems in aquaculture [5] [11] 11 [20].

The first problem is improper use of drugs. Aquaculture personnel may directly use unapproved drugs, chemical substances without medicinal description, or drugs not used in accordance with label instructions for a variety of expedient, though misguided, reasons such as: they inhibit the growth of parasites and microorganisms; they prevent or treat diseases of aquatic animals [15] 158 to protect or maintain animal health [21] 2; some animals have low resistance [17] 145 to diseases; or fish diseases happen frequently due to poor conditions in the aquatic environment[19]40. Aquaculture personnel often do not have enough technical knowledge to use drugs appropriately. In addition, lack of veterinarians also limits progress in this area.

The second problem is illegal drug use. Some additives contain ingredients of related drugs. For example, feed additives for increasing weight gain and preparations used for seafood freshness have drug residue problems. This is mainly because aquatic drug development is not adequate and the government does not provide comprehensive support. Pathogens have become resistant to drugs that have long been allowed for use, forcing some producers to resort to prohibited drugs, especially for serious infestations of aquatic parasites.

The third problem is the growth of pathogens or viruses caused by improper operations during processing. For example, if the temperature and time are out of control when processing, it can lead to the growth of pathogens, histamine

formation, development of toxins due to insufficient drying, cooked pathogen residues, survival of pathogens after pasteurization, etc.

The fourth problem is caused by parasites, viruses or drug ingredients carried by humans and also cross-infections coming from the handling of aquatic animals.

The fifth problem is improper storage of aquatic products that leads to the formation of other toxins, such as biogenic amines, putrescine and cadaverine, etc.

3. Comments and suggestions

3.1. Focus on international situation and understand drug limits and standards of import countries.

China's government should concentrate on the international situation and value international influence of public opinion in order to lead the public to a good development oriented. Improving China's seafood quality safety credit is also needed through a way of reporting positively in seafood quality safety by the media and society. The foreign importers emphasize much on corporate integrity. Therefore, China can establish some integrity brands less with or without quality safety problems in aquatic product exports for a long-term cooperation.

Different countries have different aquatic drug limits and standards. Each country has its own language of standards. It is so hard for the exporting corporates to understand them. Government should help the corporates to understand these standards so that they can produce and export purposefully to avoid exports detaining.

3.2. Enhance supervision and management of aquatic drug use

3.2.1. Perfect quality supervision, testing and certification, and a product traceability system

If an importing country detects quality problems in China's exported aquatic products it is an indication that the level of detection in the Chinese system is lower than that of those importing countries. Thus improvement in these systems is essential for the solution of aquaculture quality/safety problems.

3.2.2. Enhance the supervision of drug residue regulations and standards and management of aquaculture production personnel

Several agencies are responsible for establishing and enforcing the laws,

regulations and standards for the aquaculture environment, seed cultivation, feed, medicines, processing and packaging, transportation and other sectors. These agencies include the Chinese Department of Agriculture, Ministry of Commerce, National Quality Supervision, Inspection and Quarantine. When aquaculture producers cannot meet these requirements the Chinese government should enhance the supervision power of all aspects of the supply chain, reinforce the importance of aquaculture quality/safety, and improve the comprehensive authority of law-enforcement officials in order to make sure that no illegal operations exist, no harmful facilities are used, no improper inputs are utilized, and adulterated feeds, drugs, additives and aquatic products are eliminated. Additionally, government should also prevent water pollution caused by humans, discourage additives that may lead to quality/safety problems and enhance the supervision of drug use. For example, producers should be trained to avoid use of prohibited drugs, materials containing prohibited ingredients, feeds with prohibited drugs, and use of drugs in improper ways. Moreover, government should remind the producers about preventing body-carrying hazardous substances and cross-infection and should strengthen the management of processing and storing of high-histamine fish.

3.2.3. Rectifications of the existing regulations and standards

China needs to perfect current drug regulations to prevent drug residue problems. On the one hand, China needs to enhance implementation efforts of regulations and standards, consolidate the existing laws and regulations enacted by various departments, and strengthen current laws that do not meet current market demands. On the other hand, China needs to reform or update some inadequate regulations and standards referring to international aquatic quality detection standards.

3.3. Reinforce operations and managements of aquaculture circulations

3.3.1. Enhance the infrastructure establishment

China should enhance the infrastructure and facilities of the aquaculture environment, producing and processing areas, to levels that can meet hygiene requirements, as well as to prevent water pollution and decrease the use of drugs and the prevalence of various forms of microorganisms (for example, keeping processing water at low temperatures can prevent the growth of Salmonella). Innovations in transportation equipment could help reduce the use of preservatives, anticorrosives, etc. Innovations in processing technology can

reduce the growth of pathogens due to improper processing temperatures and times, toxins formed by insufficient drying, pathogen residues after cooking, survival of pathogens after pasteurization and deterioration problems caused by damage to packages. Innovations in aquatic breeding techniques can foster high quality and health of juvenile fish and crustaceans, thus decreasing the need to treat aquatic animal diseases.

3.3.2. Control the aquaculture environment -- pollution

This includes control of the environment surrounding aquaculture facilities. For instance, eutrophication problems arising from industrial pollution and solid waste emissions should be investigated; crop pesticides used around aquaculture should be controlled; water should be checked regularly to control intake of toxic and hazardous substances; and oil spills should be mitigated.

3.3.3. Enhance the management of aquaculture inputs

Firstly, China needs to provide high-quality, high-efficiency feeds and use drugs that are not harmful to human health. Secondly, China should concentrate on the management and control of the aquatic organisms that become the food of aquaculture species. Thirdly, China should reinforce the control of feeds, drugs, additives and so on, especially the management of drug residues caused by some inputs. For example, China should increase the supervision of drug use, and prevent personnel from using banned drugs like nitrofurans, chloramphenicol and so on.

3.3.4. Adjust aquaculture operating modes

Scaling-up operations helps achieve scale economies. Larger scale operations can improve problems of uneven development across regions, management inefficiencies in different operational situations and, particularly, the misuse of drugs and additives. However, scale operation may not be suitable for the entire aquatic product supply chain. For instance, if aquaculture could realize optimal scale in operations, it could overload the carrying capacity of the aquatic system and cause whole bodies of water to lose their capacity for self-purification. Moreover, short-sighted objectives of scale aquaculture could lead to reduced genetic diversity and problems due to inbreeding. Therefore, China may wish to avoid scale production of the aquaculture stage, but could consider encouraging private capital to invest in some competent corporations to forge integrity of brands and encourage the scale production of feeds, distribution and cold-storage facilities.

4. Conclusion

Drug residue problems restrict Chinese aquatic products exports and international competition. China should solve these problems at their sources, that is, find the root causes and reasons for the drug residues so that it can control the pollution sources affecting aquatic animal cultivation, production, processing and distribution. In addition, China should improve the level of aquatic products' quality/safety to enhance competitiveness of aquatic product exports as a way of coordinating and strengthening the economy.

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