

Indonesia

Dr. Simson Masengi and Dr. Setia Mangunsong
Directorate General of Fishery Products Processing and Marketing
Ministry of Marine Affairs and Fisheries, Republic of Indonesia

1. Introduction

The total production of Indonesian fish and fish products over the period of 2000 to 2005 has increased steadily from 4,875,649 tonnes in year 2000 to 5,452,651 tonnes in year 2005, by volume, with an average increase of 3.51 % annually. The total production from aquaculture in year 2005 was about 238,656 tonnes of which the black tiger shrimp (*Penaeus monodon*) was 134,682 tonnes and *Penaeus vannamei* shrimp was 103,874 tonnes.

In recent years, international trade for fish and fish products has been hampered by various tariff and non-tariff barriers particularly on the standards of quality, hygiene and safety of products. Therefore, efforts to improve the quality and safety of the products as well as to ensure the compliance with international standards are highly imperative. Such efforts will enhance market access and competitiveness in the international market and more importantly, it will also help to boost and stabilize the production and marketing of fish products.

Under the Indonesia Food Law No. 7/1996 and Fisheries Law No. 31/204 as well as Government Regulation No. 28/2004 pertaining to Food Quality, Safety and Nutrition; it was clearly stipulated that all food products including fish and fish products put in the market place intended for human consumption shall comply with the prevailing laws and regulations, to ensure that the products are safe and shall not pose any threats to human health.

With the above laws and regulation, it is imperative to formulate Ministry of Marine Affairs and Fisheries Decree, and clearly define the important requirements to guarantee quality and safety of fish products derived from fishing, collecting vessel, landing sites, auction centers, processing unit and distribution facilities. The 4 newest Indonesian Regulations and Decrees of Ministry of Marine Affairs and Fisheries are effectively implemented from 1st August 2007.

These Regulations and Decrees focused on, (1) The Control of Quality Assurance and Food Safety System of Fisheries Products; (2) Monitoring of Drug Residues, Chemicals, Biological Substances and Contaminants in Aquaculture; (3) Requirements for Quality Assurance and Safety of Fishery Products During Production, Processing and Distribution; and (4) Good Aquaculture Practices. In addition, two guidelines for monitoring are described in:

- 1) Decree of Director General of Fisheries Products Processing and Marketing covering the Inspection and Monitoring Program for Fisheries Products,
- 2) Decree of Director General of Fisheries Aquaculture covering the Guidelines on the Implementation of Residue Monitoring of Fish Drugs, Chemical, Biological Agents and Contaminants in Aquaculture.

Both decrees are parallel with the activities under the Japanese Trust Fund II Project such as regional surveys on drug residues (chloramphenicol and nitrofurans). These activities are useful and valuable to implement in Indonesia in order to support our national residues monitoring program to produce good and safe of Indonesia fish products.

In order to ensure that Indonesian aquaculture products are free from drug residues contamination such as chloramphenicol (CAP) and nitrofurans (NF), it is mandatory to survey and monitor the aquaculture products. If the drug residues obtained is higher than the maximum residue limit (MRL) the corrective actions would be taken according to the procedure stipulated in the regulation.

2. Objectives and Goals

Through the participation of the research and analysis of drug residues in aquaculture products of Indonesia, we expect to be able to:

- Obtain an understanding of the level of drug residues in aquaculture products in Indonesia;
- Set up and implement the monitoring program on drug residues in aquaculture products;
- Strengthen the fish inspection and quality control system, including improvement of laboratory personal skills in conducting fish inspection and quality analysis;
- Improve and facilitate the analysis of chemical contaminant and drug residues in aquaculture products in Provincial Laboratories for Fish Inspection and Quality Control; and
- Supply fish and fish products including aquaculture products that comply with the international market standard and food safety requirements.

3. Survey Methodologies

a. Sampling Method, Location, Species, Number of Samples and Sampling Size

Sampling method was conducted according to the National Sampling Plan and the monitoring program of each Provincial Laboratory for Fish Inspection and Quality Control (PL-FIQC). From 2005 to 2008, the sampling of raw materials for drug residues analysis was carried out at 8 provinces which are representatives of shrimp producing areas. The sampling locations were:

- (1) North Sumatera
- (2) South Sumatera
- (3) Lampung
- (4) West Java
- (5) Jakarta
- (6) East Java
- (7) East Kalimantan, and
- (8) South Sulawesi

All the samples collected were aquacultured products such as shrimp *Penaeus monodon* and *Penaeus vannamei*. In most cases, the samples were collected from farms but some other frozen shrimp samples were also collected from some processing plants. After sample collection from the farms, the samples were frozen at -18°C prior laboratory analysis. Frozen shrimp samples collected from some processing plants were usually analysed for drug residues (CAP and NF) directly. The period of sampling was quarterly in 2005 and 2006; every two and three months in 2007 and 2008.

b. Method of Analysis

The High Performance Liquid Chromatography

(HPLC) method was used to analyse drug residues and the Liquid Chromatography Tandem Mass Spectrometry (LC-MS/MS) method was used for analyzing NFs in some samples.

c. Limit of Detection and Limit of Quantification

Limit of detection (LOD) :

CAP : 0.12 ppb

Nitrofurans : 1 ppb

Minimum Required Performance Limit (MRPL):

MRPL for CAP : 0.3 ppb

MRPL for Nitrofurans : 1 ppb

Note:

Latest method validation results for drug residues analysis methods conducted by NCQC are as follow:

Limit of Detection (LOD):

CAP: 0.12 ppb

Nitrofurans:

Antibiotic	Name of Metabolite	LOD (ppb)
Furaltadon	AMAZ	0.93
Nitrofurazon	SEM	0.81
Nitrofurantoin	AHD	0.61
Furazolidon	AOZ	0.23

d. National Regulatory Limits

The setting of the standard limits for chloramphenicol and nitrofurans are under progress. Hence, the standard limits are currently based on the European Union (EU) regulation or importing countries standard.

4. Results and Discussion

a. Participation of Inter-laboratory Proficiency Testing and Results

Inter-laboratory proficiency testing are usually conducted routinely by the NCQC to all the Provincial Laboratory for Fish Inspection and Quality Control (PL-FIQC) in Indonesia. The focus for proficiency testing is usually microbiology (*E-coli*, *Salmonella* etc.) and chemical testing such as heavy metals. Indonesia did not participate in any interlaboratory proficiency testing for drug residues.

b. Survey Results and Discussion

Survey of drug residues in 2005 only focused on chloramphenicol (CAP). Five sampling locations or provinces were targeted in, Lampung, North Sumatera (Medan), East Java (Surabaya), West Java and South Sulawesi. The samples collected from these locations were aquacultured shrimp (*Penaeus vannamei* and *Penaeus monodon*). The sampling period was every 3 months and 3 times a year, that is, on July, October and December 2005. The total number of samples were 48 samples and the results showed that all sample was negative (not detected).

In 2006, the survey of drug residues focused on chloramphenicol (CAP) and nitrofurans (NF). The sampling locations were different from the survey conducted in 2005. The sampling locations in 2006 were, Lampung, South Sumatera, Jakarta, East Java (Surabaya), South Sulawesi and East Kalimantan. All samples collected from these locations were aquacultured shrimp (*Penaeus vannamei* and *Penaeus monodon*). The sampling period was every 2 months and 4 times a year, that is, May, July, September and December 2006. From the 177 samples analyzed, 7 samples showed positive results for chloramphenicol and the results were between 0.17 to 2.50 ppb.

Survey of drug residues in 2007 was carried out 6 locations, namely, North Sumatera (Medan), Lampung, Jakarta, West Java (Cirebon), East Java (Surabaya) and South Sulawesi (Makassar). However, the survey of nitrofurans was conducted only for samples collected from East Java. All samples collected from these locations were aquacultured shrimp (*Penaeus vannamei* and *Penaeus monodon*). The sampling period was quarterly, on April, June and August 2007. For the

sampling at East Java, the samples were collected three times with the first sampling conducted on March to April; second sampling on June to July and the third sampling on August to September 2007. The results showed that from the 63 samples analysed for CAP and 13 samples analysed for nitrofurans, most of the samples were not detected of both residues. One sample collected from Lampung (*Penaeus monodon*) was found to contain CAP (0.31 ppb) higher than the MRPL stipulated at 0.3 ppb. For NF, the result from one sample (1.15 ppb) was found to be higher than the stipulated MRPL at 0.1 ppb.

Comparing with the survey results of drug residues obtained in 2005 and 2006, the violation in shrimp products decreased in 2007. This might due to the new revision of the regulation issued in the beginning of 2007 and since it's implementation, the shrimp farmers pay more attention to the issues of food quality and drugs residues. The shrimp farmers are also more aware in issues such as prohibition for using of some chemicals or antibiotics in aquaculture farms. Moreover, according to the Indonesian regulation, all aquaculture farms must be evaluated for Good Aquaculture Practices certification. These requirements are very stringent and hence the monitoring of veterinary drugs residues in farms must be done continuously.

Survey of drug residues in 2008 was focused on 6 locations, namely North Sumatera (Medan), Lampung, Jakarta, West Java (Cirebon), East Java (Surabaya), and South Sulawesi. All samples collected from these locations are aquacultured shrimp products (*Penaeus vannamei* and *Penaeus monodon*). The results showed that all of samples analysed for CAP and NF (AOZ and AMOZ) were negative (not detected).

Table 1. Data Monitoring of Drug Residues in Shrimp Conducted in Lampung, North Sumatera, East Java, West Java and South Sulawesi in 2005.

No.	Location	Time of Sampling	Species/ Products	Number of sample	CAP (ppb)
1.	Lampung	July	<i>P. monodon</i>	3	ND
		October	<i>P. monodon</i>	4	ND
		December	<i>P. monodon</i>	3	ND
2.	North Sumatera	July	<i>P. monodon</i>	4	ND
		October	<i>P. vannamei</i>	4	ND
		December	<i>P. monodon</i>	3	ND
3.	East Java	July	<i>P. vannamei</i>	6	ND
		October	<i>P. vannamei</i>	6	ND
		December	<i>P. vannamei</i>	2	ND
4.	West Java	July	<i>P. vannamei</i>	3	ND
		October	<i>P. vannamei</i>	2	ND
		December	<i>P. vannamei</i>	2	ND
5.	South Sulawesi	July	<i>P. vannamei</i>	1	ND
		October	<i>P. vannamei</i>	2	ND
		December	<i>P. vannamei</i>	3	ND

Table 2. Data Monitoring of Drug Residues in Shrimp Conducted in Lampung, South Sumatera, East Java, South Sulawesi and East Kalimantan in 2006.

No.	Location	Time of Sampling	Species / Products	Number of sample	CAP (ppb)	Nitrofurantoin (ppb)
1.	Lampung	May	<i>P. monodon</i>	4	ND	ND
		July	<i>P. monodon</i>	3	ND	ND
		Sep.	<i>P. monodon</i>	4	ND	ND
		Nov.	<i>P. monodon</i>	3	ND	ND
2.	South Sumatera	May	<i>P. monodon</i>	4	ND	ND
		July	<i>P. monodon</i>	8	ND	ND
		Sep.	<i>P. vannamei</i>	4	ND	ND
		Nov.	<i>P. monodon</i>	2	ND	ND
3.	Jakarta	May	<i>P. monodon</i> *	3	ND	ND
		July	<i>P. vannamei</i> *	8	1 sample (0.46 ppb)	ND
		Sep.	<i>P. vannamei</i> *	3	1 sample (2.5 ppb)	ND
		Nov.	<i>P. vannamei</i> *	3	1 sample (0.17 ppb)	ND
4.	East Java	May	<i>P. vannamei</i> *	8	ND	ND
		July	<i>P. vannamei</i>	6	ND	ND
		Sep.	<i>P. vannamei</i>	7	ND	ND
		Nov.	<i>P. vannamei</i>	6	ND	ND

5.	South Sulawesi	May	<i>P. vannamei</i>	2	ND	ND
		July	<i>P. vannamei</i>	2	ND	ND
		Sep.	<i>P. vannamei</i>	4	ND	ND
		Nov.	<i>P. vannamei</i>	6	1 sample (0.99 ppb)	ND
6.	East Kaliman-tan	May	<i>P. monodon</i>	6	ND	ND
		July	<i>P. vannamei</i>	9	1 sample (0.18 ppb)	ND
		Sep.	<i>P. vannamei</i>	9	1 sample (0.54 ppb)	ND
		Nov.	<i>P. vannamei</i>	3	1 sample (1.42 ppb)	ND

Table 3. Data Monitoring of Drug Residues in Shrimp Conducted in North Sumatera, Lampung, Jakarta, West Java, East Java and South Sulawesi in 2007.

No.	Location	Time of Sampling	Species/ Products	Number of sample	CAP (ppb)	Nitrofurant (ppb)
1.	North Sumatera	April	<i>P. vannamei</i>	3	ND	-
		June	<i>P. vannamei</i>	2	ND	-
		August	<i>P. vannamei</i>	3	ND	-
2.	Lampung	April	<i>P. monodon</i>	3	ND	-
		June	<i>P. monodon</i>	4	ND (1 sample 0.31 ppb)	-
		August	<i>P. monodon</i>	3	ND	-
3.	Jakarta	April	<i>P. vannamei</i> *	2	ND	-
			<i>P. monodon</i> *	2	ND	-
		June	<i>P. vannamei</i> *	3	ND	-
			<i>P. monodon</i> *	2	ND	-
August	<i>P. vannamei</i>	3	ND	-		
4.	West Java	April	<i>P. vannamei</i>	4	ND	-
		June	<i>P. vannamei</i>	4	ND	-
		August	<i>P. vannamei</i>	3	ND	-
5.	East Java	March-April	<i>P. vannamei</i>	2	ND	ND
			<i>P. monodon</i> *	2	ND	ND
		June	<i>P. vannamei</i>	2	ND	ND
			<i>P. monodon</i> *	3	ND	ND (1 sample: 1.15 ppb)
July-August	<i>P. vannamei</i>	2	ND	ND		
	<i>P. monodon</i>	2	ND	ND		
6.	South Sulawesi	April	<i>P. vannamei</i>	2	ND	-
		June	<i>P. vannamei</i>	2	ND	-
			<i>P. monodon</i>	2	ND	-
August	<i>P. vannamei</i>	3	ND	-		

Table 4. Data Monitoring of Drug Residues in Shrimp Conducted in North Sumatera, Lampung, Jakarta, West Java, East Java and South Sulawesi in 2008.

No.	Location	Time of Sampling	Species / Products	Number of sample	CAP (ppb)	Nitrofurant (ppb)
1.	North Sumatera	February	<i>P. vannamei</i> *	2	ND	-
		April	<i>P. vannamei</i> *	4	ND	-
2.	Lampung	February	<i>P. vannamei</i>	3	ND	-
		April	<i>P. vannamei</i>	4	ND	-
3.	Jakarta	February	<i>P. vannamei</i> *	4	ND	-
		April	<i>P. vannamei</i> *	4	ND	-
4.	West Java	February	<i>P. monodon</i>	2	ND	-
		April	<i>P. vannamei</i>	1	ND	-
5.	East Java	February	<i>P. vannamei</i> *	4	ND	ND (AOZ & AMOZ)
		April	<i>P. vannamei</i> *	4	ND	ND (AOZ & AMOZ)
6.	South Sulawesi	February	<i>P. monodon</i> & <i>vannamei</i>	6	ND	-
		April	<i>P. monodon</i> & <i>vannamei</i>	6	ND	-

Note:

Methods of Analysis: HPLC and LC-MS/MS for Nitrofurans (AOZ & AMOZ)

ND = Not Detected

* Sample taken from fish processing plant

c. Corrective Action

The corrective action will be taken when the results of monitoring does not comply with the standard or higher than the standard. The corrective action process for non-compliant results is as follows:

1. Carry out the investigation such as traceability to the fishing ground or aquaculture areas.
2. Verification of sampling and analysis methods.
3. Perform repeat sampling.
4. Exclusion of products with higher than the maximum residue limit allowed from

establishment or continue processing as products not for human consumption.

5. Intensively control the drug residues in fish during aquaculture or farming.

Moreover, in order to ensure the food safety of aquaculture products, Indonesia Government undertakes continuous actions such as: (1) Surveillance of stakeholders to ensure their compliance with rules and regulations in the standards/procedure and (2) Obtain data and information periodically on the level of veterinary drug residues and contaminants in aquaculture products.

5. Problems and Challenges Encountered

Problems faced during implementation of the drug residues monitoring and surveys are:

- 1) Lack of suitable equipment such as LC-MS/MS especially for analysing nitrofurans and its derivatives (between 2004 to 2006).
- 2) Laboratory personnel are not trained/qualified to perform drug residues analysis using HPLC and LC-MS/MS.
- 3) Lack of networking system to harmonize the standard and analysis methods for drug residues among ASEAN countries.
- 4) Lack of law enforcement in Indonesia to control the distribution of chemicals and veterinary drugs.
- 5) Implementation of the National Residues Control Plan (NRCP) due to the stringent requirements set by importing countries such as European Union (EU).

6. Recommendations and Suggestions for Future Follow up Action

- 1) Need training program for methods validation and verification especially in the determination of the limit of detection and minimum residue performance limit for drug residues.
- 2) Need training on LC-MS/MS for analysing nitrofurans and its derivatives such as FTD, NFZ, NFT and FZD.
- 3) Need to establish networking system to develop the analysis method for drug residues among ASEAN countries.
- 4) Need to establish a harmonised standard among ASEAN countries for the maximum level of drug residues when conducting the NRCP. This will fulfill the requirements set by the importing countries such as EU.
- 5) Need to improve the accuracy of testing results by participating in proficiency testing program especially for drug residues among ASEAN countries