


RESEARCH ARTICLE

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Risk-based approach to develop a national residue program: prioritizing the residue control of veterinary drugs in fishery products



Hui-Seung Kang^{1*} , Songyi Han², Byung-Hoon Cho¹ and Hunjoo Lee^{3*}

Abstract

Veterinary drugs are widely used to protect production-related diseases and promote the growth of farmed fish. The use of large amounts of veterinary drugs may have potential risk and cause adverse effects on both humans and the environment. In this study, we developed risk-based ranking based on a scoring system to be applied in the national residue program. In this approach, the following three factors of veterinary drugs that may occur as residues in fishery products were considered: potency (acceptable daily intake), usage (number of dose and withdrawal period), and residue occurrence. The overall ranking score was calculated using the following equation: potency \times usage (sum of the number of sales and withdrawal period) \times residue occurrence. The veterinary drugs that were assigned high score by applying this approach were enrofloxacin, amoxicillin, oxolinic acid, erythromycin, and trimethoprim. The risk-based approach for monitoring veterinary drugs can provide a reliable inspection priority in fishery products. The developed ranking system can be applied in web-based systems and residue-monitoring programs and to ensure safe management of fishery products in Korea.

Keywords: Risk, Priority, Veterinary medicine, Inspection, Fishery products

Background

Aquatic products are a major food resource with a low-cost and high-efficiency productivity, and farmed fish production have been continuously increasing (Kim et al. 2010; Kim et al. 2014). In Korea, seafood consumption per capita was approximately 60 kg in 2014–2016, maintaining the highest level of fishery product consumption in the world (FAO 2016). To meet the demand for fish and crustaceans, most of them are produced under dense farming conditions, which can be a stress factor and increase the possibility of disease prevalence (Uchida et al. 2016). Thus, the authorized veterinary drugs such as antibiotics and anthelmintics have been continuously used to prevent diseases in fishery

farm (Kim et al. 2019). However, overuse or noncompliance of withdrawal period of veterinary drugs has been increasing due to the shift in farming environment such as changes in climate and incidence of antibiotic resistant bacteria (Kang et al. 2018).

An analysis of the sales of antimicrobials in animal husbandry and fish farm by the Korea Animal Health Products Association (KAHPA) revealed that approximately 1000 tons of antimicrobials was sold each year during 2011–2015. The highest volume of antimicrobials was sold for use in pigs farms (53%, 481 tons) followed by fishery (22%, 201 tons), poultry (17%, 157 tons), and cattle industries (8%, 71 tons) (KAHPA 2019; Lee et al. 2018). As a large amount and several kinds of veterinary drugs are used yearly, useful tools are needed to develop more effective risk management strategies under limited budget of governmental authorities (Kang et al. 2019). The Irish government has developed a national residue program for effective prioritization residue evaluation and sampling plan such as veterinary drugs and

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pesticides in livestock products. The risk-based approach is applied in the national residue program to determine the prioritization of veterinary drugs through ranking system based on risk factors such as potency, usage, and residue occurrence (Danaher et al. 2016). The ranking system reflects the factors considering the risk through a simplified model for prioritization of compounds to save cost and time. Thus, similar ecological models have been proposed in other countries for the management of veterinary drugs. Indeed, Italy has developed the priority model “RANKVET” considering 48 veterinary drug residue occurrences in environment compartments to assess the potential risks (Di Nica et al. 2015). Portugal applies prioritization based on antibiotic usage, ecosystem exposure, and antibiotic metabolism in livestock and humans (Almeida et al. 2014).

Global regulatory authorities have established the maximum residue limits (MRLs) for veterinary drugs in animal products to protect potential human health effect. The Korean Ministry of Food and Drug Safety sets the MRLs for 55 veterinary drugs in fishery products, and 18 substances are managed as prohibited substances in consideration of their carcinogenicity and genotoxicity (MFDS 2019). However, risk-based priority study to support national residue inspection remains still limited in Korea. In this study, we classified three factors that can evaluate the risk for effective management of veterinary drugs used in fishery products: (1) potency, (2) usage, and (3) residue occurrence. We then collected data and assigned scores according to each indicator. Our results of risk-based prioritization can be applied to the safety management of veterinary drugs and the establishment of domestic inspection sampling plans in aquatic animal products.

Methods

Prioritization model

In previous studies, most of the priority models and systems have been applied in eco-surveillance. Thus, to prioritize veterinary drugs used in fishery products, a priority equation based on risk-based approach in domestic animal production by the Food Safety Authority Ireland (FSAI) was used. The collected data, the coded data, and the score were applied in the following equation. Based on the calculated scores, the substances were classified into four groups according to the quartiles.

$$\text{Priority}_r = P_r \times U_r \times R_{r,f}$$

where Priority_r is the risk-based predicted priority of veterinary drugs in fishery products,

P_r is the ADI of veterinary drugs, U_r is the usage (number of sales + withdrawal period), and $R_{r,f}$ is the

residue occurrence (detection rate + noncompliant sample number).

Sample selection and data collection

Taking into consideration the detection characteristics, the substances were selected (Table 1). In terms of the selected veterinary drugs, data on ADI, number of veterinary drug sales (usage), withdrawal period of veterinary drugs in fishery products, and veterinary drug residue occurrence in fishery products (detection rate, noncompliant history) were collected.

Compilation of data for risk analysis

To select the priority of test samples, the classification criteria were divided into three categories as follows and coded, and the priority was determined by scoring.

1) Potency (P_r): ADI was used as a basic data for assessing the safety of veterinary drugs for risk-based prioritization. The data provided by the European Medicine Agency (EMA) and FAO/WHO Joint Expert Committee of Food Additives (JECFA) were utilized as the ADI used in this study.

2) Usage (U_r): The number of sales was calculated based on the Korea Animal Health Product Association's 2013 statistics (KAHPA 2019). The withdrawal period was used in the veterinary drug guidebook for fishery products presented by National Institute of Fisheries and Science (NIFS 2016).

3) Residue occurrence ($R_{r,f}$): It was calculated based on the research data conducted by the National Institute of Food and Drug Safety Evaluation in 2014–2016 (Kang et al. 2018; Shin et al. 2018). In addition, the number of noncompliant sample and detection rate were utilized for the residue occurrence.

Ranking for prioritization

The collected data were scored by dividing the data on the potency, usage, and residual level into four classes to prioritize the veterinary drugs used in fishery products. For easy substitution in the calculated equation, the scores were assigned up to 4 points.

- 1) The potency was calculated based on the ADI. The ADI was scored as 0.1<, 0.01–0.1, 0.001–0.01, and < 0.001 mg/kg bw/day. When there was no ADI, it was calculated based on the maximum score.
- 2) The usage was calculated by dividing the number of sales and withdrawal period of the veterinary drugs, scoring them, and adding the scores. The unit of dose was kg, and it was assigned scores as follows: high (10,000 kg or more), middle (1000–10,000 kg), low (1–1000 kg), and very low (< 1 kg). The withdrawal period was assigned scores as follows:

Table 1 Target veterinary drugs and their MRL in fishery products by the Food Code

Class	Compound	MRL (mg/kg)
Amphenicols	Florfenicol	0.2 ^b
	Florfenicol amine	0.2 ^b
	Thiamphenicol	0.05
Cephalosporins	Cefalexin	0.2
	Ceftiofur	n.a. ^a
	Desfuroyl Ceftiofur	n.a.
Quinolones	Ciprofloxacin	0.1 ^b
	Difloxacin	0.3
	Enrofloxacin	0.1 ^b
	Flumequine	0.5
	Nalidixic acid	0.03
	Norfloxacin	n.a.
	Ofloxacin	n.a.
	Oxolinic acid	0.1
	Pefloxacin	n.a.
	Macrolides	Clindamycin
Erythromycin		0.2
Josamycin		0.05
Kitasamycin		0.2
Lincomycin		0.1
Spiramycin		0.2
Penicillins		Amoxicillin
	Ampicillin	0.05
Pleuromutilins	Tiamulin	0.1
Sulfonamides ^c	Sulfachlorpyrazine	0.1
	Sulfachlorpyridazine	0.1
	Sulfadiazine	0.1
	Sulfadimethoxine	0.1
	Sulfadoxine	0.1
	Sulfaguandine	0.1
	Sulfamerazine	0.1
	Sulfamethazine	0.1
	Sulfamethoxazole	0.1
	Sulfamethoxyipyridazine	0.1
	Sulfamonomethoxine	0.1
	Sulfaphenazole	0.1
	Sulfaquinolaxaline	0.1
	Sulfathiazole	0.1
	Sulfisoxazole	0.1
	Trimethoprim	0.05
	Tetracyclines	Chlortetracycline
Doxycycline		0.05
Oxytetracycline		0.2 ^b
Tetracycline		0.2 ^b
Others	Ormethoprim	0.1
	Praziquantel	0.02

^aNon-applicable^bMRL is given for the sum of the parent drug and its metabolite or epimer^cMRL is given for the sum of sulfonamides

not set, 50–100 days, 10–50 days, and 10 days or less.

- 3) The residue occurrence was calculated based on the number of noncompliant samples and detection rate. The frequency of noncompliant samples with respective Korean MRL values was assigned scores as follows: 5 times or more, 3–5 times, 1–2 times, and zero. The detection rate of each veterinary drug in aquatic animals was assigned scores as follows: 1% or higher, 0.1–1%, 0.01–0.1%, and < 0.

Results and discussion

Data collection of veterinary drugs

The target veterinary drugs with set MRLs were selected as study substances (Table 1). To determine risk-based priorities for the target drugs, five indicators (viz., ADI, number of sales, withdrawal period, number of noncompliant samples, and detection rate) were selected, and the scores of 1–4 were assigned to each indicator (Tables 2 and 3). Priority_r is described in the Methods. Priority_r was calculated based on the calculated scores and classified into four groups based on the quartiles of the scores. Ten substances were assigned the 75th or

Table 2 Scoring categories for risk-ranking of veterinary drugs in fishery products

Parameter	Score	Description
Potency (P_r)		
Acceptable daily intake	1	> 0.1 mg kg ⁻¹ bw day ⁻¹
	2	0.01–0.1 mg kg ⁻¹ bw day ⁻¹
	3	0.001–0.01 mg kg ⁻¹ bw day ⁻¹
	4	< 0.001 mg kg ⁻¹ bw day ⁻¹
Usage (U_r)		
Number of sales	1	< 0 (very low)
	2	1–1000 (low)
	3	1000–10,000 (medium)
	4	> 10,000 (high)
Withdrawal Period	1	< 10 days
	2	10–50 days
	3	50–100 days
	4	-
Residue occurrence (R_r , ρ)		
Noncompliant samples	1	Zero
	2	One or two
	3	Three to five
	4	Greater than five
Detection rate	1	< 0%
	2	0–0.1%
	3	0.1–1%
	4	> 1%

Table 3 Overall-rank coding and scoring of veterinary drugs in aquatic products

Substance	ADI (mg/kg)	ADI Rank	Number of Sales (kg)	Number of sales rank	Withdrawal period (days)	Withdrawal period (days) rank	Number of noncompliant samples	Number of noncompliant samples rank	Detection rate	Detection rate rank
Amoxicillin	0.002	3	112,021	4	20	2	4	3	0.88	3
Ampicillin	0.003	3	37,359	4	20	2	0	1	0	1
Cefalexin	0.5	1	656	2	5	1	0	1	0	1
Ceftiofur	0.02	2	7308	3	-	4	0	1	0.07	2
Chlortetracycline	0.03	2	75,454	4	-	4	0	1	0.07	2
Ciprofloxacin	0.002	3	0	1	-	4	0	1	3.82	4
Clindamycin	0.03	2	600	2	15	2	0	1		1
Difloxacin	0.01	3	-	1	-	4	0	1		1
Doxycycline	0.003	3	1553	3	-	4	0	1		1
Enrofloxacin	0.002	3	40,668	4	-	4	7	4	11.61	4
Erythromycin	0.0007	4	6671	3	30	3	0	1	0.22	3
Florfenicol	0.01	3	63,815	4	14	2	0	1	0.44	3
Flumequine	0.03	2	2704	3	8	1	0	1	0.44	3
Josamycin	0.002	3	0	1	-	4	0	1		1
Kitasamycin	0.5	1	572	2	-	4	0	1		1
Lincomycin	0.03	2	7300	3	10	2	0	1	0.07	2
Nalidixic acid	0.002	3	0	1	-	4	0	1	0.51	3
Norfloxacin	-	4	0	1	-	4	0	1		1
Ofloxacin	-	4	0	1	-	4	0	1		1
Ormethoprim	0.1	2	-	1	-	4	0	1	0.29	3
Oxolinic acid	0.0025	3	6349	3	28	3	1	2	2.79	4
Oxytetracycline	0.03	2	191,780	4	30	3	0	1	7.71	4
Pefloxacin	-	4	0	1	-	4	0	1		1
Praziquantel	0.17	1	-	1	-	4	0	1	0.07	2
Spiramycin	0.05	2	1322	3	-	4	0	1	0.29	3
Sulfachlorpyrazine	0.05	2	-	1	30	3	0	1		1
Sulfachlorpyridazine	0.05	2	873	2	30	3	0	1	0.07	2
Sulfadiazine	0.05	2	8487	3	30	3	1	2	0.51	3
Sulfadimethoxine	0.05	2	1606	3	30	3	0	1	0.15	3
Sulfadoxine	0.05	2	332	2	30	3	0	1		1
Sulfaguanidine	0.05	2	38	2	30	3	0	1		1
Sulfamerazine	0.05	2	219	2	30	3	0	1		1
Sulfamethazine	0.05	2	10,269	4	30	3	0	1	0.37	3
Sulfamethoxazole	0.05	2	21,816	4	30	3	0	1	0.07	2
Sulfamethoxypyridazine	0.05	2	219	2	30	3	0	1	0.15	3
Sulfamonomethoxine	0.05	2	198	2	30	3	0	1		1
Sulfaphenazole	0.05	2	-	1	30	3	0	1		1
Sulfaquinoxaline	0.05	2	780	2	30	3	0	1		1
Sulfasoxazole	0.05	2	-	1	30	3	0	1		1
Sulfathiazole	0.05	2	22,902	4	30	3	0	1		1
Tetracycline	0.03	2	0	1	-	4	0	1	0.07	2
Thiamphenicol	0.045	2	82	2	15	2	0	1		1
Tiamulin	0.03	2	13,598	4	-	4	0	1	0.07	2
Trimethoprim	0.02	2	6614	3	-	4	1	2	2.2	4

higher scores and, therefore, were selected as priority substances (Table 4).

The ADI value can be an indicator of safety of veterinary drugs. Among the veterinary drugs collected, four veterinary drugs including erythromycin had no ADI or had low values (< 0.001 mg/kg bw/day), and therefore, they were assigned 4 points. The usage of drugs was as follows: oxytetracycline $>$ amoxicillin $>$ chlortetracycline $>$ florfenicol $>$ enrofloxacin. There were 17 veterinary drugs, including ceftiofur, which did not have a withdrawal period or had no set withdrawal period and, therefore, were assigned 4 points. When the usage was ranked by adding the scores of the number of sales and withdrawal period, enrofloxacin and tiamulin showed high values. Thus, frequently used veterinary drugs occupied a high proportion of those with high scores. In terms of residue occurrence, 4 points were assigned to a high number of noncompliant samples, and enrofloxacin showed the highest number of noncompliant samples (7 cases); thus, 4 points were assigned. Moreover, substances with the detection rate of 1% or more were assigned 4 points, and they included chlortetracycline and enrofloxacin (Table 3).

Determination of risk-based priority

Enrofloxacin (fluoroquinolone) had the highest score of 192. Enrofloxacin had 3 ADI points (0.002 mg/kg bw/day), a high value of usage (40,668 kg), and withdrawal period, and the highest number of noncompliant samples (7 cases). Enrofloxacin is used for the prevention and treatment of infection by pathogenic bacteria such as Vibriosis, and the amount of active ingredients is 100 g/kg or L (NIFS 2016). In this study, enrofloxacin had high scores in potency, usage, and residue occurrence, and therefore, it was ranked high among the prioritized substances, but it was ranked low in the risk-based national residue program in Ireland. In the corresponding study, the use of enrofloxacin, in livestock products, was analyzed, and therefore, it was difficult to compare the results of the corresponding study with those of this study because of lack of sufficient information when used in fishery products (FSAI 2014). Next, the total score of amoxicillin was 108, indicating a high score among the investigated substances. In fact, amoxicillin, trimethoprim, and sulfadiazine among quartile (Q4) substances among the substances investigated in this study were shown to have high priority for management in consideration of frequency of use in the UK and toxicological results based on ADI (Capleton et al. 2006). Moreover, amoxicillin was shown to be a high-priority substance as a result of Ireland's national residue program monitoring, which was derived using the same formula as in this study. Oxolinic acid, trimethoprim, ciprofloxacin, florfenicol, and oxytetracycline were

Table 4 Risk-based ranking of veterinary drugs in aquatic products

Substance	Score	Priority	Quartile
Enrofloxacin	192	1	Q4
Amoxicillin	108	2	
Oxolinic acid	108	2	
Erythromycin	96	4	
Trimethoprim	84	5	
Ciprofloxacin	75	6	
Florfenicol	72	7	
Oxytetracycline	70	8	
Nalidixic acid	60	9	
Sulfadiazine	60	9	
Spiramycin	56	11	Q3
Sulfamethazine	56	11	
Chlortetracycline	48	13	
Sulfadimethoxine	48	13	
Tiamulin	48	13	
Ceftiofur	42	16	
Doxycycline	42	16	
Sulfamethoxazole	42	16	
Norfloxacin	40	19	Q2
Ofloxacin	40	19	
Pefloxacin	40	19	
Sulfamethoxyipyridazine	40	19	
Ormethoprim	40	19	
Ampicillin	36	24	
Flumequine	32	25	
Difloxacin	30	26	
Josamycin	30	26	
Lincomycin	30	26	
Sulfachlorpyridazine	30	26	
Tetracycline	30	26	
Sulfathiazole	28	31	
Sulfadoxine	20	32	Q1
Sulfaguanidine	20	32	
Sulfamerazine	20	32	
Sulfamonomethoxine	20	32	
Sulfaquinoxaline	20	32	
Clindamycin	16	37	
Sulfachlorpyrazine	16	37	
Sulfaphenazole	16	37	
Sulfasoxazole	16	37	
Thiamphenicol	16	37	
Praziquantel	15	42	
Kitasamycin	12	43	
Cefalexin	6	44	

mostly detected in fishery products in Korea, and the occurrence pattern was similar to the results of this study (Kang et al. 2018). Nalidixic acid had no number of sales but had higher priority than that of other compounds due to the detection rate and ADI. Our findings suggest that nalidixic acid can be used continuously in fishery products according to veterinarian prescription. On the contrary, cephalosporin-based cephalexin had the lowest score (total 6 points) because of a high ADI value and short withdrawal period. Cefalexin was also found to have a very low priority in the results.

Applications of the study

In this study, a risk-based approach was used to prioritize veterinary drugs used in fishery products for the development of new governmental risk management. The risk of veterinary drugs was ranked based on the risk-based approach by using the following three risk factors: (1) potency, (2) usage, and (3) residue occurrence. These factors were investigated based on the risk of the substances, priority was set up based on scientific grounds, and monitoring test was conducted, thereby increasing the efficiency of the national inspection priority. Ireland not only applies the priority of the substances to be tested to the actual national residue program using the risk-based priority in the calculation program but also uses it to estimate the minimum number of samples required for the monitored livestock products. To effectively accomplish the safety management of national residue substances, a risk-based prioritization program is necessary. As of May 2018, the Korea Food Code suggested simultaneous multi-residue method (50 substances) as a qualification method (MFDS 2019). However, it is difficult for an individual food safety lab to analyze all veterinary drugs including illegal use in terms of time and cost. Analyzing substances according to the priority presented in this study is expected to increase the efficiency of analysis in the food safety lab.

Limitation of this study

Risk-based priority has an uncertainty for each factor in the calculated model. Although the usage is calculated based on the data of veterinary drug sales, priority should be calculated by analyzing the actual dose of veterinary drugs used in aquatic products. In this study, we used the withdrawal period data according to veterinary drug guidebook for fishery products presented by the National Institute of Fisheries and Science. However, a low-cost intraperitoneal or intramuscular injection has recently been developed. Thus, the withdrawal period might differ with the administration route (injection and oral). Additionally, in 2016–2018, the MRLs were updated by the Korean regulation. Ceftiofur, trichlorfene, and ethoxyquin were updated by the Korean Food Code.

Thus, newly generated data need constant updating through a web-based system. Lastly, carryover from feed to food of unavoidable and unintended residues of veterinary drugs and pesticides should be added in risk-based priority for the national residue program.

Conclusions

This study can be applied to the prioritization of monitoring and safety management of veterinary drugs in fishery products, and it can be actively utilized in the establishment of future national residue programs and domestic food re-inspection system in fishery products. In the future, dataset and equation for all factors of the risk-based approach should be updated in newly developed web-based system.

Abbreviations

ADI: Acceptable daily intake
EMA: European Medicine Agency
FSA: Food Safety Authority
Ireland: JECFA Joint Expert Committee of Food Additives
KAPHA: Korea Animal Health Products Association
MRL: Maximum residue limits

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Hui-Seung Kang and Songyi Han contributed equally to this work.

Authors' contributions

The authors contributed to this manuscript as follows: H-S K. studied the design, data analysis, and writing of the manuscript; SY H. contributed the writing of the manuscript and drafting of the manuscript; B-H C. reviewed the manuscript; and HJ L. studied the design and data analysis. All authors reviewed, edited, and approved the manuscript for submission.

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Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Consent for publication

Not applicable

Competing interests

The authors declare that they have no competing interests.

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