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# Improving the level of food safety and market access in developing countries

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## Abstract

The EU has been implementing strict food laws and regulations that de facto constrain exports from Indonesia, particularly regarding agricultural products. This study uses the comparative law method and the FSO/ALOP framework to analyze how to design better strategies for Indonesia when dealing with the more stringent food laws and regulations of the EU, particularly in the case of shrimp and nutmeg. This study proposes that the choice of strategy should depend on the nature of the hazard, the existing national food control system, and the availability of the relevant international standard.

Keywords: Food safety, Law

## 1. Introduction

Access to markets in developed countries has always been an important factor for the success of economies in developing countries. It stimulates dynamic export growth for developing countries and raises domestic revenues (Trebilcock, 2015). In food trade, the lack of national food control systems in developing countries has been a major constraint to obtaining access (Athukorala and Jayasuriya, 2003) to export

markets of developed countries, which usually impose more stringent food laws and regulations (Ferro et al., 2015). While such laws and regulations are conventionally viewed as an obstacle for developing countries, they can also act as an opportunity for developing countries to innovate and improve their national food control systems. If the system adapts to the lack of data and resources present in developing countries, these strict laws and regulations can also act as catalysts for upgrading the level of food safety in developing countries and at the same time an increase in access to export markets (Henson and Jaffee, 2006; Jongwanich, 2009), the so-called market access effect (Purnhagen, 2015b).

Both shrimp and nutmeg are the most imported food product by the EU from developing countries, and Indonesia is one of the most important suppliers of these commodities. In most areas, the EU fosters the most stringent food laws and regulations; these laws and regulations can be categorized as non-tariff barriers (NTBs), particularly for raw or lightly processed goods, such as frozen shrimp or dried nutmeg (Shepherd and Wilson, 2013). An explicit indicator of the export market can be found in the number of import notifications, including border rejections (Henson and Jaffee, 2006). In the case of exports of Indonesian agricultural products to the European Union (EU), shrimp and nutmeg have received recurrent notifications in a certain sequential period due to the use of chloramphenicol and the contamination of aflatoxins (AFs) respectively. Chloramphenicol is prohibited in foods due to its implication in the generation of aplastic anemia in humans and causes reproductive hepatotoxic effects in animals (2014). Whereas, Aflatoxins, particularly Aflatoxin B1 poses the most serious health effect to mammals, causing hepatotoxicity, teratogenicity, and mutagenicity, resulting in diseases such as toxic hepatitis, hemorrhage, edema, immunosuppression, hepatic carcinoma, equine leukoencephalomalacia (LEM), esophageal cancer, and kidney failure (Reddy et al., 2010). There were in total 44 notifications related to prohibited substances (antimicrobials) found in shrimp in the period of 2001 until 2008, 23 of which were due to the use of chloramphenicol (EU-RASFF, 2017). Whereas, there were in total 68 notifications related to aflatoxins (AFs) in nutmeg in the period of 2000 until 2017 (EU-RASFF, 2017). The fact that the recurrent import notifications of chloramphenicol in shrimp occurred throughout the 7-year period and have been absent since 2009 up until now and the fact that recurrent notifications of aflatoxins in nutmeg have occurred throughout for at least the last 17 years and are still happening up until now need to be investigated and analyzed to find the causalities and a way to prevent recurrent notifications in the future. We investigate the risk management of these two different case studies to further propose better strategies for Indonesia to deal with more stringent food laws and regulations and at the same time to increase their access to the export markets in the EU.

The remainder of this paper is structured as follows: In section 2, we describe the methodology. In section 3, we elaborate the analysis by using the comparative

law method and FSO/ALOP framework. In section 4, we describe the discussion and management implication. Finally, in section 5, we summarize our findings in the conclusion and recommendation.

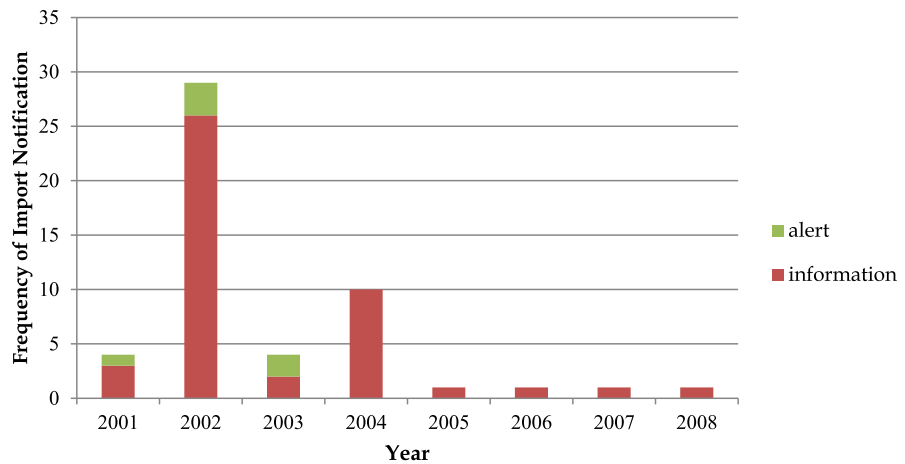
## 2. Methodology

In this study, we use the textual and contextual data of relevant food laws and regulations in Indonesia and the EU. We use the regulations on the maximum level of contaminants in foods as our primary data. We use a comparative law method to analyze those regulations. Whereas, for secondary data, we use journals, books, internet databases, and government reports. We obtain trade and import notification data from the government/international organization reports and the EU-RASFF portal respectively. Moreover, we use the food safety objective/appropriate level of protection (FSO/ALOP) framework of our previous work to analyze risk management applied in those aforementioned case studies and to further propose better strategies in dealing with more stringent food laws and regulations (Wahidin and Purnhagen, 2017).

### 2.1. Trade and import notification

Indonesia is the second largest fish producer in the world, with more than six million tons of marine captures and 13 million tons of aquaculture production annually (EUMOFA, 2015; FAO Globefish, 2016). Moreover, Indonesia is the second largest producer of crustaceans, with the production of more than 600 thousand tons per year (FAO Globefish, 2016). Shrimp has been Indonesia's main fishery export commodity, for which vannamei shrimp dominates the nation's shrimp productions and exports (GBG, 2014; MMAF, 2015). Whereas, the EU has been the world's biggest importer of fish, seafood, and aquaculture products (DG SANCO, 2016a). In 2009, Indonesia accounted for 6% of the frozen shrimp supplied by foreign suppliers to the EU market (Lord et al., 2010) Therefore, Indonesia has the potential to become a major exporter of shrimp to the EU. Indonesia is also well known as a major exporter of nutmeg in the world, with a market share of approximately 75% (CBI, 2016). Indonesia's main trading partners are Vietnam, the US, Japan, and the EU (particularly Germany, the Netherlands, Italy, and France). As for Vietnam and the Netherlands, most of the Indonesian nutmeg are processed into ground nutmeg (powder) and re-exported to other countries.

Exported shrimp and nutmeg from Indonesia have a long history of import notifications from the EU due to noncompliance with the regulations related to the maximum level of contaminants in foods (European Commission, 2017). Import notifications that occurred in the period of 2001 until 2008 concerning the non-compliant exported shrimp shipments from Indonesia were mostly due to the use of banned antimicrobials (e.g., chloramphenicol) (Fig. 1). In contrast, import

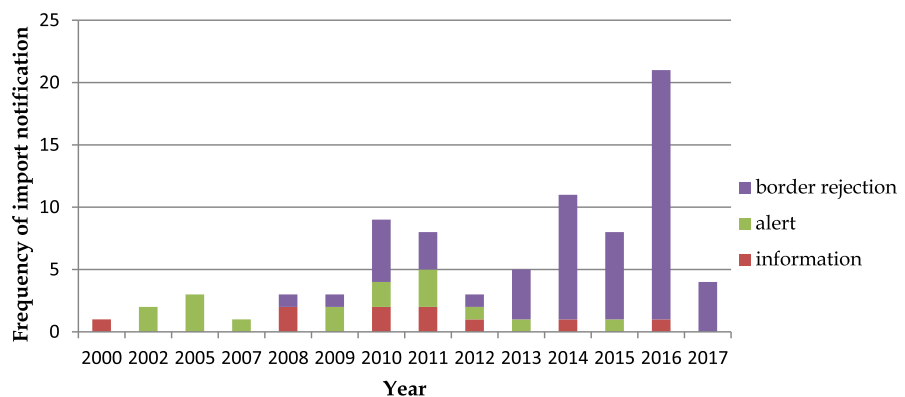


**Fig. 1.** Frequency of notifications by the EU concerning banned antimicrobials in shrimp imports from Indonesia.

notifications related to the non-compliant exported nutmeg are mostly due to the contamination of AFs. The import notifications have been occurring since 1999, with 23 notifications in 2016 alone (Fig. 2) (European Commission, 2017).

## 2.2. FSO/ALOP analysis

In order to analyze risk management both by Indonesia and the EU and to propose better strategies for Indonesia in dealing with the strict food laws and regulations in the EU, particularly in relation to shrimp and nutmeg imports, this study uses the FSO/ALOP framework for the application in developing countries (Wahidin and Purnhagen, 2017). The framework follows the principle of farm to fork, where the level of contaminants should be kept lower than the FSO at all stages of the food supply chain to contribute to the ALOP (Eq. (1)) (Wahidin and Purnhagen, 2017).



**Fig. 2.** Frequency of import notifications by the EU concerning aflatoxins (AFs) in nutmeg imports from Indonesia.

The ALOP refers to “the level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory” (WTO, 1995). The FSO refers to the maximum level of a contaminant at the point of consumption and can be applied directly to previous stages of the food supply chain (primary producers, manufacturers, and retailers) (ICMSF, 2006; Wahidin and Purnhagen, 2017). Food safety management systems, e.g., Good Agricultural Practices (GAP), Good Handling Practices (GHP), Good Manufacturing Practices (GMP), Hazard and Critical Control Point (HACCP), and Good Distribution Practices (GDP), applied in the food supply chain can minimize or eliminate the level of contamination throughout the food supply chain. However, if the FSO is too low, like the cases of genotoxic and carcinogenic hazards, then performance objectives (POs) must be established for each specific stage of the food supply chain (Wahidin and Purnhagen, 2017). For example, if the initial level of contamination ( $H_o$ ) has already been high on the primary production stage, there is a high possibility that the level of contamination can increase at this stage ( $\sum I$ ) and at the same time a minimum control measure that can be implemented to reduce the level of contamination ( $\sum R$ ). Thus, the actual level of contamination ( $H$ ) will also be high beyond the stage of primary production. The actual contamination level at the primary production stage will become the initial level of contamination at the manufacturer and retail stages. In practice, a food manufacturer becomes the key player in establishing POs for its suppliers (primary producers) and distributors following the traceability system.

$$H_o + \sum I - \sum R \leq H \leq PO \leq FSO \quad (1)$$

Where

$H$  = Actual level of contamination

$H_o$  = Initial level of contamination

$\sum I$  = Total increase level of contamination

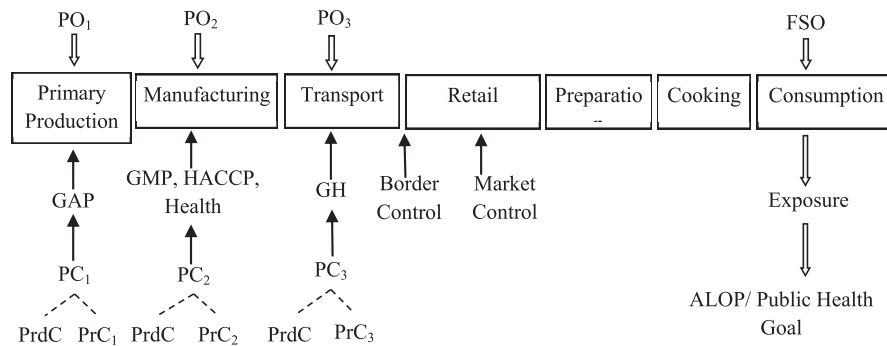
$\sum R$  = Total reduction level of contamination

PO = Performance objective

FSO = Food safety objective

**Eq. (1).** Food safety objective (FSO) and its relationship to performance objectives (PO) at different stages of the supply chain.

In the context of international trade, an FSO is determined by importing countries and generally set as a regulatory requirement (Fig. 3). Hence, exporting countries are required to apply appropriate food control systems to meet the FSO of the importing countries. The POs act as targets of FSMSs at each specific stage of the

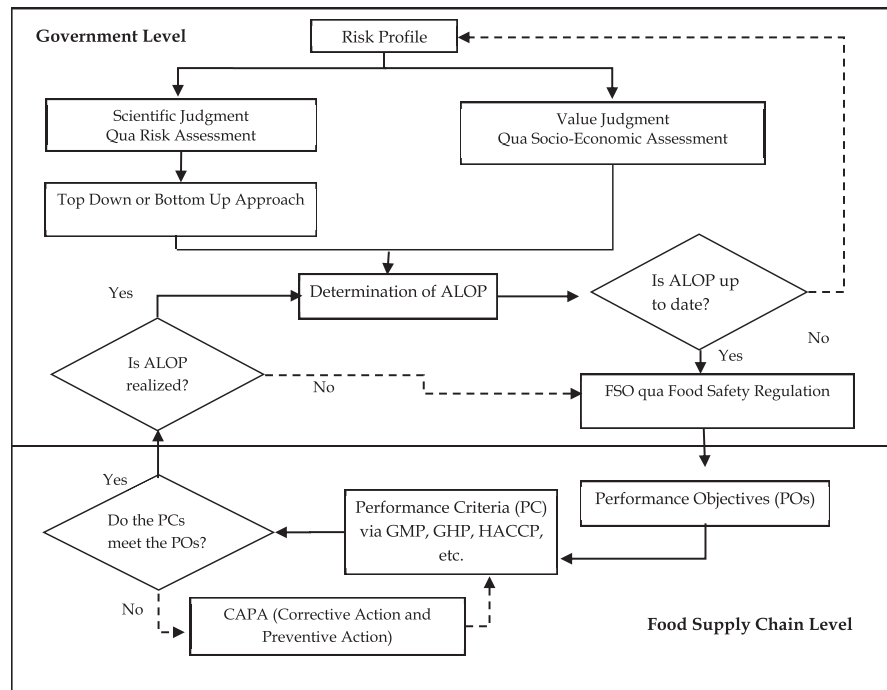


**Fig. 3.** Model of the FSO/ALOP in the international food supply chain.

food supply chain that contributes to the FSO and ALOP. Both an FSO and PO function as critical levels, and both are equivalent, meaning that the food is safe if the level of the hazard remains below the levels defined by them and unsafe if the hazard is beyond those levels.

To ensure food safety, a food safety matrix other than a FSO or a PO needs to be established, which should be a performance criteria (PC), which is defined as the effect in terms of frequency and/or concentration of a hazard that must be achieved by the application of one or more control measures to provide or contribute towards a PO or FSO (CAC, 2016). This PC should encompass two elements: a process criteria (PrC) and a product criteria (PrdC). Both the PrC and PrdC determine how the PC is achieved. The PrC is controlled parameters regarding the processes of food production, whereas the PrdC is intrinsic parameters of the food that need to be met to guarantee food safety. For example, to achieve an FSO of 10 µg/kg of Aflatoxin B1 (AFB1) in nutmeg and a PO of 5 µg/kg of AFB1, a specific control measure (PrC) at the production stage, such as drying at a temperature no higher than 60 °C for 14 days, is required to keep the moisture content of the nutmeg below 10% (PrdC).

Developing countries need to design a quantitative ALOP to define a food safety matrix to be used by actors in the food supply chain in the development and implementation of FSMSs (Fig. 3). The FSO links the ALOP to the FSMSs of food supply chain actors. However, to determine the ALOP and later the FSO (FSO/ALOP), the government needs to establish an appropriate risk profile by conducting a qualitative risk assessment that consists of a hazard assessment, a hazard characterization, an exposure assessment, and a risk characterization (Fig. 4). Subsequently, if it is found that the risk estimate is high, the government can assign an independent scientific authority to conduct a more sophisticated scientific assessment (quantitative assessment). The government (food safety authorities) can use the risk estimate as the result of that scientific assessment and combine it with the value judgment (socioeconomic assessment) to determine an FSO/ALOP.



**Fig. 4.** Management model for developing the FSO/ALOP for the application in developing countries.

As mentioned previously, there are two ways to determine an FSO/ALOP: a top-down and bottom-up approach. In the context of regulation where relevant international standards or similar regulations from other countries are available, it is recommended that a country adopt those standards or regulations in the determination of its FSO/ALOP (top-down approach). Whereas, if relevant international standards and similar regulations from other countries are not available, then countries must determine their FSO/ALOP based on a risk assessment (bottom-up approach).

To evaluate FSMSs, whether those have achieved the FSO/ALOP or not, we need to assess whether the PCs achieve the POs (Fig. 4). If the PCs do not meet the POs, then the actors in the food supply chain are required to adjust their FSMSs through the mechanism of corrective action and preventive action (CAPA). If the FSO/ALOP is not realized, then government (food safety authority) should adjust the FSO/ALOP, verify the current FSMSs of food manufacturing, and conduct post-market surveillance. In the context of international trade, the importing countries are usually set more stringent FSO/ALOP than the one in the exporting countries. This strict FSO/ALOP has been constraining the national food control system of the exporting countries. The nature of the hazard and the availability of the international standard are other factors that need to be considered by the developing countries in developing strategies to meet the importing countries' FSO/ALOP to later increase the export market access.

### 3. Analysis

#### 3.1. The FSO/ALOP of the EU related to the imports of Indonesian shrimp and nutmeg

The EU maintains a high level of protection as specified in Article 1 of the General Food Law (GFL), which “provides the basis for the assurance of a high level of protection of human health and consumers’ interest in relation to food, taking into account, in particular, the diversity in the supply of food including traditional products, whilst ensuring the effective functioning of the internal market.” According to Article 6 of the GFL, the EU requires the use of risk analysis-based measures as tools to achieve the ALOP. However, according to Article 7 of the GFL, in circumstances where there is a lack of scientific evidence, the precautionary principle should be used as a complement to the risk analysis (Purnhagen, 2015a). In other words, where there is a lack of scientific evidence, food safety authorities can apply the precautionary principle as the pertinent option for risk management. The “zero-tolerance” approach that is applied in the case of banned antimicrobials being found in shrimp imported from South Asian countries is one of the textbook examples of the implementation of the precautionary principle by the EU.

The overarching policy of the EU regarding imported foods is to reduce non-compliant foods at designated points of entry through a comprehensive border control and audits in exporting countries (European Commission, 2016a,b). Due to a high number of import notifications related to shrimp and nutmeg imports from Indonesia, the EU has steadily increased the level of official import controls for these products that result in a more stringent FSO/ALOP. The EU Food and Veterinary Office (FVO) carried out several audits in Indonesia regarding residues and contaminants in live animals and animal products as well as the control of AF contamination in nutmeg shipments intended for export to the EU (DG SANCO, 2012a,b, 2016b). The EU has been implementing a very strict FSO in the form of the minimum required performance level (MRPL) of 0.3 µg/kg of chloramphenicol in shrimp and a maximum level (ML) of 5 µg/kg of aflatoxin B<sub>1</sub> (AFB<sub>1</sub>) and 10 µg/kg of total aflatoxins (total AFs) in spices, including nutmeg. Exporters are obliged to attach a health certificate (a statement that the product complies with the EU’s standard) from the local food safety authorities to each consignment of both commodities. At the EU borders, the local food safety authorities conduct both a check of certificates and physical checks to ensure compliance.

#### 3.2. FSO/ALOP analysis of chloramphenicol in shrimp

##### 3.2.1. Risk profile

Antimicrobials, such as chloramphenicol, have been conventionally used by shrimp farmers to treat and prevent disease outbreaks. Chloramphenicol has a wide



spectrum and thus can effectively combat gram positive bacteria, gram negative bacteria, and viruses. Despite that, chloramphenicol has both genotoxic and carcinogenic properties. The International Agency for Research on Cancer (IARC) has classified chloramphenicol in Group 2A (likely carcinogenic to humans) (IARC, 2012). Moreover, the WHO/FAO Joint Expert Committee on Food Additives (JECFA) has stated that there is no acceptable daily intake (ADI) and therefore no maximum residue limit (MRL) for chloramphenicol in food-producing animals, which is animals used in the production of food. The term “food-producing animals” includes all terrestrial and aquatic animals (that is, includes aquaculture) used to produce food. For the purposes of these guidelines, the term “food-producing animals” is considered an equivalent term to “food animals” (WHO, 2017). A Codex standard (veterinary drugs residues in foods) for chloramphenicol exists based on the JECFA opinion. No MRL is allocated and the risk management recommendation (RMR) stipulates competent authorities to prevent residues of chloramphenicol by avoiding the use of chloramphenicol in food-producing animals (CAC, 2015). In order to minimize the risk of chloramphenicol in shrimp, the EU uses the “zero-tolerance” approach, which is based on the linear non-threshold (LNT) model that trivializes the food safety regulation since one molecule may result in an irreversible health damage (Jaap C. Hanekamp and Bast, 2015). Though, the risk from the level of exposure to chloramphenicol through the consumption of shrimp is negligible (RIVM, 2001).

### 3.2.2. *The determination of FSO/ALOP*

The EU applies the principle of “as low as reasonably achievable” (ALARA) in determining its FSO/ALOP with respect to chloramphenicol in food-producing animals. This is due to the genotoxic and carcinogenic properties of the chloramphenicol. Thus, the public exposure to chloramphenicol shall be controlled to a very minimum level or even to the zero level. Chloramphenicol has been banned from use in food-producing animals in the EU since 1994, following the recommendation from the Committee for Medicinal Products for Veterinary Use (CVMP) (EFSA, 2014). The EU uses whichever level can be detected by regulatory laboratories of Member States (Jaap C Hanekamp et al., 2003), as specified in Article 5 of Regulation 2377/90 describes a community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin. Chloramphenicol is listed in Annex IV of the same regulation as a “substance hazardous at whatever limit”.

Chloramphenicol is not only classified as an anthropogenic chemical contaminant, but it is also classified as a natural contaminant since it is produced by soil bacteria, may occur in plants, and also can be found in food-producing animals as an unintentional contaminant. This means that the “zero-tolerance” approach or classification

as a “substance hazardous at whatever limit” is not feasible. Though, the most pertinent reason for not applying the “zero-tolerance” approach is the need to have an FSO for routine border inspection. Despite the need, the determination of an FSO for chloramphenicol in shrimp is difficult since the EU must ensure that chloramphenicol is not indirectly tolerated either in the EU or in exporting countries. Consequently, the EU shifted from the “zero-tolerance” approach to the MRPL concept, where the value is not related to risk assessment, but more to the ability of a laboratory to test the occurrence of a hazard. The newly appointed MRPL, as stipulated in the Commission Decision 2005/34/EC describes harmonized standards for the testing for certain residues in products of animal origin imported from third countries, is therefore not related to food safety and human health, but rather related to analytical and technological capabilities (Jaap C. Hanekamp and Bast, 2015). This MRPL acts as the FSO so that a Member State can take the necessary actions if the result of the analysis is equal or above the FSO. The EU established an FSO for banned antimicrobials by harmonizing the MRPL across member states.

In addition to the general requirement of the EU towards exporting countries to adhere to the rules and principles stipulated in the General Food Law, there are four additional legal requirements regarding the importing of shrimp into the EU that are related to the control of residues of veterinary medicines. First, the exporting countries are required to be on the list of third countries that may export food of animal origin to the EU. Inclusion on this list is obtained by submitting an annual national residue monitoring plan to the European Commission. The plan must show that the third country applies measures that have an equivalent effect as the ones implemented in the Member States, as specified in Article 29 of Directive 96/23/EC on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC. Thus, to be equivalent, exporting countries are required to implement GMP, HACCP, internal and second party audits of suppliers, traceability of products, external audits by the competent authority, catch certificates, and test certificates (Golub and Varma, 2014). After the plan is approved by the Commission, the country will be listed in Commission Decision 2011/163/EU on the approval of plans submitted by third countries in accordance with Article 29 of Council Directive 96/23/EC. Second, the exporting country is required to install a traceability system in its national food laws and regulations. The system can provide a proper information related to harvesting and production of all raw and some processed products that intended for the exports into the EU. Third, according to Regulation (EU) No 852/2004 2004 on the hygiene of foodstuffs, the exporting country is required to apply HACCP-based risk management systems. Thus, all raw and processed products must meet all basic hygiene requirements and HACCP principles. Fourth, the exported product must comply with the tolerance level set for contaminants. The exporting country must, therefore, test the consignment before exporting

to the EU to avoid border rejections. This step is indeed crucial because border rejections are mainly caused by the detection of residues of banned antimicrobials in shrimp (European Commission, 2017). Contaminants stem mostly from the use of veterinary drugs during production (European Commission, 2017). A testing result must be attached to a health certificate as specified in Regulation (EU) No 854/2004 of the European Parliament and of the Council of April 29, 2004 describes specific rules for the organization of official controls on products of animal origin intended for human consumption. The allowed level of residues or MRL is stipulated in Table 1 of Regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin. It is notable, however, that there is no MRL allocated for chloramphenicol, as specified in Table 2 of the same regulation. Technically, a “zero-tolerance” approach as the ALOP is not feasible for use in the inspection control and laboratory testing. Thus, the EU translates the ALOP into an FSO of 0.3 µg/kg, which the EU calls the MRPL. It is different from the notion of the maximum regulatory limit (MRL) since there is no ADI intended for chloramphenicol in animals intended for consumption. Another reason why the EU uses 0.3 µg/kg as the MRPL is that the European Food Safety Agency (EFSA) concluded that there is a small possibility of exposure to chloramphenicol contaminated food at or below the 0.3 µg/kg level that would result in a health issue, such as aplastic anemia or reproductive/hepatotoxic effects. In this sense, an MRPL must be allocated, as defined in Article 4 of Commission Decision 2002/657/EC implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results and the amending Commission Decision No 2003/181/EC with regards to the setting of minimum required performance limits (MRPLs) for certain residues in food of animal origin. The MRPL for chloramphenicol in aquaculture products is 0.3 µg/kg (Annex II, Commission Decision No 2003/181/EC).

In Indonesia up until now, there is no available data related to the risk of chloramphenicol in shrimp through the consumption pathway like the data available in the EU. Nevertheless, the EU’s zero-tolerance approach is in line with the JECFA’s policy to not establish an ADI and MRL for the use of chloramphenicol in food-producing animals. In other words, the government of Indonesia has limited options in the establishment of a risk profile and the design of its own FSO/ALOP. Thus, in the case of chloramphenicol in shrimp, it is reasonable to use the same FSO/ALOP as the one applied in the EU.

The initial contamination ( $H_0$ ) of chloramphenicol in shrimp most likely occurs on the primary production stage through the intentional use of chloramphenicol by shrimp farmers to treat or prevent disease outbreaks (Cabello et al., 2013; Li et al., 2016). Alternatively, the initial contamination may also occur from the environment, particularly in integrated poultry and fish farming (Neela et al., 2015). Hence, there is always a probability of detecting banned antimicrobials in shrimp

(H) that might exceed the MRPL. Based on Eq. (1), there is only a very low probability of an increase in contamination level or re-contamination ( $\Sigma I$ ) after the primary production stage, and there are also no further control measures to reduce the level of contamination ( $\Sigma R$ ) at later stages in the supply chain. Therefore, the PO should be set equal to the FSO. This means that the PC can be set simply: a very low concentration or the absence of chloramphenicol in shrimp. In this context, the PrC and the PrdC maintains that the chloramphenicol concentration in shrimp is kept as low as possible or even absent at the stage of primary production.

### 3.2.3. Indonesian risk management for shrimp

Indonesia has banned the use of chloramphenicol in foods since 1988 due to the establishment of the Minister of Health Regulation No 722/Menkes/Per/IX/1988. Besides this regulation, there is the Indonesian national standard (SNI) No 01-2705.1-2006 that stipulates the ban of chloramphenicol in frozen shrimp products. The effectiveness of this regulation and standard is seen in the absence of the EU's import notifications regarding the shrimp imported from Indonesia since 2009 up until now (Fig. 1).

The government of Indonesia has been taking further legal measures to comply with the requirements of the EU and to prevent import notifications in the future. The government has adopted comprehensive systems of safety and quality control and has enhanced the added value of seafood and seafood products, based on HACCP principles. This system is outlined in Law No 45/2009 concerning Fishery Amending Law No 31/2004 (herein after called Fishery Law), Government Regulation No 57/2015 concerning the quality control and safety of fishery products system and leverage of fishery product's added value, and Ministry of Marine Affairs and Fisheries (MMAF) Regulation No PER.19/MEN/2010 concerning the quality and safety control system of fishery products. The control of residues of veterinary drugs, chemicals, and contaminants in aquaculture is regulated in MMAF Regulation No 39/PERMEN-KP/2015 concerning veterinary drugs, chemical substances, and contaminants in fish-consumption aquaculture. This regulation also establishes the MRPL for chloramphenicol and other prohibited substances in fish and shrimp; the MRPL is identical to the one that was adopted in the EU, which is 0.3  $\mu\text{g}/\text{kg}$ .

From the perspective of the FSO/ALOP framework (Fig. 4), the government of Indonesia has therefore completely harmonized its FSO/ALOP with the one in the EU that goes with the top-down approach. This measure is taken due to the availability of the relevant international standard. Furthermore, there is one important factor that needs to be highlighted in this case, which is the relatively simple and more controllable food supply chain of shrimp that makes it possible for the food control system in Indonesia to be able to provide more effective law enforcement, despite the resources limitation.

Despite the simple food supply chain system of shrimp in Indonesia, more than 80% of Indonesia's shrimp enterprises are still using traditional and extensive aquaculture method. Hence, the application of GAP is still limited or even barely applied. However, the Indonesian shrimp sector is relatively mature and professional, especially regarding the medium- to large-scale enterprises. The shrimp processing industries usually act as exporters and become the key players in dealing with the EU's food safety laws and regulations (CBI, 2016). With the average of 60% of shrimp production per year being allocated for export, shrimp commodities are very vulnerable to the requirements and food laws and regulations of importing countries. Hence, shrimp enterprises have no option but to comply with those requirements and food laws and regulations that are set by importing countries, including the "zero-tolerance" policy of chloramphenicol in shrimp set by the EU. To comply with the EU's food laws and regulations, which are more stringent than the ones in the existing conventional export markets (the US and Japan), Indonesia should apply the GAP and HACCP certification scheme to provide a better brand image than other shrimp exporting countries. This scheme not only should be an opportunity to more deeply penetrate the EU market, which has a strong demand for shrimp, but also opens niche markets beyond the mainstream ones.

### 3.3. FSO/ALOP analysis of aflatoxins in nutmeg

#### 3.3.1. Risk profile

AFs are produced by fungi of the genus *Aspergillus*, which grows in regions with a high temperature and humidity. AFs are therefore natural contaminants in subtropical and tropical countries. There are four types of AFs that naturally occur in some foodstuffs: aflatoxin B1 (AFB1), aflatoxin B2 (AFB2), aflatoxin G1 (AFG1), and aflatoxin G2 (AFG2). The AFB1 is the most potent genotoxic and carcinogenic AF and is classified as Group 1 (carcinogenic to humans) (IARC, 2012). Indonesia is a tropical country, which puts Indonesia at a very high risk of AF contamination, a risk that applies to nutmeg. Besides that, there is a lack of food safety infrastructures and resources of nutmeg farmers to control the level of AFs. These two factors implicate the high actual level of AFs in nutmeg in the local market, particularly due to a higher water content in semi-dried nutmeg and a high number of damaged nutmeg kernels (Dharmaputra et al., 2016). On average, the EU's nutmeg consumption is about 30 grams per capita per year. Whereas, Indonesia's nutmeg consumption is about 20 grams per capita per year. Nutmeg are usually consumed in a powder (grounded) form as a condiment. Despite the relatively small amount of consumption (low exposure level), the risk estimation for nutmeg is still considered high due to the potent genotoxic and carcinogenic properties of AFs.

### 3.3.2. The determination of FSO/ALOP

There is no available international standard of AFs in spices; therefore, individual countries can set their own maximum levels (FSOs). The Scientific Committee for Food of the European Commission (European Commission, 1996) pointed out that “for that type of carcinogen, there is no threshold dose below which no tumor formation would occur. In other words, only a “zero level of exposure” will result in “no risk.” Based on this observation, the EU uses the ALARA principle to determine the FSO for AFs in food. The EU sets the FSO for AFs for the groups of spices of *Capsicum* spp. (dried fruits thereof, whole or ground, including chilies, chili powder, cayenne, and paprika), *Piper* spp. (fruits thereof, including white and black pepper), *Myristica fragrans* (nutmeg), *Zingiber officinale* (ginger), and *Curcuma longa* (turmeric), as is specified in Commission Regulation (EC) No 1881/2006 of December 19, 2006, setting maximum limits for certain contaminants in foodstuffs. This regulation amended Commission Regulation (EC) No 466/2001 sets the maximum levels for certain contaminants in foodstuffs. The Regulation specifies the FSO of mycotoxins in spices, which was absent in the previous regulation. The FSO of aflatoxin B<sub>1</sub> (AFB<sub>1</sub>) is 5 µg/kg and 10 µg/kg for total aflatoxins (total AFs). This FSO applies to all spices; there is no specific FSO of AFs in nutmeg.

For the export of nutmeg to the EU, the general requirements are the same as for the export of shrimp. However, there is no positive list of EU-approved countries for nutmeg exports. Instead, there is a regulation that specifies the criteria for an increasing level of control regarding specific agricultural products from designated third countries. For nutmeg, the European Commission has established the Implementing Regulation (EU) 2016/24 of January 8, 2016, which amends Regulations (EC) No 669/2009 and (EU) No 884/2014 2016 imposes special conditions governing the import of groundnuts from Brazil, *Capsicum annum* and nutmeg from India, and nutmeg from Indonesia. In this new regulation, the EU requires that “all consignments [...] of nutmeg from Indonesia [...] be accompanied by a health certificate (HC) stating that the product has been sampled and analyzed for the presence of aflatoxins (AFs) and has been found compliant with the Union legislation. The results of the analytical tests or the certificate of analysis (CA) also should be attached to the health certificate.” Upon arrival in the EU, consignments are still subject to document checks (100% of consignments) as well as identity and physical checks (20% of consignments), such as mentioned in the (EU) No 884/2014 2016.

Based on Eq. (1), the initial contamination level (Ho) of AFs in nutmeg imports already existed prior to harvest. The increase in the level of contamination and the possibility of re-contamination ( $\Sigma I$ ) can occur at the post-harvest stage, particularly when the drying time is delayed during the storage, handling, and transport stage, more often when the water content exceeds the critical levels of mold growth (Cornel University, 2015; Giray et al., 2007). Therefore, it is crucial to implement

FSMSs on all stages of the food supply chain to reduce or eliminate the growth of mold and to reduce the AF contamination level ( $\Sigma R$ ). The PO from the previous stage becomes the Ho of the next stage in the food supply chain.

For nutmeg, the GAP and GMP are commingled at the primary production stage. Hence, the FSMS at the primary production stage becomes the most critical element, compared to FSMSs at other stages of the food supply chain (Fig. 3). In other words, the key to ensure the compliance of goods with the FSO is to minimize the initial contamination level (Ho) on the primary production stage. PCs at the primary production stage include proper harvest time, effective physical sortation, avoiding contact with soil during the drying process, more appropriate drying process, more appropriate storage condition, better hygiene, and more appropriate packaging. For example, a proper harvest time can be done by regularly harvesting especially at rainy season to avoid mold's growth; a proper drying time can be done, particularly for drying under the sun, by keeping the nutmeg under the sun for at least 29 days to meet at least 8% of water content; and a proper packaging can be done by not using plastic bags but breathable bags.

Nevertheless, proximity between the GAP and GMP in the primary production of nutmeg can be beneficial if the farmer can implement effective FSMS to prevent the accumulation of AFs in nutmeg, which then results in a very low initial level of contamination for the next stages of the food supply chain. However, it is very difficult to define a PO at the primary production stage. This challenge is because most of the primary production actors are mainly small farmers with limited resources. This difficulty is in line with the one concerning applying HACCP at the farm level since no critical control points can be established (Cerf et al., 2011). The validation process of compliance with the PO is not feasible at the primary production level.

### ***3.3.3. Indonesian risk management for aflatoxins in nutmeg***

The EU' intensive regulations of AFs in spices have always been the triggering factors of import notifications with regards to nutmeg from Indonesia (Fig. 2), notably in 2010, 2015, and 2016. Hence, Indonesia should put more food safety efforts when dealing with this situation, especially when the current food control system is insufficient. In contrast to chloramphenicol in shrimp, the formation of AFs in nutmeg can occur throughout the entire food supply chain (farm, transportation, storage, and production). Following the system outlined in Fig. 3, actors in the nutmeg food supply chain must apply an appropriate FSMS to prevent noncompliance due to the contamination of AFs. Possible FSMSs are a good agricultural practice (GAP) at the farm level, a good manufacturing practice (GMP) and hazard analysis and critical control point (HACCP) principles at the manufacturing/processing level, and a good distribution practice (GDP) at the storage and transportation stage. Beyond that, the

government of Indonesia shall require the exporters to provide a health certificate based on laboratory testing prior to a shipment's export to the EU. It is also critical for Indonesia to establish an FSO equal to the EU's FSO (5  $\mu\text{g}/\text{kg}$  for AFB<sub>1</sub> and 10  $\mu\text{g}/\text{kg}$  for total aflatoxins), as the first and most important strategy to grant market access to the EU. However, most nutmeg farmers in Indonesia currently have not yet met the GAP and GMP standard. The initial contamination (Ho) has already been high at the stage of primary production (Roeroe et al., 2015). Currently, as stipulated in the Head of NADFC Regulation No HK.00.06.1.52.4011, the FSO of spices (powder) is 10  $\mu\text{g}/\text{kg}$  for AFB<sub>1</sub> and 20  $\mu\text{g}/\text{kg}$  for total aflatoxins. Whereas in the SNI 7385-2009 (Indonesian National Standard), the FSO for AFB<sub>1</sub> in spices is 15  $\mu\text{g}/\text{kg}$  and for total aflatoxins in spices is 30  $\mu\text{g}/\text{kg}$ . Different from the EU, there are two different FSOs, each for whole and powder spices. The FSO for powder spices is more stringent than for whole spices since the possibility to be contaminated is higher when the spice is in a powder form than when it is whole (Pesavento et al., 2016). In this case, the government of Indonesia shall provide a full risk assessment to justify the application of a less stringent FSO/ALOP than the ones in the EU. In other words, the government applies the bottom-up approach because currently, the relevant international standard is not yet available. Despite that, Indonesia and other nutmegs importers should use the Codex forum to establish an international standard on the maximum limits of aflatoxins in spices that is less stringent than the one applied in the EU.

Following the establishment of the Implementing Regulation (EU) 2016/24 of January 8, 2016, Indonesian nutmegs received the highest number of import notifications (Fig. 2). In response, the government of Indonesia through the Ministry of Agriculture has established a sufficient legal framework, such as the Minister of Agriculture Regulation No 04/2015 on food safety control of agri-food produce of plant origin at the exit and entry points; the Minister of Agriculture Regulation No 53/2012 on guidelines for post-harvest handling of nutmeg; the Minister of Agriculture Regulation No 320/2015 on guidelines for production, certification, distribution and control of nutmeg seeds for replanting; the Indonesian National Standard (SNI) 0006:2015 on nutmeg, which encompasses quality control, sampling, analysis methods and labeling; and finally the Minister of Agriculture Regulation No 20/2010, which establishes the requirements for the implementation of good hygiene practice, good manufacturing practice (GMP), and good agricultural practice (GAP) and for procedures based on the hazard analysis critical control points (HACCP) principles and the traceability of foodstuffs, which is still done on a voluntary basis. Beyond the requirement for collectors and exporters to be registered with the competent authorities under the Minister of Agriculture, there is also a plan from the Minister of Agriculture to merge Regulation No 20/2010 and Regulation No 51/2008 on fresh produce registration into a single law for the official control and sampling of all agricultural commodities. However, until now, the merge is not yet



realized. This is a cause for concern at the farmer's level, where the harvest time is not proper, and the handling is less hygienic as well as at the collector/exporter level, particularly in the process of sorting, in which all nutmeg from different farmers are mixed together and the storing and packaging is not proper. Hence, quality control, best practices (GAP and GMP), and traceability systems, as is required by the Minister of Agriculture Regulation No 53/2012 and Minister of Agriculture Regulation No 20/2010, are difficult or even impossible to apply. We suspect this condition resulted in recurring import notifications in 2017 (4 border rejections).

#### 4. Discussion

Harmonized standards have greatly facilitated trade across borders and have often been a de facto prerequisite of such trade (Jørgensen and Schröder, 2014). In many instances, however, harmonization of product requirements may not be desirable for other reasons, such as differences in cultural and socioeconomic factors (Sykes, 2000). For example, issues related to food availability in the domestic market might influence the choice for harmonization. In other words, there is no general reasoning for or against the harmonization of standards, as this depends largely on the context. In the context of food safety, however, harmonization of standards is desirable to provide a high level of protection of public health, to safeguard a consistency of food safety control systems worldwide, and to avoid negative trade effects.

Developed countries require imported products to comply with their strict food laws and regulations when crossing their borders to meet the objective of reducing food safety risks. This is particularly challenging for developing countries since a lack of technological advancements, production facilities, and infrastructure has been constraining the capacity of developing countries to comply with the requirements of developed countries (Athukorala and Jayasuriya, 2003; Murina and Nicita, 2014).

Ideally, from the perspective of regulators, businesses, and the facilitation of trade, an international standard exists for each agricultural product, which can be used by all countries. However, there are foods that are not covered by international standards. Even when international standards do exist, some developed countries can apply more stringent food safety laws and regulations due to a risk assessment. In this situation, developing countries need to design better strategies to manage their limited capacity in a way that enhances the export performance of their agricultural products and at the same time achieves a comparable level of protection as the level achieved in developed countries.

In the case of chloramphenicol in shrimp, Indonesia has chosen to harmonize its FSO with the one applied in the EU. This is an example of a standards being a catalyst (top-down approach) in the establishment of the FSO/ALOP. The approach has

been successful, which is clearly shown in Fig. 1, where the frequency of import notifications (information) from the EU dropped significantly from 2005 onwards, with zero notifications from 2009 onwards. Food businesses in Indonesia have been complying with HACCP principles to comply with the EU's FSO/ALOP and in the end penetrate the EU's market. Thus, food businesses in Indonesia can penetrate more export markets beyond the existing ones (US and Japan). The adoption of the comprehensive system for the control of safety for seafood in Indonesia (e.g., application of HACCP principles in fishery industry) was not, however, solely due to import notifications from the EU. The system was also adopted in response to the accumulation of import notifications from other important Indonesian shrimp export destinations, such as the US and Japan, which commenced in 2005 and 2006, respectively. Despite the current comprehensive food control system on seafood, including shrimp, Indonesia should put more intensive monitoring system to the shrimp' farmers and exporters. This is important to prevent any import notification in the future.

The high demand for Indonesian nutmeg from EU countries and the low supply from other nutmeg exporting countries, such as Granada, should be a great opportunity for Indonesia to apply better food control systems and meet the EU consumers' demand. Despite that, the increasing frequency of import notifications (Fig. 2) has jeopardized the perception of the quality and eventually has led to a decrease in the export value of Indonesian nutmeg. In considering whether to fully harmonize the FSO with the EU, Indonesia cannot just rely on that harmonization, but also must consider the issue of nutmeg availability in the Indonesian local market and the capability of the actors in the food supply chain to implement the FSO. For example, by weighing the risk management options and by considering the possibility of the absence of nutmeg in the local market if Indonesia applies the same FSO as the EU. Beyond that, most nutmeg farmers in Indonesia are small farmers, who may not be capable to apply GAP properly. Furthermore, the manufacturing process (drying, processing, and packaging) also occurs at this stage. Thus, GMP must also be applied to manage food safety at the primary production stage, especially when considering the nature of AFs. This places a heavy burden on the farmer to keep the initial contamination (Ho) of AFs at a low level. The application of GAP, GHP, GDP, etc. has not yet managed to eliminate the risk of AFs (Karlovsky et al., 2016). Based on the above explanation, the loophole is obvious, which is the absence of FSO at the food supply chain and the absence of critical control points where most food safety efforts should be focused on. Therefore, the initial contamination has already been high at the farmer's level. Next, the fact that the concentration of AFs can increase following fungal growth at later stages of the food supply chain and there is a minimum or even absence of control measures at the later stages beyond the primary production stage worsens the situation. Moreover, no traceability system is applied within the

food supply chain. All these loopholes have resulted in a high probability of non-compliant nutmeg with respect to the EU's requirements since the level of contamination of AFs in nutmeg cannot meet the EU's FSO or even Indonesia's FSO as stipulated by the Head of the NADFC and in the SNI 7385-2009. To deal with that, advance risk management options need to be taken, particularly on the determination of an appropriate FSO/ALOP at the national level and at the same time to push the Codex Alimentarius Commission to determine the FSO for the level of AFs in nutmeg.

## 5. Conclusion

In this study, we used the comparative law method and FSO/ALOP framework developed for the application in developing countries to propose better strategies for Indonesia to meet the strict food laws and regulations in the EU, particularly in the case of shrimp and nutmeg. We conclude that the choice of strategy should depend on the nature of the hazard, the existing national food control system, and the existence of the relevant international standard.

The FSO/ALOP analysis showed that the top-down approach is more appropriate for coping with the case of chloramphenicol in shrimp. This is due to the nature of chloramphenicol as an anthropogenic contaminant, a relatively well-established food control system, and the existing international standard that prohibits the use of chloramphenicol in food-producing animals. This has proven to be a successful strategy for Indonesia to have more market access to export shrimp not only to the EU but also to other potential export market destinations.

In contrast to the top-down approach that was successfully applied in the case of chloramphenicol in shrimp, we recommend Indonesia choose the bottom-up approach, which requires a full risk assessment. This is due to the growth of AFs throughout the stages in the supply chain, a relatively poor national food control system, and the absence of the relevant international standard of AFs in spices. Therefore, we recommend that Indonesia apply the current FSO of AFs in spices and provide a full risk assessment to justify it. Furthermore, we recommend that Indonesia become actively involved in the establishment of an international standard of the maximum limits of AFs in spices, which accommodates its national interests and constraints. As this process is lengthy, in the meantime the government of Indonesia should develop programs to train nutmeg farmers on the application of GAP and GHP and collectors/exporters on the application of GMP and GDP to minimize the initial contamination and the probability of an increase in the contamination level of AFs in nutmeg as well as programs to enhance the National Quality Assurance (NQA) to test the level of AFs in nutmeg.

## Declarations

### Author contribution statement

Dasep Wahidin: Conceived and designed the experiments; Performed the experiments; Analyzed and interpreted the data; Wrote the paper.

Kai Purnhagen: Performed the experiments; Analyzed and interpreted the data; Wrote the paper.

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### Competing interest statement

The authors declare no conflict of interest.

### Additional information

No additional information is available for this paper.

## References

Athukorala, P.C., Jayasuriya, S., 2003. Food safety issues, trade and WTO rules: a developing country perspective. *World Econ.* 26 (9), 1395–1416.

Cabello, F.C., Godfrey, H.P., Tomova, A., Ivanova, L., Dölz, H., Millanao, A., Buschmann, A.H., 2013. Antimicrobial use in aquaculture re-examined: its relevance to antimicrobial resistance and to animal and human health. *Environ. Microbiol.* 15 (7), 1917–1942.

CAC, 2015. Maximum Residue Limits (MRLs) and Risk Management Recommendations (RMRs) for Residues of Veterinary Drugs in Foods (Vol. CAC/MRL 2-2015, pp. 39). Codex Alimentarius Commission.

CAC, 2016. Procedural Manual, 24th ed.

CBI, 2016. CBI Product Factsheet: Nutmegs in Europe (Vol. 2018). CBI-EU, The Hague.

Cerf, O., Donnat, E., Group, F.H.W., 2011. Application of hazard analysis—critical control point (HACCP) principles to primary production: what is feasible and desirable? *Food Contr.* 22 (12), 1839–1843.

- Cornel University, 2015. Aflatoxins: Occurrence and Health Risks (Vol. 2016).
- DG SANCO, 2012a. Final Report of an Audit Carried Out in Indonesia from 13 to 22 March 2012 in Order to Assess the Controls of Aflatoxin Contamination in Nutmegs Intended for export to the European Union.
- DG SANCO, 2012b. Final Report of an Audit Carried Out in Indonesia from 25 January to 03 February 2012 in Order to Evaluate the Monitoring of Residues and Contaminants in Live Animals and Animal Products, Including Controls on Veterinary Medicinal Products.
- DG SANCO, 2016a. EU Import Conditions for Seafood and Other Fishery Products. Available from [http://ec.europa.eu/food/safety/docs/ia\\_trade\\_import-cond-fish\\_en.pdf](http://ec.europa.eu/food/safety/docs/ia_trade_import-cond-fish_en.pdf). (Accessed 19 October 2016).
- DG SANCO, 2016b. Final Report of an Audit Carried Out in Indonesia from 07 March 2016 to 17 March 2016 in Order to Assess the Controls of Aflatoxin Contamination in Nutmegs Intended for Export to the European Union (Vol. DG(SANTE) 2016-8723). European Commission/DG SANCO.
- Dharmaputra, O.S., Ambarwati, S., Retnowati, I., Nurfadila, N., 2016. Fungal infection and aflatoxin contamination in stored nutmegs (*Myristica fragrans*) kernels at various stages of delivery chain in North Sulawesi Province. *BIOTROPIA Southeast Asian J. Trop. Biol.* 22 (2), 129–139.
- EFSA, 2014. Scientific opinion on chloramphenicol in food and feed. *EFSA J.* 12 (11), 3907.
- EU-RASFF, 2017. RASSF Portal (Vol. 2017). EU-RASFF.
- EUMOFA, 2015. The EU Fish Market 2015.
- European Commission, 1996. Reports of the Scientific Committee for Food, 35 (Vol. 2016). Office for Official Publication of the European Communities, United Kingdom: Luxembourg.
- European Commission, 2016a. Food and Feed of Non-animal Origin. Retrieved on 27 November 2016, from [http://ec.europa.eu/food/safety/official\\_controls/legislation/imports/non-animal\\_en](http://ec.europa.eu/food/safety/official_controls/legislation/imports/non-animal_en).
- European Commission, 2016b. Veterinary Border Control. Retrieved on 27 November 2016, from [https://ec.europa.eu/food/animals/vet-border-control\\_en](https://ec.europa.eu/food/animals/vet-border-control_en).
- European Commission, 2017. RASSF Portal.
- Ferro, E., Otsuki, T., Wilson, J.S., 2015. The effect of product standards on agricultural exports. *Food Pol.* 50, 68–79.

GBG, 2014. Indonesia's Aquaculture & Fisheries Sector. Available from [http://www.gbgingonesia.com/en/agriculture/article/2014/indonesia\\_s\\_aquaculture\\_and\\_fisheries\\_sector.php](http://www.gbgingonesia.com/en/agriculture/article/2014/indonesia_s_aquaculture_and_fisheries_sector.php). (Accessed 19 October 2016).

Giray, B., Girgin, G., Engin, A.B., Aydın, S., Sahin, G., 2007. Aflatoxin levels in wheat samples consumed in some regions of Turkey. *Food Contr.* 18 (1), 23–29.

Globefish, F.A.O., 2016. FAO Globefish Reports — Shrimp February 2016. Available from <http://www.thefishsite.com/reports/?id=5972>. (Accessed 16 October 2016).

Golub, S., Varma, A., 2014. Fishing Exports and Economic Development of Least Developed Countries: Bangladesh, Cambodia, Comoros, Sierra Leone and Uganda. Paper Prepared for UNCTAD. UNCTAD, Swarthmore College.

Hanekamp, J.C., Bast, A., 2015. Antibiotics exposure and health risks: chloramphenicol. *Environ. Toxicol. Pharmacol.* 39 (1), 213–220.

Hanekamp, J.C., Frapporti, G., Olieman, K., 2003. Chloramphenicol, food safety and precautionary thinking in Europe. *Environ. Liabil.* 11 (6), 209–219.

Henson, S., Jaffee, S., 2006. Food safety standards and trade: enhancing competitiveness and avoiding exclusion of developing countries. *Eur. J. Dev. Res.* 18 (4), 593–621.

IARC, 2012. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans (Vol. 2016). IARC, Lyon, France.

ICMSF, 2006. A Simplified Guide to Understanding and Using Food Safety Objectives and Performance Objectives. International Commission on Microbiological Specifications for foods (ICMSF).

Jongwanich, J., 2009. The impact of food safety standards on processed food exports from developing countries. *Food Pol.* 34 (5), 447–457.

Jørgensen, J.G., Schröder, P.J., 2014. Harmonization versus Mutual Recognition: Some Pitfalls for the Coordination of Product Standards under Imperfect Competition. Discussion Papers on Business and Economics. University of Southern Denmark, p. 23.

Karlovsky, P., Suman, M., Berthiller, F., De Meester, J., Eisenbrand, G., Perrin, I., Oswald, I.P., Speijers, G., Chiodini, A., Recker, T., 2016. Impact of food processing and detoxification treatments on mycotoxin contamination. *Mycotoxin Res.* 32 (4), 179–205.

- Li, K., Liu, L., Clausen, J.H., Lu, M., Dalsgaard, A., 2016. Management measures to control diseases reported by tilapia (*Oreochromis* spp.) and whiteleg shrimp (*Litopenaeus vannamei*) farmers in Guangdong, China. *Aquaculture* 457, 91–99.
- Lord, M., Oktaviani, R., Ruehe, E., 2010. Indonesia's Trade Access to the European Union: Opportunities and Challenges (Vol. 2017). Transtec & Equinoccio.
- MMAF, 2015. Undang Vaname dan Undang Windu Masih Andalan Ekspor Indonesia (Vannamei and tiger shrimp are top export commodities of Indonesia) (Vol. 2018). Ministry of Marine Affairs and Fisheries (MMAF), Jakarta.
- Murina, M., Nicita, A., 2014. Trading with Conditions: the Effect of Sanitary and Phytosanitary Measures on Lower Income Countries' Agricultural Exports: UN.
- Neela, F.A., Banu, M.N.A., Rahman, M.A., Rahman, M.H., Alam, M.F., 2015. Occurrence of antibiotic resistant bacteria in pond water associated with integrated poultry-fish farming in Bangladesh. *Sains Malays.* 44 (3), 371–377.
- Pesavento, G., Ostuni, M., Calonico, C., Rossi, S., Capei, R., Nostro, A.L., 2016. Mycotic and aflatoxin contamination in *Myristica fragrans* seeds (nutmegs) and *Capsicum annum* (chilli), packaged in Italy and commercialized worldwide. *J. Prev. Med. Hyg.* 57 (2), E102.
- Purnhagen, K.P., 2015a. The EU's Precautionary Principle in Food Law is an Information Tool!.
- Purnhagen, K.P., 2015b. Mapping private regulation—classification, market access and market closure policy, and law's response. *J. World Trade* 49 (2).
- Reddy, K.R.N., Salleh, B., Saad, B., Abbas, H.K., Abel, C.A., Shier, W.T., 2010. An overview of mycotoxin contamination in foods and its implications for human health. *Toxin Rev.* 29 (1), 3–26.
- RIVM, 2001. Advies Met Betrekking Tot Chlooramfenicol in Garnalen.
- Roeroe, H.J., Marmis, J., Tongkeles, N.S., Lengkey, L., 2015. The quality of nutmegs seeds and mace from north Sulawesi. *J. LPPM Bidang Sains Dan Teknol.* 2 (1), 111–121.
- Shepherd, B., Wilson, N.L., 2013. Product standards and developing country agricultural exports: the case of the European Union. *Food Pol.* 42, 1–10.
- Sykes, A.O., 2000. Regulatory competition or regulatory harmonization? A silly question? *J. Int. Econ. Law* 3 (2), 257–264.
- Trebilcock, M.J., 2015. *Advanced Introduction to International Trade Law*. Edward Elgar Publishing.

Wahidin, D., Purnhagen, K.P., 2017. Determining a science-based food safety objective/appropriate level of protection for application in developing countries. *Eur. J. Risk Regul.* 8 (2), 403–413.

WHO, 2017. WHO Guidelines on Use of Medically Important Antimicrobials on Food-producing Animals. WHO, Geneva.

WTO, 1995. Agreement on the Application of Sanitary and Phytosanitary Measures. WTO, 1867 UNTS 493 (Vol. 1867 UNTS 493): WTO.