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Review

Status and future of Quantitative Microbiological Risk Assessment in China

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Since the implementation of the Food Safety Law of the People's Republic of China in 2009 use of Quantitative Microbiological Risk Assessment (QMRA) has increased. QMRA is used to assess the risk posed to consumers by pathogenic bacteria which cause the majority of foodborne outbreaks in China. This review analyses the progress of QMRA research in China from 2000 to 2013 and discusses 3 possible improvements for the future. These improvements include planning and scoping to initiate QMRA, effectiveness of microbial risk assessment utility for risk management decision making, and application of QMRA to establish appropriate Food Safety Objectives.

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Introduction

Several food safety issues that occurred in China in recent years have contributed to a decrease in public confidence concerning the domestic food supply. These incidents include the melamine contamination in milk powder in 2008, clenbuterol hydrochloride contamination of meat products in 2010, widespread usage of tainted cooking oil in Chinese restaurants in 2011, and plasticizer contamination in moon-cakes (traditional food for Mid-Autumn Festival in China) in 2013.

Law, regulations and structure; a historical perspective

China has been self-sufficient in food since 1995 after decades of combating food shortages (Chen, 2002; Chu *et al.*, 2011). In 1995, the People's Republic of China's Food Hygiene Law came into effect and introduced important changes to the Food Hygiene law of 1982. However, in many instances, the 1995 Food Hygiene Law was ineffective in protecting consumers from the consequences of unscrupulous food production and did not establish a system to deal with major food safety incidents (Bian, 2013). Triggered by the melamine in milk scandal of 2008, the 1995 Food Hygiene Law was replaced by the People's Republic of China's Food Safety Law 2009 (Jia & Jukes, 2013). Since 2009, the Chinese government has made food safety a top and national priority and in 2013, amendments were made to the 2009 Food Safety Law. These amendments include tougher enforcement and more emphasis on risk-based standards, and would be approved and imposed formally in 2015.

In tandem with changes in regulations on food safety, the Chinese government has taken further measures to improve the food safety management system. Previously food safety management was complex and multilayered with national, provincial, and local levels of food safety management involving 14 different national government departments. These departments included the State Food and Drug Administration (SFDA), the Ministry of Health (MOH), the Ministry of Agriculture (MOA), the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ), the State Administration for Industry

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and Commerce (SAIC) of the People's Republic of China, etc. This system caused uncertainty in the responsibilities and in identification of clear chains of accountability, whereas the food supply chain in China continually modernizes due to the rapid transformation of production and economic growth (Anonymous, 2012). In response, during the first quarter of 2013, the newly established China Food and Drug Administration (CFDA), answerable to the State Council of China, consolidated the responsibilities of the SFDA, AQSIQ and SAIC (China Food and Drug Administration, 2013). The status of the CFDA is now equivalent to a government ministry in China. By bringing food safety within the remit of a single government authority an important step was made to avoid duplication of work, clarify accountabilities, reduce the risk of contradictory or inconsistent application and enforcement and reduce the likelihood of a failure to perform vital tasks.

Microbiological contaminations

Chemical hazards constitute the majority of reported food safety incidents currently reported by the media in China. However the 2012 data published by the National Health and Family Planning Commission of P. R. China (NHFPC, the Ministry of Health before 2013) indicated that microbiological foodborne hazards were involved in over half of the recorded food safety incidents. Among 6685 reported cases of foodborne illness there were 3749 cases due to microbiological hazards, including *Salmonella* spp., *Bacillus cereus*, *Vibrio parahaemolyticus*, pathogenic *Escherichia coli*, *Aeromonas* spp., and *Staphylococcus aureus* (National Health and Family Planning Commission, 2013). The trend in food poisoning cases for 2012 was similar to that of previous years and the implicated pathogens are still the main cause of foodborne illness in China. The number of reported cases of foodborne disease in China is much lower than that in the UK (97,701 persons associated with five main pathogens in 2012 (Food Standards Agency, 2013) and in the USA (19,531 laboratory-confirmed cases reported by FoodNet in 2012) (Centers for Disease Control and Prevention, 2013). This discrepancy in reported cases may be due to the differences in the surveillance systems in these countries when compared to China (Anonymous, 2012). We believe that the real statistical data of under-notification or under-reporting or even misdiagnosis might be very high in China, due to the national illness investigation system which needed improving, and only a minority of patients with food poisoning seek formal medical care, so epidemiological investigation of outbreaks is not well developed and foodborne diseases are often invisible.

Risk concept development

For approximately 20 years the risk analysis paradigm, developed by the Codex Alimentarius Commission (Codex Alimentarius Commission, 1999), has been implemented by many countries for managing food safety and protecting public health. As such, the risk analysis paradigm, consisting of risk assessment, risk management and risk communication, may be used by these countries as a basis for setting international standards and guidelines, and for national food regulations or other initiatives (Codex Alimentarius Commission, 2007a). At the European level, for example, regulation EC 178/2002 forms the basis of Food Safety Law in the European Union member states (European Community, 2002). This regulation seeks to ensure that food safety should generally be founded on science by using the risk analysis framework (Gkogka, Reij, Gorris, & Zwietering, 2013).

Microbiological hazards are present in the food supply chain and the risk of illness from consuming food varies considerably depending on different types of hazards and food matrices as well as the susceptibility of individual consumers (Magnússon *et al*., 2012). The globalization of food trade and other trends have or may increase the challenges for assuring food safety and assessing risk in a timely fashion (Quested, Cook, Gorris, & Cole, 2010). The scientific basis for risk-based decision making by governmental risk managers is provided by the risk assessment part of the risk analysis framework. Risk assessment assesses the level of risk posed to consumers due to pathogenic bacteria possibly associated with foods and establishes options for risk reduction that risk managers then evaluate. According to the World Health Organization (WHO), microbiological risk assessment (MRA) uses scientific information to describe the likelihood and magnitude of harm attributed to a specific pathogen in food. Combining likelihood with magnitude of harm quantifies the level of risk to consumers (Gorris & Yoe, 2014). Quantitative Microbiological Risk Assessment (QMRA) applies principles of risk assessment to the estimate of consequences from a planned or actual exposure to infectious microorganisms with quantitative information (such as dose–response relationships, exposure magnitudes) (Alban, Olsen, Nielsen, Sørensen, & Jessen, 2002; Haas, Rose, & Gerba, 2014; Havelaar, Evers, & Nauta, 2008).

Progress and purpose

Since the implementation of the 2009 Food Safety Law, the Chinese government has made strides to adopt the risk analysis framework. It improved the infrastructure for food risk assessment via the National Food Safety Risk Assessment Expert Committee of China. In October of 2011, the China National Center for Food Safety Risk Assessment (CFSA) (China National Center for Food Safety Risk Assessment, 2013) was formed to provide technical support for national food safety risk assessment, surveillance, alert, risk communication and food safety standards. CFSA is the sole national research agency and a public health PSO (public service organization) responsible for improving microbiological risk assessment research. CFSA has completed a risk assessment of *Salmonella* spp. contamination in chicken meats at the retail level in China. National

QMRA studies of *Campylobacter jejuni* in broiler chicken, *Listeria monocytogenes* in Ready-To-Eat (RTE) food, and *V. parahaemolyticus* in oysters are currently being conducted since 2013.

In addition to carrying out national QMRA research, CFSA researchers and colleagues from Chinese academic institutions have published important peer-reviewed papers on QMRA. These studies included *Salmonella* in shell eggs (Zhao & Liu, 2004a, 2004b), *S. aureus* in pork (Luo, Guo, Wang, & Li, 2010), *L. monocytogenes* in bulk cooked meat products (Tian, Fan, & Liu, 2011), *V. parahaemolyticus* in short necked clam (Li, Wu, Ning, Wu, & Fang, 2012), mycotoxin ochratoxin A with dietary intake (Han *et al.*, 2013), *B. cereus* in Chinese-style cooked rice (Dong, 2013), and mycotoxins in cereal and oil products (Li *et al.*, 2014).

Historically, most of Chinese published studies on microbiological risk assessment were mainly qualitative to describe the risk characterization of pathogen in specific food. The number of QMRA papers in international journals from China was lower than that from European countries, USA, Canada and Australia. Nguyen-Viet, Nguyen, Nguyen, and Haas (2012) reported that only 3.5% of 463 papers related to QMRA until December 2011 were published by authors from developing countries, including China. Additionally, most of the peer-reviewed papers by Chinese authors on QMRA were published in Chinese journals. Nguyen-Viet *et al.* (2012) concluded that developing countries should promote the use and development of QMRA and make these studies widely available to the international scientific community.

Economic development over the past 30 years has turned China into the world's second largest economy and this development has increased the complexity of the food supply chain. Implementation of the risk analysis paradigm in full is one method to manage the complex food supply chain in China. This review summarizes the current status of QMRA in China and aims to analyze some future scenarios which include scoping, selection and application.

Research of QMRA in China

We searched the Thomson Reuters Web of Knowledge (http://apps.webofknowledge.com) and the China Knowledge Resource Integrated (CNKI) Database (http://www.cnki.net), one of the largest publication resources in China, using keywords, for QMRA or equivalent Chinese words, to establish the pathogens and the food vectors that concern scientists from China; a summary is shown in Table 1.

The Web of Knowledge returned 265 articles (non-exhaustive list) from a search with the keywords *micro* risk* assess* China* in the topic field; the survey was conducted in January 2014. Only 10 of the selected studies relate to foodborne and waterborne microorganisms in food and correspond to, or might be assimilated to, QMRA in China. Notably, some Chinese researchers conducted QMRA in other countries and therefore do not actually report national QMRA studies. Some are shown in Table 1, i.e. QMRA on fungal toxin including mycotoxin ochratoxin (Han *et al.*, 2013) and aflatoxin (Li *et al.*, 2014; Zhao, Schaffner, & Yue, 2013).

In terms of Chinese journal papers over 3700 papers published between 2000 and 2013 were found in the CNKI database with similar keywords mentioned in English above but only 121 papers concerned QMRA research. Of these, 20 papers were actual QMRA studies deploying computational techniques to yield models predicting public health outcomes, such as predictive microbiological models and/or dose-response models. Many of the papers with "microbiological risk assessment" in the title proved to be "qualitative" or "semi-quantitative" rather than "quantitative", which may be due to spelling conventions in Chinese.

The pathogens *V. parahaemolyticus*, *Salmonella* spp., *L. monocytogenes*, *B. cereus* and *S. aureus* were the main pathogens that QMRA studies were concerned with (Table 1) and seafood was the main vehicle of contamination, with oysters, shrimps and salmon as the dominant types. Other vehicles for contamination included milk, egg and rice. The study of Zhao and Liu (2004a, 2004b) might be the first comprehensive national QMRA conducted in China. The QMRA did not take pathogen growth into account, i.e. neither microbiological growth models nor storage scenarios were used. The main reason for conducting this QMRA was the high numbers of outbreaks in China involving *Salmonella* spp. as compared to other pathogens. Between 1991 and 1996, there were 731 foodborne outbreaks where *Salmonella* spp. was identified as the infectious agent and the total number of reported cases was 39,181. Amongst these were 166 outbreaks that were attributed to consumption of contaminated egg and these involved 4207 reported cases.

There are similarities between China and the rest of the world in the type, pathogen and food vector considered in QMRA studies. During 2002–2013 the World Health Organization and the Food and Agriculture Organization (WHO/FAO) published 19 reports on microbiological risk assessment on their websites (WHO/FAO, 2013). These reports included the risk assessment of *Salmonella* in eggs and broiler chickens, *L. monocytogenes* in ready-to-eat foods, *Enterobacter sakazakii* (now *Cronobacter sakazakii*) and other microorganisms in powdered infant formula, *Vibrio vulnificus* in raw oyster, choleragenic *Vibrio cholerae* O1 and O139 in warm-water shrimp, *Campylobacter* spp. in broiler chickens, *V. parahaemolyticus* in seafood, Enterohaemorrhagic *E. coli* in raw beef, *Salmonella* in beef and *Campylobacter* in chicken. These studies are conducted under the auspices of FAO and WHO by researchers from around the globe participating in the Joint Expert Meeting on Microbiological Risk Assessment (JEMRA).

While China has stepped up considerably in the area of QMRA research in recent years this effort lags behind

Table 1. The pathogen, food vector and mathematical models in QMRA research published by risk assessment researchers from China.

Pathogen	Food	Primary model[a]	Secondary model[a]	Dose-response model	Source
Vibrio parahaemolyticus	Raw oysters	Gompertz	Root-squre	Beta-poisson	Chen and Liu (2006); Shao, Wang, Zhang, Yao, and Ying (2010).
	Meretrix meretri	Exponential	Modified root-square[b]	Beta-poisson	Ning, Li, and Chen (2010).
	Portunus trituberculatus	Gompertz[c]	Bělehrádek root-square[c]	Beta-poisson	Gao *et al.* (2011).
	Shellfish	Exponential	Modified root-square[b]	Beta-poisson	Zhao, Li, Duan, and Zhou (2011).
	Short necked clam	Gompertz[c]	Bělehrádek Root-square[c]	Beta-poisson	Li *et al.* (2012).
	Raw salmon slices	Gompertz	Root-square	Beta-poisson	Liu *et al.* (2012).
Vibrio vulnificus	Shrimp	Baranyi	Response surface regression	Beta-poisson	Ji *et al.* (2013).
Salmonella spp.	Shell eggs	–	–	Beta-poisson	Zhao and Liu (2004a,b).
	Common catering foods	Two-phase linear[d]	Response surface regression[d]	Beta-poisson[e]	Fan and Liu (2008).
L. monocytogenes	Bulk cooked meat products	–	Ratkowsky root-square[e]	Exponential[f]	Tian *et al.* (2011)
	Ready-to-eat salads	Modified Gompertz[g]	Ratkowsky root-square	Exponential[h]	Dong and Zheng (2013).
Bacillus cereus	Pasteurized milk	Growth[i]	–	–	Chu, Feng, Zhang, and Xiao (2006).
	Pasteurized milk	Baranyi	Ratkowsky root-square	–	Li (2006).
	Chinese-style cooked rice	Modified Gompertz[j]	Ratkowsky Root-square	–	Dong (2013).
Staphylococcus aureus	Raw milk	Gompertz	Root-square	–	Yan (2008).
	Pork	Gompertz[k]	–	–	Luo *et al.* (2010)
Pseudomonas spp.	Pasteurized milk	Baranyi	Ratkowsky root-square	–	Li (2006).
Aeromonas spp.	Chilled pork	Modified Gompertz[l]	Ratkowsky root-square		Dong, Gao, Zheng, & Hu (2012).
Mycotoxin ochratoxin A	Different foods	–	–	–	Han *et al.* (2013).
Aflatoxin B_1[m]	Chinese spices	–	–	–	Zhao *et al.* (2013).
	Cereal and oil products	–	–	–	Li *et al.* (2014).

[a] From the classification of Whiting and Buchanan (1993).
[b] From the paper of Miles, Ross, Olley, and McMeekin (1997).
[c] From the paper of Wang and Ning (2008).
[d] From the paper of Oscar (1999).
[e] From the report of WHO/FAO (2002) and FDA/FSIS (2006).
[f] From the report of FDA/FSIS (2010).
[g] From the paper of Ding, Dong, Rahman, and Oh (2011).
[h] From the report of WHO/FAO (2004).
[i] From the paper of Zwietering, De Wit, and Notermans (1996).
[j] From the paper of Heo, Lee, Baek, and Ha (2009).
[k] From the paper of Buchanan, Smith, Mccolgan, Golden, and Dell (1993).
[l] From the paper of Dong, Tu, Guo, Li, and Zhao (2007).
[m] Also analyzed for ochratoxin A, deoxynivalenol and zearalenone.

several developed countries who have pursued QMRA, as defined by WHO, for well over 10 years providing them much experience in research and methodologies as well as opportunities to realize the potential of QMRA studies. For instance, the European Food Safety Authority (EFSA) has initiated the use of QMRA for supporting European food safety policy since 2006 (Havelaar *et al.*, 2008). A European wide QMRA for *Salmonella* in slaughter and breeder pigs was completed in 2010 (EFSA, 2010). Additionally, a European wide QMRA *Campylobacter* in broilers was completed in 2011 (EFSA, 2011). In the US, QMRA have been used to inform food safety policy on controlling *L. monocytogenes* hazard in ready-to-eat foods (FDA/FSIS, 2003), *E. coli* O157:H7 hazard in intact and non-intact beef (FSIS, 2002), and *Salmonella Enteritidis* hazard in shell eggs and egg products (FSIS, 1998).

The mathematical models used in Chinese QMRA (Table 1) are commonly used in most other published QMRA studies. One class of models, primary and secondary predictive models, describe bacterial growth over a range of temperatures or other conditions and the another class of models describes dose response relationships that connect a consumed dose with the probability of illness. A comprehensive review of bacterial growth models has been compiled by Ross and McMeekin (2003) and a comprehensive review of dose response models was published by USDA/FSIS/EPA (2012). These models form an essential component of a QMRA and the choice of models can have significant effect on the outcomes of a QMRA and research into model choice is ongoing. QMRA studies are either deterministic or stochastic and in China there is a similar pattern.

Future of QMRA in China

Why is there a need for QMRA in support of implementing the risk analysis framework in China? As indicated before China has achieved self-sufficiency in its food supply and the population has been stabilized with no incidence of famine (Chen, 2002). Risk analysis has proven to be a good conceptual model in the rest of the world (Codex Alimentarius Commission, 1999, 2007a, 2007b; EFSA, 2010, 2011; USDA/FSIS/EPA, 2012) and, while risk analysis and QMRA are still relatively young concepts and expertise areas, their development has been stimulated by both political and technical factors (Havelaar *et al.*, 2008). The Chinese government is making important efforts to adopt this framework into a national food safety regulatory system and to establish the necessary infrastructure in order to embrace the modern way to protect the public from food safety impacts on public health and to address the challenges of globalized trade in food. For China to invest in developing QMRA expertise nationally, to reap the benefits that other countries have experienced, and to possibly refine and improve QMRA methodologies would seem a logical step.

Regarding risk assessment, there are clear drivers now for implementing and deploying the concept throughout Chinese law and food regulation. Chapter 2 of the 2009 Food Safety Law was formulated to develop MRA capacity in China. Article 4 and Article 11 of the 2009 Food Safety Law [for English translation please refer to Petry and Wu (2009)], call for the establishment of a national food safety risk monitoring program and for the use of risk assessment for reducing the burden of foodborne hazards. Article 13 calls for a transparent system of regulation where public comments are invited before the implementation of national food safety standards; this supports the risk communication part of the risk analysis framework. Article 15 gives the National Food Safety Standard Review Committee of China the authority to consolidate national food safety standards in China and this committee considers risk assessment as a key input. This ensures that risk management decisions, such as setting food safety standards, are based on the sound science underpinning risk assessment. However there may be other factors, aside from a political perspective, which are important when stakeholders decide to commission a MRA and apply the results to support decision making (Havelaar *et al.*, 2008; Magnússon *et al.* 2012).

Risk Assessments are overseen and coordinated by the National Food Safety Risk Assessment Expert Committee, which was established in 2009 as part of the 2009 Food Safety Law in China. The State Council of China authorized this expert committee to manage food safety risks in China (People's Daily Online, 2009). Its 42 members were chosen from various scientific research fields, including experts from medical science, agriculture, food and nutrition. Since 2011, CFSA provides the secretariat for the meetings of the expert committee, the format of which mirrors that of the Joint Expert Meetings on Microbiological Risk Assessment (JEMRA). In November 2010, the National Food Safety Risk Assessment Expert Committee published three guidance documents, one of which was the Guidelines for Conducting Food Safety Risk Assessment (China National Center for Food Safety Risk Assessment, 2010a). This guideline introduces the requirements of MRA research in China. Following the Codex structure the general framework for MRA research includes hazard identification, hazard characterization, exposure assessment and risk characterization.

Planning and scoping

Before a MRA is conducted its purpose should be clear (i.e. the risk assessor should fully understand what risk management questions are being addressed). Additionally the MRA should be fit for purpose (i.e. it should be possible to answer the risk management questions, there should be relevant data and sufficient resources and gaps in data and the data handling should be appropriately dealt with). Finally the MRA should address an appropriate risk management problem(s)/issue(s) (Parkin, 2008). Planning and scoping is a process that defines the purpose and scope of a risk assessment and focuses the issues and approaches involved in performing the assessment (Codex Alimentarius Commission, 1999, 2007a, 2007b; EFSA, 2010, 2011; USDA/FSIS/EPA, 2012). A clearly articulated purpose and scope provides a sound foundation for later judgments on the outcome of the risk assessment, such as an effective risk characterization and relevant risk management options.

A number of criteria can be used for identifying a candidate risk assessment: characteristics and importance of the hazard(s) of concern; magnitude (e.g., presence, prevalence, concentration of hazards) and severity (e.g., impact on public health) of the risk; urgency of the situation; population(s) of concern; other factors associated with specific hazards (e.g., water treatment processes, food processing, cooking, cross contamination); and availability of resources (e.g., time, money and staff) (USDA/FSIS/EPA, 2012). Using the European Council (EC) regulation no. 2160/2003 as an example, legislators indicated that reduction of the prevalence of *Salmonella* spp. at different stages of the food production chain in member states would reduce risk to public health and the EFSA panel on Biological Hazards (BIOHAZ) was requested to carry out a QMRA of *Salmonella* spp. in slaughter and breeder pigs. Information from this assessment could then be used to provide the inputs for a future cost-benefit analysis for setting a European wide target for reducing the prevalence of *Salmonella* spp. in slaughter pigs (EFSA, 2010; Romero-Barrios, Hempen, Messens, Stella, & Hugas, 2013).

We assume that many of the Chinese QMRA studies identified in Table 1 did not have such a robust planning and scoping component. The main criterion for performing these QMRA studies was based on the severity of observed foodborne outbreaks in China, as in the case of the studies of Zhao and Liu (2004a, 2004b) on *Salmonella* spp.. However alternatively in China, and also in developed countries, QMRA studies are driven by particular research interests and not initiated to answer specific risk management questions developed by competent authorities. In 2013, the National Food Safety Risk Assessment Expert Committee commissioned two QMRA studies, based on surveillance data from China, on *V. parahaemolyticus* in raw shellfish and *L. monocytogenes* in Ready-To-Eat (RTE) foods (China National Center for Food Safety Risk Assessment, 2014). The planning and scoping for these QMRA studies were not made explicit; unlike the general practice for the EU and the US. However it is expected that the call for transparency laid down in Article 13 of the 2009 Chinese Food Safety Law will encourage planning and scoping of QMRA studies to become more accessible to various stakeholders including the public in the future (Mol, 2014).

Qualitative or quantitative?

Once a decision is made to initiate a risk assessment, a major consideration is how much detail or "depth" is needed to address the risk management question(s) or decision (USDA/FSIS/EPA, 2012). A quantitative risk assessment expresses detail and depth of the risk in terms of a mathematical statement(s) whereas a qualitative risk assessment uses verbal descriptors of risk. In the Chinese Guidelines for Conducting Food Safety Risk Assessment (China National Center for Food Safety Risk Assessment, 2010a), guidance is available on classification of MRA which takes into account food safety management's needs, available information and data.

Risk assessment outputs are only as good as the data on which they are built (Oscar, 2004). A significant challenge throughout the risk assessment process is the combination of enough useful information and data to lead to an effective reduction of risk. Such information and data may be derived from empirical data or from expert opinion (Greiner, Smid, Havelaar, & Müller-Grafa, 2013). The National Food Safety Risk Assessment Expert Committee has issued a guideline regarding the Data Collection Requirements for Food Safety Risk Assessment in 2010 (China National Center for Food Safety Risk Assessment, 2010b). Selection of qualitative or quantitative MRA is then dependent on whether the data collection requirements are achieved. Good quality surveillance data for *Salmonella* spp. contamination of shell eggs in China was used by Zhao and Liu (2004a, 2004b) for conducting a quantitative MRA. The output from this QMRA was used for mitigating the hazard and for managing the risk of *Salmonella* spp. in shell eggs in China.

However, in our literature survey on risk assessment in China (CNKI database), the majority of the MRA studies were qualitative or semi-quantitative in nature. For example, Dong, Zheng, Dang, & Gu (2012) developed a semi-quantitative risk assessment for *L. monocytogenes* in RTE food in Shanghai, P. R. China; they tried to develop a possible risk matrix tool for assessing microbial risk consequence and frequence, since surveillance data was considered insufficient to conduct a broader and quantitative MRA. In the study of Dong, Zheng, *et al*., (2012), no microbiological growth or inactivation models were used so that it was impractical to quantify risks resulting from exposure. In future, good semi-quantitative scoring systems, decision trees, and risk ranking tools are also needed in China, since there is now no general accepted or applied tools in China, like the Excel-in Risk Ranger from Australia (Ross & Sumner, 2002), and the risk ranking tool from US-FDA (Anderson, Jaykus, Beaulieu, & Dennis, 2011).

To date, most mathematical models deal with one pathogen and a single food commodity (Dong, 2011). This is the case in China as it is in the rest of the world. Generally, substantial quantities of data are derived from studies conducted under experimental conditions but this data is not immediately relevant to real life conditions for the pathogen, the food vehicle or the consumer. Mathematical models are able to bridge the gap but are also an approximation of reality. Evidently, modelers need to be diligent when relating and extrapolating data, and using or interpreting mathematical growth models and their outcomes, for conducting exposure assessment and hazard characterization as these impact on the validity of a risk characterization. Additionally estimation of pathogen prevalence and concentration in food products is key for exposure assessment and indispensable for the generation of reliable risk estimates (ILSI, 2010). Thus risk assessors require an understanding of the biology and ecology of a pathogen, and properties of food materials they investigate. Often dose response models are the element where least information is available. Together these information properties ensure that risk assessments should include an integral evaluation of the quality of data and models that are included and this is often accomplished by an explicit evaluation concerning uncertainty and variability in the risk characterization outcome. Since QMRA is still a rather immature science in China, further skills and capability development is required. Whilst some of these skills are actively sought through training outside of China, more emphasis on gaining experience in QMRA through government commissioned studies, sharing expertise broadly throughout the research community and more inclusion of skill development in the curriculum of universities in China would be prudent.

In cases where a quantitative MRA is not possible, e.g. because of complexity or information/data gaps, a qualitative assessment may be undertaken as a first step to determine if the risk is significant enough to warrant a more detailed analysis (Lammerding & Fazil, 2000). Romero-Barrios *et al.* (2013) also suggested taking the simpler form of risk profiles depending on the terms of reference provided by the risk manager's questions, although these risk profiles in essence are a form of qualitative MRA. Lammerding and Fazil (2000) included a framework for translating qualitative information from different aspects of the risk issue into an objective evaluation of the overall risk; should the qualitative MRA not address the risk management questions, they proposed to conduct a quantitative MRA, which however might require investment in, for instance, gathering of missing information and data. Importantly, both a qualitative and a quantitative MRA should follow the same systematic approach.

Currently in China gaps in information and data may pose a hurdle to conducting QMRA studies. Research and standardization of procedures to assure quality and consistency of data, for instance under auspices of the CFSA, might improve the generation of data that is suitable for QMRA. PulseNet China, a network for the molecular subtyping of bacterial strains, modeled after a similar system established by the US Centers for Disease Control and Prevention (US-CDC), that is supported by several regions or countries in the world, serves as a consistent data collection tool for hazard identification (Alcorn & Ouyang, 2012). Other tools and procedures in use elsewhere could be adopted and tailored for China and serve as a resource for Chinese agencies, their agents, contractors, and stakeholders. Evidently the greatest value can be derived from MRA studies that are quantitative and simulate real-life scenarios as closely as possible. This requires a substantial amount of numerical data for estimating risk in a statistically valid manner using mathematical models and enough information of disease incidence per annum, lives lost, or as of recently, by integrated health metrics using dose response models (Magnússon *et al.*, 2012). Although significant data collection progress has been made in recent years in China, ideally, such data should be representative of the system under study, and adequately reflect the variability of microbial contamination in these systems as explained by Havelaar *et al.* (2008).

Utility of QMRA

The outputs of a QMRA follow from combining exposure assessment and hazard characterization in the risk characterization. Quantitative outputs may relate to the consumer risk at country level in for instance a period of a year or to an individual consumer risk per consumption. When relevant, different scenarios of risk resulting from different situations or assumptions are quantified as are different options to mitigate the risk and reduce it to particular levels. Importantly, the level of uncertainty and variability associated with the various MRA outcomes should be clearly articulated in the risk assessment. Next to the quantitative outcomes of a QMRA, also the risk assessment as a whole, the information and data it brings together and gaps in these it identified, should be of great value to risk managers as a resource to understand the complexity of the risk and options for risk reduction. Ultimately, the MRA and the risk characterization outcomes are to be used by risk managers for decision making (Buchanan & Appel, 2010; Greiner *et al.*, 2013), and providing a good insight of risk managers in terms of prevailing risk and risk reduction options is the purpose of the QMRA. Since a QMRA is developed using a given set of information and data, assumptions and models, in the case that there is concern about the validity/accuracy of the outcomes or absence of scientific consensus for part of the QMRA, a precautionary approach is sometimes used by risk managers (Renn & Stirling, 2004) in order to discharge their responsibility to protect the public from exposure to harm until such time that scientific consensus has been achieved and specific decisions can be made.

In China, guidelines for Incorporating Microbiological Risk Assessment in Food Safety Risk Management have been issued (State Commission for Administration of Standardization of China, 2009), including how to identify a food safety issue, describe a risk profile and derive a primary risk management decision. However, these do not include specific guidelines or recommendations for applying QMRA outcomes, such as risk characterizations and risk management options, in decision making. There are several ways in which such information can be decided on for inclusion in regulations or policies. Codex Alimentarius encourages countries to use QMRA to establish public health metrics based on consumer risk. This would take the form of stipulating an Appropriate Level Of Protection (ALOP) or a Food Safety Objective (FSO) (Codex Alimentarius, 2007a, 2007b). ALOP or FSO can then be related to concrete guidance to the industry for instance in the form of microbiological criteria included in food safety standards (Gkogka *et al.*, 2013).

The concept of a FSO was developed in detail as a risk-based approach to microbial food safety by the International Commission on the Microbiological Specifications for Foods (ICMSF) in 2002. An FSO is defined as the maximum frequency and/or concentration of a hazard considered to be tolerable for consumer protection (ICMSF, 2002). The output of a QMRA can be used to quantify a FSO and Crouch, LaBarre, Golden, Kause, and Dearfield (2009), Zwietering, Stewart, and Whiting (2010), and Whiting (2011) have published examples on the conversion of a QMRA output into a FSO. A food business operator would use this FSO as a guide for assuring the food safety requirement of their products by taking into account the initial contamination, reductions through inactivation steps, potential recontamination, and possible growth before the food is consumed (Gorris, Bassett &

Membré, 2006; Gorris & Yoe, 2014; Jenson & Sumner, 2012). This risk-based approach allows greater flexibility in assuring food safety depending on the nature of the food and the choice of hazard control measures available to the food business operator.

In China, a National Food Safety Standard for Pathogen Limits for Food (GB 29921-2013) was enforced by the National Health and Family Planning Commission of P. R. China in July 2014. For an English translation, refer to the US Department of Agriculture (USDA) translation by Meador (2012). The standard included limits for pathogenic bacteria in 17 categories of food produced, served in, imported to, or exported from China. These pathogens include *Salmonella*, *Listeria*, *Staphylococcus* and *Shigella*. Since the pathogen limits in the specific food categories do not follow the FSO approach, these pathogen limits may need to be over conservative. However agreeing on a FSO is still problematic. Some food experts have presented possible FSO values for *L. monocytogenes* in RTE foods (Dong & Zheng, 2013; Tian *et al*., 2011; WHO/FAO, 2004). A FSO of 100 CFU/g of *L. monocytogenes* in RTE food is considered acceptable at the point of consumption (Andersen & Nørrung, 2011; Pujol, AlbertI, Johnson, & Membré, 2013). Setting risk-based pathogen limits on the outputs of a QMRA is still one of the big challenges of risk analysis in China, as it is in the rest of the world.

Conclusion

A literature search of this study only produced a limited number of QMRA studies in China when compared to the rest of the world over in the past decade. QMRA in China should now increase with the establishment of China's National Center for Food Safety Risk Assessment (CFSA) and the growth of the knowledge base and expertise among China's scientific community. Clear and transparent planning and scoping should be considered when governmental risk managers initiate a QMRA. Further improvements to the generation of consistent and quality surveillance and consumer exposure data as well as fostering sharing of QMRA expertise and capacity building is necessary. These can be achieved by conducting national QMRA studies and by the inclusion of QMRA relevant education in the curriculum of Chinese universities. This progression will be highly beneficial for improved and effective conduct of QMRA studies as well as for the utility of QMRA outcomes for risk managers. The establishment of risk-based regulation and standards based on policy decisions for ALOP or FSO values derived from QMRA studies would enhance food safety in China and would drive implementation of a modern food safety management approach based on risk analysis as advocated by Codex Alimentarius. This, however, is no less of a challenge for China as it is for the rest of the world.

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