Food Control 90 (2018) 212–221

Contents lists available at ScienceDirect

Food Control

journal homepage: www.elsevier.com/locate/foodcont

Review

Food safety risk assessment in China: Past, present and future

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ARTICLE INFO

Article history:
Available online 28 February 2018

Keywords:
China
Exposure assessment
Food safety
Risk assessment
Risk analysis

ABSTRACT

As an integral component of the risk analysis framework, food safety risk assessment has been developed in China after the promulgation of the Food Safety Law of the People's Republic of China in 2009 with the creation of the China National Center for Food Safety Risk Assessment (CFSA). This paper introduces the ongoing capacity building of risk analysis in China, in line with the development of the CFSA, with emphasis on progress in national food safety risk assessment work. Selected case examples are used to illustrate the achievements in food safety risk assessment in China. However in order to further strengthen its capacities for food safety risk assessment, China needs to continue to work on the development of risk assessment methodologies and provide more and better data for risk assessment and risk management. All countries need to work together as the problems in the global supply chain can only be resolved by all the stakeholders collaborating to ensure risk management decisions are based on the best science available.

Contents

1. Introduction

Among the three components of the food safety risk analysis framework, risk assessment is defined as a structured scientific process for estimating the probability and severity of risk with

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https://doi.org/10.1016/j.foodcont.2018.02.049

attendant uncertainty, to characterize the potential hazards and the associated risks to a healthy life resulting from exposure to biological, chemical, or physical hazards in food (Food and Agriculture Organization/World Health Organization, 2006, 2009). Risk assessment results provide the essential scientific basis for risk managers to make risk management decisions, including policy, legislation and standards (Food and Agriculture Organization/World Health Organization, 1995, 2006, 2008). In addition, risk assessment results are also useful for establishing priorities for monitoring and management, evaluating the effectiveness of risk management measures and providing scientific information for risk communication (Food and Agriculture Organization/World Health Organization, 1997, 1998, 2008). There are 2 national laws that regulate Chinese food safety risk assessment, i.e. the Agricultural Products Quality Safety Law of the People's Republic of China (QSAPL, 2006) and the Food Safety Law of the People's Republic of China (FSL, 2009). However, before the 2009 FSL, there were no systematic risk assessment activities in China (Chen & Zhang, 2017). The FSL 2009 stipulated “China shall establish a national system on food safety risk assessment for biological, chemical and physical hazard in food and food additives”. In December 2009, the National Expert Committee for Food Safety Risk Assessment (NECFSRA) comprised of 42 scientists with various expertise was established as an independent scientific body to organize and conduct risk assessment activities, under the former Ministry of Health (MOH), currently National Health and Family Planning Commission (NHFPC) (http://www.cfsa.net.cn/Article/Singel.aspx?channelcode=2A9E075016B733825769FBA04017804BB9AC0726D523E5B9&code=33DF0DA03A7D4E6C0D022A1B16CB3D4B). Subsequently, in October 2011, the China National Center for Food Safety Risk Assessment (CFSA) was set up to strengthen the technical support for the implementation of the risk analysis framework and, in particular, risk assessment at national level (Jia, 2011). CFSA also serves as the secretariat of the NECFSRA (Chen & Zhang, 2017; Jiao, Zhu, Huang, & Dong, 2017; Li & Liu, 2017; Liu, Xie, Zhang, Cao, & Pei, 2013). This paper is intended to review the development of the national risk assessment system for food safety in China and provide some specific case examples to show the progress being made in microbial and chemical risk assessment in China as well as how risk assessment results have been used in food safety standards development since 2009.

2. Development of the national food safety risk assessment system in China

The promulgation of the QSAPL 2006 and the FSL2009 established risk assessment's legal status in China. In the implementation of the risk assessment provisions in QSAPL, the Ministry of Agriculture (MOA) has set up an Expert Committee on Quality Safety Risk Assessment of Agricultural Products to carry out risk assessment of potentially harmful agents, which might affect the quality and safety of agricultural products (Broughton & Walker, 2010). However, the most important law for food safety risk assessment is the FSL 2009, which became effective on the 1 June 2009. The law was revised and the updated version became effective on the 1 October 2015 (Chen & Zhang, 2017; Jiao et al., 2017; Li & Liu, 2017; Liu et al., 2013). The current FSL requires that a national system of food safety risk assessment shall be established to assess the risks of biological, chemical and physical hazards in food and food additives in China. The system has been developed gradually and has made significant achievements in methodology development, model building, data storage and personnel training, as well as the completion of a number of quantitative risk assessment projects, which have been served as scientific basis for food safety standards development (Chen & Zhang, 2017; China National Center for Food Safety Risk Assessment, 2013, 2014, 2015, 2017, 2018; Jiao et al., 2017; Li & Liu, 2017; Liu et al., 2013).

2.1. Stage 1 (before 2009)

In this learning period, risk assessment was first applied to the development of maximum limits for cadmium, lead, and other contaminants in foods (Chen & Zhang, 2017). The risk assessment reports for Sudan I (Ministry of Health of the People's Republic of China, 2005) and acrylamide conducted by the MOH in 2005 are available online (Ministry of Health of the People's Republic of China, 2007). In 2008, during the melamine crisis, Chinese scientists carried out a risk assessment for melamine in infant formula, which served as the scientific basis for setting up a temporary action level of melamine in infant formula (Wu & Zhang, 2013). Food microbial risk assessment, especially formal food Quantitative Microbial Risk Assessment (QMRA), in China started relatively late and only a few projects were completed before 2009. According to a literature review (Dong et al., 2015), the earliest Chinese QMRA was an assessment study on *Vibrio parahaemolyticus* in ready-to-eat raw oysters (Chen & Liu, 2006). Since risk assessment was not legally required before 2009, scientists carried it out only during a food safety crisis or on research basis.

2.2. Stage 2 (2009-present)

After the FSL 2009 was adopted, a national system on food safety risk assessment was officially established and the Government devoted resources to build its capacity to perform sound, scientific risk assessment. According to FSL 2009, the former MOH (now NHFPC) was in charge of food safety risk assessment at the national level and the China NECFSRA, which consisted of 42scientists from biology, chemistry, medicine, agriculture, environment, food science and nutrition fields, was made responsible for the planning and implementation of risk assessment projects. China CFSA serves as the secretariat for all the activities for NECFSRA. Other food safety related governmental agencies, such as the China Food and Drug Administration (CFDA), the General Administration of Quality Supervision, Inspection, and Quarantine (AQSIQ) and MOA are invited to provide proposals on risk assessment and contribute scientific data and information as required. According to Article 17 of the 2015 revision of the FSL 2009 (2015 FSL), risk assessment should focus on biological, chemical, and physical agents present in food, food additives, and food-related products, such as food-contact materials. For example, Article 17 stipulates, “food safety risk assessment should use scientific methods based on data and other information from food safety risk surveillance and monitoring activities”. The 2015 FSL also defines the relationship between risk assessment and risk management, i.e., it is described in Article 21 that risk assessment results should serve as the scientific basis for developing food safety standards and deciding food safety control priorities. Article 18 of the 2015 FSL, requires risk assessment to be undertaken in the following five situations: 1) when a highly probable safety problem in food is revealed by risk surveillance or is reported; 2) in the development, or revision, of food safety standards; 3) for the identification of priorities for supervision and control; 4) for evaluation of public health significance of emerging risks; and 5) for determining whether a factor poses a high risk.

Since 2010, 13 guidance documents for risk assessment have been published, including technical guidance for conducting food safety risk assessment and requirements for data collection in risk assessment, as well as others (Zhou et al., 2014). These documents were prepared with reference to corresponding international guidelines and serve as scientific references for Chinese scientists conducting risk assessments. An effective working procedure and operational mechanism for food safety risk assessment has also been developed, which includes procedures for proposing risk assessment projects, setting top priorities, conducting risk assessments, and reviewing and submitting risk assessment technical reports. Emphasis is focused on the development of risk assessment methodologies applicable to China. Long-term food consumption and large portion dietary exposure models have been developed and applied to risk assessment in the last 8 years.

Data collection and establishment of further databases were important parts of the Chinese risk assessment system. For example, a national survey on processed food consumption was carried out to fill the data gap in the Chinese national dietary survey program, which only covered a limited number of processed foods. To date, consumption data of key processed food categories including infant formula, beverages, alcohol, Chinese tea, cereals, and aquatic products, have been collected from more than 80,000 individuals from a wide age range and from both gender groups in 16 provinces. These food consumption data, in conjunction with toxicological data and the contaminants database have played important roles in risk assessment.

CFSA, as the NECFSRA secretariat, has organized and completed nearly 100 priority risk assessment projects and emergency risk assessment tasks since 2011. These risk assessment results provided important technical support in standard development and regulatory supervision. The MOH Key Laboratory for Risk Assessment was established in CFSA by former MOH (now NHFPC) to carry out studies on risk assessment-related technologies, included in chemical, microbiological and toxicological laboratories. Since 2011, more than 30 priority risk assessment projects, and urgent risk assessment assignments, have been conducted to in response to requests from Chinese food safety regulatory agencies (China National Center for Food Safety Risk Assessment, 2013, 2014, 2015, 2017, 2018). So far, full risk assessment, or exposure assessment only, have been completed for many chemical hazards, including cadmium, aluminum, rare earth elements, iodine, lead, phalates, trans fatty acids, ethyl carbamate, and thiocyanate (Chen & Zhang, 2017; Li & Liu, 2017; National Expert Committee of Food Safety Risk Assessment, 2010, 2012, 2014). In microbial risk assessment, several quantitative risk assessments have taken place including: *Salmonella* (Zhu, Bai, et al., 2017) and *Campylobacter* (Zhu, Yao, et al., 2017) contamination in raw chicken meat at retail level and its implications for public health risk in China, *V. parahaemolyticus* in major ready-to-eat raw shellfish, *Listeria monocytogenes* in ready-to-eat food, and *Enterobacter sakazakii* and *Bacillus cereus* in infant and young child formula food (Jiao et al., 2017).

3. Case examples of roles of risk assessment in China

3.1. Providing evidence to support the national policy on salt iodization

In recent years, there is a growing concern on the attribution of increased incidence of thyroid diseases, including thyroid tumors and nodules, due to excessive iodine intake caused by the universal salt iodization (USI) levels in China that were set with no scientific basis. Such concern tempted the public, and even some scientists, to question and criticize the national USI policy implemented since 1995. In response to these concerns, NECFSEA has carried out 2 risk assessment projects on iodine status in the Chinese population in 2010 (National Expert Committee of Food Safety Risk Assessment, 2012; Sui et al., 2011; Wu et al., 2012) and 2016 (National Expert Committee of Food Safety Risk Assessment, unpublished). The results confirmed that the Chinese USI policy had played a significant role in eliminating iodine deficiency diseases (IDDs), including endemic goiter and endemic cretinism. The endemic goiter prevalence is stable at < 5% in 8–11 year old children and no adverse effects attributed to USI have been recorded. Using urine iodine concentrations and dietary iodine intake as major criteria for the assessment of iodine status, the results showed that most Chinese residents (all age and gender groups), including those living in the coastal areas, had appropriate iodine nutrition status and that the dietary iodine intake was within the safe range. It was concluded that salt iodization did not cause excessive iodine intake in the Chinese population. However, it was also found that in some regions with high water iodine level (300 μg/L or above), residents would be at a high risk of iodine excess if they consumed iodized salt (Li & Liu, 2017). On the other hand, pregnant women, especially living in regions with low water iodine were at high risk of iodine deficiency if iodized salt supply was discontinued (National Expert Committee of Food Safety Risk Assessment, 2012; Wu et al., 2012). This assessment provided solid scientific evidence to support the Chinese USI policy in preventing IDDs. Interestingly, the Chinese TDS carried out for assessing iodine exposure from iodized salt and other dietary sources discovered that the population-weighted, mean weighed salt intake of a standard person was 9.1 g per day and laboratory-analyzed sodium intake was 5.4 g per day, among 20 provinces surveyed from 2009 through 2012. Among 12 provinces surveyed twice, salt intake decreased 22.2% between 2000 (11.8 g/d) and 2009–2011 (9.2 g/d) ($t = 2.53$, $p = 0 .03$). However, the 12.3% decrease in sodium intake (from 6.4 g/d in 2000 to 5.6 g/d in 2009–2011) was not significant ($t = 1.21$, $p = 0 .25$). Weighed salt consumption yielded a calculated sodium intake (4.6 g/d in 2000 vs 3.5 g/d in 2009–2011) much less than laboratory-analyzed sodium intake. Those results are contributing to the scientific evidence informing strategies to evaluate possible salt reduction in the prevention and control of hypertension (Hipgrave, Chang, Li, & Wu, 2016).

3.2. Responding to public concern about trans-fatty acids

At the end of 2010, several media reported safety issues of *trans*-fatty acids (TFA) with the misleading statement describing hydrated vegetable oil as 'poison at the table'. The unscientific stories caused a public panic about food containing TFA, including cakes, pastries and even coffee creamer. On request from the government, the CFSA collected information on the TFA concentration in the main processed foods and conducted a food consumption survey focused on foods likely to contain TFA in Beijing and Guangzhou (Liu et al., 2015). This assumed that people in big cities have higher consumption of foods containing TFA than in rural areas due to less consumption of the hydrated vegetable oil. The 2012 assessment concluded that the energy contribution ratio of dietary TFA, which refers to the ratio of dietary energy intake contributed by TFA to total dietary energy, was 0.16 percent in the whole Chinese population, however it was 0.4 percent in Beijing and Guangzhou. These levels are far lower than the recommendation limit of 1 percent by the World Health Organization (WHO) and significantly lower than the contribution ratio in developed countries. Therefore, dietary intake of TFA in Chinese population was not a health concern at the present time (National Expert Committee of Food Safety Risk Assessment, 2012).

To promote better understanding of TFA and its risk, the CFSA published its risk assessment report online and communicated with stakeholders about scientific information on TFA through TV interviews, the official website, and Twitter. The pro-active communication efforts of CFSA, based on scientific evidence, led to a better understanding of TFAs (Li & Liu, 2017).

3.3. Facilitating the revision of standards for aluminum-containing food additives

From 2007, the national food safety risk monitoring system found that more than 40 percent of the food samples had aluminum (Al) concentration exceeding the Al limit of 100 mg/kg. These foods included mostly food categories using Al-containing food additives, such as steamed bread, noodles and jellyfish that are very popular with the public. Regulators and consumers were concerned about the potential health impact resulting from Al in food and the appropriateness of regulatory control of Al-containing food additives. To address these issues, the NHFPC commissioned the CFSA to carry out a risk assessment on dietary exposure to Al among the Chinese population (Ma et al., 2016).

The results of the risk assessment project showed that residents in northern China and children less than 14 years of age had a higher average dietary Al intake that exceeded the Provisional Tolerable Weekly Intake (PTWI) of Al of 2 mg/kg body weight/week, which was established by Joint FAO/WHO Expert Committee on Food Additive (JECFA) in 2011. Taking the Chinese population as a whole, 32% exceeded the PTWI, with 60% in northern Chinese and 8.0% in southern Chinese (Fig. 1) due to the high consumption of wheat flour products, e.g. steamed bread, noodle and fried dough stick, which use Al-containing additives. Puffed food, on the other hand, contributed to a relatively higher Al intake for school-age children (Ma et al., 2016; National Expert Committee of Food Safety Risk Assessment, 2014).

In light of the risk assessment results and recommendations in the reports, NHFPC decided to re-examine and revise the food safety standard for Al-containing food additives (GB2760). In the revised provisions effective on 1st July 2014, sodium aluminum phosphate, sodium aluminum silicate, and starch containing aluminum octenyl succinate were banned as food additives (Zhang, Zhang, Wang, Luo, & Zhang, 2016). Potassium aluminum sulfate and ammonium aluminum sulfate were not allowed to use them in flour products, such as steamed bread (except for fried flour products) and Al-containing food additives were also not permitted to use in puffed food. After this revision of Al-containing food additives provisions, it is estimated that Al intake in the general Chinese population will decrease by 84.4–86.0% and the Al intakes of residents in northern China and children less than 14 years will be way below the PTWI. It is expected that the risk of Chinese population resulting from dietary Al intake will be significantly reduced when the new Al-containing food additives provisions are fully met by the food industry. The CFDA, as a regulatory control agency, has strengthened its inspection activity on the use of Al-containing additives based on the revised standard (Li & Liu, 2017).

3.4. Resolving dispution for withdrawal of maximum limits of rare earth elements

Rare earth elements (REEs) are rich resource in China and in the 1980s, they were developed as plant growth promoters (based on lanthanum, cerium, yttrium, etc.) in agriculture usage, so called micro-fertilisation for tea, leaf vegetables and cereals. The maximum limits (MLs) of REEs (based on lanthanum, cerium, yttrium, etc.) were established in tea, leaf vegetables and cereals according to its agricultural usage and health-based reference values as acceptable daily intake (ADI) were established by toxicological testing. When MLs of contaminants in food (GB2762) was

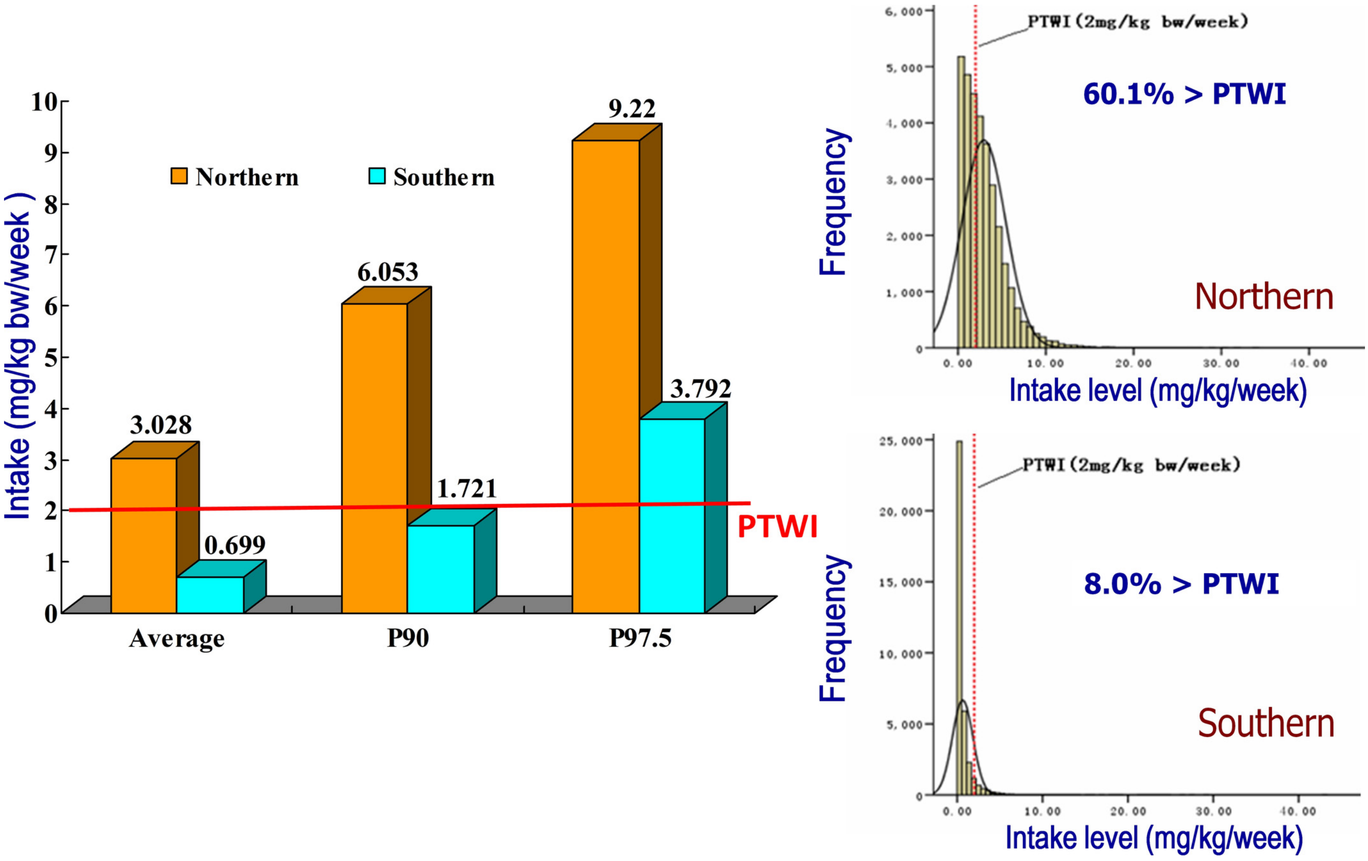

Fig. 1. Dietary Al intake: northern vs southern.

consolidated into China National Standard of Food Safety according to FSL, the REEs MLs should have been withdrawn after the calculation of ADI percent for each food groups. However, the argument existed because the original ADI was not established in Good Laboratory Practice (GLP) the MLs should remain. Due to the inconsistencies in the operation specifications of most of the toxicological tests, most of the end points selected for observation are mechanism indicators and lack of consistent evidence support. In addition, some studies have found that the health effects of REEs show low-dose excitement and high-dose inhibition. To provide basic toxicological data suitable for risk assessment of dietary REEs exposures, the CFSA conducted a 90-day oral gavage rat test of lanthanum, cerium and yttrium in the GLP Laboratory in accordance with the OECD Test Guideline and found that the three elements showed no significant toxicity and the NOAELs of lanthanum, cerium and yttrium were not observed until 10.3 mg/kg BW, 129.0 mg/kg BW and 29.1 mg/kg BW, respectively. Based on the available data, the tolerable daily intakes (TDIs) of lanthanum, cerium and yttrium were temporarily agreed as 51.5 μg/kg BW, 645.0 μg/kg BW and 145.5 μg/kg BW, respectively, by using a 200-fold uncertainty coefficient. In view of insufficient toxicology data for other REEs, considering the conservative principle, the lowest TDI (51.5 μg/kg BW) used in this assessment was taken as the health-based guide value to determine the health risk of total REEs (Toxicology Safety Assessment Report for Lanthanum, Cerium and Yttrium, unpublished).

Then, dietary REEs exposure assessment was carried out. For the general population, dietary REEs exposure is 1.62 μg/kg BW for mean value, which only accounts for 3.14% of the TDI; with P95 as 4.83 μg/kg BW, which is about three times that observed in the general population (Table 1). No food and food group have a dietary exposure that exceeds 1.50% of TDI. A further analysis found that vegetables and cereals are the main REEs sources in the diet of Chinese residents, accounting for 45.30% and 28.56% of the dietary exposure, respectively. The REEs level in tea is high, however its REEs contribution to dietary exposure only 3.61%. So, REEs MLs have been withdrawn in MLs of contaminants in food (GB2762-2017) as an integrated China National Standard of Food Safety.

3.5. *Providing the basis for the control of plasticizers in foods and proposing action level for phalates in Chinese liquor*

Since the plasticizer incident in Taiwan in 2011, phthalate esters (PAE), a type of plasticizer widely used in food industry, have become one of the targeted chemicals in the Chinese food safety inspection system. As these compounds are present widely in the environment, on the request of the NHFPC, the CFSA conducted a health risk assessment of PAE in the Chinese population in 24 categories of foods, including cereal, vegetable, meat, egg, fish, milk, vegetable oil, and liquor in 2012 (Li & Liu, 2017).

The risk assessment results revealed that the average level of PAE (Zhang, Jiang et al., 2016) in the most common categories of foods consumed was low (0.001–1.08 mg/kg). Dietary exposure to PAE was also significantly lower than the tolerable daily intake set by European Food Safety Authority in 2005 and, as a result, there were no safety concerns for the Chinese population (Sui et al., 2014). In accordance with international principles for standard development, it is not necessary to set up PAE maximum limits in foods. On the basis of this risk assessment results, CFSA, as the Secretariat of National Food Safety Standard Review Committee, suspended the proposal of setting up PAE limits in foods and simply recommended to reduce plasticizer contamination in foods by improving manufacturing process.

At the end of 2012, phalates, especially dinheptylorthophthalate (DEHP) and dibutyl phthalate (DBP) were detected in some well-known Chinese brand of distilled liquors. The public became concerned about the health risk of these plasticizers. The regulatory control agency had no idea as to how to supervise plasticizer-containing Chinese liquor and imported spirit products due to the absence of a reference level for risk management. Upon the request of the Food Safety Office of the State Council, the NHFPC commissioned the CFSA to conduct an urgent risk assessment of DEHP and DBP in distilled liquor. The results showed that the dietary intake of DEHP and DBP from the main foods and liquor consumed was not a risk even though distilled liquor contributes 57 percent DBP to the total dietary intake in liquor drinkers. After considering the worst-case scenario, the risk assessment concluded that DEHP and DBP would not cause adverse effect on health if their concentration in distilled liquor were lower than 5.0 and 1.0 mg/kg, respectively.

The NHFPC released these findings from this urgent risk assessment project and announced the action level of DEHP and DBP in liquor, i.e. 5.0 and 1.0 mg/kg, respectively (National Health and Family Planning Commission of the People's Republic of China, 2014). The CFDA and AQSIQ now use these values in the risk management of plasticizers in distilled liquor.

3.6. *Reducing risk of acute foodborne disease resulting from non-typhoidal Salmonella in chicken*

Acute foodborne disease (FBD) caused by non-typhoidal *Salmonella* (NTS) has been one of the most frequently reported foodborne diseases worldwide (World Health Organization, 2015). Chinese national food safety risk surveillance in 2010–2012 revealed that 41 percent of chicken at the retail level was contaminated by NTS. In order to assess the health risk, the CFSA carried out a risk assessment project on NTS in chicken based on a survey of NTS contamination in chicken and a study on cross-contamination in kitchens in six provinces in 2012. The risk assessment results showed that the chicken were more likely to be contaminated by NTS in cold storage than in freezing conditions. Five to eight million foodborne diseases were estimated to be

Table 1
Dietary exposure of rare earth elements from different gender-age groups of Chinese consumers.

Groups	Mean		P95	
	Daily Intake (μg/kg BW)	TDI (%)[a]	Daily Intake (μg/kg BW)	TDI (%)
2-6 y	2.80	5.44	8.22	15.96
7-12 y	2.23	4.33	6.95	13.49
13-17 y (M)	1.79	3.47	5.78	11.22
13-17 y (F)	1.72	3.34	5.89	11.43
≥18 y (M)	1.63	3.16	4.67	9.070
≥18 y (F)	1.61	3.13	4.82	9.37
All	1.62	3.14	4.83	9.38

[a] TDI (%) is the percentage of the temporary tolerable daily intake (TDI) of 51.5 μg/kg bw for lanthanum (La).

caused by NTS in chicken each year when considering other factors, such as cross-contamination in kitchens. In 50 percent of the cases associated with this, NTS would be reduced in the chicken if good operation practices in food handling and preparation were properly followed.

The Preliminary Report of Risk Assessment of *Salmonella* Contamination in Chicken Meats at Retail Level and Its Implications for Public Health Risk in China (National Expert Committee for Food Safety Risk Assessment, 2015; unpublished) recommended some key steps for preventing NTS contamination in chicken, which would provide a scientific guide for reducing the risk of illness resulting from *Salmonella* contamination of chicken (Jiao et al., 2017; Li & Liu, 2017).

3.7. Assessing the dietary exposure trend over time using China total diet study

3.7.1. Ethyl carbamate (EC)

EC occurs naturally in alcoholic beverages and most fermented foods. A national survey on EC exposure from alcoholic beverages was conducted for the first time in the 4th and 5th China Total Diet Study (TDS, 2007 and 2009–2011). The survey results showed that the average EC level in alcoholic beverages (19.8 μg/kg) in 2007 was higher than that in 2009–2011 (8.5 μg/kg). The dietary intake of EC for the Chinese population was estimated to be 8.27 ng/kg bw per day for the average population and 45.67 ng/kg bw per day for high consumers (the 97.5th percentile) in the 2009–2011 TDS. The average and high-end estimated daily intakes of EC for alcoholic beverages were both lower than the estimated daily intake (EDI) value (80 ng/kg bw per day) suggested by JECFA, indicating a low health risk of EC dietary exposure among Chinese adults at present. The Chinese rice wines, a type of traditional fermented alcoholic beverages in China, has a high level of EC and an obvious consumption regional disparity, thus the health risk of EC among Chinese rice wine drinkers should be of concern. To estimate the daily intake of EC from Chinese rice wines consumed in China, 890 Chinese rice wines samples including 468 commercial rice wines and 422 base rice fermentation liquors for further compounding were collected from various regions. Health risk assessment of EC using the MOE approach suggested that the current intakes of EC from alcoholic beverages in China are unlikely to cause health concern. However, relatively high health risks of EC dietary exposure in Chinese rice wines drinkers were observed in some high consumption provinces. Therefore, it was recommended that strategies should be developed and used on the industrial scale to control the level of EC in Chinese rice wines (Chen et al., 2017).

3.7.2. Acrylamide

Acrylamide is an industrial chemical commonly used for the production of polyacrylamides, which are wildly used in wastewater treatment, papermaking, gel electrophoresis, and cosmetics. It was found from the China TDS that the average dietary intake of acrylamide in the 2009–2012 TDS was $0.319\,\mu g \cdot kg^{-1} bw \cdot day^{-1}$. This was 70% higher than the intake in the 2000 TDS. The main food group contributors to acrylamide exposure were vegetables (35.2%), cereals (34.3%) and potatoes (15.7%). Based on the benchmark dose, lower confidence limit at 10% risk ($BMDL_{10}$) of $0.31\,mg\,kg^{-1}\,bw \cdot day^{-1}$ for the induction of mammary tumors in rats and $0.18\,mg\,kg^{-1}\,bw \cdot day^{-1}$ for Harderian gland tumors in mice, the margins of exposure (MOEs) were 973 and 565 for Chinese general population in 2000 and 2009–2013 for Harderian gland tumors in mice, respectively. These MOEs indicate a human health concern. Most importantly, the dietary exposure level has not been reduced after 10 years, which support the JECFA's call for greater industrial efforts to reduce acrylamide contamination in foods (Gao et al., 2016; Mueller U, 2011; Wu et al., 2013; Zhou et al., 2013)).

3.7.3. Other contaminants

The TDS was used in dietary exposure assessment for mycotoxins, i.e., deoxynivalenol (DON) (Sun & Wu, 2016), and heavy metals, i.e., lead, cadmium, arsenic and mercury (Wu, 2013). Assessment of dietary intake of polychlorinated dibenzo-p-dioxins and dibenzofurans (PCDD/Fs) and dioxin-like polychlorinated biphenyls (Dl-PCBs) was conducted in the 2007 and 2009–2013 China TDSs (Li, Wu, Zhang, & Zhao, 2007; Zhang et al., 2013; Zhang, Yin, et al., 2015). In these two TDS, as part of the WHO GEMS/Food programme, PCDD/Fs and Dl-PCBs were measured in human milk and the exposure of these substances in breast-feeding infants from mothers' milk was estimated (Zhang, Yin, Li, Zhao, & Wu, 2016). The results indicated that there was an increase of dietary intake and human burden from 2007 to 2011, and there was a positive correlation between dietary intake and human burden. Studies on the dietary exposure of tetrabromobisphenol-A and hexabromocyclododecanes (Shi, Wu, Li, Zhao, & Feng, 2009) as well as bisphenol A and nonylphenol (Niu, Zhang, Duan, Wu, & Shao, 2015) in the Chinese population were also carried out in the China TDS. The risk-benefit assessment for fish consumption in China was conducted in the TDS by using dietary exposure of dioxin and methylmercury contamination compared to dietary intake of ω3-fatty acids (DHA and EPA) (Gao et al., 2014; Gao et al., 2015).

4. Examples of capacity building: maximum limits of cadmium based on the dietary exposure estimation in Chinese population

Rice as the major staple food in China is also the major source of cadmium (Cd) exposure in the Chinese population (Table 2) (Song et al., 2017). Therefore, the development of maximum level (ML) for Cd in rice needs a comprehensive exposure assessment. However, different MLs for Cd in rice have been set up by difference regulatory bodies: 0.4 mg/kg by Codex Alimentarius Commission (Codex Alimentarius Commission, 2017), 0.2 mg/kg by the European Union (EU) (Commission Regulation (EC) No. 1881/2006, 2006) and China (Ministry of Health of the People's Republic of China, 1994; Shao, Wang, Chen, & Wu, 2014), and 0.1 mg/kg by the Food Standard Australia and New Zealand (Food Standard Australia and New Zealand, 2013). It was necessary to study the impacts of different MLs for Cd on its exposure and health risk for the Chinese population using the JECFA Cd PTMI 25 μg/kg bw as a health-based guidance value (Joint FAO/WHO Expert Committee on Food Additives, 2010). Facing pressure to use the Codex ML of 0.4 mg/kg and replace the current Chinese ML of 0.2 mg/kg, CFSA conducted a risk assessment. A multi-center epidemiological study was carried out in Hunan, Jiangxi, Guangdong and Sichuan Provinces to assess the concentration-effect relationship by using urinary excretion of beta-2-microglobulin (B2M) as a biomarker of renal toxicity and cadmium in urine (Zhang, Wang et al., 2015). Based on this analysis, CFSA derived a group-based $BMDL_5$ of 4.78 μg cadmium/g creatinine. In the JECFA report, a breakpoint of 5.24 (CI: 4.94–5.57) μg cadmium/g creatinine was used as a point of departure. Subsequently, a one-compartment population toxicokinetic (TK) model was fitted to 3178 paired data of cadmium intake and urinary cadmium concentrations from the molecular epidemiological studies by multi-centers in China. It was shown that by doing that, uncertainties about the right distribution to use are introduced. There are no difference between Chinese population and the meta-analysis using an international population in this study. The results supported JECFA to illustrate the impact of the choice made when establishing health-based guidance value with

Table 2
Contamination level, consumption and Cd exposure of different foods and food groups of Chinese consumers.

Foods and food groups	Cd Contamination				Consumption			Cd Exposure	
	Samples (detected/ analyzed)	Detect rate (%) (95%CI)	Mean (mg/ kg)	P50 (mg/ kg)	Consumption days (frequency[a])	Mean (g/ day)	P50 (g/ day)	μg/kg bw/ day	PTMI (%)[b]
Grain	5462/6582	83.0 (82.1–83.9)	0.058	0.017	192378 (99.6%)	414.1	395.0	0.363	45.4
Rice	2842/3378	84.1 (82.9–85.3)	0.076	0.024	147100 (76.2%)	270.4	250.0	0.292	36.5
Wheat flour	1358/1653	82.4 (80.5–84.3)	0.020	0.011	119054 (61.7%)	226.2	177.5	0.042	5.3
Others[c]	2539/3102	81.9 (80.6–84.2)	0.040	0.013	141401 (73.2%)	282.1	227.5	0.072	9.0
Vegetables	10661/13148	81.1 (80.4–81.8)	0.079	0.010	179121 (92.8%)	288.7	250.0	0.16	20.0
Leafy vegetables and celery	2778/3365	82.6 (81.3–83.9)	0.030	0.013	113195 (58.6%)	188.9	150.0	0.08	10.0
Legume, potato, stalk and stem vegetables	721/929	77.6 (74.9–80.3)	0.017	0.006	32555 (16.9%)	143.1	100.0	0.047	5.9
Others[d]	7162/8854	80.9 (80.1–81.7)	0.104	0.010	124704 (64.6%)	205.9	150.0	0.035	4.4
Meat (Including liver and kidney)	6668/7687	86.7 (85.9–87.5)	0.771	0.050	97394 (50.4%)	144.2	100.0	0.03	3.8
Fruit	1206/2025	59.6 (57.5–61.7)	0.008	0.002	37733 (19.5%)	199.2	150.0	0.005	0.6
Fish	3296/4770	69.1 (67.8–70.4)	0.031	0.005	32539 (16.9%)	143.8	100.0	0.014	1.7

[a] Frequency is the nubmer of consumption days for a certain kind of food devided by the total number of person days.

[b] PTMI (%) is the percentage of the provisional tolerable monthly intake (PTMI) of 25 μg/kg bw.

[c] The foods includes wheat flour; soybean; peanuts; grain crops (corn, millet, sorghum, potato).

[d] The foods includes beans, melons, tomato, eggplant, peppers etc.

PTMI of 25 μg/kg bw. Dietary exposure of Cd was calculated by the probabilistic approach (Boer, van der Voet, Bokkers, Bakker, & Boon, 2009; Zhang, Liu et al., 2016). Exposures were calculated as daily intakes and expressed as a percentage of the PTMI. The contamination level and the consumption data were matched according to the SHEDS-Dietary module (Xue, Zartarian, Wang, Liu, & Georgopoulos, 2010). All calculations were performed using the Chinese Dietary Exposure Evaluation Model Software, a SAS-based program developed by Southeast University, peer-reviewed by a committee of experts from the Chinese Ministry of Health and with a software copyright registration certificate from the National Copyright Administration of the People's Republic of China (register number: 2008SR32550) (Liu et al., 2011; Liu, Wang, Song, & Wu, 2010; Sun et al., 2010). A beta binomial normal (BBN) model was applied in the probabilistic assessment. Different possible ML scenarios for rice were selected to assess the impact of different MLs on Cd concentration and exposure. More than 70% of children aged 2–6 years and over 30% of the general population have a dietary daily Cd intake above the Provisional Tolerable Monthly Intake (PTMI). Table 3 shows that the Cd exposure was highest in the children; the mean levels were estimated at 158.7% of PTMI for children (2–6 years), but 90.1% of PTMI for the general population. For the P95, the dietary intakes for children and the general population were 326.50% and 193.20% of PTMI. Table 4 shows that more than 70% of the children aged 2–6 years and over 30% of the general population had daily dietary Cd exposures that exceeded the PTMI. The baselines show that Cd exposure from rice contributed to 47% of the total Cd exposure in the general population, which was far higher than that from other foods. The model was systematically re-run with the inputs set to different possible ML scenarios. Cd exposure changed greatly relative to baseline when different possible MLs were used, but the changes were not as large when compared among the different possible MLs. For rice, the different possible MLs reduced mean baseline concentrations from 33.9 to 64.1%, and the actual differences in reduction from baseline ranged from 4.4 to 30.2%. The BBN results are presented in Table 3 and show a decreasing trend in the PTMI differences (%) and risks with MLs from 0.4 to 0.1 μg/kg. The decreasing trend was relatively large between MLs of 0.3 and 0.1 μg/kg but relatively small when MLs changed from 0.4 to 0.3 μg/kg bw/day. Fig. 2 shows that the dietary structure of the general population and the upper tail (5%) of the children aged 2–6 years were very similar to each other; rice followed by vegetables contributed to more than 60% of the total Cd exposure at baseline. Then, its contribution decreased directly, and the contributions of other foods and food groups increased indirectly, with stricter MLs for rice. Cd exposure in China, especially for children, is a public health concern. It is recommended that the ML for rice be retained at 0.2 mg/kg.

Table 3
Impact of different MLs for Cd in rice on total dietary exposure in Chinese children and general population.

Population	Cd intake									
	Intake percentile	Baseline[a]	0.1 mg/kg (FSANZ ML)		0.2 mg/kg (China, EU ML)		0.3 mg/kg		0.4 mg/kg (CAC, Japan ML)	
		PTMI (%)[b]	PTMI (%)[b]	△[c]	PTMI (%)[b]	△[c]	PTMI (%)[b]	△[c]	PTMI (%)[b]	△[c]
Children (2–6 years)	mean	158.7	109.7	−49.0	123.0	−35.7	128.7	−30.0	131.9	−26.8
	P50	138.5	100.4	−38.1	111.1	−27.4	115.9	−22.6	118.2	−20.3
	P75	197.1	133.2	−63.9	150.2	−46.9	157.9	−39.2	162.2	−34.9
	P90	270.8	172.3	−98.5	198.1	−72.7	209.8	−61	215.8	−55.0
	P95	326.5	201.7	−124.8	233.2	−93.3	247.3	−79.2	255.1	−71.4
General	mean	90.1	62.8	−27.3	70.4	−19.7	73.5	−16.6	75.2	−14.9
	P50	77.4	56.5	−20.9	62.7	−14.7	65.0	−12.4	66.3	−11.1
	P75	112.0	76.9	−35.1	87.0	−25	90.8	−21.2	93.1	−18.9
	P90	157.1	101.7	−55.4	116.8	−40.3	122.6	−34.5	126.2	−30.9
	P95	193.2	120.5	−72.7	139.3	−53.9	147.6	−45.6	151.4	−41.8

[a] The scenario without any MLs.

[b] PTMId (%) is the percentage of the provisional tolerable monthly intake (PTMI) of 25 μg/kg bw.

[c] △ is the absolute change of % PTMI as compared to the baseline.

Table 4
Impact of different MLs for Cd in rice on risk in Chinese children and general population.

Population	Cd intake								
	Baseline[a]	0.1 mg/kg (FSANZ ML)		0.2 mg/kg (China, EU ML)		0.3 mg/kg		0.4 mg/kg (CAC, Japan ML)	
	Risk (%)	Risk (%)	△[b]	Risk (%)	△[b]	Risk (%)	△[b]	Risk (%)	△[b]
Children (2–6 years)	73.2	50.4	−22.8	59.2	−14.0	62.6	−10.6	64.0	−9.2
General	32.2	10.7	−21.5	16.6	−15.6	19.2	−13.0	20.6	−11.6

[a] Is the scenario without any MLs.
[b] △ is the absolute change of risk as compared to the baseline.

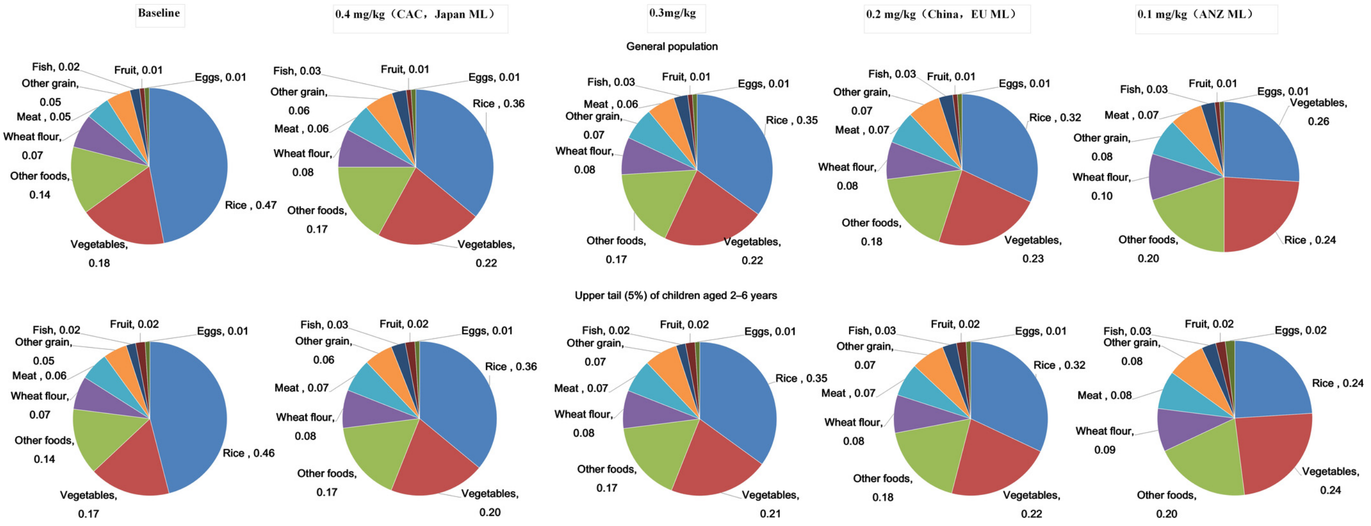

Fig. 2. Impact of different MLs for rice on contribution (percentage per product of the total intake distribution) for the commodities to the dietary exposure to Cd for Chinese general population and the upper tail (5%) of the Chinese children aged 2–6 years.

5. Challenges and future directions

An operational national risk assessment system has been established in China since 2009 and significant achievements have been made in methodology and procedure development, data storage and personnel training, as well as the completion of a number of qualitative and quantitative risk assessment projects, which have serve as important scientific bases for making risk management decisions, in particular standard development. However, with the rapid development of food and chemical industries, use of new materials, booming global trade, and the resulting complexity in food supply chains, risk assessment in China is still in a learning stage and has some major weakness as following: (Li & Liu, 2017; Wu & Chen, 2013).

1) At times, the capacity for conducting risk assessment is unable to meet the risk management demands because of the lack of qualified risk assessment experts with practical working experience. On the technical side, modeling development based on current situation in China is lags behind some developed countries.
2) Data sources are limited and mostly rely on national monitoring projects. In some cases where insufficient data exists, specific monitoring projects have to be undertaken while the risk assessment projects are being implemented. Consequently, there is a time gap between data collection and the final risk assessment.
3) In comparison with chemical risk assessment, the progress in microbial risk assessment is far from meeting the requirements of risk management. There were only a few microbial risk assessment projects completed and the results did not provide sufficient support to develop control measures. The major reason is the lack of data, since there is no reliable estimate on the prevalence (diseases burden) of foodborne diseases in China and lack of microbial contamination data from the entire food chain (from farm to table). The CFSA microbial laboratory infrastructure is developing expertise and protocols in forensic microbiology and whole genome sequencing to assist in improving surveillance systems to provide better data for risk assessment.
4) With such a large country with significant geographical variations in food production and eating habits, there is a need to carry out local risk assessment work according to local needs, for example, when certain local foods are found to be contaminated with high levels of certain chemicals. Although no systematic risk assessment is needed, local food safety control authority needs risk assessment results for rapid decision-making. However, with the exception of a few more developed provinces, most provinces do not have the capability to undertake risk assessments.

In order to overcome these weaknesses and improve the risk assessment in China, the key issue is capacity building. The best way forward is greater transparency and integrity in food supply chains with an emphasis on global alliances and new technologies. The number of professional risk assessors needs to be increased along with strong and sustainable training programmes. At the national level, international risk assessment organizations (e.g., JECFA, Joint FAO/WHO Meeting on Pesticide Residues (JMPR) and Joint FAO/WHO Meetings on Microbiological Risk Assessment (JEMRA) and well established risk assessment institutions with rich experience (e.g. European Food Safety Authority (EFSA), US Food and Drug Administration (US FDA), FSANZ) are existing by exchange of staff, workshops and collaborative projects, which have been effective and successful in the past. Microbial risk assessment should be a priority in future training. All countries need to work together as the problems in the global supply chain can only be resolved by all the stakeholders collaborating to ensure risk management decisions are based on the best science available. The EU-China-Safe project, as one of the world's - largest food safety projects, this initiative has secured a funding of 10 million Euros from the EU's Horizon 2020 program and the Chinese Ministry of Science and Technology (MOST), and involves 33 key research organizations, government agencies, and industry players needed to jointly deliver an effective, resilient, and sustainable EU-China food safety partnership. China MOST has initiated food safety project with total of 1.44 billion RMB Yuans, in the National Key Research and Development Program of China, the call for application has made to tick on the emerging risks. The successful identification of emerging risks in the food chain early is at the heart of protecting public health, also helps to improve CFSA's ability to meet future. Increasing numbers of substances present at low and very low concentrations in food and feed are now detectable due to improved analytical methods. However, for many such substances there are little or no toxicological data available. There is an increased need to assess the potential health significance of these previously undetectable trace substances but it is not always possible to generate toxicological data on every single substance found in the diet. The Threshold of Toxicological Concern (TTC) approach has been developed to qualitatively assess the risk of low-level substances in the diet. It can be used for an initial assessment of a substance to determine whether a comprehensive risk assessment is required. It is an important science-based approach for prioritising assessment of those chemicals with low-level exposures that require more data over those that can be presumed to present no appreciable human health risk. Consumers can be exposed to multiple chemicals from a variety of sources. China is launching a ground-breaking initiative to propose methods for carrying out risk assessment for this complex issue, our scientists have started to develop new approaches for assessing risks to humans and the environment from exposure to multiple chemicals in the food chain: “chemical mixtures” and their “cocktail effects”. Nanotechnologies enable the management of food ingredients on a molecular level. Nanotechnology products could have a substantial impact on the food and feed sector in the future, potentially offering benefits for industry and the consumer, although possible risks need to be considered. Companies and institutes worldwide are currently researching and developing applications in fields such as the treatment of the mechanical and sensorial properties of food – for instance to achieve changed taste or texture- and modified nutritional value. Nanotechnology may also be used in food packaging, for instance to ensure better protection or to detect how fresh food is. The specific properties and characteristics of nanomaterials need to be considered to be assessed by novel approch for any potential health risks. In recent years the development of innovative tools in genomics, transcriptomics, proteomics and metabolomics (designated collectively as Omics technologies) has opened up new possibilities for applications in scientific research and led to the availability of vast amounts of analytical data. China started mapping the use of omics tools in the risk assessment related to food and feed safety. Building further towards a concrete path of implementation, diverse topics are needed to be disscued for which CFSA intends to exploit Omics datasets to support the scientific safety evaluation, i.e., genomics in microbial strain characterisation, metabolomics for the comparative assessment of GM plants and the use of Omics for toxicological risk assessment. Those help risk assessors to start the process of incorporating Omics tools and mode of action in the risk assessment. However, these activities are often constrained by inadequate financial support. Several other measures to strengthen capacity building should also be considered, such as:

1) Improving the relationship between risk assessment and risk management at project planning stage so that limited resources for risk assessment can be used more efficiently;
2) Including specific data needs for risk assessment projects into annual monitoring plans; and,
3) Organizing well planned training activities for local risk assessors as well as specific training courses for national and local risk managers.

Acknowledgements

This work was support by the National Natural Science Foundation of China (No. 215537001), the Public Welfare Projects for Health under NHFPC (No. 201302005), and EU Horizon 2020 Research and Innovation Action (No. 727864-EU-China-Safe). We are grateful to Professors Yan Chen, Jingguang Li, Zhaoping Liu, Lei Zhang, Pingping Zhou, and Jianghui Zhu who have provided original materials for the preparation of this review.

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