

Impact of ILSI Fellowship Program with JIFSAN in Building Risk Analysis Capacity at CSFA ¹

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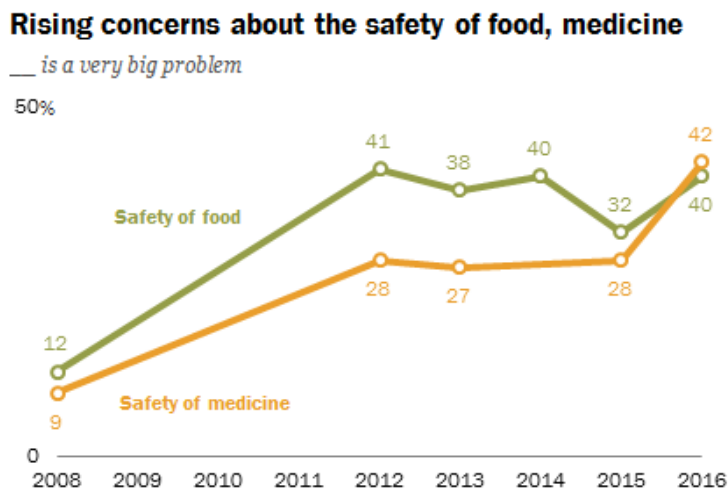
¹ Report prepared for World Bank study on making the Case for Food Safety Investment in Developing Countries

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Food Safety in China

Food safety has been one of China’s most pressing challenges, raising the concerns of the general public and drawing the attention of the government. Over the last decade, China has had a series of food safety incidents associated with chemical and microbiological hazards as well as economic adulteration (e.g. baby formula incidents in 2003 and 2008, exposed gutter oil cases since the early 2000s, e-commerce food delivery operation scandal in 2016, etc.). According to a survey conducted in China, the percentage of the Chinese public who considered food safety to be a very big problem rose from 12% in 2008 to 41% in 2012 and stayed around 40% from 2012 to 2016 (see Figure 1) (Pew, 2016). To secure food safety, ensure public health, and improve people’s welfare, the Chinese government has made institutional changes aimed at strengthening the regulatory system. In 2009, the government published the Food Safety Law of the People’s Republic of China. In 2011, the government included food safety in the country’s 12th Five-Year Plan for Economic and Social Development (2011-2015), making it one of the government’s top priorities (State Council, 2011, Chp. 41). After a central government reform in 2013, the China Food and Drug Administration was established as a ministerial-level agency under the State Council responsible for food safety regulation. In 2015, the Food Safety Law was amended significantly to reflect this change in government structure and further prevent food safety violations. Food safety continues to be a priority for the central government in the current 13th Five-Year Plan (State Council, 2016).

Figure 1 Rising concerns about safety of food, medicine in China



Source: Spring 2016 Global Attitudes Survey. Q60i, n.

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Two key aspects of food safety regulatory capacity building are risk-based decision-making and having trained human capital to do such. The former establishes food safety risk assessment as the scientific basis for designing policies and safety standards; the latter is needed to carry out the analysis needed for food safety regulation. The Risk Analysis program at the Joint Institute for Food Safety and Applied Nutrition (JIFSAN) at the University of Maryland has been training and mentoring young professionals from China's National Center for Food Safety Risk Assessment (CFSA) through a 3-month extended risk analysis fellowship since 2011. This write-up highlights the impact of the training program and how it has aided China in enhancing its food safety regulatory capacity.

In 2009, risk assessment became a more essential and integral part of the food safety framework when the Food Safety Law stipulated that only national food safety standards are mandatory and should be based on risk assessment results² (Chen, 2016). At the end of 2009, the National Food Safety Risk Assessment Expert Committee was established in accordance with the Food Safety Law. The committee's responsibility is to carry out risk assessment work by planning and organizing risk monitoring and assessment projects, conducting risk assessment, and communicating risk assessment results. A month later, the National Food Safety Standard Review Committee was founded to review and approve national food safety standards. In 2011, National Center for Food Safety Risk Assessment (CFSA) was established as an independent body to perform a series of tasks including monitoring food safety risks, conducting risk assessments, formulating and amending food safety standards, performing risk assessment-related scientific research, conducting technical training, and communicating and collaborating with international experts in the risk assessment area.

In 2012, the State Council issued the 12th five-year plan for a national food safety supervision and administration framework. The plan detailed goals and steps towards strengthening the food safety regulatory framework and curbing economic adulteration, and placed emphasis on building a risk-based preventive system and national food safety standards. According to the 12th five-year plan for food safety, the Chinese government needed to write regulations and guidelines on how to implement the food safety law and systematically update the food safety standards. Annually, the expert committee listed priority risk assessment projects according to the need for formulating food safety standards and policies and addressing public concerns (CFSA, n.d.). In 2017, the 13th five-year plan for food safety stated that food safety agencies will continue to amend and formulate food safety standards and enhance technical support through risk monitoring and assessment some of the main tasks in the near future. Under the plan, there are eleven main tasks and the focus has shifted away from establishing a regulatory framework for improving supply chain management and inspection.

There also was a move to increase the number of people able to conduct risk assessments and improve their skills. Under the 12th five-year plan, all regulators were required to receive at least 40 hours of professional training per year. In the 13th five-year plan, the State Council

² 2009 Food Safety Law, item 19.

encourages provincial-level governments to establish professional training facilities. In addition to the professional training, new regulators are required to receive at least 90 hours of orientation training, and the heads of regulatory agencies receive national-level training. CFSA became responsible for risk assessment, international communication and collaboration, and food safety training (CFSA, 2017).

ILSI Fellowship Program

The 2009 Food Safety Law established that risk assessment is essential to managing the risks of biological and chemical hazards. It required the Chinese government to build a risk-based food safety regulatory framework and acquire relevant human capital. To fulfill the requirements of the law and improve food safety in China, training in risk analysis was needed.

The International Life Science Institute (ILSI) Focal Point in China and private sector partners decided to collaborate to start a fellowship program to support capacity building in risk assessment in China. In 2011, the extended risk analysis training program was established at the University of Maryland's Joint Institute for Food Safety and Applied Nutrition (JIFSAN) and was sponsored by ILSI with support from the private sector. From 2011 to 2017, the fellowship funded ten national-level food safety professionals (one of them from China Center for Disease Control, nine from CFSA) to participate in the three-month fellowship program at JIFSAN.

Each year, China's ILSI Focal Point interviews candidates and chooses one to two professionals to come to JIFSAN for the program. The program consists of one month of classroom training and two months of applied project development under the guidance and mentorship of JIFSAN faculty. During the classroom training, the fellows learn the principals of risk analysis, including theories and applications of qualitative and quantitative risk assessment, risk management, and risk communication, and how they feed into the rule-making process in the U.S. They learn how to use popular risk assessment tools on FoodRisk.org and how to build risk assessment models in @Risk, FDA-iRISK, and Risk 21. Then, they are asked to put the principles and technical skills into application. Using actual data from China, each professional develops their own quantitative risk assessment model on a specific food safety hazard in the country. At the end of their fellowship, they present their findings to JIFSAN faculty and FDA and ILSI scientists.

In addition, the fellows visit risk assessors in various U.S. agencies, attend public hearings on Capitol Hill, and visit food processing facilities and retail establishments in the U.S. to see how food safety hazards are mitigated. They also attend international food safety conferences, where they network with professional risk assessors throughout the world. These professional activities facilitated their connection and even collaboration at international level.

When they return the ILSI China focal point collects feedback from fellows and CFSA, including organizing returned fellow meeting with CFSA. The fellows return to CFSA with the knowledge of how risk assessment research is used in writing regulations, standards, and guidelines, and addressing public concerns. They use this knowledge to continue working on the projects from their fellowship and to take on new projects. In 2016, CFSA hosted a workshop in China during

which the previous fellows presented on their progress and how their research was being used to support food safety rulemaking. CFSA also shared with the ILSI Focal Point and JIFSAN a report on the impact of the program. The report stated that since 2011 the ILSI fellowship program has become an integral part of China's food safety risk assessment capacity building, and has increased the Center's human capital to conduct risk assessments (Liu, 2016).

The fellows have been applying what they learned during the program and contributing to China's food safety capacity building in four ways. First, some of the fellows directly participated in drafting national plans, regulations, technical guidances, and food safety standards. In total, the fellows participated or played leading roles in drafting three national standards, five risk assessment technical guidances, and two plans for food safety and nutrition. Secondly, most of the fellows have led or participated in multiple national food safety priority risk assessment projects or emergency response projects. Together, the fellows have participated or played leading roles in 23 priority risk assessment projects and three emergency response projects. Three of the priority risk assessment projects were directly related to the fellows' project topics during their stay at JIFSAN. Thirdly, the fellows have built models and written reports to support the drafting of national regulations, food safety standards, and technical guidances. Some of them have provided technical support for assessing the risk in new food product ingredients. The fellows have reported that they have constructed four risk assessment models and completed 10 reports to support regulation and policymaking. One of the fellows was responsible for establishing a team for a microbial risk assessment. Last but not the least, the fellows have delivered training on various food safety risk analysis topics. Most of them have trained risk assessors from provincial-level agencies in the National Food Safety Risk Assessment Training. Some of them have lectured in graduate school classes and talked to food safety personnel from the industry. Combined, they have disseminated risk assessment information to over 2300 participants. All the fellows have become the backbones in risk assessment at CFSA.

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Appendix

Below is a(n) (incomplete) list of the contribution of the professionals after their training. The green items are from the 2016 ILSI report. The black items are from JIFSAN's follow-up surveys. The bold ones could be related to the professionals' presentation topics during their staying in JIFSAN.

1. Participation in drafting regulations, policies, guidelines, plans, food safety standards, and other government documents.

Role	Document Type	Document Title
Organize	Guideline/Technical Guidance	Food Microbial Risk Assessment Guideline
Responsible for tech support	National food safety standard	Ethyl Carbamate Limit in Fermented Alcoholic Beverage
Responsible for tech support	Guideline/ Technical Guidance	Food Safety Risk Classification Guideline
Participate	Plan	Special Plan for Food Safety Standards, Monitoring, and Assessment for the 13 th Five-Year Period
Participate	Plan	Plan for the National Nutrition Movement (2017-2030)
Participate	Guideline/Technical Guidance	Technical Guidance for Food Additive Risk Assessment
Participate	National Food Safety Standard	Mycotoxin Limits in Food Products (GB 2761)
Complete	National pesticide standard	Evaluate the effect of pesticide as endocrine disruptors
Complete	Guideline/ Technical Guidance	Animal feed risk assessment guideline
Complete	Guideline/ Technical Guidance	Guidelines for constructing health guidance values for chemicals

2. Participation in priority risk assessment projects or emergency response projects.

Role	Project Type	Food Safety Risk
Lead	Priority project	Bisphenol A (BPA)
Lead	Priority project	The Level and Risk of Heavy Metal Transfer in Stainless Steel and Aluminum Products

Participate	Priority project	<i>Listeria Monocytogenes</i> in Instant Food
Responsible for tech support	Priority project	Ethyl Carbamate in Alcoholic Beverages
Responsible for tech support	Priority project	Survey on Boron Baseline in Aquaculture Products
Responsible for technical support	Priority project	Polycyclic Aromatic Hydrocarbon in Food Products
Responsible for tech support	Emergency response	Methanol in Tequila
Responsible for tech support	Emergency response	3-Chloro-Propanol Ethanedioate in Palm Oil
Responsible for tech support	Emergency response	3-Chloro-Propanol Ethanedioate and Fatty Acid Esters of Glycidol in Baby Formula
Organize	Priority Project	Chinese Resident Dietary Aluminum Exposure Risk Assessment
Organize	Priority Project	Food Additive Caramel Coloring Risk Assessment
Participate	Priority Project	Preliminary Quantitative Risk Assessment For <i>Bacillus Cereus</i> In Powdered Baby Formula
Participate	Priority Project	Preliminary Quantitative Risk Assessment For <i>Enterobacter Sakazakii</i> In Powdered Baby Formula
Lead	Priority Project	Chinese Resident Dietary Caramel Coloring Exposure Risk Assessment
Lead	Priority Project	Food Additive BHA and BHT Risk Assessment
Lead	Priority Project	Risk Assessment of Fumonisin FB in Cereal and Cereal Products
Lead	Priority Project	Chinese Residents Dietary Aflatoxin B1, B2, G1, G2 Risk Assessment Project
Lead	Priority project	<i>Chicken-Salmonella</i>
Lead	Priority project	<i>Chicken-Campylobacter</i>
Lead	Priority project	Instant Food- <i>Listeria Monocytogenes</i>
Lead	Priority project	Raw Shell Fish- <i>Vibrio Parahaemolyticus</i>
Complete	Priority project	Rare-earth element
Participate	Priority project	Lead
Participate	Priority project	Trans Fatty Acid

Participate	Priority project	Urethane
Participate	Priority project	Phthalates

3. Other research/work supporting China's regulatory capacity building.

Role	Project	Project Title	Contribution
Build	Chemical Risk Classification Model	Food Safety Risk Classification Guideline	For normalizing local risk assessment and enhance the effectiveness of risk management
Write	Risk Assessment Report	Ethyl Carbamate in Alcoholic Beverages	For drafting national food safety standard
Write	Risk Assessment Report	Survey on Boron Baseline in Aquaculture Products	Technical support for identifying adulteration
Write	Research Report	Health, Family Planning, Food Safety Human Capital Research Report for 13 th Five-Year Planning	Support the drafting of the special plan for food safety standards for the 13 th five-year period
Write	Research Report	Research Report on the Establishment of Food Safety Risk Monitoring and Assessment and Safety Standards System	Support the drafting of the special plan for food safety standards for the 13 th five-year period
Lead	Priority Project	Chinese Resident Dietary Caramel Coloring Exposure Risk Assessment Report	To support the regulation of caramel coloring as food additive
Build	Model	Raw chicken-salmonella cross-contamination suitable for Chinese kitchen	
Establish	Team	Food microbial risk assessment team	
Write	New food ingredient safety assessment report	<i>bacillus coagulans</i>	

Write	new food ingredient safety assessment report	<i>Lactobacillus fermentum</i>	
Write	new food ingredient safety assessment report	fish oil	
Write	new food ingredient safety assessment report	<i>Lactobacillus johnsonii</i>	
Build	model	veterinary medicine residue in food	
Build	intervention method	veterinary medicine residue in food	
Analysis		Urethane in grain alcohol (<i>baijiu</i>) in Chinese household consumption	
Build	probabilistic assessment model	trans fatty acid	

4. Delivered trainings on risk assessment.

Training	Content	#	Class size	Trainees
National	chemical risk assessment methods	3	100	Provincial level risk assessors
Local/Regional	chemical risk assessment methods	2	50	Provincial level risk assessors
Graduate School	food safety risk assessment, chemical exposure assessment methods	5	20	Grad students
Technical Forum	food contact material safety assessment methods	1	300	Industry and non-admin public sector food safety personnel
National	Food Microbial Risk Assessment Principles and Methods	2	50	Provincial level risk assessors
National	Chemical risk classification guideline	2	100	Provincial level risk assessors

National	Survey on boron baseline in aquaculture products	1	50	Provincial level risk assessors
National	Ethyl Carbamate in Alcoholic Beverages	3	20-100	Provincial level risk assessors and food safety personnel in the industry
National	Quantitative Model for Risk Assessment	2	50	Provincial level risk assessors
National	Principles of Risk Assessment Data Collection	2	100	Provincial level risk assessors
National	Emergency Response Risk Assessment Methods and Case Studies	1	100	Provincial level risk assessors
National	Biotoxins Risk Assessment Method	1	100	Provincial level risk assessors
Local/Regional	Basic Principles and Methods of Risk Assessment	2	100	Local risk assessors
National	Chicken-salmonella and raw chicken-campylobacter combination, food microbial risk classification, and probability risk assessment technology using Excel	3	90	Provincial level inspectors
National/local?				local risk assessors
National	probabilistic risk assessment			