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Building a strategic alliance for sustainable food safety risk analysis capacity building in the Americas

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SUMMARY

The main goal of this paper is to provide the foundation for a coordinated effort for food safety risk analysis capacity building in the Latin American and Caribbean (LAC) region by bringing together international organizations (Panamerican Health Organization-PAHO, Food and Agriculture Organization of the United Nations-FAO and the Interamerican Institute for Cooperation in Agriculture-IICA) and universities (University of Nebraska-Lincoln, University of Maryland, University of Minnesota and Texas Tech University) through the **Strategic Alliance in Risk Analysis Capacity Building (SARAC)**. We expect that this paper, authored by the alliance, will: a) build trust and strengthen communication among all the organizations that work in the region; b) provide the foundation for coordinated, consistent, and effective approaches to capacity building and curriculum development; and c) facilitate the implementation of the risk analysis framework within the region. This paper provides the current resources by the authors, discusses some successful examples of risk analysis implementation in the region (from academia and government sectors), the challenges experienced on implementing risk analysis and a capacity building roadmap proposed by this alliance to enhance the adoption of risk analysis in the region.

FOOD SAFETY AS A GLOBAL CONCERN

Consumption of unsafe food and water continues to be one of the major causes of preventable malnutrition, disease, and death. Foodborne diseases are a major cause of human morbidity and mortality. According to recent estimates from the WHO Foodborne Diseases Epidemiology Reference Group (WHO FERG), foodborne diseases caused 600 million illnesses, 420,000 deaths, and 33 million Disability Adjusted Life Years (DALYs) in 2010. Foodborne diseases are particularly important in children. Although children <5 years of age represent only 9% of the global population, WHO FERG estimates that 40% of the foodborne disease burden is borne by

children in this age group (Havelaar et al., 2015). Food animals are the predominant source of many of foodborne diseases including infections caused by non-typhoidal Salmonella and Campylobacter. Non-typhoidal Salmonella caused an estimated 80 million infections and 60,000 deaths and Campylobacter caused 95 million infections and 21,000 deaths in 2010 (Havelaar, et al., 2015).

FOOD SAFETY IN LATIN AMERICA

There has been a tremendous growth in the production and exports of agricultural products from Latin America at a growth rate of 8% annually since the mid-nineties representing 13% of global agricultural trade (World Bank, 2013). Though there are differences between countries, the region is a net exporter of food (FAO, 2015). Most of this growth in exports has been high value agriculture. Agricultural products are more prone to food safety hazards if risks are not adequately controlled. This can affect the trade and export markets substantially.

Even though WHO FERG estimates for Latin America showed lower burden than other WHO regions, they are still considered high. Campylobacter spp., non-typhoidal *S. enterica*, Norovirus, *Taenia solium* and *Toxoplasma gondii* are the pathogens with the highest DALY values in the region. They account for more than 8,000 foodborne illnesses per 100,000 population and more than 2,500 deaths per year (Havelaar et al., 2015). Foodborne surveillance programs vary from event based surveillance systems to integrated systems along the food chain. Nevertheless, across the Americas there is a need to systematically collect data on foodborne hazards and strengthen and coordinate surveillance and trace back programs so that the public and private sector can efficiently respond to food safety risks and put cost-effective measures in place to reduce food safety risk whether the products originated domestically or in other countries.

RISK ANALYSIS: A TOOL TO PREVENT FOODBORNE ILLNESSES AND OPTIMIZE RESOURCES

Current significant challenges that developed and developing countries face is to provide food safety to protect public health and promote economic development. In the last several decades, substantial progress has been made to strengthen the food safety systems to reduce and eliminate foodborne diseases (FAO/WHO, 2005). Risk analysis has emerged as the foundation for developing food safety systems and policies by establishing the linkage between hazards in foods and the human health risks due to the food consumption and environmental exposures relevant to food production and processing (Vose, 2002). The risk analysis framework (risk assessment, risk management and risk communication) provides a realistic and scientific approach to improve the food safety decision-making process, which in turn improves food safety and contributes to the reduction in foodborne disease incidence (CAC, 2003). It can also monitor the outcomes of tailored interventions in both successful and unsuccessful scenarios. Risk analysis offers to governments a framework to effectively assess, manage and communicate food safety risks in cooperation with the diverse stakeholders involved (FAO/WHO, 2005).

The implementation of risk analysis at the country level requires that the government conduct the following steps (adapted from CAC, 2007): 1) Strategic planning to identify public health objectives (number of illnesses per 100,000 population, number of outbreaks per year, pathogen prevalence) and establish a risk management plan for meeting the public health objectives and metrics to measure the performance in a certain period of time; 2) Identify and prioritize the main food safety risks for the country by reviewing the data available related to the presence of pathogens and chemicals in the food consumed by the population and related outbreaks; 3) Allocate resources to collect more data relevant to the identified high-risk foods or to conduct a risk assessment; 4) Analysis and selection of interventions by multi-criteria decision analysis to identify and choose intervention

strategies for implementation; 5) Design and implementation of an intervention plan; and 6) Monitoring and reviewing to evaluate whether the interventions result in the desired intermediate outcomes and whether public health objectives are being met. The process is usually refined in an iterative manner and closely communicated with stakeholders (Oria 2010).

Risk managers can also request a risk assessment that is usually developed by panels composed of scientists with related expertise (Bronzwaer, 2008). Risk managers utilize the scientific findings emanating from the risk assessment in order to decide upon mitigation strategies to reduce the risk to an acceptable level. Risk communication is a key element of each step of the risk analysis process; hazards, assessments, goals, and management options are discussed with the stakeholders, such as the private sector and consumer organizations, to allow a broader consensus around risk priorities and policy decisions (CAC, 2007).

USE OF THE RISK-BASED APPROACH FOR INSPECTION AND SURVEILLANCE

Risk analysis can be also utilized to optimize resources, especially regarding the implementation of risk-based preventive inspection and surveillance programs. It is common to find countries struggling with the number of food processing establishments they need to inspect each year and the limited number of inspectors. In addition, the basic concept underlying regulatory inspections in many developing countries has not progressed from the old, product-based, reactive modality to the modern, preventive type of risk-based food control system (FAO, 2008). Furthermore, the food control system in many countries is not centralized but is composed of multiple institutions with diverse agendas and different levels of coordination. These institutions have their own separate inspection systems covering specific food sectors with frequent overlaps or gaps between them; they do not coordinate actions with each other and often use widely varying inspection procedures. Therefore, in order to advance towards a risk-based process rather than a product-based process, a risk prioritization process is necessary to ensure that products that pose greater risk to consumers and establishments that have a poor record of compliance are given special attention and inspected more frequently.

A technique that can be used to establish a priority list of primary production and food processing establishments to be inspected relies on: 1) The history of compliance by the establishment with the established national regulations in food safety and Good Manufacturing Practices (GMPs)—the establishment profile— is designated a risk level depending on its performance with existing inspection records; 2) The establishment's products are profiled on the basis of the level of foodborne disease risk factors they present (i.e. inherent microbiological and chemical risks) and marketing characteristics (e.g. large volumes reaching all populations, destined for children or infants, specialty products to niche markets). A risk level classification is assigned to the product profile (FAO, 2008).

Currently, food safety legislation may contain both hazard- and risk-based approaches (Barlow et al., 2015). Changes in food safety policy and legislation are needed in order to enable country adoption of a preventive science/evidence/risk-based approach to food safety, rather than the traditional reactive approach. Modernizing country legislation to consider risk-based approaches will require government commitment to improving all components of the national food system, such as laboratories for improved data collection; inspection (risk based import and export control), communication and information systems, training, among others. Concurrently, development of capacity (in topics ranging from risk categorization and prioritization, to decision making and risk communication) for stakeholders will be needed.

STRATEGIC ALLIANCE OF RISK ANALYSIS CAPACITY BUILDING IN THE AMERICAS (SARAC)

During the last 20 years, the international agencies that work in the region (PAHO, FAO and IICA) along with US and Latin American universities have developed and delivered training courses related to food safety risk analysis applied to pathogens and chemicals in food and water. The courses and workshops ranged from basic awareness of risk analysis concepts to a more in-depth training in quantitative risk assessment and risk communication. Unfortunately, most of these trainings have been developed in isolation and have been offered by more than one institution, leading to redundancy and less-than-optimal resource usage. Despite numerous training efforts developed in the region, country assessment tools performed by the international agencies (Performance, Vision and Strategy” (PVS) tool developed by IICA and PAHO) and surveys developed in the region (Cherry et al., 2015) still identify risk analysis as one of the technical areas that requires additional development of technical capacities.

In 2015, a group of individuals from these international agencies and US universities involved in food safety risk analysis capacity building in the region (authors of this paper) assembled to pull together a plan, beginning with this white paper on how we envision collectively working together to harness our existing training capacity to meet the growing food safety risk analysis needs for countries in Latin American and Caribbean Region. This led to the creation of the new Strategic Alliance on Risk Analysis Capacity Building (SARAC) with the objective to overcome some of the challenges mentioned earlier by bringing the agencies and universities together to develop a coordinated effort in risk analysis capacity building that will build trust and communication among all the entities that have food safety programs in the region.

Available training materials and tools at the Universities and International Organizations

There has been a substantial effort on regional capacity building led by the international agencies and universities to provide training in risk analysis. Some examples are presented below.

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS (FAO)

<http://www.fao.org/food/food-safety-quality/home-page/en/>

The implementation of the risk analysis framework, as the science advances, has brought about changes not only within national governments, but also inside FAO. This evolutive mindframe can be exemplified by the development of internal documents such as “FAO Guidance Materials on Improved Food Safety Risk Management considering multiple factors”. FAO supports the development of country capacities to effectively manage food safety and quality by providing scientific advice on specific food safety issues and guidance on a range of food control matters through training tools and other publications:

- Risk based Imported Food Control Manual. Rome 2015. <http://www.fao.org/3/a-i5381e.pdf> (Spanish version in press)
- A Handbook on Risk Communication applied to Food Safety (in Press) (Spanish version in review)
- Statistical Aspects of Microbiological Criteria related to Foods: A Risk Manager's Guide. MRA series 24 (in Press).
- Horizon Scanning and Foresight: An overview of approaches and possible applications in Food Safety. Rome 2014. <http://www.fao.org/3/a-i4061e.pdf>
- Multicriteria-Based Ranking for Risk Management of Food-Borne Parasites. Microbiological Risk Assessment Series (MRA) 23. Rome 2014. <http://www.fao.org/3/a-i3649e.pdf>

- Food Safety Risk Analysis Tools (<http://www.fstools.org/>) including the Risk Management Tool for the Control of Campylobacter and Salmonella in Chicken Meat (English and Spanish). The poultry tool contains case studies and guided exercises of increasing difficulty in both languages.
- Mycotoxin Sampling Tool <http://www.fstools.org/mycotoxins/>
- FAO/WHO National Food Control System Assessment Tool (to be released 2016).

INTER-AMERICAN INSTITUTE FOR COOPERATION IN AGRICULTURE (IICA) <http://www.iica.int/en>

IICA's mission is to encourage, promote and support the efforts of the Member States to achieve their agricultural development and rural welfare by means of international technical cooperation of excellence (IICA, MTP, 2014). Through the Agricultural Health and Food Safety Area provides technical cooperation to promote a productive, profitable, competitive agricultural sector that provides safe food to local, regional, and global markets through the application of appropriate sanitary and phytosanitary measures. In the area of food safety, to support governments in the modernization of AHFS services so that they have the necessary skills to meet market requirements and needs of consumers, and to adequately protect the health of humans, specific tools and capacity building initiatives have been developed:

- PVS tool with technical areas identified (<http://infoagro.net/programas/Sanidad/pages/modernizacion/pages/instrumentos.aspx>)
- Food safety inspection
- Online course on Quantitative Risk Assessment (microbial and chemical) through a virtual platform
- Online course on Risk Communication through a virtual platform

PAN-AMERICAN HEALTH ORGANIZATION

The aim of the Pan American Health Organization (PAHO), in food safety is to reduce the health, social and economic burdens of foodborne disease and food contamination. The achievement of this goal requires advocating and assisting member countries in the development of risk-based, sustainable, integrated food safety systems; developing science-based measures along the entire food continuum that would help prevent exposure to unacceptable levels of microbiological agents and chemicals in food; and assessing, communicating and managing foodborne risks, in cooperation with other partners. In addition, PAHO has the responsibility to support countries in complying with the International Health Regulations (IHR 2005). The training materials and other tools available at PAHO are:

- PULSENET for Latin America (<http://www.pulsenetinternational.org>)
- INFAL as the network of food laboratories in Latin America (<http://www.panalimentos.org/rilaa/ingles/index.asp>)
- GFN as the global network in enteric infections and detection labs (<http://www.who.int/gfn/en/>)
- Course on food attribution models for foodborne outbreaks (<http://bvs.panalimentos.org/php/index.php?lang=es>)
- Global course on Antimicrobial Resistance (<http://bvs.panalimentos.org/php/index.php?lang=es>)
- Course on Risk Analysis general awareness (<http://bvs.panalimentos.org/php/index.php?lang=es>)

- Use of SQMRA tool (<http://foodrisk.org/exclusives/sqmra/>)
- Course on advanced Quantitative Risk Assessment (Manual in Portuguese)
- (<http://bvs.panalimentos.org/php/index.php?lang=es>)
- Course on Meta-analysis and systematic literature review
(<http://bvs.panalimentos.org/php/index.php?lang=es>)

UNIVERSITY OF NEBRASKA -LINCOLN

- Graduate level course of Food Safety Risk Analysis
- Four-week international workshop “Microbial and Chemical Risk Analysis of Foods” in both English and Spanish
- Risk assessment research projects (Appendix 1)
- Texas Tech University
- Use of the web-based platform FAO/WHO JEMRA Risk Management Tool for the control of Campylobacter and Salmonella in Chicken Meat
- Poultry School en español workshop
- Food safety management workshops in the beef production chain
- Meat School en español workshop
- FSMA requirements for fresh produce
- Development of microbial baseline studies on the prevalence of pathogens

UNIVERSITY OF MINNESOTA

- Curriculum developed for courses (Spanish and English) on the use of risk prioritization tools (risk ranger, decision matrices and decision trees) to identify the food safety priorities (pathogens and chemicals) in a country or region including case studies and hands-on exercises.
- Curriculum developed for courses (Spanish and English) on the use of predictive microbiology tools (COMBASE), quantitative microbial and chemical risk assessment (@Risk and IRISK) and risk management tools (ICMSF risk management tool, cost-benefit analysis) including case studies and hands-on exercises.
- Curriculum developed for courses (Spanish and English) on how to implement a risk-based inspection and surveillance scheme in a country or region including decision trees to classify the food categories by the level of risk.
- Curriculum developed for courses (Spanish and English) on risk communication (entry and advanced level) including case studies and hands-on exercises.

UNIVERSITY OF MARYLAND-JIFSAN

- Online courses on Introduction to Risk Analysis, Qualitative and Quantitative Risk Assessment, Risk Management. <http://risk.jifsan.umd.edu/catalogue/>

- Intensive in-class room training in Risk analysis for technical analysts including: qualitative risk assessment, quantitative risk assessment (entry level and advanced), risk management, risk communication, risk analysis for risk managers, food defense, food law and regulation, epidemiology for risk analysts. <http://risk.jifsan.umd.edu/catalogue/>
- Training on modeling tools developed for the risk analysis community (i-Risk, R, FDA-iRISK®: a Comparative Risk Assessment Tool, U.S. EPA's What We Eat In America - Food Commodity Intake Database, ICRA: The Interactive Online Catalogue on Risk assessment, PPOD-Produce Point of Origin Database, HolyRisk: Scientific Uncertainty & Food Risk Regulation <http://foodrisk.org/>)
- In country trainings on Good Agricultural Practice, Good Aquacultural Practices with HACCP certification, Good Fishing Vessel Practices with HACCP certification, Food Inspection Training, Supply Chain Management for Spices and Botanical Ingredients, Inspection of Meat and Meat Products, Foodborne Illness Outbreak Investigations, Traceability, and Emergency Preparedness, Inspection of Dairy and Dairy Products, and Preventive Controls. <http://international.jifsan.umd.edu/>
- Hands on Laboratory methods (Microbial and chemical) training; including Whole genome sequencing. <http://ifstl.jifsan.umd.edu/>
- Conduct monitoring and impact evaluation on all trainings <http://research.jifsan.umd.edu/metrics/>

SUCCESSFUL EXAMPLES ON IMPLEMENTATION OF RISK ANALYSIS IN LATIN AMERICA AND THE CARIBBEAN

Changes at policy and legislative levels

FAO is providing technical and legal assistance to several countries in the region to update their food safety legislations, helping in the development of national food safety policy, reviewing the different laws for food safety, animal and plant health, within a risk analysis framework. This ongoing work strengthens national food safety systems, allows the countries to modernize their systems, and improves intersectoral coordination among government institutions responsible for food safety.

Implementation of risk-based inspection

At the request of the countries, FAO has assisted the Ministry of Agriculture in some LAC countries in the development of a risk-based inspection and surveillance scheme to improve allocation of resources (personnel and monetary) directed to high risk food safety areas. The different projects have focused on different commodities (dairy, meat, fresh produce, seafood, grains). The process followed different steps consisting of: 1) [Risk categorization of food products using decision trees for biological and chemical hazards, respectively] Develop a decision tree for each food production chain to categorize the food products as low, medium and high risk based on the presence of biological and chemical hazards, separately; 2) Identify the biological and chemical hazards to be present in each category; 3) Design a decision matrix to categorize the level of risk of the processing establishments based on the characteristics of the plant (HACCP, monitoring, traceability, etc.); 4) Design a score system to establish a risk-based inspection frequency; 5) Design a decision matrix to categorize the severity of the hazards present in the high risk categories; 6) Design a score system to establish a risk-based surveillance frequency for pathogens and chemicals.

Establishment of a Regional Virtual Food Inspection School in Central America and Dominican Republic

The project implemented by IICA responded to the need to harmonize food inspection protocols across the region to parallel the harmonization process that is taking place within the Central American economic integration and customs union processes. The creation of a cadre of food inspectors, trained in modern risk-based inspection techniques and having an attitude leading to proactive participation in the improvement of food safety in the region, contributes not only to eliminate or minimize incidents resulting in obstacles to trade, and to overcome the distrust of each country in the food inspection system of its regional partners, but also to continuous modernization and improvement of food safety regulations. Harmonized food inspection procedures across the region will make it easier to advance towards a customs union and positively impact the health of consumers. A virtual training on food inspection is now available at the IICA virtual platform.

Incidence of gastrointestinal illnesses and food attribution models

Several initiatives to develop regional or country baseline studies of incidence of gastroenteritis and food attribution models have been done by countries and facilitated by PAHO. In the Caribbean, studies were executed from 2008 to 2014 in eight countries (Barbados, Belize, Dominica, Grenada, Guyana, Jamaica, Saint Lucia, and Trinidad and Tobago) with the objective of understand the epidemiology of foodborne diseases, measure its burden and impact, and thereby develop appropriate prevention and control measures (Ahmed et al., 2013; Fletcher et al., 2013; Gabriel et al., 2013; Glasgow et al., 2013; Ingram et al., 2013; Lakhan et al., 2013; Persuad et al., 2013). Chile, Cuba and Argentina (Aguilar Prieto et al., 2009; Thomas et al., 2010 and 2011) and Costa Rica (unpublished data) also developed studies on gastroenteritis caused by microbiological hazards allowing the calculation of the burden of disease.

Besides these efforts, still few examples exist in countries in Latin America and the Caribbean on the systematic studies to evaluate the hazards in food, the likelihood of exposure to these hazards and their impact on public health. Different microbiological risk assessment studies conducted in Mexico, specifically in seafood, (Hernandez et al., 2014), in fresh produce for Latin America (Peña and Fernández, 2011) and egg production in Trinidad and Tobago (Indar et al., 2001) have pointed out the need of more microbiological risks assessments and risk communication.

Risk Assessment Unit

Colombia at the National Institute of Health has a Risk Assessment Unit for Food Safety which is a technical-scientific group with the responsibility of developing risk assessments to support risk managers in the developing appropriate measures to contribute to the health of the Colombian population. They have developed different risk assessments and risk profiles in microbiological hazards (*Listeria*, *Campylobacter*, *Salmonella*, *Bacillus cereus*, *Staphylococcus*) and chemical hazards (mercury, acrylamide, arsenic) in different food commodities. (<http://www.ins.gov.co/lineaaccion/investigacion/ueria/Paginas/publicaciones.aspx>).

SPS compliance

Latin American countries notify the World Trade Organization (WTO) concerning Sanitary and Phytosanitary (SPS) compliance under the food safety objective and/or rationale. An analysis performed between 2012 and 2016 (Jan-April) revealed 348 notified regulations, 238 (68,4%) related to maximum residues levels of pesticides, contaminants or veterinary drugs. Pesticides comprising the vast majority. 95 notified regulations (27,3%) are concerned to domestic requirements for products imports, production and or commercialization and

15 regulations (4,3%) are related to specific diseases control measures and/or programs or other matters. In 83,6% of the cases (291 notifications/regulations) the notifying country informed that no international standard was available, particularly in regulations concerning maximum residues levels of pesticides, contaminants or veterinary drugs. This data shows the importance of improving the LAC risk assessment capacities due to the lack of international standards on relevant matters, as well as the need for increasing support to the Codex Alimentarius Experts Committees in order to provide them an additional capacity to assess the risks of a higher amount of substances per year.

Implementation of a Regional Tourism and Health Program in the Caribbean

Tourism is the mainstay of many of the economies of Caribbean nations and contributes to more than 50 per cent of their gross domestic product (GDP). Closures of hotels and cruise ports due to outbreaks of communicable diseases, environmental challenges like climate change, and poor health and wellness in the tourism workforce, can result in significant losses in revenue. Outbreaks of food and water-borne diseases may be the most common health problem in visitors with major negative economic impact. In the early 2000's, within a five-year period, losses of over US\$250 million were estimated to have occurred in the Caribbean tourism industry due to preventable outbreaks. There is an innovative Regional Tourism and Health Programme geared at strengthening the links between tourism, health and environment for more resilient and sustainable tourism in the Caribbean. It works under the risk analysis framework including awareness raising for intersectoral and interagency collaboration, partnerships for addressing tourism and health as a joint priority, food safety and environmental management training and certification, public health surveillance and response systems and developing a healthy tourism workforce.

Proposed capacity building framework for the region

SARAC has the objective of developing a coordinated effort in risk analysis capacity building that will build trust and communication among all the entities that have food safety programs in the region. The proposed training and capacity building framework needs to meet the different audiences needs (academia, policy makers and industry) and countries with a different level of food safety infrastructure. Training can be focused on individual sectors or actors, or audiences can be mixed (government and academia, for example) to allow better communication and understanding of the different risk analysis roles (assessor and manager, for example).

In order to account for the different food safety infrastructure level in the countries, we propose to gather, and develop if needed, training materials for three levels:

- 1) Entry level: No previous exposure or training in risk analysis
- 2) Medium level: Previous training but no practical experience
- 3) Advanced level: Practical experience but only qualitative risk assessment or risk profile

A survey will be developed and disseminated among the countries in the region to know the level of risk analysis implementation and food safety infrastructure and classify the countries in each of those levels (1, 2 or 3).

For countries with no previous training on risk analysis (entry level or level 1) we propose to develop a training focused on:

- Sensitization on the role of the different sectors in the risk analysis framework (assessors and managers, independence, scientific process).
- Level up the technical concepts among all sectors.
- Scientific methods for data acquisition and systematic literature review.
- Provide practical examples and structure to introduce the risk concepts (including risk communication) into the decision making process in food safety.

This training will allow countries to build the risk analysis framework and understand the roles of the different sectors, the different technical documents needed for decision making (literature review, risk profile, quantitative risk assessment) and the risk communication principles.

For countries with previous training but no practical experience in risk analysis (as they are ready to implement the concepts into the decision making process), we propose to develop a training focused on:

- Risk-based inspection and surveillance
- Baseline studies and sampling plans (e.g. FAO/WHO generic sampling plan, aflatoxins and histamine)
- Risk prioritization (e.g. use of decision matrices, decision trees, risk ranger)
- Risk profiles (microbiological and chemical)

This training will allow countries to establish risk-based sampling and inspection focused on the high risk foods consumed in the country, to obtain information regarding the prevalence of pathogens and chemicals in high risk food commodities and develop risk profiles and qualitative risk assessments that will serve as the basis for policy making or the need of a more in-depth quantitative risk assessment.

For countries with practical experience in risk analysis and implementation in the country but only applying qualitative assessments, we propose to develop training focused on:

- Modeling tools and software (COMBASE, FAO/WHO Poultry Tool, FDA Irisk, @Risk)
- Cost-benefit analysis

This training will allow countries to develop their own quantitative risk assessments in particular food safety issues that have identified as a priority in previous trainings.

Countries with higher level of risk analysis implementation will help to deliver the courses by showing case studies based on their own countries. This will help countries less developed to better prepare for further implementation. All the trainings will include an evaluation and mentoring piece to assure the desired impact is achieved. After the trainings each country will be assigned to develop a risk analysis project in the country aimed to put in practice all the tools learned during the training.

A continuous process of information exchange, case studies presentation and sharing applied research would occur on a biannual basis. This exchange will take place through the establishment of conference and symposia that will be in different countries. This biannual conference will generate data and knowledge that will improve

the current conditions in risk analysis in the Americas. Training and workshops will take place before and after the conference and an integral part of SARAC.

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APPENDIX I

Current Capacity within SARAC Member Organizations

Food and Agriculture Organization (FAO) of the United Nations and World Health Organization (WHO)

FAO and WHO are the main specialised UN agencies with a mandate to address food safety and quality issues. Through their complementary mandates, FAO and WHO cover a range of issues to support global food safety and protect consumer's health, typically with WHO representing issues related to public health and FAO issues related to food production along the food chain. Activities may be implemented jointly at country level or through global joint programmes (e.g. scientific advice, INFOSAN, etc), while both Organizations also have an active programme of work implemented independently.

FAO and WHO work with government authorities, food industry and producers, and other relevant stakeholders to improve systems for ensuring food safety and quality based on scientific principles, with the aim of reducing foodborne illness, protecting consumer's health and supporting fair and transparent trade. Safe-guarding public health, contributing to economic development and improving livelihoods and food security are at the centre of this work.

FAO and WHO are engaged in a wide range of capacity building activities which take place in a number of different contexts, including at country level, through technical and policy meetings as well as deskwork to prepare and/or review guidance materials and project proposals. These capacity development activities directly support the Codex Strategic Plan 2014-2019.

Both international organizations provide scientific advice, within the risk analysis framework, to the Codex Alimentarius Commission (CAC) through the joint administration of three international expert ad hoc scientific committees: the Joint FAO/WHO Expert Committee on Food Additives (JECFA), the Joint FAO/WHO Meeting on Pesticide Residues (JMPR), and the Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment (JEMRA). The results from these expert meetings are used in the development of Codex texts and standards. They can also be used by member countries of FAO and WHO to strengthen science-based decision making on food safety issues at national and regional levels.

JECFA (<http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/es/>)

JECFA has been meeting since 1956, initially to evaluate the safety of food additives. JECFA has evaluated more than 2,500 food additives, approximately 40 contaminants and naturally occurring toxicants, and residues of approximately 90 veterinary drugs. The Committee has also developed principles for safety assessment of chemicals in foods that are consistent with current thinking on risk assessment and take account of developments in toxicology and other relevant sciences. The areas of work: are risk assessment/safety evaluation (food additives, processing aids, flavoring agents, residues of veterinary drugs in animal products, contaminants, natural toxins), exposure assessment, specifications and analytical methods, and development of general principles. JECFA publications are available on the following websites:

- FAO <http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-publications/en/>
- WHO <http://www.who.int/foodsafety/publications/jecfa/en/>

JMPR (<http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmpr/en/>)

JMPR has met annually since 1963 to conduct scientific evaluations (risk assessment) of pesticide residues in food. It provides advice on the acceptable levels of pesticide residues in food moving in international trade. JMPR consists of independent internationally-recognized specialists who act in a personal capacity and not as representatives of national governments. The current JMPR comprises the WHO Core Assessment Group and the FAO Panel of Experts on Pesticide Residues in Food and the Environment. The WHO Core Assessment Group is responsible for reviewing pesticide toxicological data and estimating Acceptable Daily Intakes (ADI), acute reference doses (ARfDs) and characterizes other toxicological criteria. The FAO Panel is responsible for reviewing pesticide data residue and for estimating maximum residue levels, supervised trials median residue values (STMRs) and highest residues (HRs) in food and feed. The output of JMPR constitutes the essential basis for Codex maximum residue levels (MRLs) for food and agricultural commodities circulating in international trade. Its health-based guidance for pesticides (i.e. ADIs and ARfDs) and recommended maximum residue levels also benefit the governments of the member countries and regions. JMPR publications are available on the following websites:

- FAO <http://www.fao.org/agriculture/crops/core-themes/theme/pests/jmpr/en/>
- WHO <http://www.who.int/foodsafety/publications/jmpr/en/>

JEMRA (<http://www.fao.org/food/food-safety-quality/scientific-advice/jemra/en/>)

JEMRA began in 2000 in response to requests from the Codex Alimentarius Commission and FAO and WHO Member Countries and the increasing need for risk based scientific advice on microbiological food safety issues. JEMRA aims to develop and optimize the utility of Microbiological Risk Assessment (MRA) as a tool to inform actions and decisions aimed at improving food safety and available to both developing and developed countries. The use of microbiological risk assessment in food safety risk management is an area that is still developing. MRA is a useful decision-support tool that requires risk managers to understand when and how it can be used. JEMRA publications are available on the following websites:

- FAO <http://www.fao.org/food/food-safety-quality/scientific-advice/jemra/risk-assessments/en/>
- WHO <http://www.who.int/foodsafety/publications/microbiological-risks/en/>

FAO and WHO have other related activities that can support the development of risk analysis in the countries such as:

1. Improvement of data sharing. The GEMS/Food system is a web-based platform designed to facilitate the sharing of chemical monitoring data and of food consumption data (<https://extranet.who.int/gemsfood/>). The website is accessible for all National Institutions willing to support the international risk analysis process i.e. FAO/WHO Scientific Advice and Codex Alimentarius. Codex Members are encouraged to contribute to this important resource tool and also to use the information available.
2. Global Food Consumption Databases. Reliable information on food consumption collected at individual level is needed to estimate nutrient intake and to identify key sources of nutrients in the diet. To address the issue of insufficient access to such data, FAO and WHO are developing the pilot version of a tool called FAO/WHO GIFT (FAO/WHO Global Individual Food consumption data Tool). This comprehensive database will collate micro data for the production of indicators in the field of nutrition, dietary exposure and environmental impact. The pilot version is under development based on four datasets from low income

countries. The food categorization system is the one developed by the European Food Safety Authority (EFSA) which was implemented for use at global level. For more information, visit <http://www.fao.org/food/nutrition-assessment/foodconsumptiondatabase/>.

3. WHO also improved the tools available for Member States to access data and information (<http://www.who.int/foodsafety/databases/en/>). In particular WHO launch a series of “dashboard” displaying the assessments done by FAO/WHO Expert Committees together with Adopted Codex Maximum Limits and other relevant information. Currently, dashboards for contaminants and pesticides are available, and for veterinary drugs the development is on-going.
4. FAO GM Foods Platform (<http://fao.org/gm-platform>): In response to Codex members’ needs and expressed during the side event organized at the Commission in 2015, FAO has further improved the FAO GM Foods Platform, an online platform to share data and information on the conduct of food safety assessment of foods derived from recombinant-DNA plants according to the relevant Codex guideline (CAC/GL 45-2003, annex III adopted in 2008) ". As of May 2016 a total of 173 countries have nominated Focal Points to the Platform and 168 countries registered to the Platform. The Platform is currently hosting a total of 897 records of national safety assessment data. All countries are requested to nominate their Focal Points and actively share relevant data and information with regards to national GM food/feed safety assessment. Contact GM-Platform@fao.org for questions and comments.

University of Nebraska-Lincoln

- Quantitative risk analysis training via distance

UNL has worked with Inter-American Institute for Cooperation on Agriculture (IICA) to provide a four-week international workshop “Microbial and Chemical Risk Analysis of Foods” from July 13 to August 07, 2009. A total of 62 participants from 10 Latin American countries attended the workshops with training materials and videotaped lectures available in DVDs. Training materials were provided in both English and Spanish. During the workshop, the following topics are covered, including strategies to develop risk assessment models, demonstrations showing @Risk and Analytica software for developing risk models, case examples of WHO and United States Department of Agriculture (USDA) risk assessments, interpretation of risk assessment outputs for risk management decision making, and risk communication.

- Food allergen risk assessment training and research

The Food Allergy Research and Resource Program (FARRP), at the Department of Food Science and Technology, University of Nebraska-Lincoln has collaborated with TNO in the Netherlands to develop quantitative (probabilistic) models for the purposes of food allergen risk assessment and management. The risk assessment approach utilizes an extensive database of clinical threshold data from allergic individuals (co-owned by FARRP and TNO) and dietary consumption databases to evaluate the potential risk associated with accidental exposure to food allergen residues. This research and outreach effort aims to provide scientific support for accurate food labelling and food allergen mitigation strategies. Selected research examples include 1) the quantitative evaluation of levels of unintended food allergens in pre-packaged foods bearing precautionary allergen statements and the potential risk to allergic consumers in the United Kingdom, 2) quantitative risk assessment to assist with determining when advisory labeling is most appropriate, demonstrated by the example of advisory labeling of may containing peanuts in nutrition bars, and 3) the use of quantitative risk assessment to evaluate the potential allergenic risk associated with commingled grains.

- Graduate semester long course on quantitative risk assessment

UNL is offering a graduate level course of Food Safety Risk Analysis. It is an introductory course that applies risk assessment methods to real-world food safety issues. The course covers an introduction of risk analysis principles applied food safety issues, introduction to quantitative approaches that are commonly used for quantitative risk assessment, such as epidemiological, statistical and simulation tools, overview of risk-risk, risk benefit trade off analysis, introduction of risk communication and risk management. Real-world examples are used to explain the principles, including microbial risk assessment, food allergen risk assessment, nutritional risk assessment and chemical risk assessment. Students are also expected to complete term project in groups by the time of course end. List of lectures throughout the course include:

1. Introduction/Overview and History of Risk Analysis
2. Risk Assessor's toolbox 1 – Epidemiology and Evidence Synthesis
3. Risk Assessor's toolbox 2 – Statistics and Probability
4. Risk Assessor's toolbox 3 – Microbiology, Food Allergy, Toxicology
5. Case example – Foodborne Pathogens in Red Meat
6. Problem Formulation and Hazard Identification
7. Exposure Assessment – Model Building and Simulation for Different Hazards
8. Hazard Characterization – Dose-response Model for Different Hazards
9. Risk Characterization – Sensitivity Analysis, What-if Scenario Analysis, Common Health Metrics of disease burden, Risk-risk/Risk-benefit trade-offs and Cost-effectiveness Analysis
10. Term Project - First Presentation
11. Case example – Food Allergen Risk Assessment
12. Case example – Chemical Hazards in Food
13. Case example – Nutritional Risk-benefit Analysis
14. Risk Management
15. Risk Communication
16. Final Presentation and Final Report

Texas Tech University

FAO/WHO Poultry tool and Food safety

The FAO/WHO JEMRA Risk Management Tool for the control of *Campylobacter* and *Salmonella* in Chicken Meat is a web-based platform that allows risk managers at official or industry levels to consider processing scenarios, and account for the residual risks associated with the implementation of interventions in the line to control pathogen levels (both prevalence and concentration per carcass). A similar guidelines has also been published by the USDA-Food Safety and Inspection Service (FSIS) and other poultry trade associations. These guidelines have been used to develop a training curriculum focused in describing the implications of each processing step in the potential contamination of poultry products, and the alternative control measures that can be implemented to reduce such risk. The tool has been reviewed by a panel of experts and has since been described in a series of training workshops worldwide. The workshops have been planned to describe the steps in the poultry production and processing chain, and the effect of control measures on pathogen contamination

levels. The workshops are then focused in familiarizing participants in how to utilize the risk management tool, how to input information, and how to build a processing scenario, input control measures effects, interventions and final model results. The output provides users with a residual risk value that supports the effect of a particular control measure on prevalence and concentration of both pathogens for decision making purposes. Workshops have been conducted by FAO, IICA, University of Minnesota and Texas Tech University in: Panama (participants from Mexico, Belize, Guatemala, El Salvador, Honduras, Nicaragua, Costa Rica, Panama and Dominican Republic), Chile, Colombia and Uruguay.

Poultry production chain risk analysis training

The risk analysis framework concepts have been incorporated in food safety training workshops focused in the poultry chain and conducted by IICA and Texas Tech University on an annual basis during the Poultry School en español workshop. This recurrent event is held every January in conjunction with the International Poultry Production and Processing Expo (IPPE) in Atlanta and has received participants from all Spanish-speaking countries in Latin America, and the major poultry processing operations in such countries, for a total of 10 editions with 45 participants annually. A separate edition in Portuguese has also been conducted in Brazil from 2011 until 2013 and is called the Escola de Processamento Avícola, this partnership between SENAI-Brazil, IICA and Texas Tech University will be relaunched in 2016. In addition, on-demand food safety workshops coordinated with trade associations and official institutions have been conducted in Colombia, Panama, Dominican Republic, Uruguay, Ecuador, Nicaragua and Honduras. Individual talks that incorporate the risk analysis framework concepts applied to poultry production and processing for pathogen control have also been conducted in: Mexico, Honduras, Argentina, Chile, Colombia, Ecuador, Peru, El Salvador, Uruguay, among others. Therefore, processors and personnel from government institutions have become familiar with the risk analysis framework and the application of these concepts to support risk management programs in the poultry production and processing industry in the region. However, the outcome of such capacity building activities has not been formally measured, and it is just based on anecdotal experiences that can be described on a country-by-country basis. Nonetheless, it is well-known that these concepts and tools are now actively being used in Colombia, Chile, Panama and Honduras, not only by processors in their food safety management systems, but also by regulators in their inspection systems and priorities.

Beef production chain risk analysis training

A similar approach has been applied for the beef production and processing value chain. A series of food safety management workshops, conferences and symposia have been delivered in the region, with the focus of including risk analysis framework concepts as they apply for the control of pathogens in the meat chain, and as they interact with good production and processing practices, HACCP implementation, and consumer handling practices. These activities have included special emphasis in controlling contamination of meat with enterohemorrhagic *Escherichia coli*, and the associated shiga toxin-producing strains: O157:H7, O26, O45, O104, O111, O145, O103. Texas Tech University, the University of Nebraska-Lincoln, the University of Minnesota have conducted week-long workshops and specific conferences describing the risk analysis framework concepts as they apply to risk management efforts in the beef processing value chain. Activities have been conducted in: Brazil, Argentina, Uruguay, Colombia, Panama, Dominican Republic, Nicaragua, Honduras and Mexico. In addition, Texas Tech University launched the Meat School en español workshop in 2015 in Lubbock, Texas, where the concepts of risk analysis are included in the food safety talks related to the beef and pork value chains.

This workshops will also be held annually with expected participation of countries in the Latin American region as is the case for the poultry-focused counterpart.

Produce

Some activities have been conducted in the region with the focus on produce safety. A significant factor for the increase in produce safety efforts, is the approval process of the Food Safety Modernization Act (FSMA), a regulatory update for food safety inspection of produce production and processing operations in the U.S. but with implications for trade partners in the region. A series of capacity building activities describing these requirements have been coordinated by IICA and Texas Tech university in partnership with USDA, USAID and local governments in: Guatemala, El Salvador, Honduras, Nicaragua, Costa Rica, Panama, Dominican Republic, Jamaica, Barbados, Trinidad and Tobago, Colombia, Peru and Paraguay. In addition, a series of web conferences have been coordinated by IICA in all countries in the region to discuss the reach and impact of these FSMA rules on produce safety in the region, especially countries exporting produce to the U.S.

Similar efforts have been conducted in the region by several institutions including IICA, OIRSA, and government agencies, trade associations and exporting promoting entities to focus on Good Agricultural Practices. However, the incorporation of risk-based concepts in these activities has not been a priority.

IICA

Establishment of a Regional Virtual Food Inspection School in Central America and Dominican Republic

The project implemented by IICA with financial resources of the Standard Trade and Development Facility (STDF) started in 2012 and ends in June 2016, responds to the need to harmonize food inspection protocols across the region to parallel the harmonization process that is taking place within the Central American economic integration and customs union processes. The creation of a cadre of food inspectors, trained in modern risk based inspection techniques and having an attitude leading to proactive participation in the improvement of food safety in the region, contributes not only to eliminate or minimize incidents resulting in obstacles to trade, and to overcome the distrust of each country in the food inspection system of its regional partners, but also to continuous modernization and improvement of food safety regulations. Harmonized food inspection procedures across the region will make it easier to advance towards a customs union and positively impact the health of consumers.

General objective: To improve the safety of fresh and processed food products from the region, and thus facilitate trade and improve public health, through harmonized, modern inspection procedures conducted by a properly trained cadre of food inspectors and food safety auditors in all countries of the region through the implementation of a virtual training course for food inspectors and a course for food safety auditors consistent with modern food inspection and food safety assessment techniques and responding to the national, regional and international needs of

Results:

Virtual Training on Food inspection is now available at the IICA virtual platform

Two installments of the training for food inspectors (staff of the Ministers of Health and Agriculture) has been delivered:

- 214 inspectors finished the first training on food inspection
- 586 inspectors started the second course on food inspection
- network of food safety experts from the academia supporting the initiative. Seven letters of agreement were signed with Universidad Jose Matias Delgado (El Salvador), Universidad Rafael Landivar (Guatemala), Universidad Nacional de Agricultura (Honduras), UNAN Leon (Nicaragua), Universidad de Costa Rica (Costa Rica), Universidad de Panamá and Universidad ISA (Dominican Republic).
- The initiative has been added to the agenda of the Agricultural Health and Food Safety Technical Group led by OIRSA under the framework of the Central American Agricultural Council (CAC)
- Virtual training on food safety auditing will be available in July 2016.

APPENDIX II

Summary of Risk Analysis Examples

➤ Economic impact – UNL

- Modeling food safety and economic consequences of surveillance and control strategies for Salmonella in pigs and pork
- This study was aimed to evaluate the food safety and economic consequences of different surveillance and control strategies for Salmonella in pigs using an epidemiological model and an economical model (cost-effectiveness analysis). A stochastic simulation model with two modules was developed, one epidemiological and the other economical. The epidemiological model allows us to simulate the changes in prevalence on the carcasses and the economic one to assess the economic efficiency of each of the surveillance and control scenarios. The cost-effectiveness of three interventions – steam vacuum (SV), hot-water decontamination (HD) and steam ultrasound (SU), in combination with the slaughterhouse size (small, medium and large), were simulated to assess the best reduction procedure of prevalence of Salmonella on pigs and hog carcasses. Data needs for the epidemiological model are two Salmonella baseline studies in Denmark and surveillance data from the Danish Agricultural & Food Council. Pig populations and slaughterhouse sizes were provided by the Danish Veterinary and Food Administration. Data required for the economic model are intervention costs for SV, SU and HD and prevalence-cost ratio from literature. Based on the slaughterhouse size and a series of interventions, nine scenarios were proposed. The most cost-efficient and lowest overall cost scenarios were SV in small and medium sized slaughterhouses and SU at large slaughterhouses, or SV in small sized slaughterhouses and SU at medium and large slaughterhouses. Through a combination of quantitative microbial risk assessment and economic analysis, the most cost-effective alternatives to reduce the prevalence of Salmonella in pigs and pork can be determined and allows scientists to systematically determine the data needs and regulatory agencies to effectively allocate resources.

[Baptista, F. M, Halasa, T., Alban, L., and Nielsen, L. R. 2011. Modeling food safety and economic consequences of surveillance and control strategies for Salmonella in pigs and pork. *Epidemiological Infection*. 139: 754-764.]

- Streamlined analysis for evaluating the use of preharvest interventions intended to prevent Escherichia coli O157:H7 illness in humans

This study was aimed to demonstrate the usefulness of an integration of quantitative risk assessment and marginal economic analysis in the development of food safety policies. Through a hypothetical E. coli O157:H7 vaccine in cattle, the reduction in illness in human caused by consuming beef was simulated. Data required for the analysis include epidemiological data such as, number of human illnesses due to E. coli O157:H7 and outbreak surveillance data from Center for Disease Control (CDC), together with veterinary data such as number of E. coli O157:H7 colonized cattle slaughtered each year and prevalence of E. coli O157:H7 in the U.S. cattle among others. An optimal illness prevention cost was determined. The prediction model provides useful information considering changing scenarios (such as the vaccine price). The optimal illness prevention estimate provides very useful information about how many cattle heads should be vaccinated in order to obtain a cost-effective reduction in illnesses caused by consumption of beef. The simulations were run successfully and the research team was able to prove the usefulness of this model based on the hypothetical model. Through quantitative microbial risk assessment

and the marginal economic analysis procedures, prediction models can be established to give risk managers the best information to implement cost-effective interventions to prevent human illnesses.

[Withee, J., Williams, M., Disney, T., Schlosser, W., Bauer, N., and Ebel, E. 2009. Streamlined analysis for evaluation the use of preharvest interventions intended to prevent *Escherichia coli* O157:H7 illness in humans. *Foodborne Pathogens and Disease*. 6(7): 817-825.]

➤ Nutrition – UNL

- Integrated risk-benefit analyses: method development with folic acid as example

This study presented an application of quantitative risk-benefit analysis in aiding the development of nutrient related regulatory standards. The example is used to demonstrate the usefulness of quantitative risk-benefit analysis in the field of nutrition in the determination of appropriate fortification level of folic acid in bread products in Netherland. Several different health outcomes with various severity are holistically included in the model to evaluate the association between the probability of those outcomes and consumption level of folic acid. The disability-adjusted-life-years (DALY) was used to combine the health outcomes as a common health measure to qualify the effect of different fortification levels of folic acid in bread on the overall public health risks. The findings suggested that a modest fortification level (140ug/100g bread) seems reasonable to improve public health. The case study showed how the risk-benefit approach may assist a policy maker in decisions on food fortification programs.

[Hoekstra, J., Verkaik-Kloosterman, J., Rempelberg, C., van Kranen, H., Zeilmaker, M., Verhagen, H., and de Jong, N. 2008. Integrated risk-benefit analyses: method development with folic acid as example. *Food and Chemical Toxicology*. 46:893-909.]

➤ Natural resources: UNL

- An operational agricultural drought risk assessment model for Nebraska, USA.

This study was conducted in Nebraska, where drought is a common issue (especially for the agriculture sector). The model includes multivariate techniques. It is specific for corn and soybeans crops and evaluates real-time-agricultural drought risk, related to yield losses at phonological critical stages before and during the growing season. This program provides information for the decision making process associated to the impacts of drought on dryland crop yield, before growing season. The average possibility to assess correctly corn yield before growing season on dryland was 65.3%. This study shows that assessing drought risk before growing season is feasible with the use of weather information. The rate accuracy is higher as the grown stage progress for corn. The same was observed in soybean, but this crop showed more resistance to water stress. Results from this study provides key information for the decision making process related to agricultural issues. Stakeholders can create strategies to reduce potential economic losses due to drought before plantation.

[Hong, W., and Donald, A. W. 2003. An operational agricultural drought risk assessment model for Nebraska, USA. National Drought Mitigation Center, University of Nebraska, Lincoln, Nebraska, 68583-0728, USA.]

- Assessing risk of heavy metals from food grown on sewage irrigated soils

In this study, contamination by heavy metals at Musi River and its environs was evaluated. Metals assessed included Zn, Cr, Cu, Ni, Co and Pb. Metals residues were determined in products like forage grass, milk from cattle, leafy and non-leafy vegetables. The partitioning model in soils reflected high

levels of labile fractions of these metals, which made them more mobile and accessible for plants. The risk in human health due to consumption of the evaluated products, was evaluated by measuring the concentration of metals in venous blood and urine samples. A hazard quotient (HQ) was calculated using the following equation: $(W \text{ plant}) \cdot (M \text{ plant}) / (RfD \cdot B)$, where W plant is the amount of contaminated product consumed per day measured in dry weight (mg/d), M plant is the metal density found in vegetable(s) (mg/kg), RfD are reference doses values, B is the average weight of an adult (68 kg). Compared to acceptable levels, the results showed high levels of Pb, Zn, Cr, and Ni, mainly in leafy vegetables and especially in spinach and amaranth. This investigation suggests that irrigation water from this region should be treated before its usage until the HQ reach values less than one, in order to reduce the adverse effect in human health. Results from this study will offer key information to the risk management decision, on the water sources that are safe to be used in irrigation. In addition, it provide insights in the level of treatment required to bring irrigation water quality to levels that are safe to be use in the food production. Consequently, standards or regulations can be established considering the risk of heavy metal residues and their effects on health.

[Sridhara Charya, C.T. Kamalaa, D. Samuel Suman Rajb. 2008. Assessing risk of heavy metals from consuming food grown on sewage irrigated soils and food chain transfer. *Ecotoxicology and Environmental Safety*. 69 (3): 513–524.]

- Application of microbial risk assessment to the development of standards for enteric pathogens in water used to irrigate fresh produce

Nonpathogenic surrogates (coliphage PRD1, and E. coli ATCC 25922) were used to evaluate two methods of irrigation: subsurface drip and furrow. A quantitative microbial risk assessment was used to determine the maximum concentration of the surrogates that can be present in irrigation water, in order to comply with the 1:10000 annual risk of infection for hepatitis A virus (HAV) and Salmonella established by the U.S. Environmental Protection Agency. The risk of infection depends on the type of crop, the system of irrigation, and the interval of time between the last irrigation and harvest. Microbial concentration one day after irrigation were 0.7 and 2.1×10^{-2} MPN/100 ml in Cantaloupe, Not detected value and 7.3×10^{-5} MPN/100 ml in lettuce and not detected values in bell peppers for subsurface drip and furrow, respectively. Microbial counts 14 days after irrigation were 1.4×10^6 and 1.7×10^4 MPN/100 ml in Cantaloupe, 1.7×10^9 and 1.2×10^7 MPN/100 ml in lettuce and not detected values in bell peppers or subsurface drip and furrow, respectively. The values for Salmonella one day after irrigation were 5.9×10^2 and 7.4 CFU/100 ml in cantaloupe, 6.2×10^6 and 1.5×10^2 CFU/100 ml in lettuce and not detected values in bell pepper for subsurface drip and furrow, respectively. The values 14 days after irrigation were 1.4×10^6 and 1.7×10^7 CFU/100 ml in cantaloupe, 4.2×10^6 and 9.1×10^1 CFU/100 ml in lettuce and not detected values in bell peppers for subsurface drip and furrow, respectively. The worst-case scenario simulated was product consumption one day after the last irrigation. Under such conditions, an annual risk of 1:10000 can be reached when concentrations of 2.5 CFU/100 ml and 2.5×10^{-5} MPN/100 ml (for Salmonella and HAV, respectively) are present in irrigation water. When harvest occurs two weeks after last irrigation, concentrations can reach 5.7×10^3 CFU for Salmonella and 9.9×10^{-3} MPN for HAV per 100 ml. This study provided maximum concentration levels of pathogenic bacteria and virus in irrigation water to avoid exceeding the maximum annual risk of infection. Results from this study contribute to risk management on establishing maximum acceptable limits on target microorganism present in irrigation water.

[Stine, S. W., Song, I., Choi, C. Y., Gerba, C. P. 2005. Application of microbial risk assessment to the development of standards for enteric pathogens in water used to irrigate fresh produce. *Food Protection* (5): 900-1111, 913-918.]

➤ Waste/losses reduction: UNL

- Human risk assessment of organic contaminants in reclaimed wastewater used for irrigation

Today most of the regulations for reclaimed wastewater, are concentrated in hazards related to microorganisms. However, guidelines for chemical parameters are not well estimated. The study analyzes the functions of hazard identifications, exposure assessment, and the distinguishing of the dose-response relation for chemical hazards. Trichloroethane, and others chlorinated solvents are widely employed in industrial agriculture, thus they have been detected in the aqueous environment in the lower concentration (ng/L) Three chemicals were chosen in this study (chloroform, 1,1,2-trichloroethane and pyrene). The risk was calculated from the ratio of the predicted environmental concentrations and the predicted no effect concentrations. A value lower than 1, was considered to be an acceptable level of risk. The calculated values were: chloroform (10^{-7}), pyrene (10^{-7}) and 1,1,2-trichloroethane (10^{-6}). The simulation model showed that the three chemicals included in the theoretical analysis represent an acceptable risk for population via the single pathway of exposition considered (consumption of crops grown in irrigated soil). Results indicate that the evaluated components are not chemical hazards and therefore do not represent a risk for human health. The study contribute to risk management decision on the selection of contaminants that should be monitored in irrigation water.

[Webera, S., Khanb, J., Hollendera, N. 2006. Human risk assessment of organic contaminants in reclaimed wastewater used for irrigation. *Desalination*. 187 (1–3): 53–64.]