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Commentary

Investments in Food Safety Risk Assessment and Risk Analysis as a Requirement for Robust Food Control Systems: Calling for Regional Centers of Expertise

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Abstract

Risk Assessment is the scientifically-based process that characterizes the possible human health implications of hazards found in food. This scientific approach is part of the risk analysis paradigm that governs the food decision-making process. It is a prerequisite for the development and execution of robust and consistent food safety regulatory decisions. This paper reviews food regulatory decision-making scenarios where risk assessment plays a key role. It discusses challenges associated with the access to capacity and competencies from various disciplines necessary to enable risk assessment and overall risk analysis. The paper illustrates the urgent need for the provision of additional support to capacity building initiatives in this area by means of mutually beneficial resource-sharing with the objective to establish regional and/or sub-regional centres of food regulatory science, including expertise in risk assessment. Regional Centres of Expertise may be the answer to provide the needed competencies and up-to-date tools to operationalize food regulatory systems, where food risk analysis is the foundation of decision-making, as advocated by the guidance of the Codex Alimentarius commission. It may also be the response to support economic regional integration, where food and agrifood trade needs to be supported by the removal of Sanitary and Phytosanitary (SPS) constraints and through achieving a more coordinated and harmonious food safety standard setting framework, at the regional level.

Food safety continues to be a key public health issue for all countries and regions of the world[1] and an essential driver for the trade of food and agri-food commodities. The Codex Alimentarius Commission (CAC) – the international food safety standard setting body – has recommended that food safety regulatory decisions be based on a structured science-based decision-making process with three distinct but closely interconnected components: Risk Assessment, Risk Management and Risk Communication (Figure 1)[2].

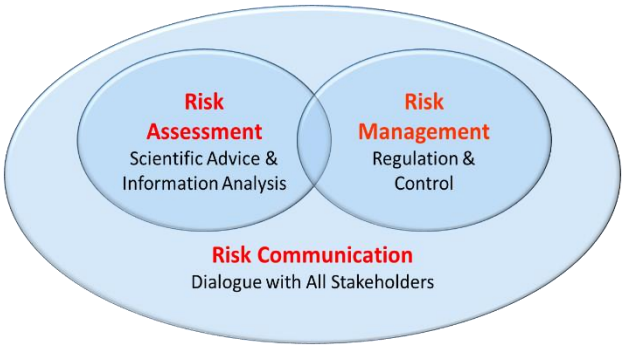

Figure 1: Representation of the Food Risk Analysis Principle advocated by the Codex Alimentarius Commission[3]

The CAC also called for "constant interactions between risk managers and risk assessors within an environment characterized by risk communication". Risk analysis is in fact most effective when all three components are successfully integrated as part of the food safety decision-making framework. Application of the risk analysis paradigm results in decisions that are more likely to be consistent, and in proportion with the health risks being managed, given that they are anchored in the analysis of the scientific and other policy evidence, according to agreed-upon methodologies. Risk analysis also allows a country's obligations under the Sanitary and Phytosanitary Agreement (SPS) to be met, supports the credibility of the food control system and contributes to identify gaps and uncertainties in scientific knowledge, which in turn drives the establishment of food safety research priorities.

Importance of Risk Assessment

Risk Assessment is the science-based process that characterizes the possible health implications of a given hazard in food when consumed by humans[4]. It can define a hazard's occurrence and transmission at various stages from food production to consumption, is supportive of risk estimation and can account for the relative impact of food control measures employed to mitigate such risks – this is particularly applicable for microbial hazards.

Risk assessment can also represent a "safety evaluation" – relevant, more specifically, to chemical hazards – aimed at characterizing the situation where consuming a food carrying such hazards would pose no appreciable health impact for the consumer. It is this scientific approach, based on sound methodologies, when executed correctly that supports both robust and consistent food safety regulatory decisions.

Generally, a food safety competent authority strives to be the most trusted organization within a given jurisdiction and is regarded by other stakeholders, in particular consumers and food industry actors, to be the reference and focal point for food safety decisions. They offer advice, guidance and apply the required regulatory and non-regulatory measures with the objective to protect consumers and ensure a fair environment for food trade. Adopting a decision-making framework based on the risk analysis paradigm, with risk assessment as the foundation for the development of management options, enables a food safety competent authority: (1) to ensure consistent food safety decisions within their district of oversight and in alignment with international partners; (2) to support cost effective measures that are justified and commensurate with the risk being managed and; (3) to provide a predictable food safety regulatory environment that is more conducive

to investments in the food and agri-food production sectors and is supportive of fair trade in food and agri-food commodities.

When is Risk Assessment Needed?

A food safety competent authority will conduct a risk assessment in response to, at minimum, two situations:

a. Managing Food Safety Incidents and Foodborne Illness Outbreaks

Food safety incidents associated with the occurrence of hazards in foods, regardless if they lead to illnesses and/or outbreaks, should be managed on the basis of science-based risk assessments. The result of these assessments should underpin food regulatory decisions on the ground, including but not limited to product recall, product seizure, interruption of a food business operation and advice to consumers. A capacity is therefore needed to undertake such assessments on a regular basis and in a timely manner in order to protect consumers' health and to avoid any unduly detrimental impact on food business operators. It is therefore indispensable for food safety competent authorities, tasked with the management of food safety incidents, to be equipped with a skillfully trained human resource capacity to carry out the function of rapid risk assessment, which are assessments undertaken in a short period of time, to address a given food safety incident, based on the information available at a given time. It is also essential that internal procedures and protocols be developed for this function to be exercised in a consistent fashion and synchronized with the occurrence and identification of the food safety incident. The same methods and scientifically-based approaches should be applied for food safety incidents involving both domestically produced and imported food. Applying this overall approach supports consistency of food safety management decisions and contributes to the predictability of each jurisdiction's food regulatory environment.

b. Development of Domestic and Regional Food Safety Standards

Reliance upon food safety standards anchored in a scientific assessment is paramount to ensure their acceptability by domestic and international stakeholders, as well as to satisfy obligations of the SPS agreement regarding predictability, consistency and fairness as they relate to food safety regulatory provisions. The development of these risk assessments is necessary whether the intention is to adapt an international (Codex) standard before its adoption or to develop a new standard to address a country or region's needs. While scientific assessments to ensure the adaptation of a given international standard to the national situation – accounting for domestic food exposure scenarios and food production practices – are more accessible to national regulators, assessments required to derive a new standard can be very resource intensive. Capacity building programs and investments in the development of risk assessment and food regulatory science competencies, tools and procedures need to be envisaged in a realistic and feasible manner such that they address these needs. This is required to help propagate food risk analysis as the foundation of food regulatory decisions and to strive towards the harmonization of food safety measures at the regional and international level.

Benefits and Consequences of Adopting Food Safety Risk Assessment as Part of Competent Authorities' Food Decision-Making Process

Producing food safety decisions that are systematically anchored in a food safety scientific assessment further enhances the acceptability of these decisions by all parties and stakeholders. It strengthens the trust and confidence of consumers, food business operators and international partners in the level of oversight exercised by a given competent authority. It also serves to protect the country or the jurisdiction applying this practice from challenges of legitimacy and fairness under the

SPS agreement regarding decisions taken. However, this approach includes accountabilities that food regulators must accept and fulfill, in particular, the systematic nature of the reliance on risk assessments for decision-making should be clearly demonstrated. A competent authority investing in food safety risk assessment should not be witnessed issuing food safety decisions independently from these risk assessments – whether in the context of incident management or for standard setting. Similarly, decision-making procedures and protocols should be amended to clearly reflect the "trigger" of a risk or a scientific assessment when a given food safety decision is required. Also, when endorsing the dependence on food risk assessments in support of food management decisions, competent authorities must adopt certain key values that support the integrity and bolster the credibility of the outputs of the decision-making process. In particular, embracing the principle of transparency in documenting and making available the outputs of these scientific assessments, through publication or other means of dissemination, should be enshrined in the "day to day" routine practice of the authority.

Once the question has been formulated to risk assessors, ensuring the independent nature of the risk assessment is another factor that is critical to guarantee the credibility of the risk assessment conclusion. Such independence should support the risk assessors in conducting their work without interference by the decision-makers that may influence the outcome of the assessment in a biased direction. This protection from interference can be realized while ensuring continued engagement and dialogue between risk assessors and decision-makers. The manner in which uncertainty is managed, whether related to limitations in the scientific methodology or the lack of data, should be well documented, clearly explained and well communicated by risk assessors. Possessing the risk assessment's full context is indispensable for decision-makers when considering additional relevant factors during the formulation of their risk management recommendation(s).

Calling for Regional Centres of Expertise in Food Risk Assessment and/or Food Regulatory Science

Developing food safety risk assessments and formulating food standards require the availability of multi-disciplinary expertise and reliance on complex methodologies to be developed and adopted by a highly skilled scientific workforce. This includes mastering various food regulatory science disciplines (food toxicology, food microbiology, various aspects of food science, chemistry, mathematical modelling, etc.) and therefore requires important investments to be made by each food competent authority.

Leveraging existing expertise in these scientific disciplines at the regional or sub-regional level to create centres of expertise in food safety risk assessment or food regulatory science may offer a suitable alternative. These Centres of Expertise (CE) could result from a mutualized scientific capacity, both in human skillsets and in tools, data and their management systems from within a given set of countries or jurisdictions that share similar needs, economic situations, language or food production and/or consumption practices.

A model could be envisaged in the form of Joint Institutes of Food Regulatory Science, where such institutes are linked to academic organizations in a given region as well as being tied to and serving primarily the needs of food competent authorities.

These CEs can become the resource called upon by regulators in the given geographical area (e.g., region, sub-region) to address risk assessment needs in support of standard setting[(5)].These CEs could also offer cost-effective approaches to generate and maintain the scientific data needed as a foundation for food risk assessments, in particular food

consumption information and food contaminants and nutrients occurrence data collected through food surveys, whether a Total Diet Study or targeted food commodity surveys. The validation of a risk assessment for the purpose of formulating national standards as well as functions related to rapid risk assessments in response to food safety incidents and foodborne illness outbreaks, would still remain within the prerogative and the oversight of the national food competent authorities.

Figure 2 introduces a proposed operational model to a Food Risk Assessment or Food Regulatory Science (Regional Centre of Expertise or RCE). These RCEs can also become a hub for training, competency development, data collection and gathering in support of food regulatory functions, formulation and assessment of food regulatory impacts and overall scientific expertise in food regulatory scientific disciplines. The operating model can evolve from one that is supported by direct funding from contributing jurisdictions supplemented by food safety capacity development programs to a self-sustaining approach, whereby services provided by the RCEs with respect to training, food data collection and/or provision of scientific and regulatory opinions are cost-recovered. Costs would be considered minimal for users of such services due to the economy of scale anticipated as a result of sharing joint capacity.

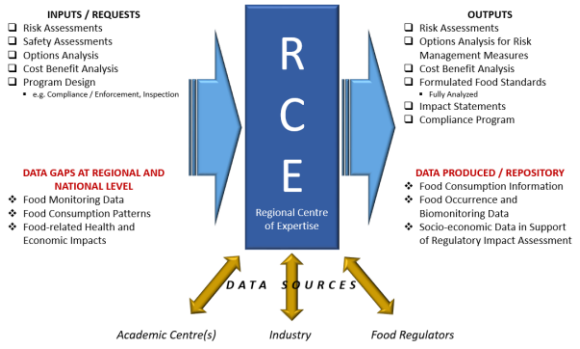

Figure 2: Proposed Model of a Regional Centre of Expertise in Food Regulatory Science

Training programs can be developed to create cohorts of scientists from a given geography / set of jurisdictions to serve as the initial workforce of these joint regional centres of expertise. The linkage with academic centres will support not only the initial training approach, but also the development of the scientific infrastructure dedicated to this purpose.

As part of its commitment to propagate food risk analysis training and competencies and in the context of the implementation of the Food Safety component of the workplan associated with the Memorandum of Understanding between the Food and Agriculture Organization of the United Nations (FAO) and University Laval (UL)[6] , the Food Risk Analysis and Regulatory Excellence Platform (**PARERA**) of UL is setting up a trust fund to support multi-stakeholder funding that could enable the design and implementation of such regional centres of expertise.

Other initiatives have been recently announced and could support the operationalisation of this concept in various regions of the world. The recent (April 2019) proposal examined by the Food Safety Ministerial Committee of the Gulf Cooperation Council (GCC) to create a GCC Food Safety Risk Assessment Centre, based on the proposal of the executive leadership of the Saudi Food and Drug Authority [7] offers the opportunity to mutualize expertise and resources amongst countries of the GCC in food risk assessment and risk analysis. GCC countries are already integrated as far as their food regulatory and standard setting requirements go. A regional centre of expertise in food safety risk assessment will provide additional assurances that food decisions issued at the GCC level are in line with international guidance and best practices and are anchored in scientific evidence.

Similarly, the 2014 Malabo declaration and the subsequent operational plans developed to

address it[8], called for the "establishment and operationalization of a food safety coordination mechanism for Africa", including the possible set-up of an African food safety agency. This goal could be achieved though the incremental development of one or more centres of expertise at the sub-regional / regional level specializing in various disciplines of risk assessment and risk analysis and shaping progressively the advisory capacity to a continent-wide food safety policy, aiming for enhanced protection of consumers along with a cohesive and more harmonious food safety standard setting framework: a pre-requisite to the removal of barriers to intra-regional trade of food and agri-food commodities.

Reliance on food safety standards anchored in a food safety scientific assessment is paramount to ensure their acceptability by domestic and international stakeholders and to meet obligations of predictability, consistency and fairness enshrined in the Sanitary and Phytosanitary agreement (SPS). New approaches must be developed to guarantee the availability of resources required to enable a consistent dependence on risk and scientific assessment and to sustain capacity building efforts in this area. Investing in the development of Regional Centres of Expertise in food risk analysis or food regulatory science responds to such a challenge through the mutualisation of resources and collective development of data, tools and competencies.

There is a clear momentum to support regional economic integration in several parts of the world, as part of economic and human development initiatives (e.g. Association of South East Asian Nations (ASEAN), African Union (AU), Gulf Cooperation Council (GCC), League of Arab States (LAS), etc.). Developing food risk analysis / regulatory science centres of expertise could be considered as a vehicle to achieve the coordination, if not the integration of food regulatory policies as an enabler to a convergent and more harmonious food safety standard setting framework, contributing to the removal of SPS constraints and as a booster to the trade of food and agri-food commodities in the targeted regions.

References

1. World Health Organization. WHO Estimates of the Global Burden of Foodborne Diseases: Foodborne Diseases Burden Epidemiology Reference Group 2007-2015. Geneva (CH): WHO Press; 2015. 255p. Available from: https://apps.who.int/iris/bitstream/handle/10665/199350/9789241565165_eng.pdf;jsessionid=7BDF405F61155E87F836BC3BCBC12599?sequence=1

2. FAO/WHO guidance document. Food Safety Risk Analysis: A Guide for National Authorities. 2005.

3. Godefroy SB, Clarke R. Development and Application of International Food Safety Standards - Challenges and Opportunities. AJWH. 2016; 11: 273-87.

4. Risk assessment [Internet]. World Health Organization. 2019 [cited 16 April 2019]. Available from: https://www.who.int/foodsafety/micro/riskassessment/en/ Copy bibliography citation Copy in-text citation Check for grammar

5. The First FAO/WHO/AU International Food Safety Conference [Conference]. Addis Ababa (ET). Intervention by Godefroy SB; 2019 Feb 12.

6. FAO - news article: FAO promotes multi-stakeholder call for action on control of high-impact Transboundary Animal Diseases in Southern Africa [Internet]. Fao.org. 2019 [cited 21 April 2019]. Available from: http://www.fao.org/partnerships/news-archive/news-article/fr/c/1197997/

7. Press report on the proposed creation of a GCC Food Safety Risk Assessment Centre [Internet]. Riyadh Newspaper. 2019 [cited 4 April 2019]. Available from: http://www.alriyadh.com/1747703

8. Prioritizing Food Safety for Africa, a report of the African Union Commission [Internet]. 2019 [cited 19 April 2019]. Available from: https://au.int/sites/default/files/documents/33005-doc-prioritizing_food_safety_in_africa-eng.pdf,