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Moving towards a risk-based food safety management

Konstantinos P Koutsoumanis and Zafiro Aspridou

Classical hazard-based approaches to food safety relying heavily on regulatory inspection and sampling regimes cannot sufficiently ensure consumer protection. It is now generally accepted that a modern food safety management system should link the hazards to public health and be based on prevention rather than end product testing and control. The last decade food safety management at international level has been moved towards a more risk-based approach to food safety control with regulators around the world adopting the risk analysis framework as the basis for their decision-making. This review paper presents an overview of the structure and function of a risk based food safety management and the interaction between risk managers, risk assessors and stakeholders.

Address
Laboratory of Food Microbiology and Hygiene, Department of Food Science and Technology, School of Agriculture, Forestry and Natural Environment, Aristotle University of Thessaloniki, Thessaloniki 54124, Greece

Corresponding author: Koutsoumanis, Konstantinos P (kkoutsou@agro.auth.gr)

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Introduction: from hazard-based to risk-based food safety approach

During the 1990s, the increased number and severity of food-poisoning outbreaks world-wide raised public awareness about the safety of foods and created a sense of mistrust among the consumers [1]. It became evident to regulatory authorities and food industry that classical hazard-based approaches to food safety relying heavily on regulatory inspection and sampling regimes cannot sufficiently ensure consumer protection. As a consequence, the need for a modern food safety management system which can link the hazard to public health and is based on prevention rather than end product testing and control was fully recognized.

The application of sanitary and phytosanitary measures (SPS Agreement) by the World Trade Organization (WTO) suggested for the first time, in the mid-1990s, a risk assessment basis for food safety. SPS Agreement introduced the term 'appropriate level of health protection' (ALOP) as the 'Level of protection deemed appropriate by the member (country) establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory'. With ALOP, WTO changed the question 'is the food safe?' to 'what is the level of product safety?' and transformed food safety from a discrete (safe/unsafe) to a continuous (risk) variable recognizing that 100% safety (or zero risk) does not exist. The European Commission followed with Regulation (EC) 178/2002 which clearly states that food safety should generally be founded on science using the Risk Analysis framework [2]. In 2003, the Codex Alimentarius Commission adopted the Principles for Food Safety and Risk Analysis to be used in the Codex framework. During the last decade, considerable progress has been made in developing a framework and principles for risk analysis with many guidance documents for the application of risk management and risk assessment by governments [3–6]. In the United States of America, the significance of a risk based food safety approach is recognized under the FDA Food Safety Modernization Act (FDA FSMA) [7].

Based on the above developments, food safety management at international level has been moved towards a more risk-based approach to food safety control [8] with regulators around the world adopting the Risk Analysis framework as the basis for their decision-making. Risk-based food safety is significantly different compared to the classical hazard-based approach leading to a major shift in thinking about the ways that science and policy-making in food safety should interplay [9•]. It is now generally recognized that the new approach allows for a sharper diagnosis of food safety problems and the identification of effective mitigation strategies to properly deal with them. The objective of this review paper is to present an overview of the structure and function of the risk based food safety management and the interaction between risk managers, risk assessors and stakeholders.

Food safety in the risk analysis context

In the context of risk analysis, a food safety management system is aiming to estimate the risks to human health from food consumption and to identify, select and implement mitigation strategies in order to control and reduce these risks. According to the Codex Alimentarius, risk analysis is a process consisting of three components: risk assessment, risk management and risk communication [3].

Risk assessment is considered to be the 'science-based' component of risk analysis for determining the risk associated with any food-hazard combination. The objective is to characterize the nature and likelihood of harm resulting from human exposure to hazards present in foods. Depending on the purpose and scope of the risk assessment different risk metrics can be used (Box 1). The microbial risk assessment process consists of four distinct steps: (i) the hazard identification; (ii) the hazard characterization; (iii) the exposure assessment and (iv) the risk characterization [10]. For public health authorities, risk assessment may serve as a means to quantify the risks attributable to certain food products. By applying the concept of risk ranking (Box 2), risks of a different nature can be compared [11]. In addition, the results of a risk assessment can provide structured information on the effect of potential interventions on the risk [12•]. Such information allow decision makers of public health authorities or food industry to compare various interventions and identify those that can lead to effective reduction of safety risk and, consequently, to public health improvement. Risk assessment can also be used to identify data gaps and target research with the greatest value in terms of public health impact.

Risk management has the overall responsibility for the protection of the consumer health. It is the process of integrating scientific information deriving from risk assessment with economic, social, cultural and ethical considerations in order to select and implement strategies for controlling food safety risks. The consideration and weighing of different policy alternatives is a critical part of the risk management. Thus, a cost–benefit analysis of the risk management options for evaluating their health impact in relation to their economic and social cost should ideally be part of risk management activities.

Risk communication has been defined as 'the interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions'. It is considered an integral component of the risk analysis with great importance for both risk assessment and risk management. Risk communication can bridge the gaps between the evaluation of risk by experts and the views of other stakeholders. It aims to foster public trust by communicating clear accessible information which ensures that stakeholders understand risk management decisions and the justification for making them.

Box 1 Risk metrics

There are different ways of expressing risk in a risk assessment [11]. Codex Alimentarius defines risk as 'a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food'. The simplest metric that can be used to account for the probability of an adverse effect in risk ranking is the number of adverse outcomes (e.g. illnesses, hospitalizations, and deaths) associated with a single hazard in multiple foods. The number of adverse outcomes can be estimated as 'per serving' or 'per annum (and standardized for population size (e.g. per 100 000 per year))'. The 'per serving' likelihood can be viewed as the risk that individual consumers face when they eat a serving of a food. The 'risk per annum', on the other hand, is a measure of the risk faced by a certain population (e.g. a country). The risk per annum is greatly affected by the number of servings per year. In the case of multiple hazards, the challenge is to find metrics to characterize the severity of the health outcomes associated with these hazards in order to compare their overall health and/or economic impact. The DALY approach (Disability-adjusted life year) was first developed by the World Health Organization's Global Burden of Disease (GBD) program to compare the risk of specific diseases in different countries. The DALY method presumes perfect health for the entire life span and, therefore, measures the loss due to ill health [23]. Death, the worst possible health state, is assigned a disability weight of 1 while 0 represents the best health state. To calculate the burden due to premature mortality, the number of life years lost is compared to a standard life table. A number of approaches have been developed for the monetary valuation of risk. In this case, the public health impact of foodborne disease is characterized by health economics. The risk metrics can significantly affect the risk management decisions and thus, their selection requires communication between the risk assessors and the risk managers.

Box 2 Risk ranking

Policy makers and food safety authorities must deal with numerous food safety issues, often simultaneously, and inevitably, resources are insufficient to manage all issues at any given time. Setting priorities and allocating resources plays a crucial role in the decision-making process. A 'priority' issue is essentially one that is considered to be a matter of greater importance, and which should thus, be addressed with more urgency and in precedence to other issues. Risk ranking in food safety can be considered as a risk assessment exercise for ranking the combined probability of food contamination, consumer exposure and public health impact of certain foodborne hazard–matrix combinations. Two approaches can be adopted; the bottom up (forward) which is based on exposure data and dose-response relationship and the top-down (backward) approach which is based on disease incidence and attribution data [24]. Risk ranking has been recognized as the proper starting point for risk-based priority setting and resources allocation, because it would permit policy makers to focus attention on the most significant public health problems and develop strategies for addressing them. The objective of the risk ranking in the general risk management framework is the evaluation of the perceived relative level of risk that each issue presents to consumers, so that the risk management resources can be optimally distributed to reduce overall food-borne public health risks. Several (semi)-quantitative risk ranking tools are available, including among others, FDA-iRISK [25], microHibro [26], Risk Ranger [27], and sQMRA [28]. EFSA recently developed a conceptual framework with nine separate stages leading to a structured, transparent and consistent approach in risk ranking [11].

Structure and function of a risk-based food safety management

The structure of a risk-based food safety management system and the interactions with the relevant parties is shown in the generic framework presented in Figure 1. The