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Moving towards a risk-based food safety management

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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.

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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.

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

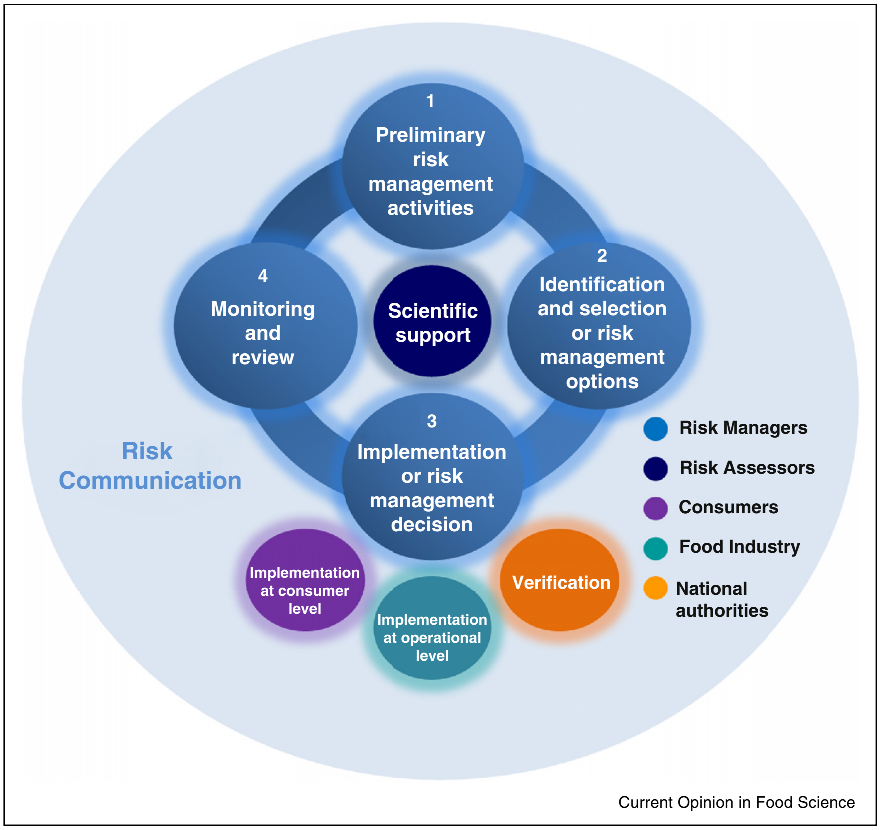
Policy makers and food safety authorities must deal with numerous food safety issues, often simultaneously, and inevitably, resources are insufficient to manage all issues at any given time. Setting priorities and allocating resources plays a crucial role in the decision-making process. A 'priority' 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].

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.

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

Figure 1



Structure of a risk-based food safety management system and interactions with the relevant parties.

framework consists of 4 steps [13]. The process starts with a number of preliminary risk management activities including: (a) identification of a food safety issue, (b) development of a risk profile [14], (c) establishment of risk management goals, (d) decision about the need for the risk assessment, (e) establishment of the risk assessment policy, (f) commission of the risk assessment and/or risk ranking and (g) analysis of the risk assessment results. In the second step, the different risk management options are identified and, after evaluation, the preferred option(s) is selected. The third step includes the implementation of the risk management measures. Measures can be implemented in the food sector using mandatory (legislation) or voluntary (codes of practice and guidelines) means. In the former case, competent authorities verify that the control measures have been effectively implemented by the industry operators. Communication tools can also be used to implement consumers-related risk management decisions (e.g. encouragement of vulnerable persons to avoid the consumption of certain foods with high risk). During step 4, monitoring activities are undertaken at appropriate points in the food chain and used to review the effectiveness of the implemented risk management measures. This step usually includes surveillance of public health to collect data on the changes in food-borne illness rates that may follow the implementation of risk management measures. When these data show that the goals are not being achieved, the redesign of food safety controls is needed and the cyclical process can be repeated as many times as necessary.

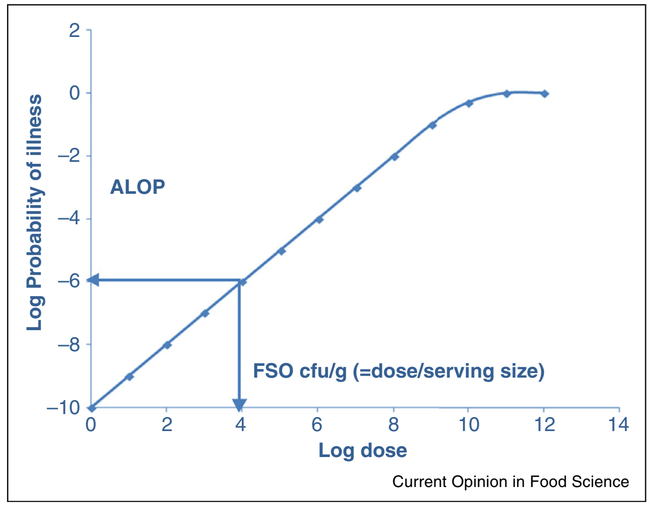
During the above risk management process, risk assessment provides scientific support to all the steps. One very important point in the integration of risk management and risk assessment is the incorporation of uncertainty in the decision-making. Risk management decisions need to take into account uncertainty as transparently as possible. Sensitivity and uncertainty analysis performed by risk assessors can determine how uncertainties in the model inputs affect the risk assessment output and describe the consequences of the overall uncertainty. When uncertainties are large enough to impede a definitive decision, additional data can be requested and gathered possibly leading to the initiation of a new cycle of risk management activities.

Using risk-based targets in food safety management

In a food safety management system it is very important to be able to articulate to the food business operators the degree of stringency that needs to be achieved at one or more steps along the foods chain which will lead to the desired level of consumer protection. In a hazard-based approach, this stringency was traditionally expressed in terms of product testing targets in order to distinguish acceptable and non-acceptable batches with no link to public health [9•]. The use of risk assessment allows for a transparent and objective connection of such targets to the intended public health outcome within a risk-based food safety management system. The Codex Alimentarius Commission proposes to use the terms food safety objectives (FSO), performance objectives (PO) and performance criteria (PC) for these targets [15].

Using a dose–response relationship, the ALOP established by the risk managers can be translated to FSO (Figure 2) which is 'the maximum frequency and/or concentration of a hazard in a food at the time of consumption that provides or contributes to the ALOP'. A PO is 'the maximum frequency and/or concentration of a hazard in a food at a specified step in the food chain before the time of consumption that provides, or contributes to, an FSO or ALOP'. In contrast to an FSO, a PO can be utilized at points of the food supply chain where control and verification are possible [16]. A PC is 'the effect in frequency and/or concentration of a hazard in a food that must be achieved by the application of one or more control measures to provide or contribute to a PO or an FSO'. When verifying POs and PCs, the initial level of a hazard and the changes occurring during production, distribution, storage and preparation must be considered (Figure 3). By integrating the changes in a hazard from the initial level (H_0), minus the sum of the reductions (R), plus the sum of increase (I), one arrives at a concentration/prevalence that, at consumption time, must be lower than a FSO, as described in the following equation [17]:

Figure 2



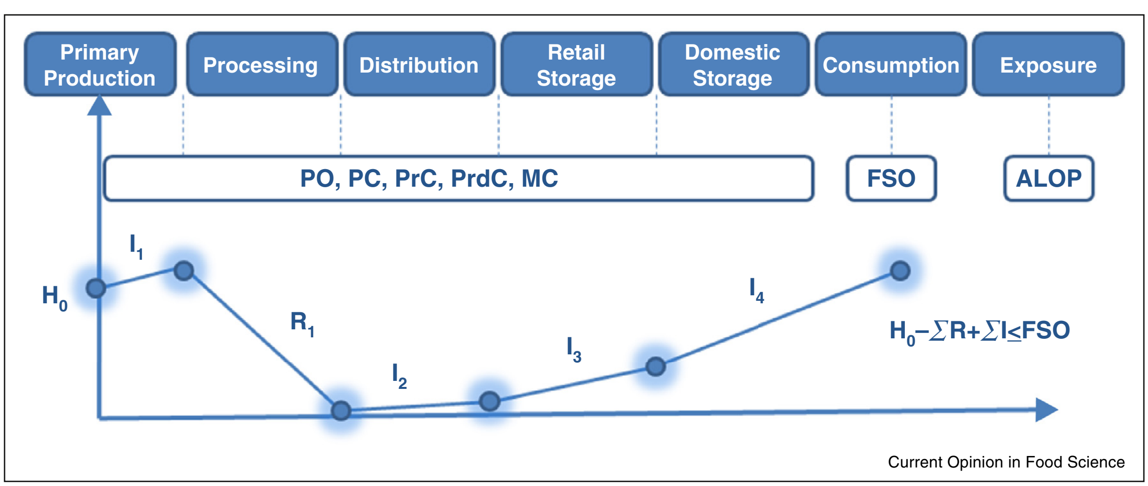
Using a dose–response relationship, the ALOP established by the risk managers can be translated to FSO.

$$H_0 - \sum R + \sum I \leq \text{FSO} \quad (1)$$

where H_0 is the initial level of the hazard, ΣR is the total (cumulative) reduction of the hazard, ΣI is the total (cumulative) increase of the hazard. FSO, H_0, R and I are expressed in log 10 units.

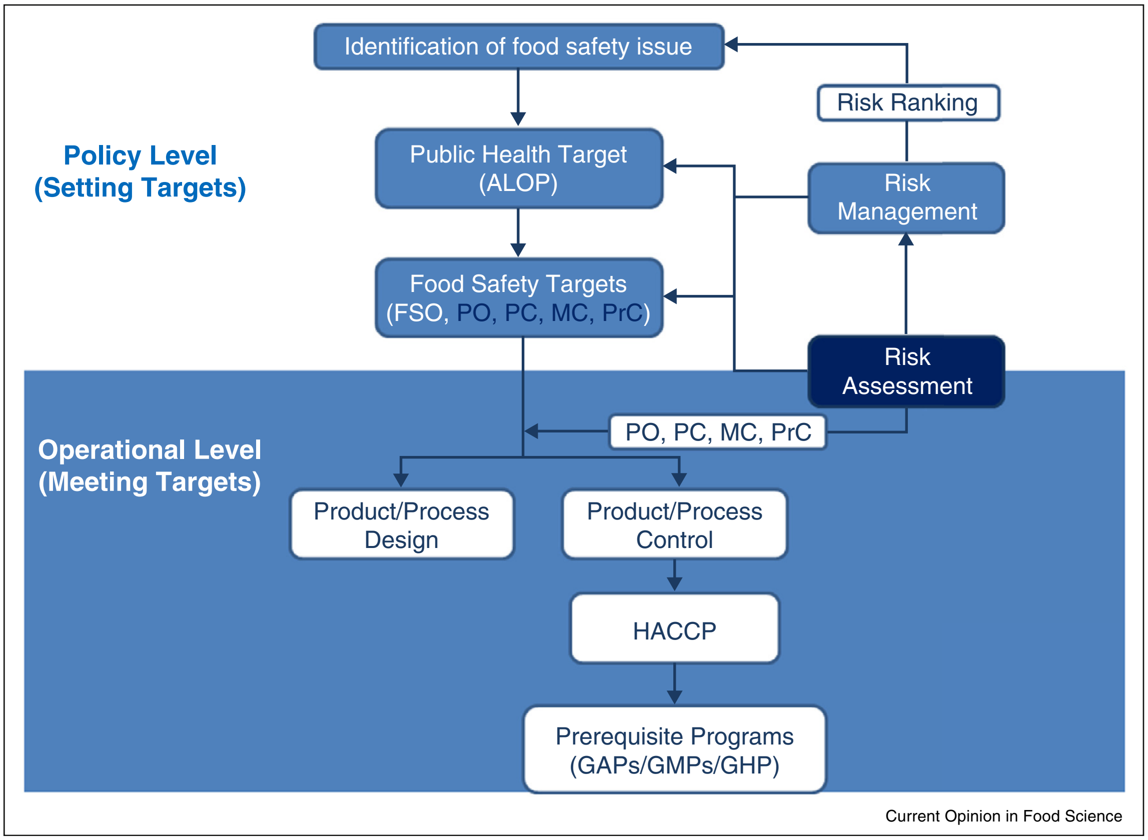
PO and PC can be translated to operation targets, such as Process (PrC) and Product (PrdC) Criteria. PrC indicate the physical process control parameters (e.g. time, temperature) at a specified step that can be applied to achieve a PO or PC. PrdC indicate the characteristic(s) of a food product that must be achieved and/or maintained to achieve a PO/PC. Verification of PO and PC through microbiological testing

Figure 3



Safety management targets applied in the food chain.

Figure 4



Risk-based food safety management at policy and operational level.

requires the establishment of Microbiological Criteria (MC) [18,19] which define 'the acceptability of a product or a food lot, based on the absence or presence, or number of micro-organisms including parasites, and/or quantity of their toxins/metabolites, per unit(s) of mass, volume, area or lot'. Risk-based MC can be derived by the application of a quantitative microbial risk assessment (QMRA) model linking the test and sampling scheme directly to an estimate of population health risk by taking into account variability and uncertainty [20•]. The European Union Regulation on microbiological criteria for foodstuffs [21] includes two MC categories according to the place of application: 'food safety criterion' is a criterion defining the acceptability of a product or a batch of foodstuff applicable to products placed on the market while 'process hygiene criterion' is a criterion indicating the acceptable functioning of the production process.

ALOP and FSO are only set by governmental risk managers while PO, PC, PrC, PrdC and MC can be set by both government and industry [8,22]. In any case, at operational level, food producers and processors are responsible for developing and applying food safety control systems, such as good agricultural practices (GAP), good manufacturing practices (GMP), good hygiene practices (GHP) and hazard analysis critical control point (HACCP) systems (Figure 4) to give effect to the decisions on risk management options and meet the targets [18].

Conclusions

A risk-based approach offers many advantages to all the parties with a stake in food safety. It provides a framework to effectively assess, manage and communicate risks in cooperation with the diverse stakeholders involved. Risk management allows for a systematic evaluation of the impacts of control measures selected to manage the risks and for the comparison between the cost of compliance and the expected benefits. In high-risk food/hazard combinations, safety will ultimately be improved, the burden of food-borne disease will be reduced and the consumer trust will be increased.

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