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4
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FOOD SAFETY RISK MANAGEMENT

EVIDENCE-INFORMED POLICIES AND DECISIONS, CONSIDERING MULTIPLE FACTORS

FAO GUIDANCE MATERIALS

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FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS
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PREFACE

Food safety regulatory authorities are tasked with safeguarding consumers' interests by ensuring the food they eat meets relevant food safety standards. Sound food safety policies and risk management decisions are required to ensure food safety issues of highest concern are identified, and the appropriate control measures are implemented. Countries face multiple and varied food safety risks and issues depending on consumption patterns, production processes, trading patterns, etc. Assuring food safety is important for a range of development outcomes, and food safety decision-making often plays out at a juncture where interests of various sectors co-exist. Decision-makers therefore need to consult broadly, consider a wide range of evidence, and balance health, trade, food and agriculture, and food security considerations.

Robust decision-making can present challenges in all countries, irrespective of their stage of development and maturity of their food safety control system. Even though many developing countries identify food safety as a priority, they face challenges in developing strategic and coherent food safety programmes that proactively address problems rather than perpetually simply reacting to problems. Sound decision-making is frequently impeded by a lack of, or inadequate, evidence; ineffective use of existing evidence; or weak communication and collaboration among different ministries and with relevant stakeholders. There is a need for food safety decision-making processes to be structured, accountable and transparent. To be credible, decisions need to be informed by a consideration of best available evidence, and include consultation with relevant disciplines and stakeholders.

All countries are concerned with the need to establish clear priorities in order to make best use of finite resources, and to ensure that decisions to ensure food safety do not negatively impact on other dimensions essential for development, e.g. trade, economics, food security, tourism, social well-being. Unsafe food has the potential to negatively impact on certain sectors e.g. nutrition and health outcomes, and food can be unsafe as a result of action or inaction in other sectors e.g. agriculture development, the environment. Discussion and feedback with food safety policy-makers and risk managers shows that while they often consider these different factors when deciding on appropriate food safety decisions, additional guidance would be very useful. They also recognize that increasing calls for governments to assure policy coherence is very relevant to the food safety sector.

To address these challenges and requirements for effective decision-making, the Food and Agriculture Organization of the United Nations (FAO) has led the development of this guidance document. Its origins lie in FAO's work to develop country capacities for improved food safety governance. Working with food safety professionals has led to the identification of needs. Concurrently, engagement in global networks and discussions has facilitated the observation of advances and evolution of decision-making in more mature countries.

The FAO/EC Global Governance for Hunger Reduction programme aimed at improving food security governance at global, regional and national levels, provided an opportunity to develop this guidance.

Although food safety decision-making continues to evolve, the risk analysis paradigm remains the cornerstone, providing a framework for assessing food safety risks, managing those risks, and communicating both the risks and decisions taken to mitigate them. While the focus is primarily on an assessment of health risks, policy-makers and risk managers are aware of the importance of considering other factors (other risk areas) when making food safety decisions. However, while they are comfortable with the assessment of risks to public health, they are less comfortable with how and when they should consider other factors in arriving at their final food safety decision. Discussions with food safety risk managers have indicated support for globally relevant guidance to supplement the existing manuals on the risk analysis paradigm. This new guidance aims to provide i) guidance on ways decision-makers can consider other factors (in addition to health); and ii) provide risk managers with a more structured process for gathering evidence and demonstrating how they have considered other factors and relevant evidence in making food safety decisions. It should improve the rigour of analysis for all factors.

This guidance document is practical, and provides a structured approach and tools to aid decision makers to incorporate public health risks as well as other relevant factors in food safety decision-making. The process included testing methodologies at country level to ensure the guidance is appropriate for a range of country situations. The project work has included pilot studies in Thailand and Uganda as well as two technical meetings – one held in Rome, Italy (November 2013) and the second held in Dhaka, Bangladesh (September 2015). Through these technical meetings, selected experts representative of different regions and countries contributed experiences, methodologies and approaches to inform the guidance for more structured decision-making.

This guidance is intended to push the evolution of food safety decision-making in all situations and countries. While it's clear that considering a range of factors in decision-making takes some work, the document shows that it is doable – and the case studies show that it can be done at different levels of detail. Only through testing and application to national decision-making will different approaches be validated. FAO is ready to learn and work with partners and country experts, and we value feedback in order to continue to improve the guidance.

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LIST OF FIGURES

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A second technical meeting was held in Dhaka, Bangladesh in September 2015 with the participation of Oumou Barry, Food Safety Consultant; Rikard Bjerselius, National Food Agency, Sweden; Raymond Ellard, Food Safety Authority of Ireland; Agaba Friday, Ministry of Health, Uganda; Mustak Hassan Md. Iftekhar, Food Safety Authority, Bangladesh; Vigdis Veum Moellersen, Norwegian Food Safety Authority, Norway; Tatiana Cruz Ramirez, Ministry of Economy, Industry and Commerce, Costa Rica; Dean Stockwell, Dean Stockwell Consulting Ltd, New Zealand, and Sasiwimon Tabyam, Ministry of Agriculture and Cooperatives, Thailand.

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ACRONYMS

AHP	analytic hierarchy process
ALOP	appropriate level of protection
CAC	Codex Alimentarius Commission
CFIA	Canadian Food Inspection Agency
CR	comparative risk
DALY	disability adjusted life year
EC	European Commission
FAO	Food and Agriculture Organization of the United Nations
FERG	Foodborne Disease Burden Epidemiology Reference Group
GAP	good agricultural practice
GHP	good hygienic practice
GMP	good manufacturing practice
GVP	good veterinary practice
HACCP	Hazard Analysis Critical Control Point
MAUT	multi attribute utility theory
MCA	multi criteria analysis
MCDA	multi criteria decision analysis
NCC	neurocysticerosis
PROMETHEE	Preference Ranking Organizational Method for Enrichment Evaluation
QALY	quality adjusted life years
RTE	ready-to-eat
SPS	sanitary and phytosanitary
WFP	World Food Programme
WHO	World Health Organization
WTO	World Trade Organization
YLD	years lived with disability
YLL	years of life lost

INTRODUCTION

WHY IS THIS GUIDANCE NEEDED?

Food safety risk managers and policy-makers charged with protecting public health and safety are working in an ever more complex world. They must make sound choices to address public health risks but there are often economic, social and political impacts that also need to be considered. Stakeholder perspectives and views must be taken into account, and decision processes are often subject to media attention. Faced with this complexity, risk managers and policy-makers can be aided by structured methods that are based on multiple decision factors.

In our day-to-day lives, we often make decisions or choices based on multiple considerations or factors. For example, when we make consumer purchases, we might consider initial cost, durability, maintenance costs and perhaps aesthetic features such as colour and style. We instinctively weigh evidence related to different factors to make a choice that is aligned with our values and appropriate for our situation. As illustrated in Figure 1, these basic steps can be developed into a formal and systematic process for making decisions. The process includes a clear statement of the decision objective, the alternatives considered, the factors and criteria used to evaluate and compare these options and the identification of the "best" choice overall.

The guidance contained in this document applies the multi-factor decision-making schema to food safety issues, highlighting how it can be used to enhance policy development, set priorities or choose risk management options. Tools and examples are included to demonstrate the consideration of different factors to these different decisions, following the structured decision making schema. Despite the effort to be as practical as possible, the use of this guidance document will require decision-makers to be knowledgeable in food safety risk analysis and the involvement of

A 5-STEP PROCESS FOR MULTI-FACTOR DECISION-MAKING

BENEFITS OF THIS APPROACH

Done well, multi-factor decision-making is an evidence informed, rigorous and clear process, able to withstand review and challenges.

other skill sets, for example experts in data collection and analysis, social analysts and experts in use of techniques such as Delphi surveys. The guidance emphasizes the importance of evidence to support the evaluation of options and a transparent process that demonstrates clear accountability.

WHO CAN USE THIS GUIDANCE ON MULTI-FACTOR DECISION-MAKING?

This guidance material has been prepared firstly for national food safety risk managers and other "decision-makers" who have responsibility for proposing, planning, developing and implementing appropriate policies and decisions.

Secondly, it has been prepared to support high level food safety policy-makers to influence those charged with health, food security, economic and social development policy, and Finance ministries deciding on resource allocation and national priorities.

The guidance may also be helpful to a broader range of government officials, including risk assessors and other appropriate stakeholders,[1] through enabling a shared understanding of the food safety risk management decision-making process.

While the focus is on national decision-making, the guidance can also be of interest to food safety decision-making in regional and global fora, including the CAC.

1 Stakeholders can include national experts, academics, representatives of food manufacturing and processing industries, retailers, primary food producers and consumers.

WHAT IS IN THIS GUIDANCE DOCUMENT?

The sections of this guidance document focus on the application of multi-factor decision-making to food safety. Case studies are included as examples of how to apply this decision-making process, in the hope that the audience will find this practical application useful.

SECTION 1 sets the stage and context for food safety policy and decision-making in an increasingly complex environment. It outlines the benefits of considering multiple factors in risk management, and policy decisions that address food safety issues.

SECTION 2 introduces and describes the five-step decision-making process, and describes each step in the context of typical food safety decisions.

SECTION 3 applies multi-factor decision-making to evaluating and selecting risk management options.

SECTION 4 applies multi-factor decision-making to risk ranking and prioritization of food safety issues.

SECTION 5 looks at how to create an environment that provides appropriate support to facilitate multi-factor decision-making.


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SECTION 1

WHY IS MULTI-FACTOR DECISION-MAKING USEFUL FOR FOOD SAFETY

KEY QUESTIONS THAT ARE ANSWERED IN THIS SECTION:

> What is the context of food safety decision-making?

> What are current challenges for risk managers and policy-makers?

> Why is a multi-factor approach important in risk management and policy development?

> How are stakeholder voices/interests captured through multi-factor decision-making processes?

> What are the practical benefits of decisions based on consideration of multiple factors?

1.1 THE COMPLEXITY OF FOOD SAFETY DECISIONS

Governments around the world recognize that a safe food supply is one of the foundations of public health and is also essential for food and nutrition security. Furthermore, the safety of foods traded needs to be assured in order to attain and maintain international and regional markets, thus improving economic development.

The risk of illness and death must be a primary consideration in developing policies, setting priorities and choosing risk management options to address unsafe foods. However, policy-makers and risk managers also need to take into account potential repercussions to trade, food security, consumer confidence and other areas.

The following examples, taken from actual food safety cases, demonstrate that food safety issues can have widespread impacts beyond public health:

> *E coli* O157:H7 found in beef carcasses destined for export closed trade at a major international border. This resulted in a shutdown of the country's largest beef processing facility and high unemployment in a rural community. Producers were also affected as beef prices tumbled.

> In an east African country where pigs are raised in close proximity to humans, it is estimated that *Taenia solium* cysts in pork causes 30 percent of all epilepsy cases. In this region, there is a deep-seated social stigma associated with epilepsy, with those afflicted treated as outcasts. Eliminating backyard, free-range rearing of pigs can reduce the risk of neurocysticercosis and epilepsy, but fewer households would be able to pay for school fees and medications.

> Adulteration of infant food with melamine caused consumers to lose confidence in local products and they began to purchase imported products. Food adulteration will lead to consumers losing trust in public institutions and the private sector.

> There is evidence that aflatoxins in cereals and groundnuts is linked to growth stunting in young children. Stunting in childhood will have follow up effects in adulthood, impacting on productivity and quality of life.

In addition to the complexity of food safety issues, the current decision-making environment presents a number of challenges and pressures for policy-makers and risk managers. In making decisions to address food safety issues, they must:

> address strong and divergent views from a broad range of stakeholders and interest groups;

> be accountable and demonstrate sound, evidence-informed and documented decision-making processes;

> be transparent and consultative in the context of the public sector to ensure open processes, engagement of stakeholders and sharing of information;

> manage media scrutiny and the consequent pressure on obtaining evidence within practical timelines;

> be consistent with other government policy initiatives to ensure prudent expenditure of public funds; and

> demonstrate most effective use of limited resources to address priority food safety issues.

Discussions with food safety decision-makers in many countries have highlighted that they do consider a range of factors that can be affected by unsafe food across the sectors of health, agriculture, trade, food security, etc. These are complex decisions and they are tough. They advised it would be helpful to develop guidance that demonstrates the need to consider factors beyond public health, in a structured decision process informed by evidence. Furthermore, a report to the Heads of National Food Agencies in Europe in 2012 recommended that risk managers "need to be clearer and more consistent in setting out how the other legitimate factors besides risk assessment (such as economic or political considerations) have been taken into account, including the contribution and reasoning behind the consideration of other factors and the supporting evidence and/or expert analysis" (Heads of Agencies, 2012).

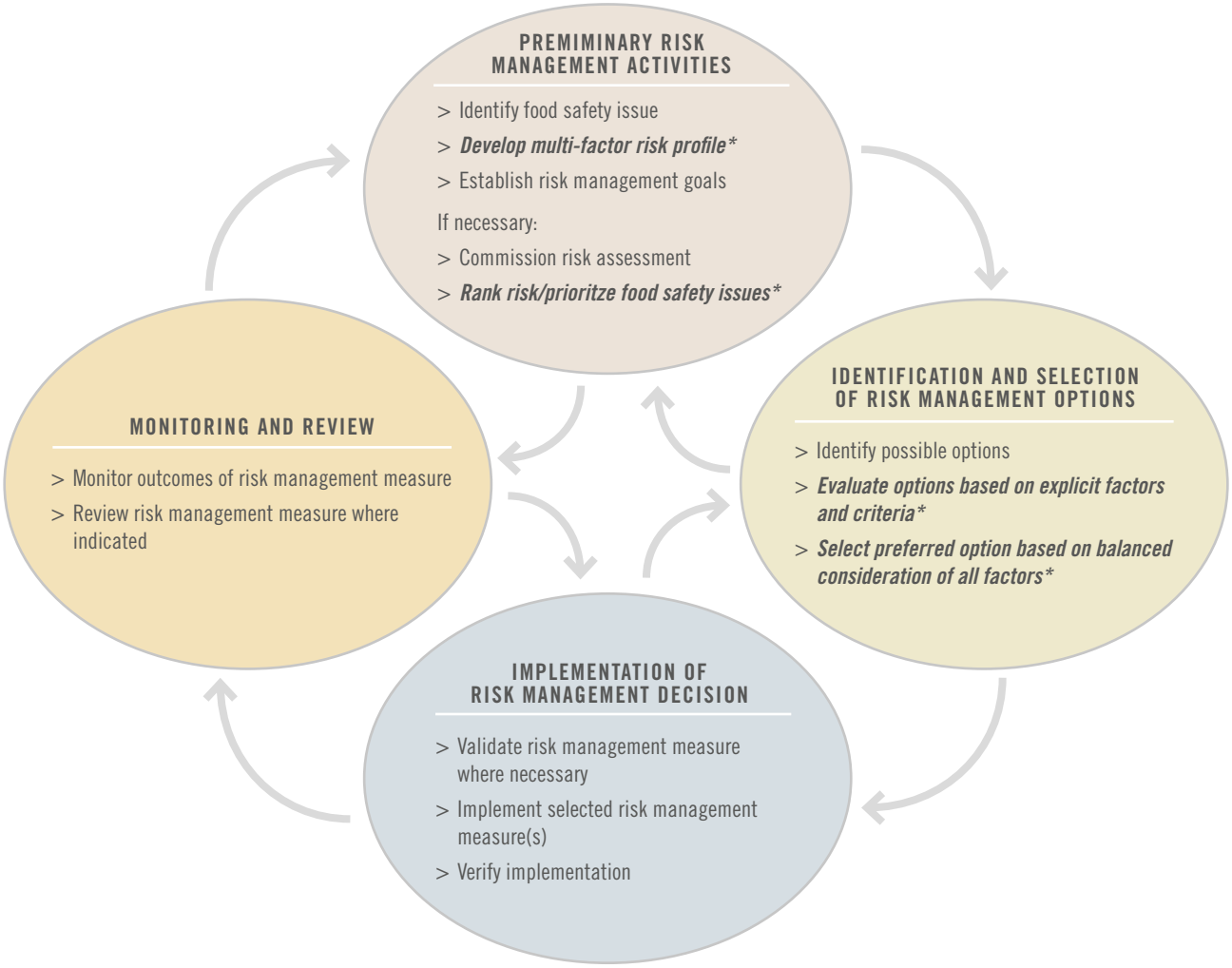
Additional guidance could assist policy-makers and risk managers in ensuring that all factors are considered in a balanced way, as consistent application of a clear and balanced approach delivers better informed decision outcomes.

1.2 THE IMPORTANCE OF MULTIPLE FACTORS WHEN MAKING RISK MANAGEMENT DECISIONS

Food safety risk management includes a broad range of activities as shown in Figure 1. This generic framework is adapted from a version that was included in 'Food Safety Risk Analysis – a guide for national food safety authorities' (FAO/WHO 2006). Risk analysis is a well-established food safety paradigm (see Box 1) and the multi-factor decision-making process respects the risk analysis principles adopted by CAC. The food safety risk analysis paradigm upholds risk management as the component in which scientific information on health risks and other factors (such as economic, social, cultural and ethical) need to be considered and weighed in choosing the preferred risk management decision. This document provides valuable guidance to enable risk managers to carry out this task.

Figure 1 is included to show specific risk management decisions that would benefit from a structured, multi-factor approach (highlighted with bold italic font in Figure 1). For example, as part of preliminary risk management activities, a risk manager may commission a formal risk assessment to better understand the health risk associated with a particular food safety issue. In the context of a multi-factor approach, risk managers might also commission formal analysis of economic risk factors or other areas of concern. All evidence about potential harm arising from a food safety issue should be documented in a multi-factor risk profile which serves as a useful information summary for decision-makers (See Box 10 in Section 5).

FIGURE 1 **GENERIC FRAMEWORK FOR RISK MANAGEMENT**



*These steps reflect the guidance prepared in this document

Adapted from 'Food Safety Risk Analysis – a guide for national food safety authorities', FAO/WHO 2006

Risk managers review and compare current food safety issues on a regular basis in order to identify priorities and allocate resources at a national level. Recognizing the paramount importance of protecting public health, the accepted practice is to first **rank food safety problems** according to the level of risk to public health. The next step is to integrate the ranking based on health risk with other considerations to **identify priority food safety issues.** Risk managers choose decision factors that are relevant for setting food safety priorities in their country context. In addition to health risks, these may include:

> food and nutrition security;

> economic earnings and impact across a range of stakeholders including consumers, rural producers, government, health providers and industry;

> impacts on food trade at local, regional and national levels;

BOX 1

CONSISTENCY WITH THE CODEX RISK ANALYSIS PARADIGM

The Codex risk analysis model sets out a systematic approach to address food safety issues that is grounded in science-based analysis of risk to human health. The roles of risk assessor, risk manager and risk communicator are clearly defined. While the roles are distinct, they must operate in an interdependent manner to achieve effective risk management. A comprehensive resource that describes the key elements of risk analysis is the FAO/WHO publication "Food Safety Risk Analysis -a guide for national food safety authorities" (FAO/WHO 2006). Depending on the level of familiarity with risk analysis concepts, readers may consult this resource. Throughout this document the risk analysis concepts are referenced rather than repeated.

The guidance provided in this document is consistent with Codex in that it reinforces the need to assess public health risk based on scientific evidence and to use this analysis in setting food safety priorities. But it also addresses the need for risk managers to consider other factors when making appropriate food safety decisions. Many of the principles that are outlined by Codex for the science-based assessment of health risk are extended and should be upheld during the consideration of other factors:

> a systematic process is followed;
> decisions are 'evidence informed';
> proceedings are fully documented;
> stakeholder engagement occurs throughout the process; and
> the process is transparent and well communicated to stakeholders throughout.

> environmental concerns arising from food production and food industry development;

> coherence with policy in portfolio areas such as rural development, animal health and welfare, environment and trade;

> consumers' perceptions and behaviour; and

> social, cultural and ethical considerations.

A structured, multi-factor decision process ensures that risk managers are clear about the factors that are considered, the evidence that is used to evaluate food safety issues and the methods for ranking risks and setting priorities.

For each food safety issue that poses an unacceptable level of harm, risk managers **identify options that could be implemented to mitigate or manage risks.** Risk managers should apply a structured decision-making process that explicitly defines the options being considered, the decision factors and criteria that are used to compare them and how all of the evaluations are balanced to identify the preferred risk management option.

Applying multi-factor methods does not change the central role of risk managers in guiding food safety decisions. However, it does reinforce the need for them to engage on a repeated basis with key stakeholders such as consumers, producers, industry associations, and government ministries with responsibilities that are connected to food safety issues. Stakeholder issues and concerns should be considered in

identifying relevant decision factors, in gathering evidence and reviewing potential risk management options. Stakeholders can also provide useful information about a range of factors (e.g. effectiveness, feasibility) that underpin multi-factor decisions.

1.3 THE POLICY ENVIRONMENT AND ITS LINK TO FOOD SAFETY DECISION-MAKING

Policy plays an essential role in public sector decision-making, as policy is one of the instruments by which governments achieve their objectives. Public sector decision-makers are required to seek out, support and implement national policy in their area of operation. Food safety policy and risk management decisions are no different. In effect, food safety policies are implemented through more specific risk management decisions.

Policy

This provides the strategy, structure and goals that underpin national and regional initiatives and provides guidance to risk managers. In common with other policy areas, food safety policy sets out in general terms the overall direction a government plans to take and provides a pathway for implementation through processes and procedures such as regulations and control measures contained in risk management steps. The principles and approaches contained in this guidance to consider multiple factors will strengthen all food safety policy decisions.

BOX 2

A standard definition of policy is: "a plan or course of action, as of a government, political party or business, intended to influence and determine decisions, action and other matters". Public policies are implemented through the adoption of "policy measures" i.e. concrete interventions and actions aimed at achieving specific objectives.

Adapted from FAO, 2017

Safe food and confidence in the food supply is essential in today's world. Furthermore, there is growing awareness at national and global levels that food and nutrition security cannot be achieved where food is unsafe. To develop and implement coherent food safety policies, we need to be mindful of two important realities at country level. The first is that a number of ministries and agencies (e.g. trade, agriculture, health) have a shared interest in ensuring food safety in order to achieve their specific mandates (e.g. increasing food exports requires investment in ensuring they are safe). The second is that policies in other sectors of national importance, e.g. agricultural production, industrial development and environmental management, can affect food safety. For example, actions to prevent over-application of agricultural chemicals benefit the environment as well as food safety.

Box 3 provides examples of food safety relevance to different ministries in policy areas such as public health, agriculture, trade, the import and export of foods and consumer affairs.

BOX 3

EXAMPLES OF SOME MINISTRIES' MANDATES AND THEIR FOOD SAFETY RELEVANCE

MINISTRY OF PUBLIC HEALTH	MINISTRY OF AGRICULTURE	MINISTRY OF ECONOMY AND TRADE	MINISTRY OF CONSUMER AFFAIRS
Public health protection, including reduction of foodborne illness, nutritional status, water quality and sanitation	Increasing agriculture production and development of food value chains, dimensions of rural development and livelihoods, animal health and welfare, and ensuring food security	Increasing food trade, facilitating market flows, increase in foreign earnings and increase in standard of living	Protection of consumers' rights, fair trading, information to consumers
Food safety relevance: foods and drinking water can be a source of biological, chemical and physical hazards which may cause acute and chronic health effects. Unsafe food resulting in diarrhoeal diseases directly affects the uptake of important nutrients in the body. Safe food is essential for public health.	**Food safety relevance:** food chain operators need to have adequate knowledge, capacity and facilities to ensure food produced is safe and accessible – essential for confidence in their product, market access and income generation.	**Food safety relevance:** meeting importing country food safety requirements is a cornerstone of market access. There have been well-publicized high profile bans where this was not the case, resulting in significant financial loss to the country.	**Food safety relevance:** manufacturers need to ensure consumers are not harmed, product representation or claims are truthful, and unsafe products are made unavailable for sale.

Policy coherence

The breadth of food safety related activities brings a high degree of complexity to policy development and a need to look across various ministries to ensure policies are synergistic and do not give rise to conflicting outcomes. The idea of 'policy coherence' or 'joined up' approaches across ministries is important in food safety, as a policy initiative in one area may directly or indirectly impact a food safety outcome in another, and it provides the opportunity to keep abreast of key issues in other portfolios.

Improving consistency with national objectives has the potential to achieve better and lasting outcomes, and greater efficiency of efforts. High-level policy-makers (charged with a country's development and strategic direction) have a key role to play in guiding different sectors towards achieving policy coherence. Different sectors should not be working in competition but should work together to achieve win-wins. For example, increasing production of foods rich in protein is an important goal in many countries to improve nutritional status, enhance farmers' income, and reduce hunger. Applying best practices to produce safe animal-source foods has concurrent benefits of economic gains, increased yields, reduced food loss and

BOX 4

WATER QUALITY – WHERE AGRICULTURE DEVELOPMENT AND FOOD SAFETY POLICY INTERSECT

Agricultural development policy may lead to localised, more intensive farming and consequentially an increase in animal derived farmland drainage "run off" leading to contamination of groundwater or aquifers and compromised fresh water quality.

Food manufacturers, adhering to **food safety policy** to maintain hygienic food handling and the cold chain, are often encouraged to use water and ice to handle and chill product – e.g. to chill fresh chicken. This water needs to be safe.

Provided local authorities are monitoring and controlling fresh water quality, food safety is unlikely to be impacted. However, if local government **water treatment and control policy** and implementation is not effective, contaminated fresh water may result in contaminated food (and drinking water). Food safely is likely to be impacted.

This demonstrates the need for coherent policies and actions in different sectors to minimize any food safety risks. Possible policy solutions include managing agricultural development and production practices to minimize "run off" which may pollute water sources, ensuring local governments actively monitor water quality in relevant areas, and upgrading industry capacity to treat and monitor in-house potable water supplies.

Actively looking across related policy areas to ensure policy coherence can identify potential conflicting outcomes and minimize or avoid compromising food safety.

waste, protecting public health and strengthening food security. Therefore, greater gains can be made in both the sector of increasing agriculture production, and that of improving food safety, when efforts are undertaken in parallel. Policy-makers and risk managers may be able to improve food safety outcomes where polices are aligned, and food safety decisions can be reinforced through other similarly directed initiatives/policies.

The approach that is outlined in this guidance document directs decision-makers to give explicit consideration to the impact of food safety issues or risk management options on other sectors and national development goals. Thus, the multi-factor decision-making method can assist policy-makers and risk managers to identify areas where policy coherence is important and feasible.

Box 4 illustrates the importance of policy coherence.

1.4 THE PRACTICAL BENEFITS OF MULTI-FACTOR DECISION-MAKING IN FOOD SAFETY

Participants in the pilot studies in Thailand and Uganda, and the regional workshops in East Africa (Kampala, Uganda, April 2015) and Asia (Bangkok, Thailand, August 2015) agreed that a structured approach was needed in food safety decisions. They recognized that multi-factor decision-making encourages cross agency and cross Ministry collaboration that can generate synergy from improved alignment of food safety policy and risk management outputs. A broader perspective also ensures that actions taken to improve food safety are consistent with national or local objectives.

Other benefits that can arise from multi factor decision-making include:

> helping to inform priorities;

> bolstering the food policy dimension and work of risk managers;

> supporting multi-sectoral approach to common food safety issues;

> supporting continuous strengthening of the food control system;

> helping to focus on where food safety evidence and data are missing;

> being flexible to a country's needs as it enables development of country specific options and consideration of country specific factors in making food safety decisions; and

> providing sound evidence to support decisions.

Multi-factor decision-making can lead to better choices, particularly where there is complexity. It should provide risk managers with more confidence in their decision-making process, and convince high level policy-makers that the risk managers' recommendations are sound.

This guidance is designed to help both food safety policy-makers and risk managers take practical steps to apply multi-factor methods in a context that is appropriate and relevant for their country.

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SECTION 2

BASIC STEPS IN FOOD SAFETY DECISIONS BASED ON MULTIPLE FACTORS AND CRITERIA

KEY QUESTIONS THAT ARE ANSWERED IN THIS SECTION:

> How can multi-factor methods be applied in food safety decisions?

> What factors are relevant in food safety decisions?

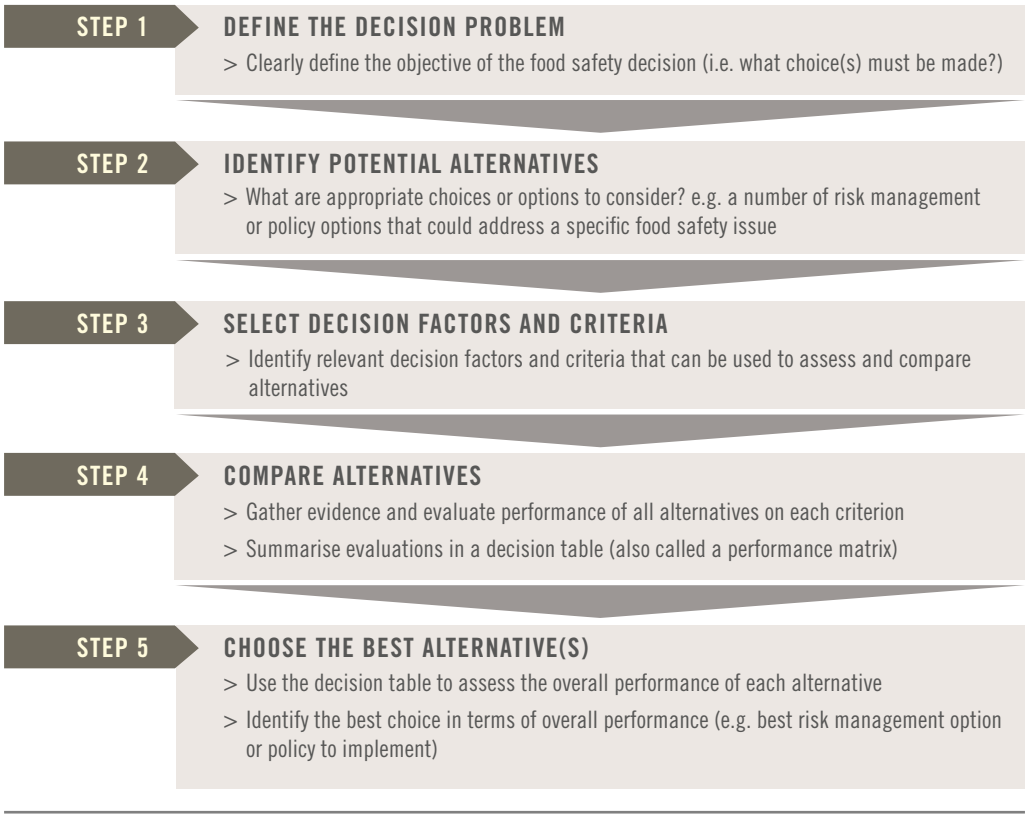
> What is a decision criterion?

> What evidence is needed to evaluate alternatives and what are some common sources of evidence?

> How do decision-makers select the “best” alternative?

The five-step decision schema shown in Figure 2 is applied consistently throughout this guidance document to a number of food safety decisions that are based on the consideration of multiple factors. The chevrons on the left side indicate the basic steps in defining the decision structure and analysing the options. There is further elaboration of each step for different types of food safety decisions in subsequent sections.

FIGURE 2 **APPLYING THE MULTI-FACTOR METHOD TO FOOD SAFETY DECISIONS**



2.1 EXPLANATION OF EACH STEP OF THE MULTI-FACTOR METHOD

STEP 1 DEFINE THE DECISION PROBLEM

The first step is to define the decision in terms of clear objectives. This guidance document examines a number of food safety decisions with related but diverse objectives. For example, in risk ranking and prioritization decisions, the objective is to classify a set of food safety issues in terms of the level of risk to public health and other types of harm. In choosing policy or risk management options, the objective is to identify the option or options that are effective in protecting public health and achieve the "best" or optimal performance in terms of other relevant factors (e.g. costs, feasibility).

IDENTIFY POTENTIAL ALTERNATIVES

STEP 2

The decision-maker considers different alternatives or options that could satisfy the decision objectives. The alternatives depend on the type of food safety decision. Alternatives may be a set of recognized food safety issues from which priorities for actions are chosen. Or alternatives may be a set of broad policies or specific measures that could be implemented to address food safety issues.

SELECT DECISION FACTORS AND CRITERIA

STEP 3

Decision-makers are required to make choices, e.g. Which food safety issues are the highest priority? Which is the best risk management option? Their choices are influenced by a number of factors that depend on the type of decision as well as the country context. Based on discussions with risk managers and policy-makers in different countries, it is clear that some decision factors are related to harm that may result from a foodborne hazard or a control measure. Table 1 outlines five decision factors that describe general categories of harm, and provides some examples of the type of harm that might arise from food safety issues.

TABLE 1 **DECISION FACTORS THAT DESCRIBE GENERAL CATEGORIES OF HARM**

DECISION FACTOR	EXAMPLES OF POTENTIAL HARM DUE TO FOOD SAFETY ISSUES
Public health impacts caused by foodborne hazards	> Immediate illness > Chronic health impairment > Mortality
Economic losses related to food products being removed from domestic or export markets due to food safety concerns	> Reduced access to, or share of, domestic and export markets due to hazards in foods > Lower market value and/or lower volumes traded or sold due to food safety concerns > Reduced employment and livelihood – potential impact(s) on producers, processors and/or distributers > Loss of community livelihood > Negative impact on non-food sectors (e.g. tourism)
Food Security including concerns about utilization, food access and food availability	> Malnutrition, wasting or growth stunting > Increase in prices due to shortages caused by removal of unsafe foods from the market > Reduced household income due to lower value or inability to sell food products > Decrease in availability due to condemned products or reduced supply > Decrease in dietary diversity
Consumer perceptions and acceptance of food safety risks	> Avoid nutritious food choices based on risk perceptions > Lower level of trust in government's ability to ensure safe food
Socio-cultural concerns related to protecting vulnerable groups	> Differential impacts on vulnerable sub-groups of the population or on one gender > Isolation and vulnerability increased due to social stigma associated with outcomes from foodborne illness (e.g. epilepsy linked to neurocysticercosis)

Other decision factors are related to practical considerations associated with implementing a risk management option or policy. Some of the common types of implementation factors are outlined in Table 2 with examples related to food safety.

TABLE 2 **DECISION FACTORS RELATED TO IMPLEMENTATION OF A FOOD SAFETY POLICY OR RISK MANAGEMENT OPTION**

DECISION FACTOR	EXAMPLES RELATED TO FOOD SAFETY
Costs	> What are the costs in terms of fixed (one-time) investments and ongoing operating costs and who bears the cost (producers, processors, consumers government) for a risk management measure?
Feasibility	> Do existing food control agencies have the capacity (in terms of technical expertise, infrastructure, staff)? > Is industry capable of meeting standards (mandatory or voluntary)?
Practicality	> Does the risk management option work within the current food production system? > Does it work for large and small producers?
Benefits	> Are there social benefits, e.g. greater acceptance by the local community of one risk management option over another? > Reduced health care costs as less people need treatment from unsafe food
Political considerations	> Pressure by lobby groups – producer, processor and/or consumer > Coherence with related government policies (e.g. environmental sustainability, One Health) or priorities

Making factors measurable

Decision-makers must be clear on the factors that influence their choices but a factor on its own is not sufficient for decision-making. Each decision factor must be framed as a criterion or a set of criteria that can be used to evaluate and compare alternatives. A criterion is a scale or yardstick that allows the decision-maker to assess, in a qualitative or quantitative sense, the performance of each alternative. For example, a number of criteria could be used to measure public health impact including qualitative levels of risk or quantitative burden of disease estimates.

Table 3 shows some examples of general decision factors and criteria that may be used to evaluate the performance of alternatives in food safety decisions. Note that some criteria are based on simple scales (e.g. "0" to indicate acceptable level of risk and "1" to indicate unacceptable risk, or a set of ordinal categories such as "low", "medium" or "high" risk). Other criteria are evaluated using continuous scales such as Disability Adjusted Life Years (DALYs) or monetary costs. The scale depends on what the decision-maker is trying to assess and the availability of information and resources. For example, DALY values are comprehensive measures of health outcomes but these calculations require a significant amount of data.

Each country chooses decision factors that are appropriate for its food safety context and resources available for evidence gathering analysis. It is important to appreciate that not all of these decision factors and criteria are appropriate for every food safety

decision. Some are specific to a particular decision. For example, implementation factors are important when comparing potential risk management options (Section 3). Finally, while the aim is to consider a broad spectrum of risks or harm that could be associated with food safety issues, it is not practical to include all possible types of harm or outcomes. Risk managers must identify a set of factors that is simple enough to be of practical use in decision-making and that can be understood by multiple stakeholders.

TABLE 3 **EXAMPLES OF DECISION FACTORS AND CRITERIA FOR FOOD SAFETY DECISIONS**

GENERAL DECISION FACTOR	EXAMPLES OF CRITERIA FOR COMPARING ALTERNATIVES	TYPE OF SCALE
Public health impact	Qualitative level of risk	> Binary – "acceptable" or "unacceptable" > Multiple categories – "low", "medium", "high"
	Burden of disease 1. Disability Adjusted Life Year (DALY) 2. Cost of illness	1. years 2. monetary scale
Economic concerns	Value of exports Value of domestic market	monetary scale monetary scale
Consumer perception and acceptance of risk	Aggregate measure based on 5 sub-criteria that assess consumer perceptions and acceptance (Ruzante *et al.* 2010)	normalized scale between 0 (=low risk/ high acceptance) and 1 (=high risk/low acceptance)
Implementation – acceptability of a risk management option in terms of food security	Potential harm to food availability if risk management option is implemented	point scale (1 = severe impact on food availability; 5 = no impact)
Implementation - costs	Initial, one-time cost to implement risk management intervention Ongoing operating costs	monetary scale

COMPARE ALTERNATIVES — STEP 4

This step focuses on the analysis of evidence to evaluate each alternative in terms of all of the criteria. The type of evidence that is needed, and the sources that are appropriate, depend on the factors and criteria that are considered in a particular type of decision. Based on the range of factors and criteria that have been suggested for food safety decisions, it is clear that evidence must be drawn from diverse sources.

Sources include government ministries and agencies, industry data, published literature and research, consumer surveys as well as expert opinion. Evidence can be derived from methods and tools from the physical, biological, information and social sciences. Since multi-disciplinary methods may not be familiar to all stakeholders, risk managers must be open and transparent about data sources and methods of analysis, and document key findings using language that experts and stakeholders from different disciplines can understand.

Some studies may have to be commissioned to obtain specific scientific, economic, consumer information. Careful selection of the breadth, range and number of subjects to be studied may have to be made for efficient use of resources. Other countries may have helpful information if they have previously considered a similar matter. Stakeholder consultation is an important further source of information, particularly that relating to implementation where practicability, effectiveness and costs are important considerations.

When this step is complete, a decision table or performance matrix[2] should be created. This is a convenient format for comparing alternatives based on a single criterion (i.e. down a column in the table) or considering overall performance of a specific alternative (i.e. across a row in the table). It is easier to get a sense of overall performance of each alternative if all the criterion scales are defined in a consistent way. That is, the "best" performance should be either the maximum or the minimum values on all the criteria scales.

STEP 5 CHOOSE THE BEST ALTERNATIVE(S)

When there are a small number of criteria, decision-makers may be able to identify the preferred (i.e. "best") alternative by reviewing and comparing the information in the performance matrix or decision table. However, when there are a large number of criteria and/or alternatives to compare, the information can become too complex to interpret. Often there are differences in performance across various criteria and no clear winner overall.

In these latter cases, there are a number of different methods to analyse information in the performance matrix and identify the "best" alternative overall. As a group, the techniques are referred to as multicriteria analysis (MCA) and are based on numerical computations[3]. In some MCA methods, this requires that the information in the performance matrix must be adjusted to numerical values on a common scale for all criteria (e.g. all evaluations are scaled between 0 and 100 based on an expected maximum value for a criterion). Qualitative levels or categories (e.g. low, medium and high) must also be converted to numerical scores on the same common scale (e.g. values between 0 and 100 such as "low" = 33, "medium" = 67 and "high" = 100).

The next step is to combine or aggregate all the scores in order to identify the "best" overall performance. The examples in this document highlight two methods of aggregation:

> linear additive models (e.g. average performance scores across all criteria)

> outranking methods (aggregation based on degree to which an alternative outranks other alternatives and degree to which it is outranked by other alternatives in the set) (e.g. Brans and Vincke, 1985).

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2 "Performance matrix" is the term that is commonly used in decision analysis tools.

3 When applied to decisions, these methods are referred to as multi-criteria decision analysis (MCDA).

Both methods allow decision-makers to apply variable weights to factors and criteria. For example, if the five general factors in Table 1 are considered with equal weighting, then each factor (e.g. economic impact) contributes a maximum of 20 percent to the final evaluation of performance. Decision-makers can apply different weights based on their judgment about the importance of each factor and stakeholder consultation. Additional details about weighting, aggregation and software resources are included in Annex.

The choice of the "best" alternative depends on the food safety decision. The selection of a particular policy or risk management option is based on overall performance related to acceptability and implementability. The goal of risk ranking and prioritizing is to identify the food safety issues that have the greatest potential to cause harm (i.e. choice is not limited to a single food safety issue). When decision-makers follow the 5 step decision-making process as outlined, they can communicate clearly with stakeholders about the evidence used and the basis for the final choice.

This schema does not replace the decision-maker(s) (i.e. risk managers and policy-makers). Decision-makers play essential roles in understanding and guiding the process, gathering the evidence, weighing the findings and validating the final choice.

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SECTION 3

RISK MANAGEMENT OPTIONS: HOW TO IDENTIFY, EVALUATE, ASSESS AND SELECT THE BEST ONES USING MULTI-FACTOR DECISION-MAKING

KEY QUESTIONS THAT ARE ANSWERED IN THIS SECTION:

> How should risk management options be identified?

> What factors and criteria can be used to evaluate the risk management options?

> What evidence is relevant and how is it analysed?

> How is the best risk management option selected?

3.1 STEPS IN SELECTING RISK MANAGEMENT OPTIONS

One of the main components in the generic framework for risk management (Figure 1) is the "Identification and selection of risk management options" to address a food safety issue. The multi-factor decision schema shown in Figure 2 is well suited to support risk managers when they need to decide on the most appropriate option(s) to address the food safety issue (e.g. *Salmonella* spp. in poultry, aflatoxin M1 in milk) and minimize the potential for harm. The structured process is a useful guide to follow as they identify potential options, select relevant decision factors and criteria to evaluate the performance of each option, and use the evaluations to select the preferred risk management option.

STEP 1 DEFINE THE DECISION PROBLEM

Risk managers must first identify food safety issues that pose unacceptable levels of risk to health and could possibly lead to other harmful consequences. They will have to confront emergency issues and food safety problems that are identified through "Preliminary risk management activities" that include a process of risk ranking and prioritization.

For each of the priority issues, the risk manager must decide on an appropriate action(s). The decision problem is to choose the preferred option from a number of potential alternatives. The preferred option must be effective in reducing the health risk. It must be broadly acceptable to the community and aligned with government policies in related areas such as health, agriculture and international trade. It should also be affordable and feasible to implement (performing well against the important implementation factors as outlined in Table 2).

STEP 2 IDENTIFY POTENTIAL RISK MANAGEMENT OPTIONS

The risk manager's primary objective is to reduce the risk to consumers. In simple terms this can be achieved by reducing the hazard or reducing the exposure to the hazard, or a combination of both. Understanding the nature of the hazard and exposure are important in devising possible risk management options. The risk manager can choose to:

> **Avoid** the risk entirely e.g. do not use the ingredient or food material, do not eat the food, change to another product.

> **Reduce** the hazard e.g. reduce physical, chemical or microbiological hazard levels through improved raw materials choices, improved processes or sanitation, altering the food matrix or composition, to prevent presence or growth of hazard.

> **Reduce** exposure e.g. limit consumption of specific foodstuffs through management of supply, modify the use of potentially harmful substances such as controlled use of agrochemicals.

- **Accept** the public health risk and communicate the risk to consumers:
  - Inform consumers to enable avoidance of risk – such as mandatory labelling of food allergens where the risk is specific to sensitive consumers, rather than the general population.
  - Inform consumers to enable them to mitigate risk, through reducing the hazard or exposure. Examples include providing food preparation instructions (labelling) for cassava products containing cyanogenic glycosides; date marking and storage information (labelling) for products having short or limited shelf life; advice to limit intake of mercury in fish through public information campaigns to reduce consumption.

Risk management actions can be seen as a continuum ranging from *strong regulatory action*, such as an outright ban or prohibition of foods that are harmful or potentially harmful to health (e.g. foods with excessive chemical residues or microbiological contamination); to *less stringent* regulatory intervention, such as imposing controls on agricultural chemical use or controlling harvesting and food production practices; and to *non-regulatory or voluntary* actions, such as industry codes of practice. Outright bans are used only where absolutely needed and when other options are considered to be ineffective.

Table 4 gives some examples of risk management options across a range of regulatory and non-regulatory responses.

TABLE 4 **POTENTIAL RISK MANAGEMENT RESPONSES**

RISK MANAGEMENT OPTIONS	EXAMPLE(S)
Establish and enforce regulations and mandatory standards [4]	> Drafting of new standards or regulations such as: > Prohibiting high risk foods or materials, or requiring product labelling e.g. allergens > Setting maximum allowable levels for contaminants including microbiological, chemical, foreign matter limits > Establishing controlled production processes (e.g. controlled agrichemicals application and withholding periods) or controlled harvesting practices (e.g. specific fishing zones or seasons) > Limiting allowable use of new food additives > Requiring product labelling e.g. allergens, date marking ingredients, composition, nutrition information > Enforcing/putting in place targeted control/surveillance programmes > Establishing industry based Food Safety Objectives that will contribute to achieving an Appropriate Level of Protection (ALOP) > Requiring Hazard Analysis Critical Control Point (HACCP)[5] and risk based product and process management frameworks
Non-regulatory approaches **a. Public information campaigns** **b. Quality Assurance schemes and certification by accredited bodies and** **c. Self regulation by industry through voluntary Codes of Practice/ private standards**	> Government- or industry- (or a combination) driven public and consumer education on appropriate use of foods (preparation, consumption, storage) > Promoting voluntary compliance and preventive approaches e.g. premium quality logos on labels and applying > Good Agricultural Practices (GAPs) > Good Manufacturing Practices (GMPs) > Good Hygienic Practices (GHPs) > Good Veterinary Practices (GVPs)
Information, Education, Communication	> Engaging in media, school/community outreach programmes, customer and consumer on-line training

4 In this context regulations and standards are taken to have similar effect in law although the development pathways may vary.

5 See Codex General Principles of Food Hygiene: http://bit.ly/2nnygVy. Last accessed 4 October 2017.

Less stringent approaches can be considered where the food hazard can be tolerated at known low levels. A more moderate regulatory intervention such as requiring consumer labelling advice concerning consumption, preparation, quantity and frequency of use can reduce the risk to an acceptable level. The objective is to use a "graduated" or "proportionate" response that addresses the health risk but is not more restrictive than is necessary. Response measures can also encompass non-regulatory or voluntary actions by one or more operators within the supply chain e.g. through application of a code of practice for production of specific foods. These measures may be suitable where the health risk is considered to be low or where matters of personal choice are important.

Risk managers must follow a systematic approach to identify opportunities to mitigate health risks considering the nature of the hazard and exposure. A combination of several measures, each having a moderate impact at a key place in the supply chain, may be the best way to reduce health risks to an acceptable level. The response to the risk of mercury in fish (Box 5) is a good example of the application of a range of measures resulting in acceptable outcomes for both consumers and producers. When developing alternatives, the risk manager can benefit from discussion with colleagues and stakeholders. They can be helped by a consideration of similar issues at local, national or international levels as well as by a review of the technical literature.

BOX 5

COMBINATION SOLUTION TO REDUCE RISK CAUSED BY MERCURY IN FISH

Heavy metal (such as mercury) contamination of certain species of fish can cause risk to public health where affected species are consumed in sufficient quantities. In determining the most appropriate action to minimize any health risk, food safety managers may consider banning harvesting and sale of fish. While clearly addressing the public health and safety risk, this option may not be the optimal solution as it does not take into account factors such as the importance of fish in the diet, the loss of an important source of protein for many, the loss of livelihood for fishers and the impact on the fish processing industry.

Combination solution:
A combined solution considering a range of less stringent risk management options may include limiting the catch of certain species, restricting the location for fish harvesting and providing advice to consumers about limiting fish consumption in terms of species, frequency and portion size.

This combination approach can be supported by ongoing surveillance and dietary modelling to check overall consumer exposure to mercury, thereby ensuring that public health and safety is protected.

SELECT DECISION FACTORS AND CRITERIA TO EVALUATE RISK MANAGEMENT OPTIONS — STEP 3

It is useful to organize the decision factors to evaluate risk management options into three general groups:

1. Effectiveness – does the risk management option reduce the public health risk to an acceptable level?
2. Acceptability – is the option acceptable based on consideration of potential social, economic and political impacts?
3. Implementation – how does the option perform in terms of cost, benefits, feasibility and practicality?

Effectiveness in reducing public health risk is the primary factor in evaluating risk management options, with the key question being "is the risk to public health managed down to an ALOP?". If an option fails to achieve a satisfactory level of risk reduction, risk managers may consider a combination of response measures to ensure effectiveness. Effectiveness of a single measure or a combination of several measures is assessed on a pass or fail criterion. Only options that pass in terms of the effectiveness criterion are given further consideration as potential risk management actions.

Acceptability of risk management options is based on consequences beyond public health impact. A risk management option must achieve the required level of public health protection but should not produce significant risks or negative outcomes in related policy areas. For example, a solution that effectively reduces the health risk but significantly increases food prices or reduces availability would not be acceptable in terms of food security.

A number of the factors outlined in Table 1 can be used to assess the acceptability of a risk management option, including: economic considerations; impact on food security at country and household levels; cultural and social acceptability; consumer acceptability; and legal and political implications (e.g. policy coherence across other ministries such as trade effects, environmental impact, rural development). Not all factors are relevant in every situation; it is up to the risk manager to choose factors that are appropriate for the food safety issue and country context. It is helpful for risk managers to "put themselves in the stakeholders' shoes", to understand what is acceptable to different stakeholders, and to bring a practical set of these factors into consideration.

It is recommended that the criteria for acceptability should be evaluated at a high level and in qualitative terms. For example, a simple binary scale such as "acceptable" (= 0) or "unacceptable" (= 1) could be used. In some decisions, it might be useful to expand the number of categories to describe negative outcomes (e.g. "none", "minor", "unacceptable"). The aim is not to quantify potential impacts since this would be challenging and resource intensive. The objective is to set flags which the risk manager can use to judge the overall level of acceptability of the proposed risk management option.

Implementation factors focus on the practical aspects associated with putting a risk management option in place. General implementation factors are outlined in Table 2. Risk managers need to consider a wide range of perspectives (i.e. those of government, manufacturers, producers, retailers, consumers) asking questions such as:

> What will it mean to producers and to industry manufacturing costs?

> What is the feasibility of implementing the risk management option?

> Is there adequate expertise or capability?

> Are resources available to support implementation?

> Is it enforceable?

> What are the costs of implementation or of enforcement?

> Will consumers understand, accept and follow food safety advice?

> What is the overall economic outcome?

> What is the overall benefit and who will benefit?

In general terms, implementation factors include:

> cost to government, industry and consumers;

> benefit to government, industry and consumers; and

> feasibility and practicality for industry, government and consumers.

The implementation factors' *costs* and *benefits* should be easily understood, with *costs* referring to the financial *cost* of implementing a measure, and benefits being the gains that can be made by implementing one option over another. The distinction between *feasibility* and *practicality* concerns whether it is possible to implement an option – is there a technical solution *(feasibility)* versus can it practically be achieved – are there any time limitations, how long would it take to implement an option, the scale of implementation, is there any political pressure *(practicality).* Once the implementation factors have been identified, it is important to establish evaluation criteria (i.e. measurement scales). Economic costs and impacts are usually expressed in terms of monetary value. Feasibility and practicality may be evaluated by using 5-point or 10-point scales that are calibrated by technical experts.

In some situations, risk managers may decide to include cost:benefit as a (single) implementation factor, which requires evaluating the cost, and at the same time evaluating the benefit of a risk management option. This enables risk managers to assess which expenditure brings the most benefit – i.e. identify the best use of funds. Benefits to be considered may vary, and may include a reduction in illness, increase in product sales, etc. These are measured in monetary terms. While cost:benefit may be helpful to weigh up different options, it is still currently considered as a highly skilled and more complex approach (see Box 6).

GATHER EVIDENCE; EVALUATE AND COMPARE THE OPTIONS

STEP 4

It is recommended that risk managers consider the three groups of decision factors (effectiveness, acceptability, implementation) in a hierarchical order. In this way, proposed options that are not effective in managing health risk, or do not meet a minimum threshold in terms of overall acceptability, are eliminated before undertaking the detailed analysis needed to evaluate implementation factors. To proceed, the risk manager now needs to obtain relevant evidence for each of the decision factor's evaluation criteria in order to evaluate the risk management options.

Effectiveness: The effectiveness of risk management options in reducing public health risk may be evaluated using:

> Advice from risk assessors: Where *risk* (hazard*exposure) has been assessed, it may be possible to calculate a revised *risk* based on the estimated change in the level of hazard or exposure achieved through the implementation of a specific risk management option.

> Information reported in the scientific literature: Evidence that a technological process effectively reduces a known public health risk (e.g. milk pasteurisation) or risk assessments and control measures for similar food safety problems (e.g. Wu and Khlangwiset (2010a) analysed the effectiveness of pre- and post-harvest control strategies for aflatoxin in maize and groundnuts).

> Stakeholder consultations: Producers, processors and distributors should be invited to share their knowledge of the effectiveness of programmes such as GAPs, GVPs and others that are listed in Table 4.

> Risk assessment tools such as Risk Ranger[6] (Ross and Summer, 2002) or the Risk tool developed by the FDA.[7] Both tools can be used to simulate simple interventions to reduce risk levels.

> Consultation with recognized experts, often known as "expert opinion".

Note:
There is additional discussion of these tools in Section 4.2

In some cases, it is not possible to estimate in advance the degree of risk reduction that will be achieved through a specific risk management measure. However, there should be reasonable confidence, based on past experience and expert judgment, that the measure will be effective. Once an option is implemented, it is good practice to verify its effectiveness (e.g. through sampling and analysis, estimation of dietary exposure or consumer research, public health data) to assure that the intervention achieves an appropriate level of protection. Verification also provides evidence that risk managers can use in future decisions about control measures.

Acceptability: Acceptability factors consider the potential for harm or unacceptable consequences in relevant policy areas. The sources of evidence for acceptability include government ministries/agencies, local authorities, industry associations,

6 See www.foodsafetycentre.com.au/riskranger.php (last accessed 4 October 2017).

7 See https://irisk.foodrisk.org/ (last accessed 4 October 2017).

consumer associations and academic experts and social scientists. As acceptability factors are often the same as those used in setting food safety priorities, the evidence sources discussed in Section 4 may also be useful here, although the measurement is general and much less detailed. As noted earlier the aim is not to quantify acceptability factors since this would be challenging and resource intensive. The objective is to set flags the risk manager can use to judge the overall level of acceptability based on consideration of a number of factors.

Implementation: Implementation considers factors beyond effectiveness and acceptability, and it is here that evaluating cost, practicality and feasibility, and benefits can be a valuable input to the decision. Risk managers need to have a very clear understanding of each risk management option i.e. the action required, and by whom, in order to determine what evidence they need to collect, and from whom. Evidence for implementation criteria comes from diverse sources (e.g. government, industry, consumers) since risk managers must consider the effect of implementing a proposed option across the broad community. Risk managers are advised to consult with interested parties or stakeholders in preparing the analysis. Consultation may invite comment and feedback on the option or options under consideration, and may also provide new or amended data that can become part of the evidence around implementability.

Feasibility and practicality

To assess the feasibility and practicality of different options, risk managers need to gather evidence on whether or not the option can be implemented, and whether it is practical to do so. The evidence needed to understand this will depend on the risk management options being considered. It is impossible to explain all possible scenarios, but some examples of type and source of evidence would include:

> If a risk management option to minimize risks from mycotoxins requires drying of grains, decision-makers need to understand the feasibility, i.e. whether the technology is available through silos or on-farm drying facilities. When considering practicality, decision-makers would consider how the supply chain is organized to determine whether all farmers and other value chain operators have access to the technology, and whether they have the required skills.

> If a risk management option requires training food handlers to improve food safety practices, when considering feasibility, evidence needs to be obtained on whether suitable trainers and training materials are already available. Evidence on practicality may include information on the number of food businesses that would need to be trained, questioning whether they can be trained within a reasonable timeframe.

> If a risk management option requires increased inspection by the enforcement authority in order to reduce a food safety risk, considering feasibility would require information on the availability of trained, skilled inspectors, while practicality may need information on whether the inspectorate can absorb this increase in inspections, within existing resources and the time available.

From these examples, it is apparent that industry, government and consumers can be a rich source of evidence when determining the feasibility and practicality of different options. Consumer views and acceptability of a risk management option (e.g. a new technology) may also be an important consideration. This information is often available through industry, government and consumer consultation or surveys. As noted earlier the evidence can be assessed on 5- or 10-point scales using expert support.

Costs

Comparing the costs of different risk management options is often a key consideration of implementation. Depending on the option, the costs can be borne by different groups, typically industry and producers, or the government or the final consumer. Costs can be one-off investment costs (e.g. installing new equipment in a food plant), or continuous investment over time (e.g. increased food surveillance by a food authority, refresher training of employees). Risk managers need to be clear on which group will bear the main cost for an option. They then need to engage with them to collect the required evidence on the potential cost. Decision-makers should remember that the final decision on the preferred risk management option is in relation to how it fares against the other options. Which is the most or least expensive? Therefore, it does not necessarily require a very detailed cost for each option, but rather an understanding of where the options rank relative to each other in terms of cost.

Types of costs that may be borne by different groups are outlined below.

> **Economic impact on industry and producers**
Food industry and producers may incur costs due to additional production or manufacturing costs (labour, materials, utilities, machine time, engineering and design) involved in finding, purchasing and using an alternative raw material, changing a process, conducting additional testing or introducing new packaging or labelling. Investment in training of food operators, or improving food safety management systems within a food business, may incur costs. There may be other effects such as increases or decreases in productivity, wastage, rework and selling price to be taken into account. Engaging with representatives of food industry and producers is the most direct route to obtain this evidence.

> **Economic impact on government**
Resource requirements, such as those required to implement and enforce risk management measures at national or local government levels, can be turned into monetary value using data and evidence obtained by consultation or commissioned research. The costs for enforcement related activities may be associated with introducing a new food standard, increasing laboratory food testing, increasing inspection, training of value chain operators, etc. At other times, the government may face a lack of capacity to carry out certain risk management measures, and may need to dedicate resources to address these weaknesses. This may be assessed as costs of new recruitment, training or contracting to external providers. Clearly,

government authorities will be the primary source of information on current costs incurred for existing risk management activities, and best placed to calculate expected increase or decrease in costs with a change in risk management activities.

> **Economic impacts on consumers**

Economic impact on consumers is probably less evident, however risk managers should consider whether any change in food prices might occur which would directly impact the consumer, and result in associated food security concerns which are clearly important to consumers. Much of this evidence may be obtained by conducting social and consumer research and surveys and while some consumer data may be monetized (calculated in dollar or currency terms), other data may be presented using numeric scales calibrated by experts.

Benefits from implementation

Considering the implementation benefits of one option over another can be an important part of the decision analysis. Benefits may be diverse and will be specific to the option and country context. Possible benefits may include a reduction in foodborne illness that can result in reduced health care costs, increased productivity due to a reduction in illness and time away from work, increased attendance at school, increased trade access, and greater support to a priority food industry sector. There may also be social benefits arising from some measures e.g. reduced family stress and disruption, improved acceptance by the local community and consumers, improvements in work-life balance.

Sources of evidence for these examples could include national health agencies, trade and industry departments and national education agencies. Involvement of social scientists may be helpful in contributing to the evidence gathering activity.

BOX 6

Cost:benefit analysis is a structured approach that considers both costs and benefits (and sometimes detriments) across the broad community. The total costs are then compared with the total benefit. To facilitate the comparison the benefits need to be converted to monetary values. Costs and benefits may be taken over a number of years and expressed as net present value.

It is often found that estimates of cost are more easily obtained than estimates of benefits, and not all economic impacts are readily expressed in monetary terms e.g. consumer detriment that might arise from changes to shopping or market structures.

Cost:benefit analysis is a detailed and potentially costly analysis tool. It introduces complexity in gathering and analysing data, and may introduce difficulties in monetizing all benefits (e.g. trying to monetize improved cognitive behaviour in children due to reduced aflatoxins exposure). For this reason it is best used when the options are well developed, with experienced decision-makers and adequate evidence and data. If badly done, it can introduce more uncertainty.

Discussion with an economist may assist in building a comparative model recognising the differences in types and robustness of the various input data.

For further information it may be useful to see link at https://www.pmc.gov.au/resource-centre/regulation/cost-benefit-analysis-guidance-note (Australian Government, 2016a).

Depending on the context, it is acceptable to measure and compare benefits using qualitative scales or flags. Informed "expert judgment" estimates may be the only way forward. When using this approach it is helpful to have more than one person making such estimates. In other contexts, decision-makers may wish to convert benefits to monetary values as a basis for comparison.

"Ball park" estimates can give guidance on relative costs and benefits and whether there are significant cost differences for different options.

Comparing the alternatives

As proposed in step 4 of the multi-factor decision method (see section 2), it is useful to summarize the evaluations for all of the alternatives (i.e. risk management options) in a decision table or performance matrix. This format makes it easy to review performance overall as well as based on individual criteria. It is easier for the decision-maker to scan the table and get a sense of overall performance if the criteria scales are defined so that the "optimum" value is consistently the bottom or the top of the scale. Many of the criteria that are used to assess implementability are related to costs and low values are preferred. Scales for criteria to assess feasibility or practicality should be defined in a consistent way. For example, a 5-point scale may be defined to evaluate feasibility where a score of 1 indicates highly feasible and a score of 5 indicates low feasibility.[8]

CHOOSE THE "BEST" RISK MANAGEMENT OPTION — STEP 5

The objective is to select the risk management option with the best overall performance across all criteria. In some cases, the choice of the best option is obvious based on a review of the decision table. When there are a large number of criteria and/or risk management options, it is more challenging to identify the "best" option. Risk managers should consider using one of the multi-criteria analysis methods suggested in step 5 of the multi-factor decision method (see section 2). The case studies at the end of this section provide examples of different methods to combine evaluations across all criteria.

It is important to remember that **people ultimately make the decision** (i.e. select the preferred risk management option). Risk managers must consider the full range of evidence and analysis that is available as well as the uncertainty in this information and make an expert judgment about the "best" option. The option with the "best" score may be passed over in favour of another option that may for example cost more but gives a solution that is more acceptable to stakeholders.

Transparency is important and it is good practice to provide stakeholders with the key analyses and reasoning that led to the final decision (i.e. choice of risk management option to implement). Consultation is one of the key elements of risk communication and is crucial to ensure successful implementation of the risk management option.

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8 Note some software tools allow the user to indicate whether the preference is the minimum or a maximum criterion value and can determine "overall" preference with mixed scales for different criteria.


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3.2 CASE STUDIES

Three case studies are presented to illustrate the stepwise decision process for identifying, evaluating and selecting the "best" risk management option to address a food safety issue. Although the examples are drawn from real world food safety issues, the evidence and information that is used to evaluate options (and hence the final recommendation) are hypothetical. A number of assumptions are made in terms of potential options, relevant decision factors and criteria to consider. These are simply examples and other factors or criteria could be applied.

The aim of the case studies is to help risk managers and policy-makers understand the multi-factor decision-making methodology so that they can apply it to similar food safety decisions with information that is relevant in their country context.

Case study 3a

EVALUATING AND SELECTING A PREFERRED RISK MANAGEMENT OPTION FOR MERCURY IN FISH

Situation

Box 5 outlines the issues relating to heavy metal (such as mercury) contamination of certain species of fish that can cause risk to public health where the affected species are consumed in sufficient quantities. This case study is set in a rural area that has a significant local fishing and fish processing industry, and fish is an important part of the local diet. Banning harvesting and sale of fish, while addressing the public health and safety risk, may not be the optimal solution as it does not take into account factors such as the importance of fish in the diet, the loss of an important source of protein for many, the loss of livelihoods for fishers, and the impact on the fish processing industry.

DEFINE THE DECISION PROBLEM — STEP 1

To choose the best overall option for reducing community health risk arising from mercury in fish.

IDENTIFY AND SELECT RISK MANAGEMENT OPTIONS — STEP 2

Three options to mitigate the risk of mercury in fish were identified:

- **Option 1** – a ban on harvesting (catching) and sale of fish with potentially high mercury levels
- **Option 2** – limit harvest and sale of certain species (and size) of fish (i.e. those with potentially high mercury levels). This restricts only certain species and harvesting areas known for higher mercury levels, and enables continuation of the local fishing and fish processing industries, although possibly at a lower level of production.
- **Option 3** – limit harvest and sale of certain species (and size) of fish plus an information/education programme to support consumer understanding about the significance of mercury in the diet and ways to limit exposure.

STEP 3 DEVELOP A RANGE OF DECISION FACTORS AND CRITERIA BY WHICH THE OPTIONS WILL BE ASSESSED

Effectiveness – reduction in community health risk to an acceptable level

Acceptability – for the purpose of illustration, three acceptability factors were selected – food security, rural economy and impact on nutrition. Acceptability was assessed as pass/fail for each of the three factors.

Implementability – three implementability factors and criteria were selected:

> Local government capacity to implement – Each option was ranked relative to the other options and a ranking of 1 indicates the best performance.

> Likely consumer compliance – Consumer compliance was considered important as there was potential for consumers to ignore or work around the restrictions by fishing themselves or purchasing fish from the informal market, thereby defeating the measure. Relative ranking scores were used to assess likely consumer compliance where 1 indicates the best likely compliance

> Cost – In this example, without actual cost data we have developed "informed estimates" and used a ranking scale where 1 is the least cost.

STEP 4 GATHER EVIDENCE, EVALUATE AND COMPARE ALTERNATIVES (RISK MANAGEMENT OPTIONS)

Effectiveness:

Each measure is considered to be effective in reducing public health risk to an appropriate level.

Acceptability criteria:

Option 1 - a ban on fish harvesting and sale fails on all three acceptability criteria (food security, rural economy and nutrition), reflecting the dependence of this community on fishing and the importance of fish in the overall diet. Option 1 is removed from further consideration, while the other two options met acceptability criteria and proceed to further analysis.

Implementability criteria:

Local government capacity – In terms of this criterion, option 2 is the least resource intensive to implement, with option 3 requiring increased resources.

Likely consumer compliance – If consumers are informed about the significance of mercury in the diet and the need to limit fish consumption, they are more likely to accept the restrictions on harvesting and sale of fish. Option 3 ranks better in terms of likely consumer compliance compared to option 2, reflecting the expected benefit arising from consumer education.

Cost – The costs that we are considering are those borne by the government to implement options 2 and 3. Without hard data we have developed "informed estimates" and again, used a ranking scale, where a ranking of 1 is most favourable or least costly. Option 2 is least costly, with the additional costs of consumer education impacting on the overall cost of option 3.

CHOOSE THE BEST OPTION (ALTERNATIVE) — STEP 5

Overall evaluation – choose the best option:

In this analysis, options have been assigned ranking scores, and the best option has the lowest total score. Options 2 and 3 score 4 and 5 points respectively – leaving option 2 as the preferred option.

There is a trade-off between cost and consumer compliance where an improvement in compliance is gained by increased costs – arising from education. This is where the judgment of the decision-maker plays an important role. That is – is the improved consumer compliance worth the additional cost? This illustrates the fact that many decisions are not clear cut and country context plays a role in the decision.

Table 5 shows the decision table that is used to compare the risk management options. Note that this is a hypothetical example designed to illustrate the evaluation and comparison of different risk management options.

Note: This case study illustrates use of ranking scales for implementability criteria and the analysis is displayed in a decision table. Additional options can be added and the decisi on-maker would need to re-evaluate all the alternatives relative to the new one. Similarly, additional implementability factors can be added and ranking scores applied.

TABLE 5 **DECISION TABLE TO COMPARE RISK MANAGEMENT OPTIONS FOR MERCURY IN FISH**

DECISION CRITERIA	EFFECTIVENESS	ACCEPTABILITY			IMPLEMENTABILITY			TOTAL
	Public health and safety	Food security	Rural economy	Nutrition	Local gov't capacity to implement (Rank 1-2)	Likely consumer compliance (Rank 1-2)	Cost (Rank 1-2)	
Option 1 Ban fish harvesting and sale	Pass	Fail	Fail	Fail	Not considered	Not considered	Not considered	Not considered
Option 2 Limit harvest and sale of fish	Pass	Pass	Pass	Pass	1	2	1	**4**
Option 3 Limit harvest and sale of fish plus consumer information/education	Pass	Pass	Pass	Pass	2	1	2	**5**

Scores: Ranking (1: most favourable to 2: least favourable)

Case study 3b

IMPROVING SAFETY OF STREET FOODS

Issue

In a major provincial town, there are reports of increasing rates of foodborne illness caused by street foods leading to increasing attendance at health centres and absence from work. Children are also affected leading to absence from school. There are growing concerns within the community and national and local governments. Local government has asked its food safety department to look into the matter.

Background

Street foods play an important role in many countries, providing a range of readily accessible, locally prepared foods at affordable prices. The street food vendors operate at a community level and are selling foods to a broad range of people from all sectors of the community. As well as providing local foods at affordable prices and at convenient locations, street food vendors play a broader role in the community utilizing local produce and providing employment.

However, street foods can present many hazards including microbiological (bacterial, fungal, viral, parasitic), chemicals (toxins and agricultural residues) and foreign matter which in turn can lead to public health risk. Some hazards cause immediate illness; other hazards cause illness based on long-term exposure.

STEP 1 DEFINE THE FOOD SAFETY DECISION PROBLEM

To choose the best overall option for reducing public health risk arising from consumption of street foods

STEP 2 IDENTIFY AND SELECT RISK MANAGEMENT OPTIONS

In considering possible risk management interventions it is important to note:

> Many street food vendors are untrained in food preparation or have inadequate understanding of food safety risks. Licensing and controls relating to street food vendors vary across countries and communities.

> Vendors are an important part of the local economy and the community values their presence.

Five interventions have been identified and developed to address the issue:

> **Option 1** - Introduce a central government training, licensing and inspection system for street food vendors. This would be managed by central government and only trained, registered vendors would be able to prepare and sell street food. This would be a new central government function and require development of necessary resources.

> **Option 2** - Introduce local government control through increased training, inspection and enforcement, coupled with a licensing programme. The effect would be similar to central government licensing, but would build on existing local infrastructure and capacities leading to efficiencies and overall lower costs in comparison with central government.

> **Option 3** - Establish an innovative, community-based local vendor training and certification system, utilizing 'street food mentors'. This relies on training of mentors and the ongoing training and certification commitment from mentors and vendors. This option brings in the concept of community or neighbourhood self-management (as compared with national or local government management).

> **Option 4** - Consumer education leading to more informed choices based on observations of street food vendors (e.g. cleanliness, methods for food preparation, storage and handling).

> **Option 5** - Combine the community based self-management option 3 and consumer education option 4. Educated consumers are likely to be more motivated to seek out certified or recognized vendors.

DEVELOP A RANGE OF DECISION FACTORS AND CRITERIA BY WHICH THE OPTIONS WILL BE ASSESSED

STEP 3

Effectiveness:

Will the risk management option reduce the risk of foodborne illness to an acceptable level? (Yes = Pass; No = Fail)

Acceptability:

In this analysis two acceptability factors are considered - food accessibility (consumers' ability to purchase food) and socio-cultural acceptability – recognizing the role of street foods in the community.

i. Does the option significantly reduce food accessibility (due to changing food cost)? (No = Pass; Yes = Fail)

ii. Does the option cause significant change in terms of social or cultural acceptability? (No = Pass; Yes = Fail)

Implementability:

Two factors were selected to demonstrate this analysis:

i. Implementation costs (USD) including costs borne by the street food vendors, and costs attributable to national or local government

ii. Likelihood of ongoing compliance

STEP 4 GATHER EVIDENCE; EVALUATE AND COMPARE THE OPTIONS

Gather evidence:

Risk managers can evaluate the effectiveness for each option based on their experience and comparisons to similar initiatives at local and national levels. Experts including risk assessors, health professionals, food scientists and technologists may be able to provide relevant advice.

Similarly, risk managers can evaluate acceptability factors for each option based on their experience and comparisons to similar initiatives at local and national levels. It may also be useful to consult with food security and community liaison experts to assess food access issues and social acceptability. If time and resources permit, social research may also be helpful to determine likely consumer and community response to proposed measures.

Implementability criteria:

Factors require more detailed analysis and given time and resources these data would be useful:

For costs

> Estimates of licensing and inspection costs at a local and national level.

> Estimates of costs for training of mentors or consumer education.

> Estimates of costs (time and money) that vendors might have to bear.

> Estimates of the impact of each option on food prices to consumers.

For likelihood of compliance

> Data from government and relevant experts concerning likelihood of success of the centrally controlled option and the local government control option (options 1 and 2).

> Data from government and relevant experts on the implementability and likelihood of successful compliance of the training/mentoring in option 3. This could include setting up a trial at a local level to provide this information.

> To understand the likelihood of success of consumer education leading to more informed consumer choice, a consumer education model could be trialled in selected areas. Measures of success could include increased consumer understanding of the nature and risk of street foods, consumers being able to select certified vendors from a range of vendors.

Analysis

Effectiveness

When considering the effectiveness of the options to reduce public health risk:

> Options 1, 2, 3, 5 apply a variety of training, licensing and inspection measures and are considered to be effective at reducing foodborne illness.

> Option 4 – "consumer education" is not considered to be effective as a stand-alone option and is removed from the assessment.

Acceptability

All remaining options meet the acceptability criteria of food accessibility and socio-cultural acceptability, noting that some considered that a locally based scheme (options 2 and 3) might be more sensitive to the vendors and community needs.

Implementability

Cost: Implementation costs are estimated using option 1, the national government training, licensing and inspection system as a reference point. It is estimated that the cost for this option would be the highest, and costs for other options are estimated in proportion to this cost. To allow numerical computations, costs are converted to a 1 to 10 scale, where lower cost (better outcome) options are assigned a lower score. Conversely, the higher the cost (worse outcome), the higher the score.

For this case study, option 1, the highest cost option, is assigned a score of 10. The analysis then scores or estimates the local government costs (option 2) as 7.5, as it is estimated that costs would be lower than option 1 due to the use of existing local infrastructure and implementation activities, compared with establishing a new centralized function.

While under option 3 there are start-up costs to recruit and train mentors, the likely ongoing costs are considered to be lower, and are scored accordingly. For example, utilizing local community members such as students is estimated as being lower cost. Option 5 (incorporating option 3 plus consumer education) is more costly than option 3, reflecting the additional cost of consumer education.

Likelihood of compliance: The second implementation criterion – likelihood of compliance to the option or scheme – is assessed on a scale of 1-10 where 1 is high likelihood of compliance.

Note that using the scale in this way where the higher the likelihood of compliance (better outcome) the lower the score, is then consistent with the lower costs criterion (better outcome) also being assigned a lower score.

TABLE 6 **DECISION TABLE TO COMPARE RISK MANAGEMENT OPTIONS FOR STREET FOODS**

DECISION CRITERIA	EFFECTIVENESS	ACCEPTABILITY		IMPLEMENTABILITY		TOTAL
	Reduce food borne illness rates	Food accessibility	Social cultural acceptability	Implementation costs (1-10 scale where low cost receives low score)	Likehood of ongoing compliance (1-10 scale where high likelihood of success receives low score)	
Option 1 Central government programme	Pass	Pass	Pass	10	3	**13**
Option 2 Local government programme	Pass	Pass	Pass	7.5	2	**9.5**
Option 3 Local vendor training and certification using "street food mentors"	Pass	Pass	Pass	5	5	**10**
Option 4 Consumer education leading to informed choice	Fail	Not considered	Not considered	Not considered	Not considered	**Not considered**
Option 5 Combine option 3 (local vendor training and mentors) and option 4 (consumer education)	Pass	Pass	Pass	7.5	4 (reflecting informed consumers making better decisions and driving compliance)	**11.5**

In this rating, option 2 (local government) scores better than option 1 (central government) reflecting the expected certainty and sensitivity of local action compared with central government control.

Option 3 – the community-based mentor option – does not score as well, reflecting the uncertainty in how well mentors will undertake their duties on an ongoing basis and the resulting effect on compliance.

Option 5, which adds consumer education to option 3, improves the compliance score over option 3 since it is expected that "informed" consumers will seek out certified vendors encouraging local compliance and more vendors to join the scheme.

Note: Where innovative, untested solutions such as option 3 are proposed it can be difficult to obtain the necessary evidence to allow comparison with already recognized interventions. Looking to comparable initiatives elsewhere may provide helpful insights. Conducting a pilot trial could provide scalable data and also help to resolve any uncertainty.

The decision table is set out in Table 6.

CHOOSE THE BEST OPTION — STEP 5

In this decision table, the lowest total score is the preferred option. On the analysis presented, option 2 (local government programme) is preferred – being the lower cost of the government options, coming with a high degree of certainty around compliance and with the benefit of local involvement.

The innovative options 3 and 5 suffer from uncertainty of successful implementation/compliance. This uncertainty can be reduced if the risk manager has the benefit of implementation and compliance data from pilot trials to inform the analysis. If the community shows strong support for a local community based initiative, the preference could turn to option 3 or 5.

Case study 3c

COMPARING INTERVENTIONS TO REDUCE RISKS CAUSED BY AFLATOXINS IN MAIZE

Issue

This case study presents a slightly different approach to comparing risk management options. The effectiveness of each risk management option in reducing hepatocellular (liver) cancer cases is estimated using a risk assessment model from the literature that takes into account the level of aflatoxin exposure and potency factors. A multi-criteria method called "outranking" is used to analyse and combine qualitative and quantitative criteria in a single step.

Background

Mycotoxins are toxic compounds produced by certain fungi that can infect maize during production, processing and storage, particularly in tropical regions. Aflatoxins (a specific group of mycotoxins produced by *Aspergilli* spp.) are known to be mutagenic and carcinogenic. The risk of liver cancer is higher for individuals who carry hepatitis B virus.

Maize is often a significant part of the diet in developing countries and has an important role in the rural economy and food security for most households. There is increasing scientific evidence to show an association between aflatoxins and childhood stunting.

DEFINE THE FOOD SAFETY DECISION PROBLEM — STEP 1

Evaluate four interventions and select the most appropriate option to reduce the risk of hepatocellular (liver) cancer caused by aflatoxins in maize.

STEP 2 IDENTIFY AND SELECT RISK MANAGEMENT OPTIONS

Risks and impacts to consider when identifying risk management options:

- Maximum limits for aflatoxin levels in maize have been established but have little effect in developing economies because:
  - Maize consumed by domestic population rarely enters any sort of regulatory inspection for aflatoxin level; and
  - Many people in developing economies consume such high levels of maize that daily aflatoxin exposure still renders them vulnerable to disease.
- Developing economies that attempt to export maize may find their access to markets severely jeopardized by strict aflatoxin standards, resulting in potential risks of exporting the best foods and keeping the worst in the domestic market.
- Growth stunting in children has a serious, long-term impact (impaired cognitive development) that has been linked to exposure to aflatoxins.

Four risk management options are considered:

1. Pre-harvest biocontrol involves applying atoxigenic *Aspergilli* to maize crops to outcompete the toxigenic *Aspergilli*. Although the harvested crops may be infected by the *Aspergillus* fungus, there is little or no aflatoxin. The first scenario assumes that the total cost of the intervention is borne by growers and consumers resulting in increased prices for maize. (Pre Harvest 1)
2. Pre-harvest biocontrol of maize crops. In this second scenario it is assumed that there are government subsidies to ensure that food prices do not increase significantly. (Pre Harvest 2)
3. Dietary additive: Calcium aluminosilcate (NovaSil) Clay (binds aflatoxin in the gut)
4. Hepatitis B Virus vaccination to reduce the synergistic effect of Hepatitis B virus and aflatoxin in inducing liver cancer. This intervention also includes an education campaign to promote vaccination and to encourage those at risk to get the three boosters needed to ensure long-term immunity.

STEP 3 DEVELOP A RANGE OF DECISION FACTORS AND CRITERIA BY WHICH THE OPTIONS WILL BE ASSESSED

Effectiveness

DALYs saved due to reduction in aflatoxin exposure or reduced potency due to vaccination. Estimates are based on a quantitative risk assessment model for aflatoxin-induced cases of liver cancer (Wu and Khlangwiset 2010b; Khlangwiset 2011).

Acceptability factors and criteria

> Food security/accessibility: 5-point score measuring the impact of the intervention on food accessibility (1 = Severe Impact; 5 = No impact)

> Food security/nutritional status: 5-point score measuring effect on childhood stunting (1 = No reduction; 5 = Very large reduction)

Implementability factors and criteria

> Cost of the Intervention ($US)

> Feasibility: 5 point score measuring the feasibility of implementing the intervention (1= Very low; 5 = Very High)

The outranking software that is used for this case study allows the user to designate either the minimum or the maximum value on each scale as the preferred or "best" value. The software computations adjust appropriately for each criterion. In this example, the maximum value is the "best" value for 4 criteria: DALYs saved, food accessibility, effect on childhood stunting and feasibility. For the cost criterion, the minimum is the preferred value.

GATHER EVIDENCE, EVALUATE AND COMPARE THE OPTIONS — STEP 4

All information and evidence was taken directly or estimated from

1. a doctoral thesis (Khlangwiset 2011), and
2. peer-reviewed papers (Wu and Khlangwiset 2010a and 2010b).

The papers and thesis outline a number of strategies to reduce aflatoxin risk and provide a thorough examination of health impacts and the technical feasibility of each strategy. The strategies were chosen, by analysing data and information representative of the context in a sub-Saharan African country. While the thesis is a valuable source of data and information that is relevant for Africa, the analysis is presented in a clear manner and can be adapted for other regions.

Scores for acceptability criteria are based on expert opinion. The cost estimates for each intervention are based on details in the thesis. The paper by Wu and Khlangwiset (2010b) presents a detailed discussion of technical feasibility based on four components: characteristics of the basic intervention, characteristics of the delivery, requirements on government capacity and usage characteristics. We used this discussion to assign a feasibility score on a 5-point scale.

The evaluation of the four interventions based on these criteria is summarized in a decision table (Table 7).

TABLE 7 DECISION TABLE TO COMPARE RISK MANAGEMENT OPTIONS TO REDUCE THE INCIDENCE OF LIVER CANCER AND GROWTH STUNTING CAUSED BY AFLATOXINS IN MAIZE

INTERVENTION	DALY REDUCTION[1] (years)	COST (US $)	FEASIBILITY (Very low=1; Very High=5)	FOOD ACCESSIBILITY (Severe Impact=1; No impact=5)	EFFECT ON CHILDHOOD STUNTING (No reduction=1; Very large reduction=5)
Option 1 Pre-harvest 1	27 900	41.9M	Low	Severe Impact	Very Large Reduction
Option 2 Pre-harvest 2	27 900	41.9M	Low	No Impact	Very Large Reduction
Option 3 Dietary (NovaSil Clay)	16 200	187.8M	Very Low	Minor Impact	Large Reduction
Option 4 HBV Vaccine	42 700	37.8M	Moderate	No Impact	No Reduction

[1] DALY reduction due to lower number of cases of liver cancer (based on reduced exposure to aflatoxin or reduced risk of Hepatitis B virus)

STEP 5 CHOOSE THE BEST OPTION

It is helpful to review the "worst" and "best" performances for individual criteria first (i.e. the green ("best") and orange ("worst") flags). In this example, it is clear that the dietary intervention is a poor risk management choice since it shows three orange flags and no green. The hepatitis B vaccination (HBV) looks very promising based on all the criteria except the effect on growth stunting and here it is the worst option. In contrast, the pre-harvest intervention (with a government subsidy) is the best option for two criteria and has no orange flags.

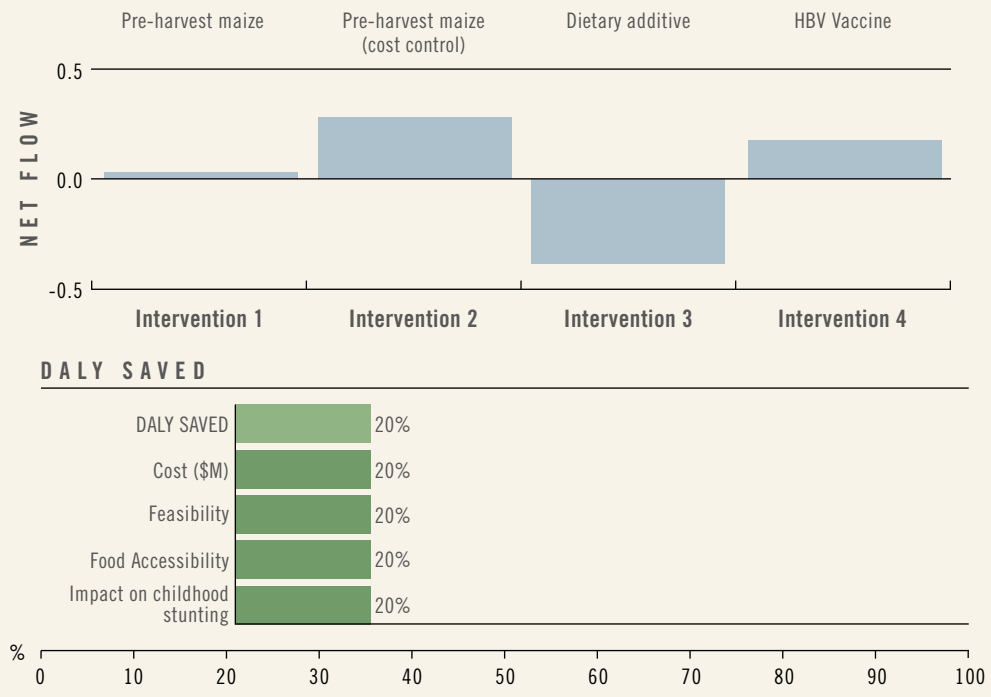
This is where a MCA method such as "outranking" analysis is useful because the decision-maker needs to make a choice between Intervention 2 and Intervention 4. A commercial software programme (Decision Lab supported by Visual Decision Inc., Montreal, QC, Canada)[9] was used to identify the "best" overall option based on performance across all criteria. Figure 3 shows the net outranking flow[10] for the four alternatives with equal weights assigned to each criterion. A higher net flow indicates better performance of the option and, based on this analysis, the Pre-harvest option with government subsidies to producers is the "best" of the four alternatives.

9 Decision Lab software is no longer available but an updated version - Visual PROMETHEE - can be accessed at http://www.promethee-gaia.net/visual-promethee.html. Last accessed 4 October 2017.

10 This calculation includes two components: the degree to which an option outranks other options and the degree to which it is outranked by other options in the set.

Note that this case study does not follow the stepwise schema but considers all the criteria together. The risk manager can choose the most effective way to use resources to evaluate and compare options.

FIGURE 3 **OUTRANKING ANALYSIS FOR AFLATOXIN INTERVENTIONS**



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SECTION 4

RISK RANKING AND PRIORITIZATION OF FOOD SAFETY ISSUES

KEY QUESTIONS THAT ARE ANSWERED IN THIS SECTION:

> What is the distinction between risk ranking and prioritization of food safety issues?

> What are the steps in risk ranking and prioritization of food safety issues?

> What criteria and evidence are used in risk ranking and prioritization?

> How are risk ranking and prioritization used to identify food safety issues that risk managers should act on?

Most countries are faced with numerous food safety issues and the reality of finite resources (including time and financial resources) to address these problems. Risk managers must ensure that resources are applied optimally when they identify the hazards. They use risk ranking and prioritization to identify food safety issues that have significant impact. Risk ranking and prioritization also help risk managers to agree on when action is needed to address priority problems.

Risk ranking is the systematic analysis and ordering of foodborne hazards and/or foods in terms of the likelihood and severity of adverse impacts on human health in a target population. Risk ranking is a primary consideration in **prioritization** but other types of impact are also considered, such as social, economic, political consequences. Examples can include pressing public or political demands, trade restrictions, reduced revenue from exports and significant impacts on vulnerable consumers.

Risk ranking and prioritization are included in 'Preliminary Risk Management Activities' (Figure 1) and are undertaken when risk managers think it is appropriate. Often these steps are part of strategic planning exercises, and when there is time to gather evidence about current and emerging food safety issues and to consult stakeholders.

4.1 STEPS IN RISK RANKING AND PRIORITIZATION OF FOOD SAFETY ISSUES

The decision-making schema outlined in Figure 2 can be used for both risk ranking and prioritization of food safety issues.

STEP 1 DEFINE THE DECISION PROBLEM

The objective of both risk ranking and prioritization is to compare a set of food safety issues and to answer the question: "Which food safety issues could have the most significant impact (i.e. potential to cause the greatest harm)?" The difference in the two analyses lies in the decision factors and criteria that are used to compare food safety issues.

Risk ranking is the systematic ordering of foodborne hazards and/or foods in terms of the public health risk based on the likelihood and severity of adverse impacts in a target population.

Prioritization is the systematic analysis and ordering of foodborne hazards (or food safety issues) based on a consideration of public health risks, and other factors such as social, economic, political consequences.

Some specific factors considered during prioritisation may include economic losses due to trade restrictions, reduced food availability and lower consumer trust in the food control system (see Table 1 for a more complete list of possible considerations).

In combination, risk ranking and prioritization sort food safety issues into an order that is based on overall impact. Increasingly, risk managers see the merit in investing in both activities to provide the most complete analysis of evidence for setting priorities for action. It preserves the importance of the scientific foundation to decision-making (risk ranking), but recognizes that an essential risk management function is to consider other areas of harm to reach the final decision.

IDENTIFY POTENTIAL ALTERNATIVES — STEP 2

The alternatives that are compared in risk ranking and prioritization include different types of foodborne hazards (i.e. biological, chemical and physical hazards) that can cause illness and possibly death. Each country needs to identify its current and emerging food safety issues through environmental scans, surveillance information, outbreaks, expert opinion and formal risk assessments.

In some countries, food safety issues are analysed on the basis of a particular hazard (e.g. foodborne *Campylobacter* spp.) or a specific hazard-food pair (e.g. *Campylobacter* spp. in chicken). The choice depends on the information that is available. For example, is there data that describes the amount of illness caused by consuming a hazard from a specific source? Other food safety issues may be considered across a number of hazards and food sources (e.g. acute diarrhoea in young children caused by food sources). There is a detailed discussion about the selection of the foods and hazards to include in risk ranking and prioritisation in the "FAO Preliminary Guide to Ranking Food Safety Risks at National Level" (FAO, forthcoming).

SELECT DECISION FACTORS AND CRITERIA — STEP 3

Public health impact is a decision factor that is common to both risk ranking and prioritization. In identifying priorities, risk managers also consider the potential for additional types of harm based on economic, food security and socio-cultural considerations. Prioritization factors are not necessarily the same in every country. Risk managers must choose a practical set of decision factors based on relevance to their country's context and the availability of resources to gather evidence.

Criteria need to be defined to evaluate health risk and prioritization factors. Criteria can be based on quantitative scales or qualitative categories. Practical examples of criteria for risk ranking and prioritization are discussed in Section 4.2.

COMPARE ALTERNATIVES — STEP 4

Risk ranking and prioritization criteria are used to evaluate a number of potential outcomes (e.g. illness, premature death, economic losses, reduced food security) that may arise from food safety issues. Given the range of potential impacts, evidence is needed from a diverse set of sources. Typical types and sources of evidence are discussed in Section 4.2 in association with specific criteria for risk ranking and prioritization.

A decision table or performance matrix should be created to summarize the evaluation of all criteria for each food safety issue. This table is a simple tool that the decision-maker can use to compare the food safety issues based on individual criteria as well as overall performance.

It is also helpful to develop an evidence summary for each food safety issue (e.g. in a similar format to the example of neurocysticercosis in undercooked pork (Box 10)). This summary highlights key evidence and sources for all the decision factors. It provides context that is helpful in risk ranking and prioritization as well as information that decision-makers may find useful in dealing with emergency situations.

STEP 5 CHOOSE THE BEST ALTERNATIVE(S)

Risk ranking and prioritization are used to place food safety issues in an order from highest to lowest risk of harm or negative consequences (i.e. the "best" alternatives or highest priorities are those that have the potential to cause the greatest damage).

In some cases, the order can be established directly from the decision table (or performance matrix). For example, if public health risk is measured by a single criterion, it is easy to sort and rank food safety issues based on numerical values or ordinal categories (e.g. low, medium and high).

However, when there are multiple criteria, the comparisons become more complex because food safety issues perform differently across various criteria. When decision-makers review the table, it is difficult to weigh all criteria and to judge which issues cause unacceptable levels of harm based on all the considerations. Furthermore, decision-makers do not necessarily put equal weight on all criteria because they think that some criteria should have a greater influence on the final outcomes (e.g. public health risk). Criteria can be weighted differently as long as there is transparency and consistency across all the food safety issues that are being compared. There should be agreement on appropriate weightings early in the decision process (i.e. when criteria are defined). Weightings should not be manipulated during Step 5 to force a particular result.

As discussed in Section 2.1, a number of computational methods have been developed to help decision-makers as they examine the evidence for multiple criteria and try to judge the overall harm caused by each food safety issue. Some of these methods are illustrated in the case studies included in Section 4.3.

Risk ranking and prioritization are based on the consideration of potential harm food safety issues may cause to public health and other relevant factors e.g. economics, social, political. The possibility to take action, and the immediacy with which priorities can be addressed is also influenced by further reflection on available resources, including finances, inspectorate and laboratory capacities, etc. It is recommended that the consideration of the available resources and food control capacities be undertaken as a separate analysis from the potential to cause harm. See section 4.2 page 61 for further detail.

4.2 CRITERIA AND EVIDENCE FOR RANKING FOOD SAFETY ISSUES AND SETTING PRIORITIES

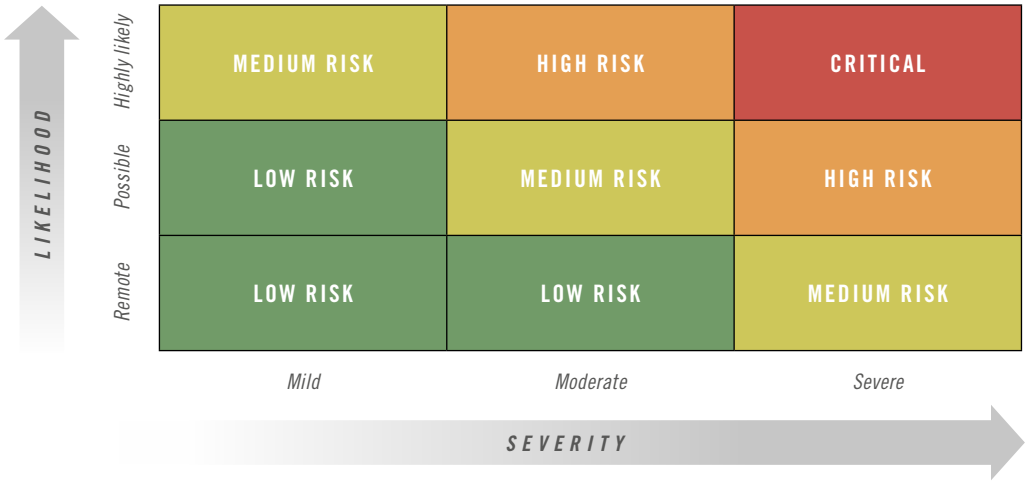
In this section we present some examples of criteria that are useful for risk ranking and prioritization of food safety issues, as well as types and sources of evidence to evaluate these criteria. These examples are based on workshop discussions as well as methods suggested in the food safety literature, and are intended to show the range of scales and evaluation methods that can be used. However, the resources (time and expertise) required to access quality evidence and to analyse each criterion should not be underestimated. While it is not practical to try to capture all possible outcomes that might arise from foodborne hazards, it is important to choose a set of criteria that would signal emerging or actual food safety problems and the need to take action.

PUBLIC HEALTH RISK

Codex guidelines make it clear that public health risk is a function of the likelihood of an adverse health effect and the severity of the effect (i.e. immediate illness, chronic health impairment, death). Assessment of public health risk can be based on qualitative, semi-quantitative or quantitative criteria. The most appropriate method depends on the availability of data and expertise, the time available to produce risk estimates and the number of food safety issues to be ranked. There is a useful decision tree tool in the "FAO Preliminary Guide to Ranking Food Safety Risks at the National Level" (FAO, forthcoming) to guide risk managers in choosing methods that are appropriate for their country context.

A qualitative model for estimating the level of health risk is shown in Figure 4[11]. The relationship between likelihood, severity and risk is defined by a set of logic statements e.g. IF the likelihood of occurrence is "highly likely" AND severity is

FIGURE 4 **GENERAL RISK MODEL**



11 Note – this is sometimes referred to as a risk matrix.

"moderate" THEN public health risk is "high". A group of risk managers may choose to modify this general risk model to align with their knowledge and values. For example, one of the common debates in workshops is about the level of risk when likelihood of occurrence is "remote" and the health effect is "severe". The model in Figure 5 indicates a "medium" level of health risk, but many groups of decision-makers may agree to change the level to "high".

The likelihood of an adverse health effect might be based on evidence such as the effectiveness of preventive controls by industry and government, compliance information, and/or evidence of foodborne illness in the general population or vulnerable groups (e.g. number of illnesses attributed to *Listeria monocytogenes*). Severity should be based on evidence about the extent of disability or impairment of health and duration for all possible health outcomes including immediate illness, long-term effects such as reactive arthritis and pre-mature death. Table 8, taken from the "FAO Guide to Ranking Food Safety Risks" (FAO, forthcoming), outlines a number of potential evidence sources for assessing the likelihood or severity of harm to human health. Some of these were used in the pilot country work in Uganda (FAO 2014). At the beginning of workshops, participants discussed and agreed to benchmarks for likelihood based on data for annual number of illnesses (immediate and long-term) and deaths associated with a particular foodborne hazard. Details about the specific benchmarks that were applied to assess likelihood and severity are provided in the case study for qualitative risk ranking (Section 4.3, Case Study 4a – A qualitative approach to risk ranking and prioritization).

TABLE 8 **POTENTIAL METRICS FOR RISK RANKING OF MICROBIAL AND CHEMICAL HAZARDS**

LIKELIHOOD	SEVERITY
> Number of illnesses > Estimated incidence/population > Population attributable fraction > Probability of illness/consumer/day > Number of outbreak cases > Cost of illness/population > Consumption (per capita, annual, number of servings) > Volume of imports (could serve as a proxy for consumption if a large portion of the food is imported) > Prevalence in foods (% positive, % above concentration threshold or action level) > Concentration level in foods	> Years lived with disability (YLD)/case > Years of life lost (YLL)/case > DALY/case > Quality Adjusted Life Years (QALY)/case > Number of hospitalizations > Number of deaths (i.e., mortality rate) > Number of cases with sequelae > Probability of sequelae > Duration of acute and chronic illness > Duration of morbidity > Cost of Illness/case > Toxicity Benchmarks (LD50, RfD, NOAEL, ADI, LOAEL, TTC) > Risk Benchmarks (Hazard index, Margin of > Exposure, Excess Lifetime Risk, Slope Factor)

Taken from FAO Guide to Ranking Food Safety Risks, forthcoming

Qualitative risk characterization is useful as long as the benchmarks for likelihood and severity are clear and evidence is interpreted consistently. The level of risk is usually assessed by a group of experts who have come to an agreement on the meaning of "low", "medium", "high" and "critical". These are ordinal categories that describe

increasing levels of risk (i.e. "high" risk is greater than "medium" or "low" risk) so they can be used to rank food safety issues. However, there are some drawbacks to using a qualitative method. One is the fact that the magnitude of differences between qualitative categories is unknown (i.e. how much greater is the "high" risk level relative to the other two categories). Another concern is the loss of information that occurs when quantitative data is converted into a finite set of categories.[12]

Semi-quantitative criteria form a practical bridge between qualitative and fully quantitative methods to measure public health risk. Some are based on empirical calculations or rules developed by experts for specific types of food safety risks. Different tools require different types of information about a food safety issue in order to produce a score. Risk Ranger (described in Box 7) is an example of a semi-quantitative tool that can be used to estimate a risk on a scale between 0 and 100 where 100 represents an extreme risk.

Semi-quantitative approaches are useful for ranking food safety issues in relative terms. The significance of the risk score is open to interpretation and needs to be calibrated as was done with Risk Ranger. Any "calibration" points need to be checked periodically against surveillance data (if available) and expert opinion.

BOX 7

RISK RANGER - A SEMI-QUANTITATIVE TOOL TO MEASURE HEALTH RISK CAUSED BY MICROBIAL HAZARDS IN FOODS

Risk Ranger was developed by Ross and Sumner (2002) in an easy-to-use spreadsheet format and can be downloaded at www.foodsafetycentre.com.au/riskranger.php. The tool is based on 11 questions related to hazard severity, probability of exposure and effects of processing steps. Users provide answers by selecting qualitative statements from the user interface or by entering specific values for the hazard of interest. The qualitative statements are converted to numeric values and used to calculate **"comparative risk" (CR)** score:

$$\textbf{CR} = \text{probability of illness over all servings} \times \frac{\text{exposures}}{\text{person·day}} \times \text{hazard severity}$$

Hazard severity is defined by a set of arbitrary weighting factors that describe health impacts. For example, patients would rarely seek medical attention for a minor hazard (hazard severity = 0.001) but a severe hazard (hazard severity = 1) causes death to most victims.

A logarithmic transformation is used to convert "comparative risk" (CR) values to a risk scale from 0 (minimal risk) to 100 (extreme risk). The developers suggest that a **risk score of 60 to 65** be used as a benchmark – values above this range indicate high risk to consumer health.

12 This is sometimes referred to as "binning" data and the pitfalls are discussed in FAO, (forthcoming).

Quantitative criteria for public health risk are based on numerical estimates of the likelihood of foodborne illness and severity of disease outcomes. These include measures such as DALY, QALY or Cost-of-Illness. All three measures take account of different health outcomes (immediate illness, chronic conditions and mortality) into an overall health impact. The magnitude of differences between values on these continuous scales is clear. The disadvantage is that these calculations require a significant amount of evidence.

Before starting a quantitative assessment, it is advisable to review the recent literature for relevant risk assessments. If none are available, there are two potential approaches to estimate risk:

> A bottom-up approach that predicts level of illness in a population based on exposure data and a dose-response relationship (e.g. FDA-iRISK web-based tool for risk assessment described in Box 8)

> A top-down approach based on the number of illnesses reported through public health surveillance systems as well as hospital and coroners' records (e.g. Ruzante *et al.*, 2010 (see also Case Study 4c – Multi-factor prioritization using an outranking method).

BOX 8

FDA IRISK (V4)

The US Food and Drug Administration developed FDA-iRISK (https://irisk.foodrisk.org/) to calculate quantitative estimates of risk for food-hazard pairs. It is a web-based tool that is freely available. The tool uses data related to exposure (i.e. consumption data, prevalence, contamination levels) and a dose-response model to estimate illness at a population level as well as an aggregate health burden calculated as DALYs. DALY values are based on levels of immediate and long-term illness and fatalities as well as weightings for severity and duration.

The FDA-iRISK tool allows the user to define simple process models to describe how hazard level and distribution change as the food is produced, distributed and handled by a consumer. Input parameters can be defined by fixed values or by probability distributions to account for variability and/or uncertainty in the values.

Recently the EFSA Panel on Biological Hazards assessed eight tools and identified FDA-iRISK as the most appropriate tool for ranking risks caused by microbiological hazards (EFSA BioHAZ Panel 2015). There is still a need to develop a quantitative tool that can be used to evaluate and compare health risks caused by biological and chemical hazards.

The 2015 report on the WHO Initiative to Estimate the Global Burden of Foodborne Diseases (prepared by the WHO Foodborne Disease Burden Epidemiology Reference Group (FERG)) provides the first estimates of global foodborne disease incidence, mortality, and disease burden in terms of DALYs (WHO 2015). The report contains a wealth of information and there is also an online tool that allows users to export data for 31 foodborne hazards and 14 sub regions.

ECONOMIC CONCERNS

As outlined in Table 1, a number of economic impacts can occur when food products cannot be sold or traded because of safety problems. Criteria for economic concerns can be framed as risks using a technical model that is similar to the Codex paradigm for health risk. That is, the economic risk posed by a food safety issue depends on the likelihood that unsafe products will be discovered and removed from the marketplace as well as the economic value that is lost as a result. The combination of both make the criterion, i.e. the likelihood of economic loss and the severity of that loss should it occur.

The economic value at risk includes lost sales, trade and employment as well as spill over effects on a local economy (e.g. loss in other sectors such as tourism) and can be estimated with measures such as those outlined in Table 9 below. This type of information is generally available from government ministries (e.g. Ministry of Agriculture, Ministry of Industry, Ministry of Trade). For example, the Australian government has produced a document that provides helpful advice on conducting trade impact assessment.[13] Economic information and financial indicators on a country basis are also available from international institutions, such as the World Bank. The informal markets that exist in many developing countries are more challenging to assess in terms of size and economic value. However, it may be possible to find reports for specific food products. For example, a report on the dairy value chain in Uganda (Technoserve Uganda, 2008) included estimates of size of informal market for milk in Uganda.

TABLE 9 **INDICATORS OF THE POTENTIAL ECONOMIC VALUE AT RISK FOR FOODS THAT CONTAIN HAZARDS**

DOMESTIC MARKET	EXPORT MARKET
> Value of sales or trade (monetary scale) > Volume of sales or trading (annual numbers) > Employment (annual numbers) > Wages (monetary scale or fraction of household income) > Rejections based on surveillance or recalls by main producers (annual number and monetary value)	> Value of trade (monetary scale, fraction domestic production) > Volume of trade (annual numbers) > Export rejections based on foodborne hazards (frequency and amount of product rejected) > Impact on market access e.g. reduced earnings where markets cannot be accessed > Export competitiveness > Size of global market (percent of global production) > Number of trade partners (annual number) > Trade concentration ratio (index based on number of partners)

Adapted from Henson *et al.* 2007

13 See https://www.pmc.gov.au/resource-centre/regulation/trade-impact-assessments-guidance-note (Australian Government, 2016b).

The economic indicators in Table 9 describe the severity of economic losses that may occur, but do not consider the likelihood that losses would occur. It is challenging to estimate the likelihood of losses due to recalls or rejection through surveillance activities. Henson *et al.* (2007) suggest a Delphi survey approach using experts on the structure of markets and possible vulnerabilities (e.g. reliance on a single export market). A Delphi survey (described in Box 9) is a structured approach to solicit experts' judgments and to achieve a consensus opinion.

BOX 9

DELPHI SURVEYS

The Delphi method is a particular type of consultation with experts, commonly used in the social sciences to answer complex questions.

The basic survey process is as follows:

- identify a panel of individuals who are recognized for their experience and judgement;
- send a first questionnaire to the panel to gather individual opinions about a specific issue or question;
- send a second questionnaire that summarizes the first set of results in a format that allows each panellist to rate or rank these opinions; and
- send a third questionnaire to show the level of group consensus for each opinion. Individuals who choose to remain substantially different from the group are asked to explain.

There can be subsequent rounds of questionnaires to improve consensus but this may not be feasible or productive. The Delphi technique produces an expert opinion, qualified by the level of agreement among experts, as well as reasons for dissent.

There are many areas of application including the management of food safety risks (Wentholt *et al.* 2010).

If the likelihood of loss (based on Delphi surveys or other methods) and the economic value at risk (severity of consequences) are defined using qualitative scales (e.g. negligible, low, medium, high) then a technical risk model that is similar to the one illustrated in Figure 4 can be used to estimate the risk of economic loss(es). In most countries, it is useful to define two criteria – economic risk in the domestic market and economic risk in the export market.

FOOD SECURITY CONCERNS

If a country is food insecure and/or it is known that hazards frequently compromise the safety or supply of staple foods, then food security criteria should be considered in setting priorities. Criteria should describe the potential for a food safety issue to affect utilization, food access and/or availability. Some examples are included in Table 10. In the context of food security, *availability* addresses the supply side and is determined by the level of food production, stock levels and net trade; access hinges on people being able to purchase food, or having direct access to food they,

themselves, produce. *Utilization* refers to the way the body makes the most of various nutrients in food (FAO, forthcoming).

In some countries there is a ministry or agency that is specifically responsible for food security and this would be a logical starting point to gather evidence to support the criteria that are outlined in Table 10. If there is no central ministry for food security, then it is likely that a number of sources need to be consulted. For example, in Rwanda information about different aspects of food security is the responsibility of the Rwanda Institute of Statistics, the Ministry of Agriculture and Animal Resources, the Rwanda Agricultural Board, and local authorities.

TABLE 10 **CRITERIA TO ASSESS IMPACT OF FOODBORNE HAZARDS ON FOOD SECURITY**

ASPECT OF FOOD SECURITY	POSSIBLE CRITERIA	SCALES
Utilization	Degree to which food safety issue contributes to 1. Chronic malnutrition 2. Wasting and growth stunting	Qualitative > Binary flags – no connection(=0), direct consequence (=1) > Likert-type scales – e.g. *no connection, some impact, significant contribution* Quantitative > DALY estimates of the health impacts (chronic malnutrition, wasting, non-communicable diseases) attributed to foodborne hazards
Accessibility	> Potential to reduce food accessibility at different levels (households, individuals, regions) > Households at risk in terms of income and/or trading capacity	> binary flags: not a concern(=0); significant concern (=1) > ordinal categories such as: *low, medium, high OR none, a few households, most households, all households*
Availability	Does the food safety issue reduce the availability of food?	Binary flag No (=0); Yes (=1) Ordinal categories: *Not at all, somewhat, to a significant degree*

The World Food Programme (WFP) produces food security and vulnerability analysis by country, and these reports also include assessments of wasting, stunting and acute malnutrition based on anthropometric measurements. The WFP reports on food security and vulnerability also include household consumption surveys which capture the main dietary staples in a country. The WFP reports in combination with FAO and WHO databases for food consumption[14] are useful in understanding the connections between food safety and food security.

It is also important to identify those consumers who are particularly vulnerable in terms of food security (e.g. young children). Conditions such as stunting and wasting in children combine aspects of food security and social concerns, and could

14 Currently in development: FAO/WHO GIFT – Global Individual Food consumption data Tool provides individual quantitative food consumption data, disaggregated by sex and age. http://www.fao.org/gift-individual-food-consumption/en/.

be considered in either category. Decision-makers need to understand the overlap so they do not create duplicate criteria under different decision factors (i.e. avoid double counting).

CONSUMER PERCEPTIONS AND ACCEPTANCE OF RISKS

The criteria to be measured are consumers' perceptions. Measurement of consumer risk perceptions is complex and needs to reflect individual concerns and perceptions (i.e. a psychological model of risk) at the level of specific food safety issues as well as more general concerns (e.g. persistent organic pollutants in the food chain). Social scientists recommend a number of approaches that include semi-structured interviews as well as quantitative survey techniques (Frewer *et al.* 1998).

Henson *et al.* (2007) has suggested that the following factors that should be considered in consumer surveys using psychometric scales from "low" to "high":

> Perception of risk of an adverse health outcome

> Perception of severity of health outcome

> Degree to which risk is perceived to be controllable by the individual consumer

> Degree to which risk is perceived to be controllable by regulators

> Degree to which risk is perceived to be known to scientists

> Degree to which exposure to the risk is perceived to be voluntary

> Degree to which the risk is perceived to be a natural phenomenon

> Degree to which exposure to the risk is also perceived to yield benefits (e.g. consuming unpasteurized milk poses a risk but provides nutritional benefits)

Each of these considerations can influence consumer choices and trust in the food control systems. A number of them can be combined into an aggregate measure of consumers' perception and acceptance of risk (e.g. Ruzante *et al.* 2010).

SOCIO-CULTURAL CONCERNS

Some of the concerns that have been raised in workshop discussions include:

> Impact on vulnerable group(s) in society (e.g. young, elderly, immunosuppressed, poor).

> Different impacts based on gender (e.g. are there higher risks for one gender?).

> Religious/cultural sensitivities and dietary preferences about consumption of particular foods.

It is clear that the assessment of each of these considerations requires particular types of evidence. If risk managers choose to include these as criteria in identifying priorities, we recommend starting with a simple set of categories to characterize potential impact (e.g. "no impact" or "significant impact") for each type of harm.

FEASIBILITY

Having completed the analysis of relevant impact factors, risk managers consider the feasibility of resolving each issue. This consideration of feasibility needs to be framed at a high level relative to the detailed feasibility analysis that is undertaken to compare risk management options for a specific food safety issue (i.e. the analysis that is outlined in Section 3).

However, food safety issues can be compared in terms of the following:

> availability of infrastructure to address the food safety problem (e.g. inspectors, laboratory capacity);

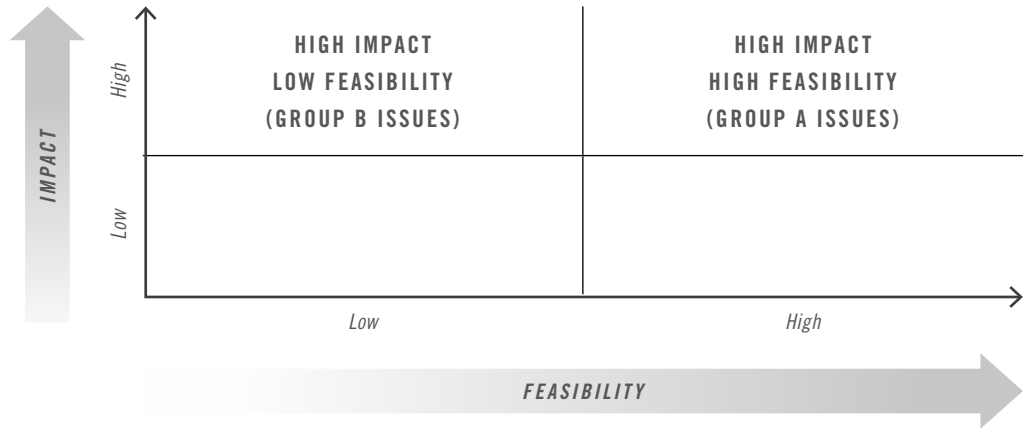
> demands on government capacity, and finances (i.e. what finances are available to address food safety priorities?);

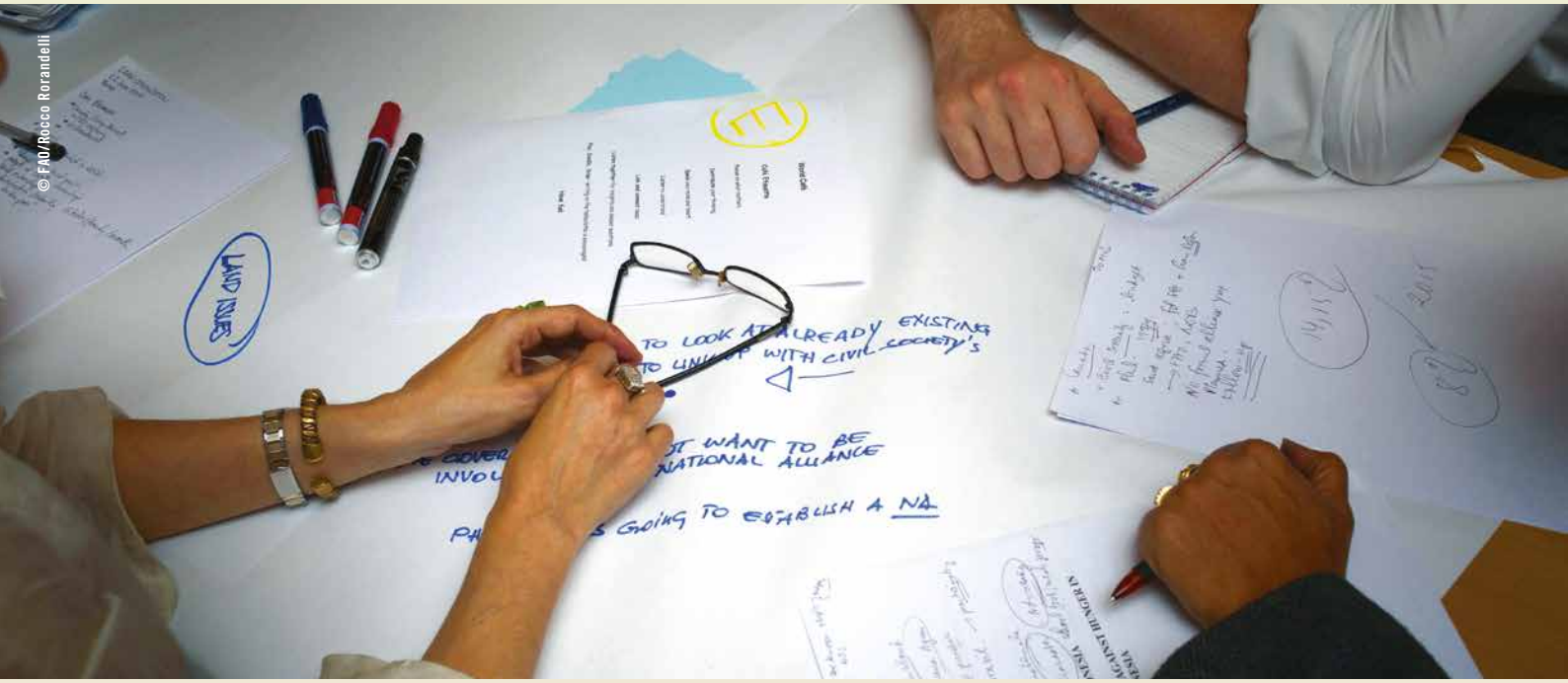
> availability of solutions to address the food safety priority; and

> likelihood of implementing a solution in the required time frame, and how easy is it to implement.

This feasibility assessment of the available resources and food control capacities should be considered separately from prioritization criteria that focus on impact (i.e. public health, economic losses, etc.) as shown in Figure 5. Separate consideration allows risk managers to differentiate between food safety issues that have significant impact and potential solutions that are highly feasible (Group A issues) as compared to those that have significant impact but where the preliminary feasibility analysis is low (Group B issues). Food safety issues in Group A are clear choices for immediate actions (e.g. identification and selection of risk management options). Food safety issues in Group B should not be ignored because they have significant impact. However, it is necessary to consider and plan for longer-term strategies to address challenges in terms of feasibility (e.g. support introduction of new food analysis capacities, identification of additional funds).

FIGURE 5 **ANALYSIS OF OVERALL IMPACT AND FEASIBILITY TO IDENTIFY IMMEDIATE (GROUP A) AND LONG-TERM (GROUP B) PRIORITIES FOR ACTIONS**





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4.3 CASE STUDIES

Three case studies are presented to illustrate a stepwise decision process for ranking and prioritization of food safety issues. These examples show how risk managers and policy-makers could apply qualitative, semi-quantitative or quantitative approaches in their decision processes. Although the case studies are drawn from real world food safety issues raised at workshops, the decision factors and metrics that are presented are simply examples to illustrate the structured decision process. Hence the final results should not be interpreted as recommendations or decisions for a specific country or region.

The aim of these case studies is to help risk managers and policy-makers understand how to apply multi-factor decision-making methodology to prioritize food safety issues using information and factors that are relevant in their country context.

Case study 4a

A QUALITATIVE APPROACH TO RISK RANKING AND PRIORITIZATION

A **situational analysis** was completed during the first phase of the pilot work in Uganda (FAO 2012).

The report provided a comprehensive overview of:

> the Uganda food control system;

> food sector analysis, trade and markets;

> analysis of the political and policy environment surrounding food safety issues in Uganda;

> food security status (national and regional);

> current food safety issues (based on outbreaks and analysis of surveillance data); and

> the positions, power and dynamics among stakeholders.

Five food safety issues highlighted in the report were selected as a test set to demonstrate a multi-factor approach to risk ranking and prioritization of food safety issues. The examples were chosen to include different types of hazards (i.e. biological and chemical) and a range of food sources. Details about the evidence gathering, analysis and discussions with national experts are outlined in Annexes 2 and 3 of the final project report (FAO 2014). A short summary is presented here to explain how the five step decision process was applied.

DEFINE DECISION PROBLEM — STEP 1

The decision problem had two parts. The first consideration was the ranking of five food safety issues based on public health risk. Then, prioritization analysis was applied based on the combination of health risks and other significant impacts.

STEP 2 IDENTIFY ALTERNATIVES

Five food safety issues were identified as a test set to demonstrate a multi-factor approach for risk ranking and prioritization. The issues, which are important in Uganda, included:

> Acute diarrhoea in children

> Brucellosis – milk products

> Methanol – unregulated gin

> Aflatoxin – maize

> Cysticercosis – pork

STEP 3 SELECT DECISION FACTORS AND CRITERIA

Decision factors and criteria were developed by national experts who participated in a workshop in Kampala (November 2012). Table 11 summarizes the areas of risk that participants agreed upon as well as criteria that would be useful for evaluating and comparing different food safety issues.

TABLE 11 **DECISION FACTORS AND CRITERIA FOR RISK RANKING AND PRIORITIZING FOOD SAFETY ISSUES IN UGANDA (IDENTIFIED AT NOVEMBER 2012 WORKSHOP IN KAMPALA)**

IMPORTANCE*	BROAD AREA OF RISK (I.E. DECISION FACTOR FOR RISK RANKING OR PRIORITIZATION)	SPECIFIC CRITERIA FOR COMPARING FOOD SAFETY ISSUES
1	Public health	> Number of illnesses and severity (including chronic illness) > Mortality > Outbreaks > DALYs
2	Economic	> Impact on trade within domestic and export markets > Impact on producers > Impact on livelihoods/employment > Impact on other sectors (e.g. tourism)
3	Food security (individual and household levels)	> Nutritional adequacy > Accessibility > Availability > Utilization
4	Social factors	> Impacts on vulnerable sub-groups > Indirect consequences (e.g. children dropping out of school)

* based on number of votes from workshop participants

Please note that not all of these criteria were used in this case study, as can be seen in the analysis below.

COMPARE ALTERNATIVES

STEP 4

Public health impact was assessed in terms of three separate criteria based on risk of immediate illness, chronic health impairment and death. The analysis was based on evidence from national health records, expert opinion and the research literature (FAO, 2014, Annex 2).

The first step in the workshop exercise was to come to a group consensus about the meaning of the linguistic categories in the general risk model (Figure 4). Benchmarks were established for likelihood of harm to human health based on the number of cases or deaths per year as shown in Table 12.

TABLE 12 **BENCHMARKS USED TO EVALUATE LIKELIHOOD OF ILLNESS (IMMEDIATE CASES AND CHRONIC CONDITIONS) OR DEATH**

LIKELIHOOD CATEGORY	NUMBER OF CASES OR DEATHS CAUSED BY FOODBORNE HAZARD(S) PER YEAR
Remote/low	0 to 10
Possible/medium	> 10 and ≤ 1 000
Highly likely	> 1 000 and ≤ 10 000

A range of health outcomes are associated with the five food safety issues. Participants agreed to categorize the severity of possible outcomes as shown in Table 13.

TABLE 13 **BENCHMARKS FOR ASSESSING SEVERITY OF HEALTH OUTCOMES**

SEVERITY CATEGORY	IMMEDIATE ILLNESS	CHRONIC CONDITIONS
Mild	> Mild diarrhoea	> Repeat episodes of diarrhoea
Moderate	> Severe headache > Fever, fatigue, joint/back pain lasting for weeks (between moderate and severe)	
Severe	> Fever, fatigue, joint/back pain lasting for weeks (between moderate and severe) > Hospitalized cases of diarrhoea > Death at an early age	> Endocarditis > Blindness

A qualitative risk model, similar to the one shown in Figure 4 and calibrated by workshop participants, was used to evaluate each of the three criteria for health impact (summarized in the decision table below). The overall ranking was based on the combination of the three criteria and all five issues fell into one of two categories: "high" or "very high" risk to public health.

DECISION TABLE RISK RANKING	CRITERIA TO ASSESS PUBLIC HEALTH IMPACT			OVERALL RISK RANKING
Food safety issues	Risk of Immediate illness	Risk of Long-term illness	Risk of Death	
Acute diarrhoea in children	high-critical	medium	high	very high
Brucellosis – milk products	high	high	medium	very high
Methanol – unregulated gin	low-medium	medium	high	high
Aflatoxin – maize	very low	high	medium	high
Cysticercosis – pork	very low	high	medium	high

The **prioritization analysis** considered public health as well as economic and food security impacts that could arise from each of the five food safety issues.

Economic impacts

As with risk to public health, market level risks were evaluated on the basis of the severity of harm as well as the likelihood (Figure 4). Wherever possible, the severity of harm was based on estimates of monetary values (e.g. trade, sales) for both domestic and export markets. Likelihood of harm (i.e. actual losses) for the export and domestic markets was based on whether it was likely to occur, i.e. were there any reported export rejections or possibility of reduced price on the domestic market, and what was the likelihood of it being detected.

Aflatoxin in Ugandan maize was known to limit export sales (i.e. evidence of rejections by WFP) and it was considered to be a "medium" risk to the export market. The domestic market is largely informal trade with limited monitoring of aflatoxin levels (FAO, 2014) so the risk was assessed as "low". The other four food safety issues were considered to be "low" risk for both domestic and export markets, because there was no evidence that these hazards lowered the value (domestic market) and none of the food products were exported. Based on these evaluations of economic impact, aflatoxin in maize was the highest priority (i.e. 1 out of 5) and the other four examples were the lowest (i.e. all were considered equivalent at 5 out of 5).

TABLE 14 **EVALUATION OF MARKET IMPACTS**

FOOD SAFETY ISSUES	EXPORT MARKETS	DOMESTIC MARKETS	PRIORITY ORDER BASED ON MARKET IMPACTS
Acute diarrhoea in children	Medium	Low	5
Brucellosis – milk products	Low	Low	5
Aflatoxin- maize	Low	Low	1
Cysticercosis – pork	Low	Low	5
Methanol – unregulated gin	Low	Low	5

Food security impacts

To evaluate harm to food security, three areas of risk were considered:

> Reduced nutritional status – including acute malnutrition, wasting and growth stunting;

> Reduced availability – including reduced production, losses due to infestation etc.; and

> Reduced accessibility – including reduced household income and/or increased costs for food products.

There was limited concrete evidence to evaluate food security risks, and this is an area where further work is needed. A number of the decisions were really "judgment calls" based on expert opinion and knowledge of the group, to estimate whether risks to food security were "low", "medium" or "high". For example:

> Wasting affects 5 percent of Ugandan children under 5 years; 33 percent of children suffer growth stunting. Acute diarrhoeal disease caused by foodborne hazards is not the only cause, but experts at the workshop felt it was a significant contributing factor and agreed that the risk to **nutritional status** was **"high".**

> Aflatoxin exposure in children is also linked to growth stunting and impaired cognitive development. Maize is a common component in many infant foods so the risk to **nutritional status** was considered **"high".**

> A large portion (70 percent) of children suffering from acute diarrhoea are taken to hospitals or clinics for treatment. This requires the primary caregiver to take time away from work (paid or unpaid) and this can result in reduced resources to buy or trade for food. The group decision was to rate the risk to **food accessibility** as **"medium".**

> Maize is a major crop that is consumed in all parts of the country. There are many small-scale farmers who are not aware, or lack the required capacities, to control infestation and mold growth during production and storage of maize. This affects availability of supply when maize is discarded due to visible mold. In addition, while currently there may be limited control of aflatoxins in staple crops such as maize, this is expected to change. There is an important shift in attitudes and awareness, and many ongoing initiatives on aflatoxins, and it is expected to result in increased detection and enforcement over time. Taking these factors into account the risk to food availability was assessed as **"medium".**

> Brucellosis in dairy herds reduces in the availability of milk due to abortions, loss of replacement stock and impacts on the animal itself (estimated as 2-4 kg of milk/animal/year). This was assessed as a "severe" impact (in part because of the fact that Uganda is significantly below WHO recommended levels for milk consumption). Since brucellosis is endemic in Ugandan herds, the likelihood was considered "medium" (possible) and the risk to **food availability** was **"high".**

Based on the combined evaluations for the three criteria, the five food safety issues were assigned a priority order as shown in Table 15.

TABLE 15 **EVALUATION OF FOOD SECURITY IMPACTS**

FOOD SAFETY ISSUES	NUTRITIONAL STATUS	FOOD AVAILABILITY	FOOD ACCESSIBILITY	PRIORITY ORDER IN TERMS OF FOOD SECURITY
Acute diarrhoea in children	High	Low	Medium	1
Aflatoxin – maize	High	Medium	Low	1
Brucellosis – milk products	Very low	High	Medium	3
Cysticercosis – pork	Low	Low	Medium	4
Methanol – unregulated gin	Very low	Low	Medium	5

STEP 5 CHOOSING THE FOOD SAFETY ISSUES THAT ARE THE HIGHEST PRIORITY

The decision table for risk prioritization is presented in Table 16. Note that the public health risks are "high" or "very high" for these issues – each one is a significant problem in terms of public health impact.

In this example, the issue of aflatoxin in maize is the highest priority because of the impact on food security as well as economic risk for export markets. In fact economic risk is significant for this issue but not for any of the others. Acute diarrhoea in children is the second highest priority because this food safety issue has significant impact on public health and food security.

These results are based on the decision factors and metrics that were identified through workshops and discussions with risk managers. There was agreement that food security should be considered in prioritizing food safety issues but that further work was needed to develop a comprehensive analysis and appropriate metrics.

As shown in Table 16, the multi-factor prioritization is based on the relative order of issues. If a new food safety issue is added to the list, it is necessary to re-analyse the order in terms of each factor as well as the overall prioritization. It becomes challenging to use this type of approach when there is a large number of issues and/or prioritization factors.

TABLE 16 DECISION TABLE FOR RANKING AND PRIORITIZATION OF 5 FOOD SAFETY ISSUES IN UGANDA

FOOD SAFETY ISSUES	PUBLIC HEALTH RANKING	ECONOMIC RISK*	FOOD SECURITY IMPACT*	PRIORITIZATION ORDER (OVERALL)
Aflatoxin – maize	High	1	1	Highest priority
Acute diarrhoea in children	Very high	5	1	Second highest
Brucellosis – milk products	Very high	5	3	Third highest
Cysticercosis – pork	High	5	4	Fourth highest
Methanol – unregulated gin	High	5	5	Lowest priority

* 1= highest risk/impact; 5= lowest risk/impact

Case study 4b

A SEMI-QUANTITATIVE APPROACH TO RISK RANKING AND PRIORITIZATION

This example was shared at the technical meeting held in Rome in November 2013. The methodology was developed and used by the Food Safety Science Committee in Canada on an annual basis to establish priorities based on public health risk and other considerations. Although this process has been discontinued, the methodology is a practical and transparent way to identify priorities.

DEFINE DECISION PROBLEM — STEP 1

To establish priorities through a national level, annual review of food safety issues.

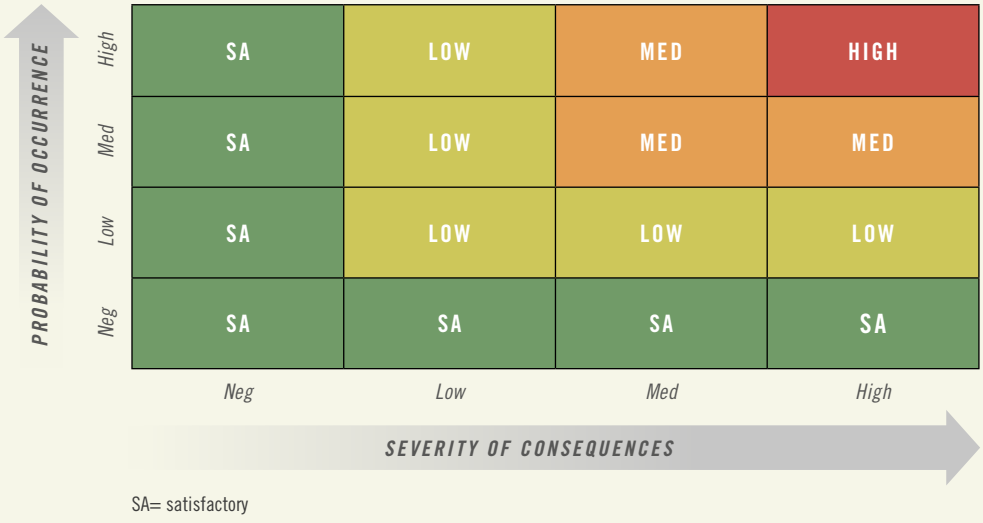
IDENTIFY ALTERNATIVES — STEP 2

A set of current and emerging food safety issues in Canada. The issues are defined as hazard-food pairs (e.g. *Campylobacter* in poultry, *Listeria* in ready-to-eat meat).

SELECT DECISION FACTORS AND CRITERIA — STEP 3

The primary decision factor is risk to public health and experts assess each food safety issue using the qualitative risk model shown in Figure 6. (Note – this risk model is slightly different from general model shown in Figure 4.) Other considerations for setting priorities include: **consumer concerns, industry concerns, interest from pressure groups and media as well as political interest.**

FIGURE 6 **QUALITATIVE MODEL FOR PUBLIC HEALTH RISK**



STEP 4 COMPARE ALTERNATIVES

Public health risk

Food safety issues were grouped into four categories of health risk, and each category was assigned a score (satisfactory = 0, low = 30, medium = 65, high = 80 points).

Other considerations

Each of the four factors was assigned a score to a maximum of 5 points (i.e. maximum value for all 4 factors = 20 points).

In completing their evaluations, committee members included a short summary of key assessment details (e.g. probability and severity estimates).

Table 17 shows an example of the data and methodology used to evaluate *Listeria* in ready-to-eat meats. The one-page summary documents the evaluation of likelihood and severity as well as the points for health risk and for establishing priorities. The final evaluation (Total points) represents a consensus of expert opinions achieved by discussion at the committee meeting. The same process would be followed to evaluate each food safety issue.

TABLE 17 **RISK ANALYSIS FORM USED BY THE FOOD SAFETY SCIENCE COMMITTEE IN CANADA TO PRIORITIZE FOOD SAFETY ISSUES**

SCIENCE COMMITTEE RISK ANALYSIS FORM	PRIORITY (TOTAL POINTS) 81
ISSUE: *Listeria* / Ready-to-Eat Meat	
Risk Assessment	
Probability: MEDIUM · Recalls occurred for Listeria containing Ready-to-Eat (RTE) meat products last year	
Severity: MEDIUM	
Level of Risk (from the model - probability of occurrence and severity of consequences): MEDIUM (65 points) + 16 points (see Other Considerations below) = 81 (HIGH priority) (SATISFACTORY (0 points); LOW (50 points); MEDIUM (65 points); HIGH (80 points))	
Other Considerations in Establishing Priority - Maximum 20 points: Consumer Concerns (max. 5 points): 3 points Industry Concerns (max. 5 points): 5 points Pressure Group/Media Interest (max. 5 points): 5 points Political Interest (max. 5 points): 3 points > Unknown situation in non-registered sector > High volume of RTE meat products consumed (frankfurters etc.) > Outbreak associated with cold cuts in the US	
Risk Management Tools: Tools needed to support management of the issue	
Existing regulatory requirements, standards, policies, guidelines, or those needed to manage the issue: > Health Canada (HC) had *Listeria* policy updated October 2004 > Environmental monitoring in federally registered plants	
Laboratory methodology needs: none	
Research needs: > Need research for different serotypes and virulence factors	
Information and risk assessment needs: > Need information for different serotypes and virulence factors	
Risk Management Options: Identify options or strategies to manage the issue	
> Provide feedback on problems with environmental swabbing (i.e. use of lab forceps) > Implementation of the revised HC policy on *Listeria* > Consider requiring industry to realize their own environmental testing and Canadian Food Inspection Agency (CFIA) may audit > Improve communication regarding products jointly regulated between CFIA and each province to clearly determine responsibility for non-registered plants and implement > High pressure pasteurization and other interventions > Further policy development required	

CHOOSING THE FOOD SAFETY ISSUES THAT ARE THE HIGHEST PRIORITY — STEP 5

The priority score is based on total points (i.e. a linear additive model for combining criteria scores) shown at the top right corner of the form. Risk to public health is the main factor in setting food safety priorities. Other factors are considered but contribute a maximum of 20 points to the final score. It is clear from the point attribution system, 80 for public health, and 20 for all four factors, that there is strong weighting/importance given to ensuring that those food safety issues of highest public health risk are given a higher importance in the prioritisation decision.

The risk managers consider the results of the evaluation and scoring for each food safety issues, in order to inform the prioritization decision.

The summary in Table 17 also includes details about existing risk management activities and an assessment of needs. Although this goes a step beyond setting priorities, it is a good foundation for identifying actions that should be considered to address priority food safety issues.

Case study 4c

MULTI-FACTOR PRIORITIZATION USING AN OUTRANKING METHOD

The third case study is taken from the literature (Ruzante *et al.* 2010). A multi-disciplinary group of researchers proposed a prioritization framework for foodborne risks that considered public health impact and three other factors (market impact, consumer risk acceptance and perception and social sensitivity). Canadian-based evidence was gathered for six pathogen-food combinations in order to demonstrate multi-factor prioritization in practical terms.

STEP 1 DEFINE DECISION PROBLEM

Prioritize a set of food safety issues to demonstrate a new multi-factor approach.

STEP 2 IDENTIFY ALTERNATIVES

Six pathogen-food pairs were selected as examples:

> *Campylobacter* spp. in chicken
> *Salmonella* spp. in chicken
> *Salmonella* spp. in spinach
> *Escherichia coli* O157 in beef
> *Escherichia coli* O157 in spinach
> *Listeria monocytogenes* in ready-to-eat meats.

STEP 3 SELECT DECISION FACTORS AND CRITERIA

Three major factors were included and both continuous (years, Canadian $) and Likert-type scales were used for decision criteria:

DECISION FACTOR	CRITERIA	TYPE OF SCALE
Public health impact	DALYs based on a top-down approach to quantitative risk assessment	Years
Market impact	economic importance of the domestic market = total value at retail + value of exports - value of imports	Canadian $
Consumer perception and acceptance of risk	3 point, Likert-type* scales to assess degree to which risk is: > uncontrollable > unknown to the consumer > unknown to scientists > involuntary > believed to have a severe outcome	total score (maximum 15 points) is normalized and reported on 0-1 scale

* a scale commonly used to measure consumer responses in surveys

COMPARE ALTERNATIVES — STEP 4

TABLE 18 **DECISION TABLE FOR PRIORITIZATION OF 6 PATHOGEN-FOOD ISSUES**

PATHOGEN-FOOD	DISABILITY ADJUSTED Life Years (YEARS)	ECONOMIC IMPORTANCE (CAN$ Million)	CONSUMER PERCEPTION & ACCEPTANCE (0 to 1 scale)*
Campylobacter **spp. in chicken (C–C)**	808	5 472	0.3
Salmonella **spp. in chicken (S–C)**	449	5 472	0.25
E. coli **O157 in beef (E-B)**	260	5 264	0.6
L. monocytogenes **in ready-to-eat meat (L-RTEM)**	58	974	0.6
E. coli **O157 in fresh spinach (E-S)**	3	118	0.8
Salmonella **spp. in fresh spinach (S-S)**	1	118	0.5

*0 is preferred value

CHOOSING THE FOOD SAFETY ISSUES THAT ARE THE HIGHEST PRIORITY (RISK RANKING AND PRIORITIZATION) — STEP 5

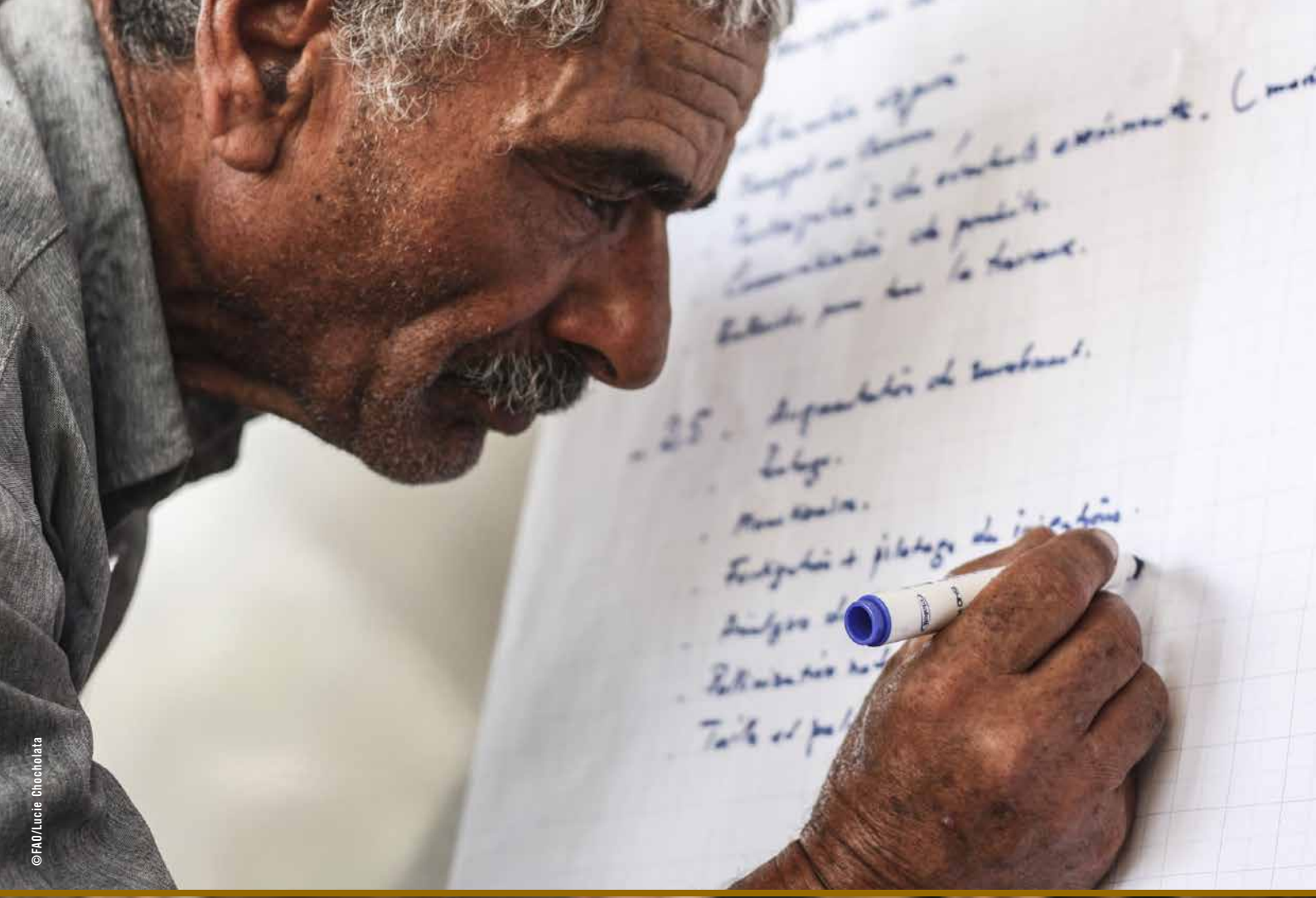
Two different scenarios are considered. In the first scenario, only public health impact is considered (i.e. risk ranking based on DALY values). The second scenario is prioritization based on all three factors (public health impact, market impact and consumer perception and acceptance). A multi-criteria analysis method called "outranking" is used to aggregate the three factors with equal weights on each factor. The software is based on the PROMETHEE (Preference Ranking Organization Method for Enrichment Evaluation) algorithm. Software and technical support for PROMETHEE can be found at http://www.promethee-gaia.net.

The order of food safety issues is as follows:

SCENARIO 1- RISK RANKING (PUBLIC HEALTH ONLY)	SCENARIO 2 - PRIORITIZATION (3 FACTORS; EQUAL WEIGHTS)	
C - C	C – C	Highest priority
S - C	E – B	
E - B	S – C	
L - RTEM	L – RTEM	
E - S	E – S	
S - S	S – S	Lowest priority

The order of the six food safety issues is very similar in both scenarios. However, in Scenario 2 *E. coli* O157 in beef moves ahead of *Salmonella* spp. in chicken based on greater consumer concerns about *E. coli* O157 in undercooked beef. (The economic importance of beef and chicken are comparable).

Although not included in the original research paper, the next step would be to assess the feasibility of addressing each of these food safety issues.



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SECTION 5

CREATING AN ENABLING ENVIRONMENT FOR MULTI-FACTOR DECISION-MAKING

KEY QUESTIONS THAT ARE ANSWERED IN THIS SECTION:

> What are the features of an enabling environment to facilitate multi-factor decision-making?

> Why it's worth investing in structured, multi-factor decision making?

> How to get started and make the most of this guidance document?

This guidance document aims to improve food safety policy and risk management decisions through the use of structured, multi-factor analysis based on evidence. This multi-factor approach is based on the Codex risk analysis model and recognizes the paramount importance of protecting public health. However, it also includes formal methods to consider and account for other outcomes that may result from food safety issues, such as harm to food security, economic well-being and trade. Although the relevance of multiple factors may be understood and accepted by risk managers and policy makers, for many it will require a change in the status quo to integrate them into decision-making processes. For example, additional efforts may be required for evidence-gathering and analysis, or stakeholder engagement, or documenting decisions, etc. We have discussed the need for change in our pilot country projects and technical meetings with experts and have identified a number of key features that are needed to support multi-factor decision-making in risk management and policy development. Many features are integral to a country's food control system and its capacity to assure food safety. Countries are actively encouraged to reflect on the different features and strive to strengthen them where necessary and appropriate to the national context.

5.1 KEY FEATURES OF AN "ENABLING ENVIRONMENT"

SUPPORTIVE LEADERSHIP

Leaders create the environment and culture that supports innovation and a willingness to engage in new ideas and processes. While multi-factor decision making may not be totally new to all, it is viewed and accepted differently within the community of risk managers and in different countries. Some decision-makers consider multiple factors, but not in a very systematic or structured way. Strong leadership is needed to make a clear commitment to using structured, multi-factor approaches in food safety decision-making. Leaders at senior levels must demonstrate their commitment by clearly stating their support and by allocating adequate resources for multi-factor analysis (e.g. resources for training decision-makers, evidence-gathering, analysis and engagement with stakeholders). When the decision requires work across ministries and agencies, leadership is critical in order to gain cooperation and to foster a willingness to share evidence. By promoting multi-factor decision-making, leaders demonstrate their confidence and commitment in the process and support to work with decision-makers to implement the resulting decisions. This should inspire decision-makers to invest in the process.

POLICY FRAMEWORK

Governments need a comprehensive food safety policy framework that sets the strategic context for decision-making and policy development. Commitment to invest in food safety policy is a critical foundation for using the approaches promoted in this guidance document. It is essential in order to ensure that the time and resources invested in multi-factor decision-making are warranted and optimal results are obtained.

Policy frameworks may vary in different countries, ranging from a single policy document, developed by a single ministry with a clear connection to food safety (e.g. agriculture, health) to policy direction stated in sector policies prepared by ministries that oversee rural development and trade, food security, industry development or the environment. In the context of this document, risk management interventions to implement policy are also a part of overall policy.

The policy framework is stronger when potential impacts on relevant factors in the national context (e.g. health, local economy, social, etc.) are considered. As policies are developed and modified, policy-makers need to be aware of potential impacts these changes may have on food safety, and communicate these changes to the appropriate risk managers. This should improve the safety of all foods, including those sold and consumed on the domestic market.

INTERAGENCY COOPERATION AND CROSS-MINISTRY WORK

As different ministries have an interest in, and responsibility for, food safety according to their mandate, interagency cooperation, communication, and coordination is essential for coherent policy development and decision-making. This will facilitate the exchange of information and sharing of evidence needed to consider different factors, and determine the best course of action to address a food safety issue, which may include joint implementation of risk management solutions. The level of interagency cooperation required for the multi-factor approaches requires decision-makers to adopt common thinking and agree to work together which may be different to the usual status quo. For some it will require a shift in mind-set, including agreement to follow a more structured approach to decision-making, sharing of information and data, and recognizing that consideration of different factors may be important to arrive at the optimal decision. Although there may be multiple ministries involved, structured multi-factor decision-making benefits from one ministry taking the lead, with the resources and authority to do so.

Communication channels should be clear and functional and will be most effective when there is a true willingness to share information and data. Agriculture and fisheries, health and industry portfolios may be involved in the food sector, including a role in food safety. Implementation of the decision and course of action may require specific actions by a number of ministries. Where relevant ministries have been involved and/or consulted in the decision-making process, there is a greater chance of success to jointly implement risk management measures, with everyone understanding and willing to play their part.

CAPACITY AND RESOURCES TO GATHER EVIDENCE

Having access to relevant evidence is the basis of robust decision-making. The type of evidence to be analysed varies depending on the decision and the factors under consideration and both qualitative and quantitative information are useful in multi-factor decision making. In-country expertise is important to ensure the number of

factors and criteria scales chosen are practical and feasible. As mentioned earlier evidence needs to be gathered for each factor and criteria.

Irrespective of the level of maturity of a country's food control system, strengthening the evidence base for decision-making, is an important, and ongoing task for most countries. Countries, in particular developing countries, face challenges in having credible, robust evidence available. There may be data gaps, or concerns about the quality of data. In other instances, decision-makers may not easily know which evidence exists in their country, as it is often scattered between different ministries, scientific and academic institutions, the private sector, etc. At other times, there may be a reluctance on the part of the custodian to share the evidence and data with others. Again, this is an example of where strong leadership and trust are needed to facilitate cooperation.

To facilitate multi-factor decision-making it is important to establish a common agreement on evidence management and use early in the process and to think about ways to connect to existing information systems where possible. To ensure appropriate evidence is available to decision-makers as and when needed, a programme for investment in continual improvement and access to evidence is required. It should include the development of systems to facilitate the generation, collection, analysis and archiving of evidence (qualitative and quantitative) for current and future use. Doing this properly requires expertise in risk management, and scientific and data management experts to gather and manage the evidence. The latter group includes risk assessors working in scientific disciplines relevant to food safety, and other disciplines including economists, trade specialists, social scientists. At times, additional resources may be required, e.g. to commission further risk assessments or economic analysis, or to cover the additional workload for risk managers.

Efforts to improve coordination and presentation of evidence will be enhanced if the providers (academia, scientific institutes, international agencies such as WFP) understand the basic types of information that are used to support common food safety decisions.

It would also be prudent to consider developing archives that can be used when decisions need to be made very quickly (e.g. emergency response). Through the process of structured decision making, data gaps and needs are identified, which inform the cycle of continual improvement of evidence generation, collection, storage and so on.

CAPACITY TO ENGAGE AND CONSULT WITH STAKEHOLDERS

Stakeholders of all types – government, policy-makers, public health professionals, industry, academics, advocacy groups, consumers and the broader community – are rich sources of information. Many stakeholders have practical experience that is useful in developing polices, in selecting relevant criteria for multi-factor decision-making and developing feasible risk management interventions. Risk managers

need the resources and expertise to engage and consult with stakeholders through a variety of channels (e.g. public presentations, interviews, surveys, focus groups, email and social media).

Involvement of stakeholders in decision-making processes facilitates greater understanding of the food safety issue, the evidence considered, and any trade-offs made in reaching the final decision. This can be especially important when the balance of potential positive or negative impacts of a food safety decision needs to be understood, e.g. impacts on health, agriculture, economic, trade, social, etc. Where implementation of a decision requires joint or simultaneous action by different stakeholders in different ministries, or the private sector, there will be a greater chance of success if they have been involved and consulted in the decision-making process.

Stakeholder consultation takes time and resources. Decision-makers need to be mindful that not all stakeholders need to be engaged and consulted on all decisions. The ministry or group of ministries managing the decision-making process should agree which stakeholders they need to consult, the appropriate stage(s), and the process for engagement. The purpose of the consultation and expected results should be clear, focused and efficient for all concerned.

CHAMPIONS

All initiatives can benefit from champions or innovators to carry them forward. While leaders are generally in positions of authority or at senior levels in the governance hierarchy, champions can be found at all levels in an organisation and are often non-positional leaders within the community of risk managers and policy-makers. Champions exhibit a desire to move from the status quo to a new and better situation and they are successful because they have tenacity, courage and the ability to engage and motivate others. Champions are skilled at starting conversations with colleagues and supervisors and gaining agreement to test some new ideas such as multi-factor decision-making approaches. The results of their efforts can provide concrete examples of considering multiple factors in the decision-making process as well as the benefits.

The pilot work in Uganda demonstrates the value of getting started with some concrete examples and a champion. When the pilot country work began, neurocysticercosis (NCC) linked to consumption of undercooked pork was a recognized food safety issue. However, there was no readily accessible evidence for any of the four prioritization factors: public health, markets, food security and social considerations. An in-country expert worked to develop a combination of quantitative and qualitative information based on research findings reported in the scientific literature as well as evidence from local public health and abattoir records. Information was obtained for each of the four prioritization factors and is summarized in the multi-factor risk profile in Box 10. Although some of the evidence is sparse, this summary was an important starting point to better understand the overall impact of this food safety issue on different factors and to

gather all available evidence from different stakeholders. This information provided a broader understanding of this food safety issue and was the foundation for the qualitative ranking of NCC within a set of five food safety issues (see Section 4.3, Case study 4b – A semi-quantitative approach to risk ranking and prioritization).

Information on the other four food safety issues and their impact is available in Annex 2 of the report of the Uganda pilot study: www.fao.org/3/a-bc265e.pdf.

BOX 10

MULTI-FACTOR RISK PROFILE - GETTING STARTED WITH EVIDENCE GATHERING FOR MULTIPLE RISK FACTORS

Eating undercooked pork that contains viable *Taenia solium* cysts (i.e. the larval stage not the adult tapeworm) can lead to NCC when cysts develop in the brain and spinal cord. The most common symptoms include epileptic seizures and headaches.

Public Health: It is difficult to estimate the number of NCC-related epilepsy cases directly because the cost of the medical test means that the link to NCC is rarely confirmed. Ndimubanzi P.C *et al.* (2010) conducted a study in a number of countries where pigs are raised by backyard free-range methods in close proximity to humans (i.e. the general practice in Uganda) and estimated that NCC caused 30 percent of all epilepsy cases. The level of transmission due to consumption of contaminated pork in Uganda was estimated at 50 percent based on expert opinion. This information was used to estimate the likelihood of disease and mortality attributed to contaminated pork. Based on national health records, 2013, it was estimated that 73 900 outpatient visits, 845 inpatient visits and 10 deaths were linked to NCC caused by contaminated pork. This was used to estimate the likelihood of NCC relative to other foodborne illnesses.

The severity of different health outcomes was based on DALY weights for epilepsy relative to acute diarrhoea (a common condition associated with foodborne illness) and a report by Roberts *et al.* (1994) that estimated treatment time for NCC.

Markets: Although pork production is significant in Uganda (113 000 tonnes in 2010), export markets are closed to because of the high prevalence of the *T. solium* parasite. The price of pork in the domestic market is reduced in regions with high parasite prevalence but it is not possible to quantify the total loss because all of the trade is informal. The number of pork carcasses that were condemned due to cysts was taken from abattoir records and used to make a conservative estimate of UGX 3 billion or USD 1.2 million as the annual economic loss for the domestic market.

Food Security: There are more than 1 million households in Uganda raising pigs, and the sale of a pig often covers basic household needs (e.g. medications, school fees). Reduced prices for infected animal result in a loss of income and small farmers are more vulnerable.

Social considerations: There is a strong social stigma associated with epilepsy in many African countries (Zoli *et al.* 2003). Those who are afflicted are treated as outcasts and many require psychological counselling and support. It is clear that these are significant consequences at personal and societal levels and further work is needed to develop appropriate ways to use this evidence in food safety decisions.

5.2 THE VALUE OF INVESTING IN STRUCTURED, MULTI-FACTOR DECISION-MAKING

Methods and approaches in this document will help food safety decision-makers to adopt structured processes for decision-making, consider relevant evidence in order to assess multiple factors as a basis for making a final decision that identifies the best option. Even with a strong enabling environment, it will take time to integrate multi-factor approaches into policy development and risk management activities. The Codex guidelines for risk analysis provide a clear, accepted method to assess harm to public health. It will take time to develop methods which assure all decision-makers have valid evidence sources for other factors and suitable processes to ensure objective analysis of the evidence.

However, as these goals are achieved, there will be many positive outcomes such as:

> Strong evidence is developed for all decision factors that are relevant in risk management and policy development (e.g. public health, economic, food security and others). Monitoring and review processes continue to add evidence over time and this results in more comprehensive knowledge of current food safety issues.

> Integration of multi-factor analysis into food safety decisions at multiple levels – problem identification, setting priorities, selecting risk management interventions, monitoring and evaluation and policy setting.

> Engagement of stakeholders at various stages of decision-making leading to better understanding of their concerns as well as consideration of these concerns in the decision.

> Improved coordination of activities and sharing of information across ministries and agencies before decisions or policies are implemented, achieving better "policy coherence".

> Governments and ministries are clear on why a specific risk management option or policy is recommended.

> High level authorities and policy makers are able to compare food safety issues or risk management alternatives on a consistent basis when making decisions about resource allocations and strategic directions.

Any of these outcomes will produce better risk management decisions and better policies, leading to improved public health and safety and reduced potential for unintended consequences.

Once risk managers have made a decision and recommend certain action, the advice needs to be presented in a brief and succinct way. Applying documented, structured decision-making approaches provides food safety risk managers with a record of the decision taken and the process undertaken to arrive at it. This is invaluable for a range of possible communication activities, including explaining the rationale behind the decision, the evidence considered, stakeholders consulted, and any trade-offs made.

Furthermore, risk management decision-making is not static. It is a continuously evolving process, as food safety situations and potential risks change. A structured, documented process is a very useful reference for risk mangers when they need to re-consider a decision taken in the past. Many organisations and decision-makers follow a simple work flow of making a decision, documenting it, analysing it over time, re-visiting and improving it.

5.3 GETTING STARTED, MAKING THE MOST OF THE APPROACHES IN THIS DOCUMENT

Decision-makers are actively encouraged to apply and test the approaches in this document. This can be done in many different ways, it will depend on the context, and the types of decisions to be taken. Sections 3 and 4 address the common decisions of choosing the optimal risk management options(s), or prioritizing food safety risks. These are planned decisions, and the approaches described are most appropriate when there is time to collect and consider evidence. Risk managers will need to decide when it is warranted to embark on a lengthy decision-making process by considering evidence on multiple factors. It should be clear that not every decision requires the same level of investment in a formal, structured process.

Although some of the approaches are more suited to planned decisions, the principles and method of thinking can also be applied when decision-makers need to act quickly, and make decisions to address food safety issues in a shorter timeframe. A good starting point in many decision-making processes will be to gather any available evidence to understand the risks associated with a single food safety issue. The example in Box 10 above, shows how to gather evidence on the multiple risks associated with a food safety issue. Undertaking this activity alone can be very useful and can convince resource allocators of the need to address a food safety issue. It often sets a good evidence-base for other decisions, e.g. prioritisation of food safety issues.

Some practical suggestions to move ahead, include starting a conversation with colleagues and supervisors about the importance of good decisions, and gain agreement to test some of the approaches to improve current decision-making, with the objective of better outcomes. It will require a discussion and agreement on the need to discuss multiple factors and risk areas. A team from your office or agency, can examine the structured approaches and determine the decision to be undertaken. Depending on which factors need to be considered, you may need to work with other agencies or ministries. Applying the approaches to current decisions, gathering the evidence, and working through a decision to a final result will be an important exercise. Once completed, the team should reflect and see if the approach helped gain a better understanding of a food safety issue, or make a better decision. What needs to be done in order to further use and refine the approach? Were there data and evidence gaps? Sharing the results with colleagues within your ministry and

in others, in addition to superiors, should gain broader stakeholder support for more structured decision making, and support that it is important and possible to consider multiple factors.

To sum up in a few final words:

Everyone likes to be on solid ground when making an important decision. Whether it is being used to address policy development, set priorities or make a significant food safety risk management decision, **multi-factor decision-making** supports that strong ground leading to a clear statement of the objective or problem, the options considered, the decision made and why. Done well, it is an evidence informed rigorous and robust process, able to withstand scrutiny and challenge!


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GLOSSARY

It is always a challenge to ensure a common understanding of vocabulary in multi-disciplinary efforts such as this guidance document, because some terms have come to have specific meanings in different disciplines. The intent of this glossary is to provide short, working definitions of terms that are used frequently to help readers understand these terms in the context of food safety decision making. Each term is explained in more detail in the guidance document.

ALTERNATIVES: Decisions come down to making a logical choice from a set of alternatives. Alternatives may be a set of food safety issues from which priorities must be identified, or a set of potential risk management options that could be implemented to address a particular food safety issue.

APPROPRIATE LEVEL OF PROTECTION: The level of protection deemed appropriate by a member of the World Trade Organization (WTO) establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory. This concept is also referred to as the appropriate level of risk [WTO, SPS Agreement, 1995].

CRITERION: A criterion is a scale or yardstick that is used to evaluate and compare alternatives. This makes it possible to identify those that produce the "best" results and those that are the "worst" performers in terms of each decision factor.

DECISION FACTORS: The objectives and considerations that influence decisions or choices, e.g. public health impact, consumer trust, cost of implementation. Food safety decision-makers need to identify the decision factors that are relevant to the type of decision and country context, to build a structured approach for comparing alternatives in food safety decisions.

DECISION TOOLS: Aids to assist decision-makers and to facilitate systematic decision-making. In this guidance document, decision tools are suggested primarily to assist in the consideration of multiple factors and to improve accountability and transparency in decision-making.

EVIDENCE: Evidence refers to a broad body of facts and information available on a given issue which enables a critical analysis of an issue, and informs any related decisions. Evidence may include scientific, statistical, economic and other information, in addition to stakeholders' views and perspectives, and expert opinion.

EVIDENCE INFORMED DECISIONS: The term "evidence informed" is used instead of "evidence based" to emphasize the fact that decision-makers must make choices regarding the appropriate evidence to consider and that the final decision is based on their analysis and judgment. Evidence alone does not produce a decision.

FOOD SAFETY RISK MANAGEMENT DECISIONS: Decisions made by risk managers to identify and address food safety issues and reduce risks to an acceptable level. There are a broad range and variety of types of decisions, such as identifying food safety priorities, introducing a regulation or standard, strengthen food surveillance, training food operators, inspection of food imports, etc.

FOOD SAFETY POLICIES: High level policies which set out in general terms the overall direction a government or organization wishes to take to ensure food safety (often informing resource allocation).

FOOD SECURITY: Food security exists when all people, at all times, have physical and economic access to sufficient, safe and nutritious food that meets their dietary needs and food preferences for an active and healthy life [FAO, 1996].

MULTI-CRITERIA DECISION ANALYSIS (MCDA): Formal, structured methods help decision-makers compare a set of complex issues or management options. MCDA methods require decision-makers to develop explicit criteria and to assess all alternatives or options on the basis of these criteria.

"MULTI-FACTOR" DECISION-MAKING: This is based on a structured five-step process that includes a clear statement of the decision objective, the alternatives considered, the factors and criteria used to evaluate and compare these alternatives, and the identification of the "best" choice overall.

PRIORITIZATION: The systematic analysis and ordering of foodborne hazards (or food safety issues) based on a consideration of public health impacts (resulting from risk ranking), and other factors such as social, economic, political.

RISK ANALYSIS: A process consisting of three components: risk assessment, risk management and risk communication [Codex Alimentarius Commission (CAC), 1999].

RISK ASSESSMENT: A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment and (iv) risk characterization [CAC, 1999].

RISK COMMUNICATION: The interactive exchange of information and opinions concerning risk and risk management among risk assessors, risk managers, consumers and other interested parties [CAC, 1999].

RISK MANAGEMENT: The process, distinct from risk assessment, of weighing policy alternatives in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options [CAC, 1999].

RISK RANKING: The systematic analysis and ordering of foodborne hazards and/or foods in terms of public health risks, as assessed by the likelihood and severity of adverse impacts in a target population.

ANNEX

ADVANCED COMPUTATIONS IN MULTI-FACTOR DECISION-MAKING

Experts in the field of operations research have developed a number of different methods for MCA and these have been used to address a wide range of complex problems including public health (Bots 2000; Jehu-Appiah *et al*. 2008) and food safety (Fazil *et al*. 2008) decisions. This Annex is intended as an overview of MCA to help readers to understand the analysis in the case studies that are presented in this guidance document. Further details about methodologies for multi-criteria analysis can be found in Figueira *et al*. (2005).

Some MCA methods are well suited to certain types of decisions because of the nature of the criteria (i.e. quantitative vs. qualitative scales). Relative ranking methods (i.e. first, second, third …) are acceptable when there is a small number of food safety issues and criteria. However, if new alternatives are added part way through the analysis, then the relative rankings for all alternatives need to be re-evaluated.

One important consideration is whether trade-offs between criteria are acceptable. For example, a risk management option may have a significant positive impact on trade that offsets (i.e. compensates for) a negative impact on food security. When compensation is acceptable to the decision-maker, performance across individual criteria can be combined or aggregated into an overall performance that is used to compare alternatives. The best-known methods for aggregation are:

> multi-attribute utility theory (MAUT), (Baker *et al.*, 2002)

> linear additive models (i.e. weighted averages of criteria scores)

> analytic hierarchy process (Saaty 1980)

> outranking methods (Roy 1991 and Brans and Vincke 1985)

The MAUT methods are relatively complex and are best suited to having a lot of quantitative data. To use these approaches, specialists would need to be consulted and involved in the process.

Linear additive models are fairly intuitive approaches based on weighted averages of performance scores across all criteria. They are used in a number of the case studies presented in Sections 3 and 4. The calculations are straight forward and can be implemented with simple tools such as calculators and spreadsheets. The decision-maker must be careful to define all criteria scales in a consistent direction (i.e. either the maximum or the minimum value on all scales is the preferred or "best" value) and with the same range (e.g. all criteria values are scaled between 0 and 100).

The analytic hierarchy process (AHP) is based on pairwise comparisons of alternatives to evaluate relative performances on each criterion. The method takes advantage of the fact that decision-makers find it easier to make relative rather than absolute judgments, and it is well suited to qualitative criteria. The decision-makers' judgements are translated into scores on a 9-point scale and each criterion is compared against the others to define normalized weights. Scores and weights for each criterion are combined using a linear additive model to produce an overall assessment for an alternative. Even if the number of alternatives and criteria is relatively small, the decision-maker is faced with a large number of judgments when using the AHP method. If a new alternative is added, then all of the comparisons must be re-evaluated. However, the calculations can be set up in a spreadsheet and commercial software packages are available.

In outranking, alternatives are first compared within each criterion, so it is not necessary to adopt a common scale for all criteria. Comparisons are based on the degree to which an alternative outranks other alternatives and degree to which it is outranked by other alternatives in the set. The complete ranking of alternatives is based on the aggregation over all criteria with specific weights assigned to each criterion to calculate a net outranking flow for each alternative. The higher the net outranking flow, the better the performance of the alternative. Two of the case studies (3c and 4c) use the PROMETHEE algorithm for outranking. Although the software tool that was used for this analysis is no longer available, there is an updated version Visual PROMETHEE.[15] The new version also includes visualization tools to help decision-makers better understand the decision problem (e.g. to detect conflicting groups of criteria and identify clusters of similar alternatives).

There is also ongoing work to develop a software tool that combines outranking and AHP methodologies.[16] This allows the user to choose a MCA approach best suited to the criteria scales.

Finally, it is important to note that computational tools do not replace the skilled decision-maker. Their expertise is critical at every step of the decision-making process – defining the problem, identifying alternatives, factors and criteria, gathering evidence and making the final decision. They need to interpret the aggregate score for each alternative based on their knowledge of the uncertainty that is associated with the evaluation of individual criteria. Computational tools are helpful but decision-makers are responsible for the final choice(s) (i.e. risk management option to implement, priority food safety issues to address).

15 http://www.promethee-gaia.net/visual-promethee.html. Last accessed 3 October 2017.

16 http://www.mamca.be/en/ Last accessed 3 October 2017.




FOOD SAFETY RISK MANAGEMENT

These FAO guidance materials were developed to support food safety risk managers and policy-makers in applying structured, evidence-informed processes to decision-making. Food safety issues can have widespread impacts beyond public health. They may contribute to, or detract from the achievement of goals in areas including nutrition, food security, food trade and market access, economic and rural development. The risk analysis paradigm guides risk managers to ensure their decisions are based on an assessment of risks to health, and consideration of other factors in choosing the preferred risk management decision. The materials assist decision-makers in applying a multi-factor approach and is applied to two key decision areas – setting food safety priorities, and selecting risk management options. The principles and approaches can be applied to all food safety decisions. Case studies are included as examples of how to apply this decision-making process. Using this guidance will lead to improved food safety decisions, where decision-makers can demonstrate how evidence was used and any trade-offs made. It also facilitates stakeholder engagement, transparency and accountability throughout the decision-making process.

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