

Evidence-informed food safety policies and risk management decisions

FAO Technical meeting
18-22 November 2013, FAO, Rome

Context paper and supporting reference materials



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European Union

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Food and Agriculture Organization of the United Nations
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PREFACE

This paper was prepared as a background document for participants to facilitate technical discussion during the FAO Technical meeting on Evidence-informed food safety policies and decisions, Rome, 18-22 November 2013. It includes contextual information (multi-criteria approaches and initiatives at national level) and results of the preparatory activities for the meeting, namely literature reviews in a number of relevant areas and semi-structured interviews.

The meeting has been convened with support from the European Union (EU) through the food safety component of the *EU/FAO Improved Global Governance for Hunger Reduction Programme*. The Programme aims at improving food security governance at global, regional and national levels.

BACKGROUND

Food safety agencies at national and regional levels are responsible for strategic decisions related to the prioritization of current and emerging hazards in foods and the allocation of resources to assess and manage these risks including the need to implement policies that define permitted levels and guidelines for safe food-handling. Decisions relate to all foods, whether traded or domestically produced, consumed and take place in the first instance as part of a risk-based planned food control system, but on occasion will also address food safety incidents and food safety emergencies. All decisions need to be evidence-informed.

The Codex Alimentarius Commission has defined a widely accepted, science-based framework for analyzing evidence related to health risks – the risk analysis paradigm. While public health is clearly a primary concern, many risk analysts recognize that food safety decisions are made within a context that includes social, economic and political risks. For example, bacterial and chemical hazards in export products can have disastrous impacts on trade, employment and household food security. Some sub-groups in a population may be particularly sensitive to foodborne hazards, e.g. chronic exposure to mycotoxins may cause growth stunting in children. In reality food safety agencies often do consider a range of risk factors that are based on country- or region-specific issues. However the evidence that is used to assess factors other than public health is often produced by *ad hoc* methods that are not as rigorous as the Codex risk assessment guidelines.

One of the key recommendations in a recent report to the Heads of National Food Agencies in Europe¹ was to support efforts to develop “robust, evidence-based analysis of other factors [in addition to health risks]”. The report also stressed the importance of accounting for all decision-making factors in a clear and transparent way so that stakeholders,

¹ Working Group of the Network of Heads of National Food Agencies in Europe “Report on the Transparent Use of Risk Assessment in Decision Making”, December 2012, available at www.food.gov.uk/science/sci-gov/decision-making#.U1IXgeAZdUQ

including industry, trading partners and consumers, understand and accept the need for food controls.

I. Facilitating a technical discussion

FAO launched an EC-funded programme *Improved Global Governance for Hunger Reduction* in 2012 to improve food security governance at global, regional and national levels. Accessing adequate amounts of safe and nutritious food is central to food security². Within the programme, there is a project to develop improved tools for formulating food safety policies by adopting a multi-factor approach to risk analysis. Currently there are pilot projects in two countries – Uganda (initiated in March 2012) and Thailand (November 2013). In addition to these country-level initiatives, FAO is convening a meeting “*Evidence-informed food safety policies and decisions*” 18 – 22 November 2013 bringing together a group of international experts who are directly involved in developing food safety policies or those who advise policy-makers.

FAO is supporting countries (including the development of guidance) to improve food safety decision making considering a range of multiple factors. This meeting has been convened to ensure that we are well-informed and up to date on approaches, experiences in this field, and as a result best equipped to support countries. In particular, through the meeting we aim to:

1. Gain a global update on formal frameworks and approaches being applied to consider relevant evidence (e.g. scientific assessments of health risks, socio-economic factors such as food availability and accessibility, market access, etc.) when developing food safety policies and making food safety decisions, e.g. allocation of resources, risk management options.
2. Share experiences on changes/approaches applied at national level to implement or test these frameworks and approaches (e.g. institutional changes, stakeholder³

² “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” (World Food Summit, 1996).

³ Stakeholders refer to responsible ministries, food manufacturing and processing industries, retailers, primary food producers, national experts, academic and consumers.

involvement/dialogue, changes in data use/collection, ways to inform policy makers leading to policy recommendations), and identify common principles, and issues to consider based on collective wisdom and experiences.

3. Identify essential issues to be addressed and the type of support required to enable countries to make (move towards) evidence-informed decisions considering a range of relevant factors. The emphasis will be on the needs of developing countries, although the results of the Meeting can be of interest to all countries.

In preparing for this Technical Meeting, the core organizing team has completed a broad review of the literature in a number of relevant areas, and conducted a series of semi-structured interviews with 15 experts to collect additional information on approaches and considerations related to evidence informed decision making across a number of factors.

This context paper has been developed to provide background information for participants in advance of the meeting. Specifically, the paper:

- Sets out the issue of considering multiple factors when making food safety risk management decisions and hence the rationale for this meeting;
- Provides examples of approaches/frameworks that have been proposed or implemented to take into account multiple risk factors in food safety decision-making;
- Explains the content and format for the 5 day meeting
- Outlines some of the implementation challenges that have been identified in the literature and in the semi-structured interviews conducted with international experts; and

Please note that Annex 1 explains some of the key terms used in this paper.

II. Multi-factor approaches for food safety decision-making – underpinning evidence

Based on the literature review and the interviews, it is clear that the issues outlined in the meeting objectives are being discussed in the international food safety community, and

there are a range of approaches and initiatives ongoing at country level in terms of the factors that are considered and how they are assessed. Experiences do vary however, and countries are at different stages of maturity in how they manage national food safety decision making processes and how they consider evidence on different factors.

A number of those who were interviewed provided examples of recent food safety decisions and explained the factors considered, including public health and other impacts (e.g. trade, consumer perceptions ...):

- Dioxins in pork (Ireland) – based on scientific risk assessment, there was no significant risk to human health but there were significant risks to the entire pork industry as well as the reputation of Ireland as a producer of safe food. Since the contaminated product could not be traced and separated, the decision was to withdraw all products from the market.
- Food Additives (EU) - the large majority of EU decisions regarding authorisation of additives or their limits are based on the corresponding scientific assessments. However, special provisions do exist for certain (named) traditional foods produced in a specific territory, and Member States are entitled to prohibit the use of some additives based on a consideration of societal, traditional factors.
- Acute methanol poisoning (Uganda) – this is recognised as a major public health problem, with death and blindness resulting in extreme cases. While the driver for action was public health protection, determining appropriate preventive, control and management measures included discussion with the Manufacturers of Spirits.

III. Systematic, structured approach for multi-factor risk based decision-making

The semi-structured interviews highlighted that countries do consider a range of factors in decision-making, that it is seen as important to do so, but that how it is done varies greatly between countries. Overall, interviewees expressed a common interest in having more structured methods to assess diverse risks - in developing common agreement on principles and *how* it can be done. This was seen as important for a range of reasons including transfer of knowledge to countries with less developed approaches, and moving towards a more harmonized understanding of this issue to support dialogue between

countries on import food requirements. At the same time, it was recognized that it is challenging to consider a range of evidence across different factors, and interviewees also cautioned against prescriptive approaches. Any guidance should be flexible enough to allow food safety authorities to apply as appropriate for different situations. The most relevant papers from the literature review completed prior to this meeting are included in Annex 2.

To our knowledge, a complete system for multi-factor risk-based decision-making has not yet been implemented but there are some examples of general frameworks and structured approaches that have been proposed or are in development. Additional details about each framework are provided in Annex 3.

The SAFE FOODS Framework⁴ for integrated risk analysis includes five steps: framing, risk assessment, evaluation, risk management and review. The framing step is the starting point for planning the governance of each food safety issue. At this step, the critical decision is whether there is a need for new or updated risk assessment related to human health as well as environmental risks and societal impact. In the evaluation stage, all interested parties – experts, policy makers and consumers – review the risks, costs and benefits and their distribution. The framework is intended for food safety governance at a national or EU level.

A risk-based approach to food safety decision-making was developed by a study committee that was established by the National Academies to conduct a review of the role of the U.S. Food and Drug Administration in ensuring safe food⁵. The committee recognized the need to conduct analysis and prioritization at several distinct levels. These include strategic planning, ranking of priorities - initially based on public health followed by secondary consideration of other factors (e.g. public acceptance, market impacts), analysis and choice of intervention strategies (including allocation of resources), and the evaluation of outcomes. These steps form a continuous cycle of risk prioritization and regulatory

⁴ The Safe Foods framework for integrated risk analysis of food, Knudsen I. Food Control 21(12)1653-1661, 2010

⁵ *Enhancing Food Safety: The Role of the Food and Drug Administration*, A report of the Institute of Medicine and National Research Council, 2010.

(intervention) activities and each step in the cycle includes consultations with stakeholders.

There is a pilot project underway in Uganda as part of the FAO Food Security Governance Programme. It is being carried out in collaboration with the Ministry of Health Task Force that is responsible for the WHO/FERG⁶ study on Burden of Foodborne Disease in Uganda. Three workshops have been held in Uganda to develop a multi-factor approach that is useful for food safety policy-making. Workshop participants have recommended that food safety decisions in Uganda should consider four broad areas of risk: public health, economic, food security and social factors. At the May 2013 workshop, risk characterization approaches were developed for each of these areas using 3 case studies. Multi-criteria decision analysis was used to rank the 3 issues and to discuss appropriate weightings for each area.

The Multi-factor Risk Prioritization Framework⁷ was developed in Canada for strategic decision-making (e.g. prioritization, resource allocation, risk management) at a national level. It considers four major risk factors: public health, consumer risk perceptions and acceptance, market-level impacts, and social sensitivity. The framework is based on the systematic organization and analysis of data on these multiple factors at the basic level of food-pathogen pairs. A number of operational tools have been proposed to assist decision makers: information cards that provide systematic information that is not pre-processed or aggregated across factors, cobweb diagrams or graphical profiles of aggregate metrics for the four risk prioritization factors, and multi-criteria decision analysis that requires decision makers to place explicit values on different risk factors in order to rank priorities or choose management options.

⁶ Foodborne Disease Burden Epidemiology Reference Group (WHO). See for more information.

http://www.who.int/foodsafety/publications/foodborne_disease/FERG_Nov07.pdf.

⁷ A multi-factorial risk prioritization framework for food-borne pathogens, Ruzante J. M et al, 2010, Risk Analysis 30:5 724-42.

All of the approaches outlined here are intended to provide rigorous evidence concerning public health impact and other risk factors for government policies and management decisions related to food safety. Public health impact is based on Codex risk assessment guidelines in the context of the risk analysis paradigm, but more limited guidance has been developed as to how to assess other risk factors.

IV. Implementation challenges

In calling for broader risk-based approaches to food safety decision-making, we recognize that there are challenges in accomplishing this goal. Implementation requires a number of resources including methods and analytical tools, data and information systems and people who can interpret evidence from diverse sources and apply it as appropriate. In addition to resource needs, there must be changes in attitudes and possibly governance structures to ensure that policies and decisions are not being developed in silos. Responses through the semi-structured interview process support these challenges, and provide additional insights – a synthesis is included in Annex 4. Additionally, the interviewees provided a number of documents relevant to this meeting as listed in Annex 5.

A number of issues are identified here to stimulate thinking about implementation issues in advance of a more complete discussion at the upcoming meeting.

IV.1 Methods to assess other factors:

There is a clear interest in having structured methods that are as rigorous as the Codex guidelines to assess the impacts of food safety issues on consumer confidence and socio-economic outcomes. These evaluations require discipline-specific methods, largely from the social sciences and a broad range of evidence (e.g. consumer surveys, trade data, employment data...). While each agency would determine which factors were appropriate to include in its decision-making, these are some of the general areas of risk that might be included in a multi-factor approach:

- *Economic risk* estimates the expected economic losses arising at an industry- or country level from foodborne hazards. Outbreaks can have high economic impact for a sector/industry or individual producers. In many cases, these are rare events and expert judgments (e.g. Delphi panels) may be a useful approach for estimating likelihood. Potential impacts on domestic and export markets and livelihoods would be included in the economic risk characterization.
- *Consumer perceptions and acceptance* of the risks associated with food are an important determinant of public confidence in the security of the food system and in government regulation and oversight. Perceptions can shift market demand for certain food products, particularly after highly publicized outbreak events. In this area, risk perceptions may change quickly and frequently.
- *Social factors* may include consideration of vulnerable sub-groups (e.g. young children, elderly, and persons with compromised immune systems) that are at higher than average risk. Society's duty to care for those who cannot protect themselves may be considered as a separate factor from public health impact. Wider social consequences associated with foodborne illness (e.g. environmental issues, animal welfare and First Nations⁸ rights) may also be flagged. Methods for social implications and ethical considerations that are suggested in the SAFE FOODS Framework may be useful here.
- *Food security* may be impacted at national or regional levels in terms of changes in nutritional status, food availability and food accessibility. These factors are particularly important in developing countries.

Methods to assess other risk factors have been put forward by economists (e.g. cost of illness, willingness to pay, quality adjusted life years) and social scientists (e.g. consumer surveys, focus groups with specific demographic groups). For some factors, new information and methods of analyzing risks may need to be developed. Ultimately the evidence that is produced for other factors must be explained to the wider community of

⁸ First Nation's refers to the various aboriginal people in Canada who are neither Inuit nor Métis.

risk managers and decision-makers in ways that they can understand and accept as being comparable to the science-based risk assessments for public health impact.

IV.II Methods to integrate multiple risk factors:

Metrics for different risk factors are often measured on different scales (e.g. DALYs⁹, trade value, Likert-scales for consumer opinions) and can be quite different in magnitude making it challenging to integrate multiple risk factors into an overall ranking. Multi-criteria decision analysis (MCDA) tools ensure consistency in the treatment of different criteria and measurement scales. Some MCDA methods are well suited to stakeholder participation in setting the “weights” for the different criteria. This contributes to greater transparency and can be helpful in reaching consensus in decision-making. MCDA methods have been used in a number of different applications, including environmental and health-related applications.

Policy culture/governance structures: The meeting discussion will focus on the use of multi-factor approaches for strategic food safety decisions such as ranking of issues and to inform policy-making, particularly policies that cut across departmental and ministry boundaries. Some key questions that will be explored include:

What are compelling ways to present the evidence to policy makers so that they understand it and use it effectively?

What barriers currently prevent policy makers from utilizing multi-factor risk evidence? This may include governance structures and agency mandates that contribute to working in silos and unwillingness to share data with other groups.

Where and how should stakeholders participate in a multi-factor, risk-based system for food safety decision-making?

⁹ Disability- Adjusted Life Year (DALY) can be thought of as one lost year of "healthy" life. The sum of these DALYs across the population, or the burden of disease, can be thought of as a measurement of the gap between current health status and an ideal health situation where the entire population lives to an advanced age, free of disease and disability (WHO, 2014).

v. Approach for technical meeting in Rome

The goal of the meeting is to move forward on the use of multi-factor, risk-based evidence in food safety decision-making. A draft version of the meeting agenda is being circulated to participants with this context paper. The agenda includes a few formal presentations but a significant amount of time is allocated to discussions – in plenary and smaller groups. During the discussions, meeting facilitators and recorders will capture key points and recommendations. These will be organized around common themes for a summary report.

Annex 1: Working definitions for terms used in the context paper

Food safety decision-making: We are focusing on decisions made by government agencies at national and regional levels to prioritize current and emerging hazards in foods and to allocate resources to assess and manage these risks including the need to implement policies that define permitted levels and guidelines for safe food-handling. It includes identifying the most appropriate risk management decisions to minimize risk from potential food safety hazards, as well as decisions that are required in the event of a food safety incident or food safety emergency.

Evidence-informed: Evidence is needed to understand and assess the risk of foodborne hazards to human health as well as social and economic consequences.

This requires a broad range of evidence sources including: the best available research evidence (i.e. findings that have been vetted by a credible peer-review process), experience and contextual information from experts, and stakeholder perspectives (consumers, producers, food processors).

“Multi-factor” approaches recognize that foodborne hazards that cause harm to human health and can threaten economic well-being, consumer confidence, food security and social values. While there are clear guidelines for assessing risks to human health, structured methods need to be developed to assess other areas of risk.

Multi-criteria decision analysis (MCDA) refers to formal, structured methods developed by Operations Research to help human decision-makers compare a set of complex issues or management options. MCDA methods require decision-makers to develop explicit criteria for ranking options or making choices and to assess all issues or options on the basis of these criteria. In the overall analysis, weights are assigned to each criterion, usually with input from stakeholders as to the appropriate values. A number of MCDA methodologies have been used by government agencies (e.g. U.S. Department of Energy, Fisheries and Oceans, Canada) to make decisions related to environmental issues.

Annex 2. Resources from literature reviews

Tools: Google engine and Scopus database (publication date 2000 – present)

1st literature review

Search terms used:

1. Use of risk assessment in food safety risk management
2. Science and other factors in risk management
3. Science and other factors in food safety decision making
4. Science and economic, social, trade factors in food safety risk management
5. Transparent food safety risk management
6. Sound principles for food safety risk management
7. Translating science into food safety risk management decisions
8. Making sound food safety risk management decisions in developing countries
9. Translating science into food policy
10. Developing sound food safety policies
11. Influencing food safety risk managers decisions
12. Influencing food safety policy makers
13. Food security considerations in food safety decision making
14. Linkage between food safety and food security

2nd literature review

Search terms used:

- Food safety AND
 - Risk Governance
 - Cost Benefits
 - Risk Management Decisions
 - Decision-making Experiences
 - Risk Prioritization

Science-based Policy Making

Decision-making framework

Transparent decision-making

Managing health risks

Stakeholder participation

- Food safety decisions AND framework
- Food Safety Reforms

Relevant papers from literature reviews (first and second stages): Note: This table is organized by the Folders that are on the ftp site. Folders are broad categories that capture some of the meeting themes. Within each folder or sub-folder, the papers are listed by title (alphabetical order). Numbers are assigned as reference tool that can be used during meeting discussions.

Ref No.	Title	Reference source	Year	Author(s)	Relevant details	Folder on FTP site	sub-folder
1	Choices, choices: The application of multi-criteria decision analysis to a food safety decision-making problem	Journal of Food Protection 71 (11), pp. 2323-2333	2008	Fazil, A., Rajic, A., Sanchez, J., McEwen, S.	multiple criteria defined for comparing intervention options, weights for criteria, transparency	Computational tools	
2	Science and Decisions: Advancing Risk Assessment	National Academy Press	2008	Committee on improving Risk Analysis Approaches Used by the US EPA.	need for risk assessments to include multiple factors; simplified tools for screening risks	Computational tools	
3	Use of computational tools in the field of food safety	Regulatory Toxicology and Pharmacology 60 (3), pp. 354-362	2011	Piparo, E.L., Worth, A., Manibusan, M., Yang, C., Schilter, B., Mazzatorta, P., Jacobs, M.N., Steinkellner, H., Mohimont, L.	survey suggests national regulatory bodies do not make use computational tools but perceive as useful; need for guidance & training	Computational tools	
4	A tale of two crises: The Belgian and Irish dioxin contamination incidents	British Food Journal 112 (10), pp. 1077-1091	2010	Casey, D.K., Lawless, J.S., Wall, P.G.	emergency response; trade impact; consumer confidence	Country examples	
5	Improving Food Safety in Canada: Toward a More Risk-Responsive System	Report by Conference Board of Canada	2012	Daniel Munro, Dr. Jean-Charles Le Vallée, and James Stuckey	risk considerations at government, industry and consumer levels	Country examples	
6	New Zealand's Food Safety Risk Management Framework	New Zealand government	2010	New Zealand Food Safety Authority	risk management framework; scientific inputs (Fig 4); emergency management	Country examples	
7	The Complex Risk Governance Issues Posed by Radionuclides in Food After the Fukushima Disaster	draft paper Earth System Governance Tokyo Conference: Complex Architecture , Multiple Agents	2013	Matsuo, M.	possible example/case study; emergency response - risk trade-offs; refers to need to consider health and socio-economic risks (incl food availability) but no details on how this was done	Country examples	

Ref No.	Title	Reference source	Year	Author(s)	Relevant details	Folder on FTP site	sub-folder
8	A multifactorial risk prioritization framework for foodborne pathogens	Risk Analysis 30 (5): 724-742	2010	Ruzante, J.M., Davidson, V.J., Caswell, J., Fazil, A., Cranfield, J.A.L., Henson, S.J., Anders, S.M., Schmidt, C. Farber, J.M.	Canadian framework - concept and 6 case studies to demonstrate metrics and ranking	Frameworks Multiple factors	MFRPF
9	Expanding the Focus of Cost-Benefit Analysis for Food Safety: A Multi-Factorial Risk Prioritization Approach	Dept. Res Econ, U Mass (Amherst), working paper 2008-8	2008	Caswell, J	rationale for multiple criteria	Frameworks Multiple factors	MFRPF
10	The international quest for an integrated approach to microbial food-borne risk prioritization: Where do we stand?	J Risk Research 14 (2): 215-239	2011	Anders, S and Schmidt, C.	literature review (2008) for Canadian multi-factor framework	Frameworks Multiple factors	MFRPF
11	Scientific Opinion on the development of a risk ranking framework on biological hazards	EFSA Journal 10(6):2724	2012	EFSA Panel on Biological Hazards (BIOHAZ)	recent review of ranking tools; focus on health metrics comprehensive (88 pages)	Frameworks Multiple factors	Other Examples
12	Towards an integrated approach in supporting microbiological food safety decisions	Zoonoses Public Health 54(3-4):103-17	2007	Havelaar AH, Bräunig J, Christiansen K, Cornu M, Hald T, Manges MJ, Mølbak K, Pielaat A, Snary E, Van Pelt W, Velthuis A, Wahlström H	public health, economic factors; risk management to reduce campylobacteriosis in broiler meat chain; health impact used to prioritize/determine need for policy; argues for economic analysis in management decisions	Frameworks Multiple factors	Other Examples
13	Compatibility of the SAFE FOODS risk analysis framework with the legal and institutional settings of the EU and the WTO	Food Control 21 (12): 1638-1652	2010	König, A	focus on compatibility of SAFE FOODS framework with EU, WTO & Codex	Frameworks Multiple factors	SAFE FOODS
14	Economic assessment of food safety standards: Costs and benefits of alternative approaches	Food Control 21(12):1611-1619	2010	Traill, W.B. and Koenig, A.		Frameworks Multiple factors	SAFE FOODS

Ref No.	Title	Reference source	Year	Author(s)	Relevant details	Folder on FTP site	sub-folder
15	Including social impact assessment in food safety governance	Food Control 21(12):1620-1628	2010	Dreyer, M., Renn, O, Cope, S. and Frewer, L.J.		Frameworks Multiple factors	SAFE FOODS
16	Potential methods and approaches to assess social impacts associated with food safety issues	Food Control 21(12):1629-1637	2010	Cope, S., Frewer, L.J., Renn, O. and Dreyer, M.		Frameworks Multiple factors	SAFE FOODS
17	The SAFE FOODS Framework for improved risk analysis of foods	Food Control 21(12):1566-1587	2010	König, A et al.	expanded risk assessments; health & environmental risk/benefits; explicit consideration of economic and social impacts in risk management	Frameworks Multiple factors	SAFE FOODS
18	The SAFE FOODS Framework for integrated risk analysis of food: An approach designed for science-based, transparent, open and participatory management of food safety	Food Control 21(12):1653-1661	2010	Knudsen, I.	background on project; outlines 5 step procedure for framing and evaluation	Frameworks Multiple factors	SAFE FOODS
19	The views of key stakeholders on an evolving food risk governance framework: Results from a Delphi study	Food Policy 34:539-548	2009	Wentholt, M.T.A., Rowe, G., König, A, Marvin, H.J.P. and Frewer, L.J.	feedback on strengths and weaknesses of SAFE FOODS framework	Frameworks Multiple factors	SAFE FOODS
20	Towards safer foods and more democratic decisions Is this a contradictory goal?	OCL 14(2):92-99	2007	König, A	early paper on SAFE FOODS framework	Frameworks Multiple factors	SAFE FOODS
21	Managing Food Safety Practices from Farm to Table: Workshop Summary	National Academy of Sciences	2009	Pray, L. and Yaktine, Y.	workshop based on Food Forum discussion - inputs from government, industry, consumer & academics; includes summaries of presentations & discussion; some interesting points but requires significant effort to sift through (117 pages)	Miscellaneous	

Ref No.	Title	Reference source	Year	Author(s)	Relevant details	Folder on FTP site	sub-folder
22	Responding to Health Risks along the Value Chain	2020 Conference: Leveraging Agriculture for Improving Nutrition and Health	2011	Pippa Chenevix Trench, Clare Narrod, Devesh Roy and Marites Tiongco (International Food Policy Research Institute, Washington)	comprehensive; many examples in developing countries	Miscellaneous	
23	State of the art in benefit-risk analysis: Introduction & Food and Nutrition	Food and Chemical Toxicology 50 (1), pp. 2-25	2012	Tijhuis, M.J., de Jong, N., Pohjola, M.V., Gunnlaugsdóttir, H., Hendriksen, M., Hoekstra, J., Holm, F., Kalogeras, N., Leino, O., van Leeuwen, F.X.R., Luteijn, J.M., Magnússon, S.H., Odekerken, G., Rompelberg, C., Tuomisto, J.T., Ueland, Ø., White, B.C., Verhagen, H.	integrated risk-benefit analysis in food and nutrition	Miscellaneous	
24	Consumer perceptions of best practice in food risk communication and management: Implications for risk analysis policy	Food Policy 35 (4), pp. 349-357	2010	Cope, S., Frewer, L.J., Houghton, J., Rowe, G., Fischer, A.R.H., de Jonge, J.	consumer perceptions	Non-health factors	Consumer
25	Consumers' perceptions of food risk management quality: Chinese and Korean evaluations	Agricultural Economics 58 (1), pp. 11-20	2012	Kim, R.B.	multi-attribute model to predict consumer behaviour	Non-health factors	Consumer
26	Mechanisms for assessing food safety risk	British Food Journal 115 (3), pp. 460-484	2013	Manning, L., Soon, J.M.	includes business and consumer risk considerations as part of HACCP	Non-health factors	Consumer
27	Overview of bovine spongiform encephalopathy and related events in	International Journal of Risk Assessment and Management	2010	Lewis, R.E., Krewski, D., Tyshenko, M.G.	public reaction to identification of BSE in Germany; emergency response	Non-health factors	Consumer

Ref No.	Title	Reference source	Year	Author(s)	Relevant details	Folder on FTP site	sub-folder
	Germany	nt 14 (1-2), pp. 121-132					
28	Survey of public perceptions of prion disease risks in Canada: What does the public care about?	Journal of Toxicology and Environmental Health - Part A: Current Issues 72 (17-18), pp. 1113	2009	Lemyre, L., Gibson, S., Markon, M.P.L., Lee, J.E.C., Brazeau, I., Carroll, A., Boutette, P., Krewski, D.	consumers view as economic (trade) and political issue rather than health concern	Non-health factors	Consumer
29	Why consumers behave as they do with respect to food safety and risk information	Analytica Chimica Acta 586 (1-2 SPEC. ISS.), pp. 2-7	2007	Verbeke, W., Frewer, L.J., Scholderer, J., De Brabander, H.F.	psychological responses to risks; social amplification of risk	Non-health factors	Consumer
30	Economic approaches to measuring the significance of food safety in international trade	Internat. J of Food Microbiology 62 (3): 261-266	2000	Caswell, J.A.	costs of regulation	Non-health factors	Economic
31	Food safety policy and economics	Resources for the Future Discussion paper	2010	Hoffmann, S.	some good insights (e.g. role of economics in risk assessment)	Non-health factors	Economic
32	International trade and food safety in developing countries	Food Control 16:L491-496	2005	Schillhorn van Veen, TW	developing country perspectives	Non-health factors	Economic
33	Community food assessment: A first step in planning for community food security	Journal of Planning Education and Research 23 (4), pp. 356-377	2004	Pothukuchi, K.	Community food security - safe, culturally acceptable, nutritionally adequate diet through a sustainable food system that maximizes self-reliance and social justice	Non-health factors	food security
34	Food Safety and Ethics: The Interplay between Science and Values	Journal of Agricultural, Biological, and Environmental Statistics 15 (3), pp. 245-253	2010	Jensen, K.K., Sandøe, P.	need to understand societal values and ethical context	Non-health factors	Social

Ref No.	Title	Reference source	Year	Author(s)	Relevant details	Folder on FTP site	sub-folder
35	Building the Science Foundation of a Modern Food Safety System. Lessons from Denmark, the Netherlands, and the United Kingdom on creating a more coordinated and integrated approach to food safety information	The Produce Safety Project at Georgetown University	2010	Michael Batz and J. Glenn Morris Jr.	public acceptance, economic and social factors also play important roles in public health decisions	Non-health factors	
36	Communicating food-safety risks to key stakeholders	EuroChoices 4 (2), pp. 42-49	2005	Peddie, S., Stott, A., Oglethorpe, D., Gunn, G.	need to include public concerns in decision-making but raises questions about when and how	Non-health factors	
37	Measuring the perceived pressure and stakeholders' response that may impact the status of the safety of the food chain in Belgium	Food Research Internat. 48(1): 257-264	2012	Baert, K et al	identifies economic, social, environmental pressure factors related to food safety	Non-health factors	
38	Overview of National Food Safety Systems and Activities	Ad Hoc Group on Food Safety	2000	Organisation for Economic Co-operation and Development [OECD]	p. 11- addressing socio-economic concerns; alludes to but does not identify countries that use socio-economic factors	Non-health factors	
39	A framework for the application of precaution in science-based decision-making about risk	Government of Canada, National Library of Canada	2003	Government of Canada	guiding principles for the application of precaution to science-based decision making in areas of federal regulatory activity for the protection of health and safety	Policy making	
40	Food regulation policy, options consultation paper for the review of the 2003 Ministerial Policy Guideline	Options Consultation paper for review of the 2003 Ministerial Policy Guideline	2010	Food Regulation Standing Committee, Australia	some elements are relevant (69 pages) eg. impact of regulations on public health, consumers, industry & government	Policy making	
41	Food safety governance and social learning: The Spanish	Food Control 18(7): 834-841	2007	Todt, O, Muñoz, E, Plaza, M	EU imposed regulatory governance; not driven by consumer demand; unexpected	Policy making	

Ref No.	Title	Reference source	Year	Author(s)	Relevant details	Folder on FTP site	sub-folder
	experience				consequences (creates new roles and demands)		
42	Framework for science governance	Food Standards Agency UK	2012	Food Standards Agency UK	use of science in policy and decision-making; tools & guidance for good practice	Policy making	
43	Heads of National Food Agencies Working Group on Transparent Use of Risk Assessment in Decision Making	A report of the European Commission	2012	Heads of National Food Agencies Working Group (European Commission)	principles of good practice include transparency, use of science-based risk assessment and other factors	Policy making	
44	How do we translate science into public health policy and law?	Journal of Law, Medicine and Ethics 30 (3 SUPPL.), pp. 22-32	2002	Fielding, J.E., Marks, J.S., Myers, B.W., Nolan, P.A., Rawson, R.D., Toomey, K.E.	framework for developing policy on sound science base (social and natural sciences); examples of success	Policy making	
45	Monitoring Policy and Research Activities on Science in Society in Europe (MASIS). National Report Norway	National Report, Norway	2010	Torben Hviid Nielsen and Kenneth Dahlgren	context - impact of off-shore petroleum economy on Norwegian policy making Chap 2 - priority setting, governance & policy-making; interesting analysis of actors & influences	Policy making	
46	Reducing risks, protecting people – HSE’s decision-making process	UK Government	2001	Health and Safety Executive	level of individual risk & societal concerns considered with acceptability of risk is assessed	Policy making	
47	Risk Characterization Handbook	US Environmental Protection Agency	2000	Members of the Risk Characterization Implementation Core Team, a group of EPA’s Science Policy Council	principles of transparency, clarity, consistency & reasonableness - adapt to economic and other factors	Policy making	
48	Scientific Advice, Risk and Evidence Based Policy Making	UK House of Commons	2005–06	Science & Technology Committee	2 recommendations about evidence-based policy (p. 103); Table 1 (p 94) outlines a risk scale - linguistic label; probability and examples; Box 6 (p 96) less acceptable risks;	Policy making	
49	The pitfalls of European risk	Innovation (Abingdon,	2013	Giorgi, L		Policy making	

Ref No.	Title	Reference source	Year	Author(s)	Relevant details	Folder on FTP site	sub-folder
	governance: a question of design or application? Some empirical results from the food safety sector	England)					
50	The role of "science" and "other factors" in risk	TACD, DOC NO. FOOD-16PP2-00	2000	Trans-Atlantic Consumer Dialogue	urges the US and EU governments to commit themselves to completing a policy on "other legitimate factors"	Policy making	

Annex 3: Examples of multi-factor approaches – additional details

SAFE FOODS Framework for integrated risk analysis of food	
Approach	A multi-disciplinary research group developed a risk analysis approach that integrates “a consistent risk assessment of human health aspects with consumer preferences and values and analysis of socio-economic aspects” (also includes active mechanisms for consumer participation in risk assessment and risk management). An initial “framing” stage is used to identify the scope of risk assessment that should be undertaken. Human health risks and benefits are primary considerations but some food safety issues may also include economic, social and ethical risks/benefits. The researchers recommend explicit risk assessments for these factors using the best scientific tools in the fields of economics, social sciences and applied ethics. Also suggest that the feasibility and costs of additional assessments need to be considered at framing stage. Only consider when benefits outweigh costs.
Additional reference materials	Multiple papers on different aspects of SAFE FOODS project in Special Issue of Food Control 21 (12) 2010: 1563-1676(multiple papers)
Potential Risks	Methods/metrics
Human health	Is the primary consideration for all food safety issues; Recommend including adverse health effects due to hazards as well as nutritional benefits
Environment	Recommend same tools/approaches used to assess health impacts
Economics	Recommend similar approach to regulatory impact assessments used in the UK
Social	Use experts from social sciences to produce a profile for each food safety issue based standard criteria for social implications. Based on profile, identify areas that warrant comprehensive social assessment.
Ethical	Use an ethical matrix based on 4 principles (absence of harm, do some good, protect dignity and fairness). Identify meaning of each principle for moral stakeholder groups (e.g. producers, consumers, livestock and

	the environment). Analyze consequences and make judgments on what is ethically acceptable.
Status/ implementation	At conceptual stage - to our knowledge, has not been implemented as complete framework. Specific tools are available to facilitate assessment of health impact (electronic platform of food consumption and chemical concentration databases; model to link exposure to health effects and to include exposure to multiple chemicals)

Risk-based Food Safety System (proposed for U.S. Food and Drug Administration)	
Approach	<p>Step 1: Strategic Planning</p> <ul style="list-style-type: none"> Identify public health objectives Establish risk management plan Establish metrics to measure performance <p>Identify key public health objectives and intermediate outcomes using quality, timely data.</p> <p>Step 2: Public Health Risk Ranking</p> <ul style="list-style-type: none"> Develop/select tools for public health risk ranking Rank risks based on public health outcomes Report results and solicit feedback <p>Comprehensive, integrated data used to develop attribution models and rank public health risks.</p> <p>Step 3: Targeted Information Gathering</p> <ul style="list-style-type: none"> Identify and consider additional criteria for decision making Conduct targeted information gathering Identify priority risks for intervention analysis <p>Additional data collected to identify priority risks.</p> <p>Step 4: Analysis and Selection of Interventions</p> <ul style="list-style-type: none"> Identify appropriate level of protection for high-priority risks Identify intervention options and technical analysis needed for evaluation Gather information and choose intervention strategies Report results, solicit feedback and, if needed, modify <p>Data collection and analysis serve as basis for selecting intervention strategies.</p> <p>Step 5: Design of Intervention Plan</p> <ul style="list-style-type: none"> Develop plan for implementing selected interventions Allocate resources Implement interventions <p>Collect data before, during and after implementation of interventions.</p> <p>Step 6: Monitoring and Review</p> <ul style="list-style-type: none"> Collect and analyze data on evaluation measures Interpret data and evaluate intervention results Determine if public health objectives have been met Communicate results to stakeholders Review/refine process to achieve continuous improvement <p>Use data that relates interventions to public health outcomes to evaluate efficacy of system.</p>
Additional reference material	Study committee of the National Academies 2010. Chapter 3 in “Enhancing Food Safety: The Role of the Food and Drug Administration”.
Potential Risks	Methods/metrics
Public health	Recommends a number of semi-quantitative risk-ranking methods: Foodborne Illness Risk-Ranking Model (FIRRM); iRISK, Risk Ranger and Food Safety Universe Database.

Other factors	Recognizes that the FDA must consider additional factors such as the feasibility of mitigation, economic constraints (costs and economic consequences), additional public health and welfare concerns of stakeholders and the environmental impacts. Recommend that other factors are considered after ranking based on public health risk.
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FAO Food Security Governance Program – Uganda	
Approach	Three workshops have been conducted in Uganda to identify food safety issues, relevant risk criteria for food safety decisions and metrics to assess risk criteria. Five case studies, based on priority food safety issues, were analyzed in terms of multiple risk factors. Multi-criteria decision analysis was used to rank the food safety issues using criteria weights proposed by the workshop participants. Participants included representatives from the Uganda Ministry of Health, Ministry of Agriculture, academia and other related institutes and agencies.
Additional reference materials	A presentation on the project will be made at the November meeting.
Potential Risks	Methods/metrics
Human health	Immediate illness and sequelae (estimates of foodborne cases per year), number of deaths per year; DALY estimates will be used when WHO-FERG country study in Uganda is completed.
Market-level	Value of trade - domestic and export markets
Food Security	Risks to nutritional status, food accessibility and food availability are characterized on a 5-point scale (not significant, low, medium, high and critical)
Social factors	Direct impacts on vulnerable sub-populations and regions as well as indirect impacts (e.g. educational development) were assessed on a 3-point scale (no concerns, some concerns, and significant concerns).
Status/ implementation	In development; project runs until 2015. Additional information is available at: http://www.foodsec.org/web/what-we-do/food-safety/en/

Multi-factor Risk Prioritization Framework – Canada	
Approach	A framework to provide key evidence about 4 major risk factors (public health, market-level impacts, consumer awareness and social sensitivity) for food-pathogen pairs. Case studies, based on Canadian data, were developed to demonstrate the components of the framework and tools that can help risk managers compare and prioritize food safety risks as well as interventions.
Additional reference materials	Ruzante, J.M <i>et al.</i> 2010. Risk Analysis, 30(5): 724-742.
Potential Risks	Methods/metrics
Human health	Disability-adjusted life years (DALY); Cost-of-illness (COI)
Market-level	Estimate of market value for food product = total value at retail + value of exports minus value of imports
Consumer perception & acceptance of risk	Delphi-based rating of five criteria related to perception and acceptance of risk (scaled between 0 and 1).
Social sensitivity	Delphi-based ratings (0 or 1) for sensitivity based on: <ul style="list-style-type: none"> • vulnerable consumers (e.g. pregnant women and Listeriosis, elderly, immune-compromised); • vulnerable firms (e.g. small firms, firms in marginal economic areas)
Status/ implementation	Currently working with provincial ministry (Agriculture and Food) and the Canadian Food Inspection Agency to integrate a new measure for public health risk into the framework and to refine the metrics for other factors as required. The modified framework will be tested with potential end users to ensure that the methods are practical and effective in developing management strategies. Chemical hazards will also be included in the analysis.

Annex 4. Semi-structured interviews - A synthesis

INTRODUCTION

An important preparatory step for the FAO Technical Meeting Evidence-informed Food Safety policies and Risk Management Decisions, 18 – 22 November 2013 were the semi-structured interviews completed during October – November 2013. In all, 15 persons were interviewed; all except 2 interviewees will participate in the upcoming meeting.

The purpose of this document is to provide a synthesis of the interviewees' responses to the questions, ensure we have the same baseline information, and to stimulate discussion. This is not a verbatim summary, and there is no prioritization or ranking of the information, some comments were mentioned by many interviewees, others only by one person (some specific "quotes" are included). Assimilating this information also enables us to focus in on issues which need to be considered in more detail – highlighted by targeted questions/comments (in RED). Please consider and dwell on the questions and comments made in the Boxes - there will be time during the meeting to discuss these specific issues either in plenary or working group sessions.

In addition, please note that interviewees made relevant documents and information on national approaches available to FAO, and these provide important input to the meeting. Separate summary document has been prepared.

RANGE OF FOOD SAFETY DECISIONS and VIEWS ON CONSIDERING MULTIPLE FACTORS

When considering the range of possible risk management food safety decisions where multiple factors are considered, it was recognized that there are many different types of decisions. Some relate to prioritization, others determining which risk management option/intervention is more appropriate to minimize risk from a known food safety issue (including non-compliance with a law and determining appropriate action), other decisions related to food import/export, while others related to recall of food products. When describing the *how food safety risk management decisions are made, most respondents described the process for setting regulations* as this was the main instrument for implementing risk management decisions and policies. This covered from the decision on

whether there is a need to develop a regulation, explaining the institutional process for regulation development, stakeholder engagement at all levels. It included all the main food safety regulations, but also extended to health claims in some cases.

There is a need to separate between big P policies, set at political Ministerial level, and those setting regulation under that policy.

What do people understand as “big P policy” vs. “little P policy? Do we agree that more of our discussions will focus on “little P policy”?

When considering the importance of look at a range of factors as the basis for decision making, all agreed that it is important “sometimes the science alone is not enough”. While a diverse range of factors are considered when making food safety decisions, many respondents stressed the primary importance of health as the main factor for food safety decision making. Some respondents noted that understanding aspects/impact on different factors has been around for a long time, and provided examples of how it is being done - regulatory impact assessments (often cover social, administrative burden, economic, environmental implications), cost/benefit, improved scientific approaches, regulatory burden, efforts to compare options, costs on industry, paperwork reduction review (less paper for industry), impact on consumers. Reference was made to greater efforts to explore what actually works, test it in practice, and understand what is achievable.

A main conclusion is that considering multiple factors is a recognized reality of national decision making “countries are doing it anyway” – “no one is making their decisions solely on public health”. Some reasons for considering multiple factors included - to be sure that no one left behind; and ensures all stakeholders’ interests are taken into account in decision making. Eventually it should give a greater level of acceptance to the decision. “Considering other factors does not mean that you always lower the standard [for health protection], sometimes the opposite”.

While, on one hand respondents advised that a range of factors are considered, most highlighted that it can be difficult to discern how it is done, and it is often done in an *ad hoc* manner. Many felt it could be done in a more transparent and consistent way.

In looking ahead to address the issue of having a consistent approach, it was noted that consideration of multiple factors is very country specific – sets out the context and cultural dimensions, therefore any guidance/tool to be developed needs to be *guiding* rather than prescriptive, and *flexible*.

**HOW STRUCTURED ARE APPROACHES TO CONSIDER MULTIPLE FACTORS:
Countries vary in how structured and transparent their processes are to consider multiple factors – a general description is:**

Country 1 - Guidance exists on how to consider different factors in a structured way, but the best developed part is the health assessment. Results of decisions are clearly documented and made publicly available.

Country 2 – Other factors are considered in making food safety decisions, but there is no policy/guidance written down on how to do it. Working in a more integrated way, across Ministries is considered an important factor.

Country 3 – Other factors are considered in “silos” (e.g. different aspects of food safety issue are considered by separate Ministries according to the mandate of each Ministry). It can result in a conflict between different decisions from different Ministries on the same food safety issue. In these countries, there can also be an additional challenge due to lack of evidence and scientific risk assessment capacity.

Based on your experience, would you consider your country to be closest to Country 1, 2 or 3?

RECURRING THEMES/ISSUES/PRINCIPLES IN DECISION-MAKING

In food safety decision making, there is a fundamental role of **risk assessment and science**. The **risk analysis framework** is still seen by many as THE framework, and there is no need to reopen the debate on this.

In addition to the central role of science and evidence, the following are very important - **transparency, avoiding over legislation, need for better regulation, and regulation/decisions should be proportional to the risk**. “All regulatory provisions should provide a real benefit to the community (very important)”.

High priority was given to **stakeholder consultation** – “we need to be aware of stakeholders and other major players’ viewpoints”. Consultation is an important part of transparency.

How is transparency achieved? (By Stakeholder consultation, feedback, explanation etc.)

Others noted, that while the context of **food safety decision making is technical and scientific, it is also a political, societal field**. “Food safety is not a science it is an Art – balances perception, cultures etc.” Some respondents advised of the importance of looking at food safety decisions in a broader health context.

When discussing how multiple factors are considered, many respondents referred to the **organizational changes within the food control system**, that have been brought about which have been key to facilitate information exchange, it includes the progression in many countries to more integrated or single food safety agencies. A few respondents advised that the mandates of their agencies, and laws had a bearing on the ease with which different factors are considered, e.g. this was facilitated where legislation stated other factors need to be considered, while it could be hampered where a food safety agency was mandated to protect public health.

The **political dimension/reality** was noted as an important consideration. What do politicians care about? Is it evidence or opinion? - It is important to try to understand the role of evidence in policy making. Politicians have a short attention span – hence the need to communicate in succinct manner - political agenda of the current government needs always to be considered too.

In addition, how to engage with higher level policy makers, politicians? “Toughest stage however is to bridge to the political level in government to access funding -making the link to political process, to those persons who make \$ allotments”.

Related to this is the need to take into consideration broader government policies (to be successful for sustainable funding, food safety needs to link to government priorities and political needs).

What evidence is credible to policy makers and politicians? Is there a high level of variability? Based on the decision/issue at stake?

VIEWS ON EVIDENCE-INFORMED

Not all respondents were familiar with the term evidence-informed. Those who were familiar with the term advised of their understanding that it refers to the **use of data and information from a range of sources on a range of issues**, including health risks (but not limited to health only). One respondent referred to the renewed priority to address fraudulent practices. Comments were made on having available evidence on different factors, and how you handle the data – sometimes which can sometimes be “conflicting data”.

Evidence based is likely to get a better decision, or avoid unforeseen consequences of a decision (as you have considered as broad an evidence base as possible).

One respondent mentioned that “The use of the expression ‘evidence-informed’ implicitly recognizes that the former slogan ‘evidence-based’ was naive in pretending that evidence alone could determine policy. On the other hand, it also leaves wriggle room for policy-makers to selective invoke some, but not all, of the available evidence when making policy-judgments. “

In a number of countries, the **Freedom of Information Act** applies, so access to data can be requested, except investigations are off-limits.

RANGE OF FACTORS BEING CONSIDERED

Main factors:

Health, Economic (trade), impact on industry, Cost, Consumer views (consumer acceptability).

Other factors (or nuances of these main factors):

International competitiveness (trade), viability of certain agricultural sectors, feasibility and practical implementation issues, religious requirements (halal), impact on business, need for the regulation, risks from inaction, sustainability, competitiveness of self-reliant

industry, environmental stewardship, industry interests, media, political interests, ensuring the company does not make the price too high – needs to be the same price as other similar products. Risk/benefit, cost/benefit. Consumer interest, diversity ethics, animal welfare, origin of product need to be taken into consideration.

While multiple factors routinely need to be considered, their **relative weighting and trade-offs between them is a matter that needs to be addressed on a case-by-case basis**. All agreed weightings will vary.

How and when to consider other factors?

The **majority of respondents consider it should be a step approach** – look at health risk assessment first, then look at other factors in the risk management stage. Some considered it logical to address science/health first – and then if you know there is a problem, you look at other factors.

A few respondents (from research field) – did promote a more integrated consideration of factors, at the risk assessment stage (rather than the current focus on health only).

How are your current approaches (such as cost-benefit analysis, regulatory impact assessment) supporting you in considering multiple factors? Do you face any limitations in integrating the information or making trade-offs among competing factors?

One respondent, while currently favoring a step approach did advise “Don’t rule out moving towards a more integrated risk assessment in the future (where factors are considered at the risk assessment stage).”

In considering this issue of how and when to consider other factors, some words of caution were made:

- When considering other factors are not to weaken the priority/importance given to health.
- There are a lot of advantages to integrate into the risk assessment level, but do not let complexity take over.

CHALLENGES (when considering evidence spanning a range of factors)

Conceptual aspects

- Some respondents raised the issue of the mandate of their Agency, either as facilitating or limiting an open, transparent consideration of a number of factors, e.g. some agencies with a “consumer health protection” mandate May not so openly show how they consider trade aspects for example.
- Decision-making environment is very country specific – politics vary, transparency, different level of maturity of food control system/capacity
- Should not undermine health assurance by looking at other factors, should not be over-protective or end up with inadequate protection
- Getting everyone up to speed in the food safety area, with the same mind-set.
- Trying to balance different factors across different Ministries e.g. trade, agriculture, fisheries

Data/evidence concerns

- Respondents recognized that data can be richer/more available for some factors e.g. costs. The majority identified gathering and comparing information and evidence on *social aspects* as one of the challenging areas, e.g. ethical issues, consumer views, consumer risk perception, others?
- Need to ensure adequate and reliable evidence on the different factors is available
- Who decides on what is adequate data
- Dealing with gaps in information / data
- Exact types of data to be considered for different factors are not necessarily mapped out. Measures for the factors more related to social sciences.

What are acceptable types of data/evidence for the different areas of factors? We will need to look at what works in practice.

- Using qualitative data/evidence effectively
- Having a suitable means to compare different data, e.g. something cannot be costed so easily e.g. labelling, consumer right to know/information.

- Because some factors are more subjective, and can vary in different local environments, it is more challenging to consider all factors in a consistent way. We are not always comparing like with like. Factors are not always understood/valued the same by different people.
- Gender matters – but having the evidence to support that statement can be challenging

What is working in practice? How to handle value judgements?

Considering multiple factors in practice

- It adds a layer of complexity to consider multiple factors
- It was not easy to sit all stakeholders together, for example it is not easy to put together interests of health and agriculture. It requires a change in mindset, and agreement on the potential benefits.
- There can be a challenge in identifying the right persons to provide necessary input on multiple factors, e.g. identifying and engaging with social/political scientists can be weak, as we don't know who they are.
- It should be noted that we often have 8 hours to do a risk assessment, to make a decision, and therefore there is little time to reach out and make sure that we have consulted and collected all evidence on different factors.
- Communication problems, so many different groups involved, often not speaking the same language – so can be difficult to have a joined up conversation or reach a decision/consensus.
- Another reality/challenge is that the process is SLOW. To weigh up and consider all the factors, not nimble. Glacial. This can lead to frustration.
- Trading partners can question protectionism – sometimes friction.
- Also need to have time to reflect and evaluate impact of a decision – to be sure you are following the right approach
- Continual need to improve *transparency* and make sure that our tools are well used *properly* (impact assessment), consistency (impact assessment).
- A risk is to over analyze – some decision making does not always need to be too sophisticated. Paralysis through analysis.

Developing guidance for member countries

- Need to transmit this work/guidance to member countries in an easily understood way, and not as a new approach and new system to be applied. “Marketing” is very important. Need to have buy-in.

Specific challenges in developing countries

- How to deal with the informal food sector – food produced and traded without any regulatory control (in country and across borders with neighboring countries).
- That’s why my argument is to have a simple way to set it out, to consider the factors – giving options and suggestions for frameworks – recipe book approach. But in context that they have, and helping people to do it, not just told is – NB.
- Lack of data (including surveillance) and basic scientific/risk assessment capacities – realistically – getting the basic science right – should be the priority for countries where it is still weak. This would support decisions on determining priorities in food safety.
- Better management of data and data sharing from laboratories, to follow major risks and to make decisions
- Where there is a lack of data/evidence, it is difficult to convince politicians of your decision
- Need to continue to strengthen food control system – moving to a single agency – better coordination.
- A challenge is trying to ensure that decisions are really taken with a scientific base.
- Lack of resources – staff and budget

PROCESS ASPECTS in order to support multi-factor decision making

Through the semi-structured interview, emphasis was given to the “environment of food safety decision-making” with the following elements mentioned –

- Documenting and communicating on the actual decision, and the actual basis for that decision – to explain judgment and which factors were considered, and how.
- Infrastructure is required to gather data and evidence on broad issues.
- A process and culture to bring experience/expertise together, and all agree that it is considered a positive, speak the same language.

- Establishing a single, more integrated food safety agencies (decision making mechanisms) was flagged as an important step to facilitate considering of evidence on a number of factors as basis for food safety decision making.
- As multi factor consideration, involves a lot of work – if your final decision/regulation fails it looks bad – therefore having a trial period would be helpful before making the final decision.
- Engagement with stakeholders at beginning on defining the question, some countries have Boards dedicated to look at this.
- Be aware and build on government/politicians priorities and strategies and budget allocation processes.
- Important aspects of current processes – regulatory impact assessments, cost-benefit (with work to continually improve their application)
- Efforts to assess/measure impact, and feedback loops important
- Proposed to focus on one factor at once (if not don't make progress) and the importance of an iterative process and feedback loops were mentioned.
- Link food safety and food and nutrition security? Integrated assessment between food safety and food security is link between everything

A number of people said “framing/defining the question properly is very important” – as the basis of ensuring relevant factors are considered correctly.

In your country, do you explicitly go through a “framing” step to start a decision-making process? If so, how is it done? Are there specific challenges?

NEED AND INTEREST IN THIS MEETING IN NOVEMBER?

There is a strong interest in this topic, and importance given to this meeting. Some also see it as a timely event to build on existing initiatives, and to facilitate sharing of experiences and lessons from different countries/regions. In terms of what should be attained from the meeting..... the following was offered.

- An important opportunity is to get **recognition of what we are talking about.** We already do this (consider multiple factors), but in minimally transparent way. We are likely to get better food safety decisions if we look at it in a more structured way.

- We could lay out a case on **why multi-criteria is desirable** – place it in the context of risk analysis (the next generation)
- Having a **common understanding** (formal consensus) on use of multiple factors – will make decisions more acceptable / gives more structure to the decision-making process. But cannot be very rigid (certain degree of flexibility).
- Try to agree on **consensus on principles** -explain extent of consensus on principles and then see where gaps are? Don't have enough understanding of where gaps are.
- **Help people to speak the same language.** “We have seen that rivalry, fighting finishes once they understand each other.”
- As it is difficult to disagree with this work/multi-factor approach in principle – **it is more a Q of how to do it.**
- Develop **a roadmap on how to do it**, and even if you want to put all weight on public health, you will still have a better decision if you also have systematic information of other factors – other factors give input in how to make better public health decisions.
- Data sources for different factors, **what type of data is credible**, quality of data – not already done and it will be really helpful. E.g. indicators, values.
- Another important issue is **better integration of risk assessment and economic assessment.** They are together, not separated. Come up with a monetary impact cost effective way of assessing different options.
- Another thing to explore **is avoiding the silo approach**, and focusing on building on the back of some movements – e.g. One Health – useful eco-health.

Developing guidance on this/preparing the ground work

Some insights shared regarding the utility and considerations in preparing guidance -

Yes, there is need for a structured approach – to ensure there is consistency in the decision making process and a transparency? This cannot be prescriptive.

In response, many stated having guidance/tool in this area would be important to improve transparency. Quite exciting - to have a framework for decisions – establishes priorities in a government – resource allocation – translate into actions. For countries with fragmented systems, this guidance would help in joining up decision making and control. Show how it

can strengthen collaboration, linkages and reduce duplication currently, and more effective resource utilization.

The guidance would address

- The acceptable role of other factors – some level of consensus on the need and how to look at other factors (being flexible in the process) – some consensus could minimize conflicts and misunderstanding on food safety decisions/requirements (eg. in the trading context).
- Principles (agree on these-what they are and gaps)/resources/big governance issues-transparency (issue on developing countries-fundamental). Acknowledge however that transparency does vary from country to country (understanding and what is possible) – is a fundamental issue on how countries work.
- Could focus on how to consider other factors. What are the other factors? Fleshing some out - How to gather other information/evidence.

Any guidance on Multi-criteria decision making should reflect developing country contexts. An option, and not a prescription – as there is not only one way to do something.

RELATED INITIATIVES/RESOURCES/OPPORTUNITIES FOR SYNERGIES

One respondent in particular recommended exploring needed linkages with ongoing work and initiatives eg. OIE/WHO/WB (GFSI initiative) or link to CAADP initiative in Africa. It can increase how seriously the work is taken, and efficiency - piggy-back, multiply.

Other related initiatives identified:

- The Paris Risk Group, next meeting in March 2014.

What are other initiatives, meetings, conferences etc.

Annex 5. Resources submitted by interviewees

“Background” folder on ftp site; sub-folder for each interviewee

Agaba Friday, National Drug Administration, Ministry of Health, Uganda

Title/file name	Related to	Details
Examples of Food Safety Decisions activities.docx	Food safety decisions in Uganda	Outlines components of National Food Safety Strategic Plan (incl responsibilities of Ministries and non-govt bodies); provides examples of multi-factor food safety decisions and lessons learned (fish exports, methanol poisoning, meat inspection)

Andrew Stirling, University of Sussex, United Kingdom

Title/file name	Related to	Details
EFSA Biohaz scientific opinion	EFSA J (2012)	Also referenced in literature review documents Recent review of ranking tools; focus on health metrics based on quantitative risk assessment & modelling
Stirling article in nature on uncertainty	Nature (2010)	Comment by A. Stirling – Keep it Complex Experts should avoid pressures to simplify their advice; accountability of decision-makers
Stirling article in PLoS Biology on participation and power.pdf	PLoS Biology (2012)	Opening Up the Politics of Knowledge and Power in Bioscience

Carlos Alvarez-Antolinez, Veterinary and International Affairs DG Health and Consumers (SANCO), European Commission

Title/file name	Related to	Details
Regulatory Fitness.pdf	EU (2012)	Review of EU practices for Smart Regulation (i.e. impact assessment, evaluation, stakeholder consultation)
Smart Regulation.pdf	EU (2010)	Whole policy cycle – design, implementation, enforcement, evaluation & revision
		http://ec.europa.eu/smart-regulation/index_en.htm (additional reference)

**David Oryang Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA), United States of America**

Title/file name	Related to	Details
Food Safety Summit Session_BarryHoberman.pdf	Food Safety Summit 2013	Risk-Informed Decision Making: How to make a risk based Food Safety decision
Food Safety Summit Session_SherriDennis.pdf	Food Safety Summit 2013	Risk Assessment at FDA; reviews RA basics, involving stakeholders & tools for RA (quantitative & qualitative), RR (i-Risk) and RP (i-Prioritize)
Practical Tools for Prioritizing Food Safety Projects and Research-12-2-11-Final Draft.pdf	CFSAN/USDA	Slides for SRA meeting; outlines CFSAN activities in risk prioritization; 3 examples & lessons learned
Risk Management Framework.pdf	CFSAN	CFSAN's Risk Management Framework: Best Practices for Resolving Complex Risks
http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/ucm242929.htm	Report to CFSAN (2002)	Recommendations for risk analysis framework

Delia Grace, International Livestock Research Institute (ILRI) Kenya

Title/file name	Related to	Details
Dairy review.pdf	Dairy policy in East & West Africa (2007)	Developing policy based on health risks and economic benefits (consider smallholder producers and poor consumers)
Development of a participatory methodology to prioritise milk-borne disease in data-scarce environments.doc	Soc. for Veterinary Epidemiol. Proc. (2009)	Ethiopian case study; used key informant interviews and syndromic surveillance with stakeholder groups to generate evidence for risk assessment & prioritization
Ecohealth editorial.pdf	Trop Anim Health Prod. (2012)	Eco health and One Health studies – some key findings related to food safety risks
Impact of livestock disease on poverty.pdf	Phil. Trans. R. Soc. B (2009)	Disease control needs to consider links to poverty and impact on poverty reduction

Title/file name	Related to	Details
JFP-E Coli Risk Assessment.pdf	JFP 71:257-263 (2008)	Risk assessment for STEC in unpasteurized milk in East African countries
Multiple burden disease.pdf	Trop Anim Health Prod (2012)	Estimates zoonoses and diseases recently emerged from animals make up one quarter of disease burden in low-income countries
Participatory Risk Assessment RASAP.pdf	Rev Afric Sante Prod Anim (2010)	Participatory risk assessment in African countries to address food safety problems in informal markets
Participatory risk assessment_approach for safer food in vulnerable a new African communities.pdf	Develop in Practice (2008)	Participatory approach for risk assessment and management; importance of including gender analysis
Place of Food Safety in Evolving Pro-Poor Dairy Policy in East and West Africa.pdf	Rev Élev Méd vét Pays Trop (2007)	Understanding dairy policy within broader development policy; evidence for producer & consumer benefits as well as human health risks
Research Priorities for the Environment, Agriculture and Infectious Diseases of Poverty.pdf	WHO Technical Report (2013)	Considers all transmission routes for human infectious diseases, MCDA (MAUT) used to rank research priorities (12 criteria used to score health and non-health criteria)
Safe foods in informal markets – Brief safe food fair food.pdf	ILRI Issue Brief (2011)	Recommends integrated metrics for health and economic benefits and burdens (risk based)
Vietnam research evidence for policy – Food RISK Policy Brief.pdf	Evidence for Policy Series, Southeast Asia ed. (2013)	Policy messages & recommendations

Erik Millstone, University of Sussex, United Kingdom

Title/file name	Related to	Details
Can food safety policy-making be both scientifically and democratically legitimated.pdf	J Agri Environ Ethics (2007)	Scientific and democratic legitimacy in food safety policy-making
Science, risk and governance_Radical rhetorics and the realities of reform in food safety governance.pdf	Research Policy (2009)	

Greg Orriss, former Canadian Food Inspection Agency (CFIA), Canada

Title/file name	Related to	Details
Copy of FSAHD Issue Assessment Tool v 6 0 (2012 10 29).xls	Food Safety & Animal Health Div. (FSAHD), Alberta Agriculture	Scores based on scientific, economic, social & political assessments (16 criteria)
FSAHD Issue Assessment Tool Guidance Document v 6 0 (2012 10 29).doc	FSAHD, Alberta Agriculture	Guidance for spreadsheet tool to assess issues
General Principles of Food Hygiene.docx	Canadian Food Inspection Agency (CFIA)	Outlines good hygienic practices (including composition & labeling) for Canadian food manufacturers; includes assessment criteria and rating guides
Science Committee and Risk Prioritization.ppt	CFIA-Food Safety Science Committee (2005)	Outlines process for establishing risk-based priorities; risk analysis includes health & other considerations (consumer & industry concerns, pressure group/media interest and political interest)
TAB 9 – Micro – Risk Analysis forms and ranking.docx	CFIA	Ranked list of microbiology issues (numeric & linguistic) and risk analysis forms for each issue

Janine Lewis, Food Standards Australia New Zealand (FSANZ), Australia

Title/file name	Related to	Details
Analysis of Food Related Health Risks .pdf	Food Standards Australia New Zealand (FSANZ) (2009)	Focus on health risks (adverse effects) but recognizes need to include benefits in future
Engaging in the Australian and New Zealand joint food regulation system.pdf	Food Regulation Secretariat (2012)	Outlines opportunities for stakeholder engagement in the joint food regulation system (policy and standards development, food standards implementation)
Example of multi factorial risk management mandatory folate fortification.pdf	FSANZ (2006)	This assessment report went to Ministers for approval but instead they asked FSANZ to review. More information at http://www.foodstandards.gov.au/code/proposals/Pages/proposalp295considerationofmandatoryfortificationwithfolicacid/Default.aspx
Folate Fortification Cost	FSANZ (2007)	Cost effectiveness analysis of alternative strategies to reduce incidence neural tube defects (Centre for Health

Effectiveness report.pdf		Economics, Monash University)
Folate Fortification First review report.pdf	FSANZ (2007)	FSANZ reviewed options to identify most cost-effective approach
Example of Primary Production standard and associated risk management, Final report is called APPROVAL report.pdf	FSANZ (2012)	3 categories of raw milk were defined in terms of the effect of processing and product properties on pathogen survival and growth; Code amended to permit Category 1 products based on acceptable level of health risk; Consultation process outlined
FSANZ Act 1991 (Comp as at 30 June 2013).pdf	Australian government	Refer to Section 18 (page 17) which outlines regulatory objectives
Isomaltulose as a novel food Assessment report.pdf	FSANZ (2007)	Decision to allow use of isomaltulose with risk management strategy to protect consumers who need to avoid; cost-benefit analysis
Science Strategy 2010-20151.pdf	FSANZ (2010)	7 strategic areas to enhance scientific capacity and resources

Jeff Farber, Bureau of Microbial Hazards, Food Directorate, Health Canada, Canada

Title/file name	Related to	Details
Action on Weatherhill report recommendations to strengthen food safety system_final report to Canadians.pdf	Min. Agricult. Agri-food Canada (2011)	Government response to recommendations in Weatherhill report (see below); improved decision-making processes (p. 11-14) and improved emergency response (p. 29 -39) and stakeholder consultation (p. 41-46)
Health Canada Decision-making Frameworkpdf.pdf	Health Canada (2000)	Figure 1 (p 11) shows risk management decision-making framework
Report of the Independent Investigator into the 2008 Listeriosis Outbreak_ the Weatherhill Report.pdf	Report to Gov. of Canada (2009)	Review of Canadian food safety system after 2008 Listeriosis outbreak

Julie Caswell, University of Massachusetts, United States of America

Title/file name	Related to	Details
Foodborne Infections and Intoxications – Caswell Chapter on Dev of Risk-based Food Safety Systems 4-13.pdf	Foodborne Infec & Intox 4 th ed (2013)	Chapter 4 (p 53) Development of Risk-based Food Safety systems
The Risk-based Food Safety System.pptx		PowerPoint slides with visuals for risk-based food safety systems
http://www.iom.edu/Reports/2010/Enhancing-Food-Safety-The-Role-of-the-Food-and-Drug-Administration.aspx	National Research Council (2010)	Recommendations for U.S. FDA; chapter on data, information (Part III: Implementation)

Ousmane Touré, Institute of Public Health Research, Mali

Title/file name	Related to	Details
National Policy for Food Safety.doc	Min. of Health, Mali (2002)	Risk assessment and risk management (structures and responsibilities) in Mali (French)

Patrick Miller, Food Standards Agency (FSA), United Kingdom

Title/file name	Related to	Details
Thursday B1 - RA and decision making - Agency heads – final.doc	Heads of Agency WG on transparent risk assessment in decision making	2011 paper from UK FSA to initiate discussion on transparent risk assessment
Action plan Outline v2.docx	Heads of Agency WG on transparent risk assessment in decision making	Draft ‘Action Plan’ to support implementation of the WG recommendations, discussed at the HOA in Dublin in June 2013
FSA framework for policy making.pdf	UK FSA	FSA approach to policy, lists some of the factors used in decision-making
fsa-policy-statement-consultation.pdf	UK FSA	
Template for Impact Assessment .dot	UK Government	outlines some of the criteria to be considered and need for evidence for these
Extract from IA Toolkit on wider impacts.doc	UK Government	Questions related to Economic/Financial, Social and Environmental impacts
Better-regulation-framework-manual-guidance.pdf	UK Government	Detailed guide on ‘better regulation’ framework for policy

Title/file name	Related to	Details
Guidance on developing and appraising options for policy_the Green Book.pdf	UK Government (2011)	Presents economic principles that should be used to assess new policies and programs Frameworks for evaluation incl. Regulatory Impact Assessment
Guidance on evaluation_the Magenta Book.pdf	UK Government (2011)	Complements Green book – guidance on how to design & implement assessment
Multi-criteria analysis_manual.pdf	UK Government (2009)	Dept. Environ., Transport & the Regions – principal guidance document on MCDA methods (case study in Chapter 7)
Paris Risk Group-statement final draft.docx	Paris Risk Group	Network of social scientists working in food safety, occupational and environmental health; share knowledge on methodologies & tools
Proceedings workshop Anses - CSO Social Sciences 2013.pdf	Paris Risk Group	January 2013 workshop – agenda, summarized presentations, next steps

Robert Buchanan, University of Maryland, United States of America

Title/file name	Related to	Details
FDA Redbook.pdf (Redbook 2000, revised 2007)	US FDA	Guidelines for toxicity studies
Sherri Dennis – Risk Ranking and Risk Prioritization Tools.pdf	FDA/CFSAN	Slides used for “Produce safety in Schools” workshop; “risk ranking” is used to identify most sig public health risks; “risk prioritization” compares scenarios (food/hazard combinations, control measures) using multiple criteria; examples of semi-qualitative risk ranking

Vigdis S. Veum Moellersen, Norwegian Food Safety Authority, Norway

Title/file name	Related to	Details
Documents – reference for the meeting.docx	Risk analysis in Norway	<ul style="list-style-type: none"> ✓ Document on the new organization of the food administration in Norway, 2003 ✓ The Norwegian Food Law 2002 – 2003 ✓ Instructions for Official Studies and Reports The documents are in Norwegian so there is a table to explain contents

