



The SAFE FOODS Risk Analysis Framework: Progress and outlook

Lisbon, 3 October 2007

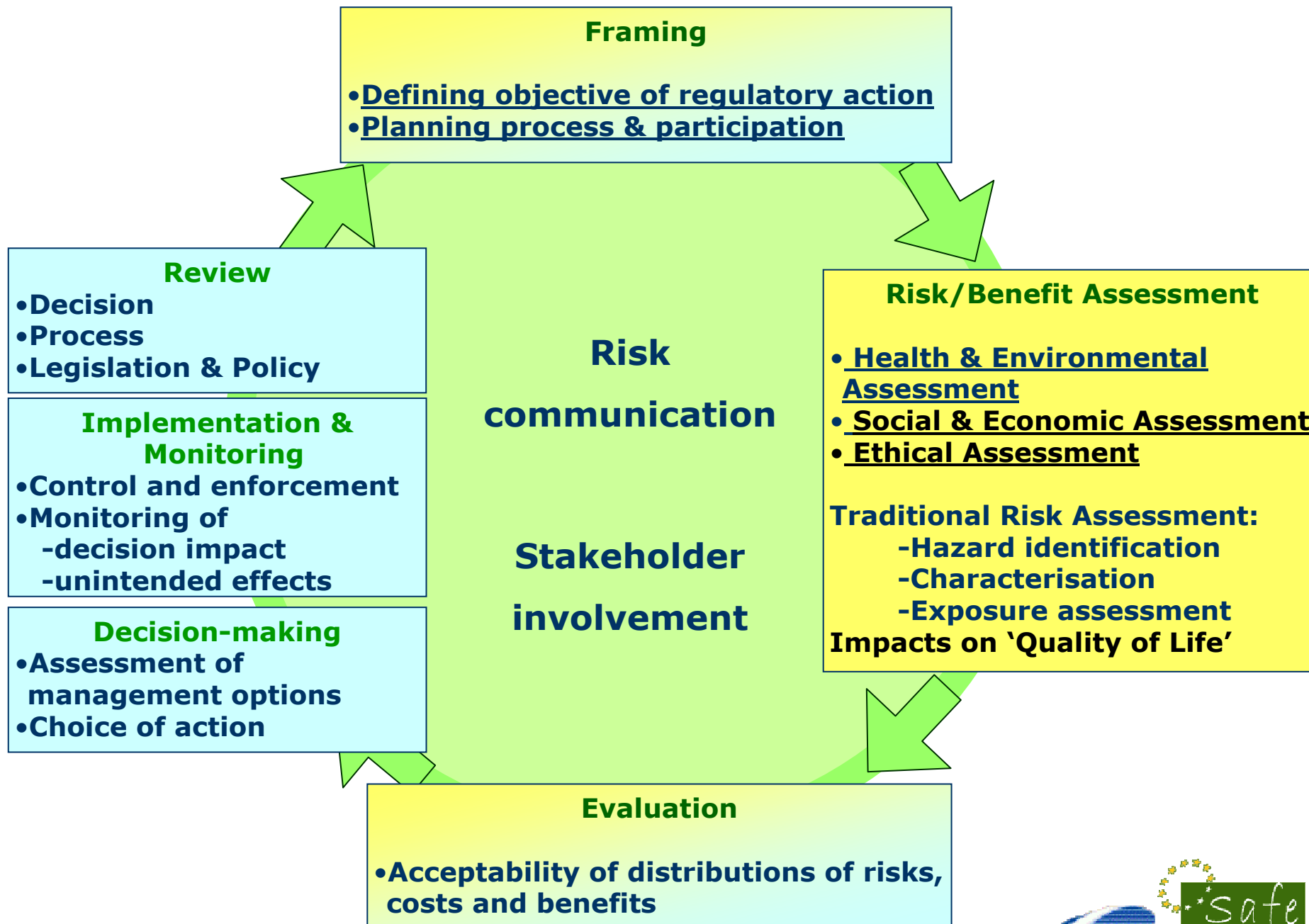
Meike Wentholt, Gene Rowe, Lynn Frewer, Marion Dreyer, Ortwin Renn, EUFIC,
and others



Overview Presentation

- Overview on the SAFE FOODS risk analysis framework
- Key issues raised by our stakeholders
 - The Delphi surveys (Meike Wentholt et al.)
 - WP5 workshops (Marion Dreyer et al.)
 - Two SAFE FOODS stakeholder workshops (WP6 & EUFIC)
- What are we doing to address these issues?
 - Considering ethics in risk analysis
 - More detailed legal and institutional analysis
- Open questions and next steps





Delphi survey: Feedback on key issues

- **EU** round 1: 33 respondents; 2nd round: 21
- **Non-EU** round 1: 19 respondents; 2nd round: 12

EU

- **Collection of risk & benefit data at the assessment stage**
 - Agreement: health data
 - Fair agreement: environmental
 - Lack of consensus: social; economic; ethical
- **Minority views should be taken into account and reported**
- **Transparency achieved by publication of reports/ opinions; peer review; clear/ short messages to public**

International

- **Collection of risk & benefit data at the assessment stage**
 - Agreement: health
 - Lack of consensus: environmental; social; economic; ethical
- **Minority views should be taken into account and reported (*case-by-case basis*)**
- **Transparency achieved by publication on the Internet; only the necessary/clear messages to public**

Assess stakeholder views using the Delphi technique *key results*

■ Who should be involved..?

(50% majority cut-off)

<i>Stakeholders should have input (%)</i>	Framing		Risk/benefit assessment		Evaluation		Risk management	
	EU	Int	EU	Int	EU	Int	EU	Int
Regulator, institutions	75	100	61	75	75	88	82	94
Scientist scientific institutions	68	81	82	94	64	75	53	69
Consumer associations	89	75	46	31	68	50	50	81
Environmental organisations	79	63	54	25	71	44	57	56
Industry	78	75	57	44	64	50	50	75
Farmers (organisation)	68	75	36	25	50	50	43	75
Retailers, trade organisation	75	63	43	25	64	44	43	81
General public	71	56	25	12	46	31	39	75

Assess stakeholder views using the Delphi technique *key results*

■ Who should be involved..?

(60% majority cut-off)

<i>Stakeholders should have input (%)</i>	Framing		Risk/benefit assessment		Evaluation		Risk management	
	EU	Int	EU	Int	EU	Int	EU	Int
Regulator, institutions	75	100	61	75	75	88	82	94
Scientist scientific institutions	68	81	82	94	64	75	53	69
Consumer associations	89	75	46	31	68	50	50	81
Environmental organisations	79	63	54	25	71	44	57	56
Industry	78	75	57	44	64	50	50	75
Farmers (organisation)	68	75	36	25	50	50	43	75
Retailers, trade organisation	75	63	43	25	64	44	43	81
General public	71	56	25	12	46	31	39	75

Assess stakeholder views using the Delphi technique *key results*

■ Who should be involved..?

(70% majority cut-off)

<i>Stakeholders should have input (%)</i>	Framing		Risk/benefit assessment		Evaluation		Risk management	
	EU	Int	EU	Int	EU	Int	EU	Int
Regulator, institutions	75	100	61	75	75	88	82	94
Scientist scientific institutions	68	81	82	94	64	75	53	69
Consumer associations	89	75	46	31	68	50	50	81
Environmental organisations	79	63	54	25	71	44	57	56
Industry	78	75	57	44	64	50	50	75
Farmers (organisation)	68	75	36	25	50	50	43	75
Retailers, trade organisation	75	63	43	25	64	44	43	81
General public	71	56	25	12	46	31	39	75

WP5: Provisions for Stakeholder and Public Involvement: 'Food Safety Interface Institutions'

- **Interface Committee** (to deal with framing and evaluation)
- **Internet Forum** (to deal with all four stages)

General objective: to facilitate as **deliberation platforms** throughout the governance process the **coordination** between:

- ▶ assessors
- ▶ managers, and
- ▶ corporate and civil society actors



Interface Committee

- Bears responsibility for **framing** (sets or advises on ToR) and **evaluation** (advice on tolerability/acceptability judgement)
- Provides framing and evaluation with a **formal footing**
- Involves managers, assessors and key stakeholders
- By this means allows for the hybrid character of framing and evaluation
- Advises also on the need for employing **additional** participatory tools in a given case
- Is likely to provoke questions of representativeness, power, and fairness

Internet Forum

- Organised in **four platforms** relating to the main stages: Framing, Assessment, Evaluation, Management
- Here **documentation** of the major elements underlying governance outcomes incl. referral details, screening results, ToR, assessment results, evaluation conclusions, selection of management measures
- **Open public access**: subjects the reasons of decision-making to public scrutiny
- Allows for consultation **and** deliberation processes
- Provides platform also for Member States (multi-level governance)
- Can act as both an **entry point** of a diversity of viewpoints and as a **signal** for highly controversial issues



WP5: A Structured Approach to Participation

Governance stage	Style of discourse	Purpose As a contribution to:	Institutionalised participation	Additional participatory processes
Framing	Design	Drawing up the terms of reference	Via the Internet Forum throughout the governance cycle At the stages of framing and evaluation: via stakeholder representation on the Interface Committee	Procedurally , context dependent, and specified at the stages of framing and evaluation Prima facie default : high levels of scientific uncertainty and/or socio-political ambiguity require extended participation
Assessment	Epistemic	Gathering of knowledge and information		
Evaluation	Reflective	Value-based judgements on tolerability or acceptability		
Management	Practical	Selection of appropriate measures		

Stakeholder feedback:

- In particular at the stages of ‘framing’ and ‘evaluation’ there is room for improving the assessment/management **interaction**.
- The proposed ‘interface committee’ should only deal with the **challenging cases** to avoid bureaucratic overload and undue delay in the governance process.
- It is essential that such a committee would have a **clear mandate** and is not overburdened.
- Be aware that the involvement of a few stakeholders in the committee includes major issues of **power and inclusiveness**.



WP6 workshops: some issues raised

- **Do not loose focus on public health!**

- How can framing be formalized and who should participate?
- How to decide on resource allocation across public health measures – and what's 'proportionate'?

What is communicated

- Does the framework challenge the EU principle of subsidiarity?
- Should ethics be considered at EU-level?

Who is involved and at what stage?

- What is assessed and who does it?
- How is necessary data gathered?
- What would be EFSA's tasks?

- How to manage dialogue between irreconcilable view points?

- **More detailed consideration of EU law and institutions**



What are we doing to address these issues?

Commissioning/drafting papers on the different strands of the assessments	Health: ?/(Harry Kuiper) Environment: ?/(Harry Kuiper) Social aspects: Marion Dreyer et al. Economics: Bruce Traill Ethics: Matthias Kaiser & Ariane König	Circulated 1st draft IN PROGRESS DONE – Circulated 1st draft for discussion
Case studies	Acrylamide: Leif Busk GMOs: Harry Kuiper & Howard Davies Microbiology: ?/(Harry)	Outline
Background paper on BSE and the need of an improved risk analysis framework	G�rard Pascal	IN PROGRESS
Paper on implications for the EU institutions	Ariane K�nig et al.	IN PROGRESS
Paper on overview on WP work	Ariane K�nig et al.	IN PROGRESS (updated draft by January)
Paper on methodology for development of SAFE FOODS framework – and stakeholder input	Lynn Frewer & Marion Dreyer et al.	
Elaboration on stages of implementation, monitoring and review (and implications for our model)	Ib Knudsen	IN PROGRESS



Considering ethics in risk analysis

- Ethics can be seen as the theory of how moral values guide judgments and beliefs on a 'good life'. Ethics concerns values and value conflicts.
- For some issues there are diverse interpretations of what a 'good' course of regulatory actions is depending on underlying sets of values. On those issues it helps to make ethics and underlying values of different parties explicit.
- The Ethical Matrix is a tool that may help. It was developed in the mid-1990's by Prof. Ben Mephram (University of Nottingham).
- Prof. Matthias Kaiser (National Committee for Research Ethics, Norway) has further developed it and proposes an adapted version for SAFE FOODS.



The Ethical Matrix

- The ethical matrix juxtaposes a set of ethical principles against all affected parties.

The ethical matrix can be used in a 3 step process:

- Value matrix: Define what each ethical principle means for each party
- Consequence matrix: investigate impacts on each party (use of scientific assessment methods)
- Evaluation matrix: determine what is ethically acceptable from each perspective – all groups assign weights to all cells.



Providing an overall *ethical* assessment: the ethical matrix

Based on

B.Mephram (Nottingham) & NENT's further development:

- **A simplified ethical matrix was constructed;**
- **Four principles, similar to the ones in medical ethics, define the principal ethical considerations**
- **Stakeholder groups specify the aspect of the principles that one has to consider**

<i>Ethical matrix for gm-salmon</i>	Do not do any harm	Do try to do some good	Dignity / autonomy	Justice / fairness
Small producers	Dependencies on nature and corporations	Adequate income and work security	Freedom to adopt or not to adopt	Fair treatment in trade
Consumers	Safe food	Nutritional quality	Consumer choice	Affordability of product
Treated fish	Proper animal welfare	Improved disease resistance	Behavioural freedom	Living out natural capacities
Biota	No pollution or strain on natural resources	Increasing sustainability - Conservation	Maintenance of biodiversity	No additional strain on regional resources

THIS SLIDE WAS PROVIDED BY MATTHIAS KAISER



Safe Foods

The ethical matrix can structure the scientific assessment

- Using scientific results to order the assumed consequences
- The + implies an improvement, the – implies worsening, and the 0 implies no change
- One can see that advantages and disadvantages are unequally distributed among the stakeholders = ethically affected groups
- One may note that the situation would have been different if the gm-salmon was sterile!

<i>Consequence matrix for gm-salmon</i>	Do not do any harm (reduce risks)	Do try to do some good (provide benefit)	Dignity / autonomy	Justice / fairness
Small producers	+ less dependency on seasons - Some costs for control	+ fast production + less use of resources	+ Can choose to adopt or not	+ able to compete globally
Consumers	0 without health risk - assumedly	- no change in nutritional quality	(+ can choose, if labelled)	+ somewhat reduced price + available in weak markets
Treated fish	-Some deformities ? - more prone to diseases	- No advantage	0 No change	-Less adaptive to stress - Behavioural changes ?
Biota	-Potential loss of wild stocks - more disease transmission	- No benefit	- Danger of reduced biodiversity	- Needs more protective arrangements to isolate from the wild

THIS SLIDE WAS PROVIDED BY MATTHIAS KAISER



Conclusion: the Ethical Matrix can help

- In framing
 - To structure framing activities by single officials or decide on use of interface committee, internet forum or other participatory process
 - To identify ethical impacts (positive and negative)
- In assessment
 - To guide defining the terms for assessors and data requirements
 - To clarify relationship between scientific claims and their ethical dimension
- In evaluation
 - To assist in the weighting of impacts
 - To structure participatory evaluation processes
- In decision-making
 - To increase transparency on how diverse perspectives accounted for in decisions
 - To facilitate finding an ethical course of action in the face of uncertainties
- In communication
 - To communicate how values underlying diverse perspectives are taken into account
 - To contribute to public understanding

A working draft paper will be placed on web please send any comments to Matthias Kaiser and Ariane König by November 1st.



More guidance from EU law, institutions and practice

Current research on related policies and laws:

- **The General Food Law clarifies that Health Assessment by EFSA can only address the probability and severity of health impacts as part of health assessment. Risk-benefit comparison or trade-off analysis requires health utility or monetary measures which all under social or economic assessment.**
- **Regulation 1925/2006 on food additives specifies a new procedure**
 - **Art. 3: obligatory consultation of interested parties**
 - **Art. 14: Commission has to rely on assistance of the new Advisory Committee on the Food Chain. Some guidance on cost-benefit analysis apparently exists.**
- **REACH implementation guidelines on assessing impacts of regulatory action for chemicals**
- **Advice from practitioners: consider distinguishing between natural hazards and industrial products**



Open questions and next steps

- Require better links to work under all WPs, also through comments on manuscript by Work Package members and leaders:
 - Better link to WP1 work on new methods for risk assessment
 - Better link to WP2 work on emerging risk identification and mgt
 - Better link to WP3 work on models for probabilistic assessment of health impacts and exposure
 - Better link to WP4 work on risk communication
- How to decide when to do public consultation in addition to stakeholder consultation and how?
- How to choose stakeholders and to involve organised civil society and also address how to engage the unengaged (distribution of voices across MSs and capacity building required for more organised civil society in states where there is less organised civil society)?
- How to better link consideration of single issues to consideration of resource allocation across public health measures?
- How will reframing for policy and legislation be triggered? (Draw on BSE case for this)
- How and where to address uncertainty and precautionary principle? (Draw on the BSE case and the ethical matrix paper to address this).

Any comments and suggestions are welcome. An improved draft report on the risk analysis framework will be circulated based on discussions at this meeting and outstanding papers.

