

**Heads of National Food Agencies Working Group on Transparent Use of Risk  
Assessment in Decision Making**

**Final report to the Heads of Agencies**

**April 2012**

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## SUMMARY

The proper and transparent use of risk assessment in decision making is essential to maintaining and building trust and credibility of food regulation and the wider food system. This trust and credibility is undermined when risk managers and decision-makers selectively interpret or misrepresent the scientific aspects of risk assessments, particularly with regard to uncertainty, to justify decisions which are really based on political, social, economic or other factors.

The key principles for transparent use of risk assessment in decision making are clear, and are already set out in the *Codex Working Principles for Risk Analysis for Food Safety for Application Governments (2007)*, which are widely supported. The challenge for all bodies involved in risk assessment and risk management is to ensure that these principles are applied consistently and transparently and that final decisions are properly communicated. ***A principal challenge is for risk management to develop and promote transparency and rigour in the decision-making process comparable to that in the risk assessment process, so that the basis for risk management and the information and analysis used in this is clear, rational and justifiable***

The Working Group report discusses these issues and makes a number of recommendations to the HoA for how this can be done, and for the HoA to work with the Commission to develop and implement these recommendations.

Key among these are the recommendations (i) ***that national agencies should exchange, through HoA, experiences on developing and using frameworks for risk management, and promote their development at national level*** and (ii) ***that HoA should write to the Commission (SANCO) requesting they initiate discussions with Member States on the potential to develop such a framework at EU level.***

Some examples illustrating how these issues have been approached in different countries and contexts are provided in Annex B; references to other work are given in the text.

## **1 INTRODUCTION**

1.1 At their meeting on 30 June 2011, the Heads of national food Agencies in Europe (HoA) discussed a paper from the UK Food Standards Agency on *Transparent Use of Risk Assessment in Decision Making*. The meeting agreed to establish a Working Group (WG) to discuss the issues raised in the paper and to report back to a future meeting with a more detailed paper.

1.2 The objective of the WG was to develop recommendations for the HoA on how to ensure consistent and transparent application of the principles of good risk policy set out in the *Codex Working Principles for Risk Analysis for Food Safety for Application Governments (2007)*, in risk management decisions that affect food safety in the EU.

1.3 All the national Agencies that participate in the HoA group were invited to join or contribute comments to the WG (as they preferred). Similarly, the European Commission (SANCO) and EFSA were invited to participate as observers and/or to contribute comments. The agreed Terms of Reference and membership of the WG are at Annex A.

## **2 WHY IS TRANSPARENT USE OF RISK ASSESSMENT IN DECISION MAKING IMPORTANT?**

2.1 Risk managers will and should take decisions on risk management, and in doing this they will need to take account of other factors as well as the risk assessment. Risk assessments may be consistent with a number of different risk management options, and other factors will need to come into play to decide between them. Weighing the hazards and risks of a management action against social impacts, costs and benefits of that action is an important element in risk management. It is up to food safety agencies and ultimately to governments, who are elected to represent the interests of all members of society, to balance between these factors.

2.2 Independence of risk assessment and clear distinction between risk assessment and risk management are essential to ensure that the scientific aspects of risk assessment are not influenced by risk management considerations, or by risk managers, and that risk assessors do not seek to give decision-makers answers that reflect political rather than scientific factors. There must be an informative dialogue between risk assessment and risk management. Risk management should not unduly influence risk assessment, but needs to be proportionate to the risk assessment, and this needs to be transparent.

2.3 The proper and transparent use of risk assessment in decision making has many important benefits. First and foremost, it is essential to maintaining and building trust and credibility of food regulation and the wider food system. It has further political, economic and consumer confidence benefits, including the following:

- i. it is essential in objectively estimating the level of risk run by populations and subpopulations and in informing about the degree of uncertainty, the assessment's strengths and weaknesses, and providing plausible alternatives within the assessment.
- ii. it helps to ensure effective protection for consumers, by ensuring actions are informed by the best scientific understanding of which risks are the most significant for health, while avoiding disproportionate impacts on innovation, trade and the economy.
- iii. it helps to focus measures on the best understanding of the nature of risks and of the impact of measures to control them, it supports the principles of better regulation
- iv. it helps to ensure resources are used efficiently by targeting risks with the greatest potential effects on health; this is all the more important in times of economic pressure and restricted resources for risk assessment and for risk management.
- v. it helps to promote understanding and acceptance of the rationale for food controls by stakeholders, including industry, trading partners and consumers
- vi. it promotes the role and responsibility of consumers, as it supports the awareness of risk and the information available on which to make informed choices
- vii. it is vital for a continued and enhanced trust in the independent and scientifically-based risk assessment, which in turn is vital for maintaining effective, independent systems for risk assessment.

2.4 Conversely, a failure to use risk assessment properly and transparently can have significant negative effects, including:

- i. decisions that are not based on objective analysis of risks and impacts may fail to protect consumers in an effective, proportionate way; further, they may be less likely to work, or to achieve support – and may be challenged by other countries inside or outside the EU (e.g. through WTO), with implications for trade.
- ii. decisions based on an unjustified level of precaution – by overstating risks or uncertainties that are not soundly based on the risk assessment – can deny opportunities to employ innovations that could benefit consumers, society or the economy – for example by improving food safety or security
- iii. misinterpreting uncertainty in RA encourages others to engage in debate in the same way – so that arguments are presented in the context of food safety when they are primarily about other factors. This can paralyse debate, so that these other issues and concerns, which may be legitimate, are not debated or addressed properly.

2.5 It is not possible to say whether the perception of a trend towards less transparent risk management practices is real, partly because of the lack of objective evaluation of decision making. However, it is clear that interest in food policies and scrutiny and challenge by citizens and stakeholders is increasing, so we have to address this issue.

2.6 The WG felt that the following examples, originally described in the UK paper to HoA, illustrate how these complex issues have played out in some real decisions in Europe. Note, the WG does not take a view on whether these decisions are ‘good’ or ‘bad’, and does not argue that they should not take account of other factors, such as those given in the summaries. The WG does consider, however, that **the use of the scientific aspects of the risk assessment and of other factors should be reflected clearly and accurately in communicating such decisions and their rationale.**

### **(i) Bisphenol A (BPA) in baby bottles**

Decision: A ban on BPA for use in polycarbonate infant feeding bottles, described as a precautionary approach, citing uncertainties in EFSA's opinion. National bans on other uses.

Risk assessment: EFSA recommended that the current TDI for BPA remained appropriate to protect all consumers including those potentially most vulnerable to adverse effects. A subsequent WHO expert panel recommended no new regulations limiting or banning the use of BPA.

Other factors: Many, including: a high public and media profile with lobby and campaign groups against use of BPA *per se*; sensitivity with regard to potential effects in a vulnerable group (infants); a trend away from use of BPA in these products; uncertainty about the risks associated with possible replacements for BPA.

### **(ii) Anti-microbial treatments for poultry**

Decision: A recommendation to approve the use of four antimicrobial treatments to reduce bacterial contamination of poultry was rejected at EU level, citing concerns about uncertainties in the RA and concerns about impacts on the environment.

Risk assessment: EFSA's RA supported approval of these products. Concerns about environmental impacts do not reflect the RA. Products are widely used in other contexts, including as a permitted food additive in one case.

Other factors: Trade issues (authorisation would allow poultry produced in other countries that has been treated with these products to be exported to the EU); principles of food safety policy (does use of these treatments allow 'dirty' products to be cleaned up, and if so is this an appropriate RM approach?); possible benefits of reducing microbial load in poultry and hence in reducing food borne illness, which causes hundreds of thousands of hospitalisations and thousands of deaths each year in Europe.

### **(iii) Authorisation of GM foods**

Decision: Approvals of GM foods are routinely rejected by some risk managers, citing concerns regarding risks to food safety and the environment.

Risk Assessment: All approvals are subject to extensive RA including by EFSA for food safety, and several iterations refining the risk assessment have been introduced to address elements of uncertainty. RA processes in this area are now out of proportion with that accepted for other approvals; this difference in effort is not justified on scientific grounds.

Other factors: This area illustrates the many other factors that regulators may need to consider. These include concerns of consumers, politicians and other stakeholders, international trade issues, and potential benefits such as improved crop yields or reduced pesticide usage.

### **(iv) Limits for radioactivity in foods from Japan**

Decision: Adoption of maximum levels for radioactivity in foods from Japan set by the Japanese authorities, in place of the existing EU levels, following the contamination from the Fukushima nuclear plant.

Rationale: This did refer to the need to ensure pragmatic enforcement by applying the same levels for exports from Japan and imports to EU, in the aftermath of the Fukushima accident. However, at the same time, a review of the EU levels and the underpinning RA was announced, without a scientific explanation.

### 3 PRINCIPLES OF GOOD PRACTICE

3.1 Over the last two decades, considerable effort has been employed in building robust and trusted systems in Europe, both at national level and at EU level, including through the establishment of national agencies and EFSA, with clear remits for risk assessment. This has gone a long way to restoring rigour and trust in the European food safety management system, by consumers, industry and other stakeholders, including our trading partners globally.

3.2 The WG considers that the key principles are clear, and are already set out in the *Codex Working Principles for Risk Analysis for Food Safety for Application Governments (2007)*, which are widely supported. Some of the key elements are listed in the box below. **The challenge is to ensure that these principles are applied consistently, rationally, defensibly and transparently.**

The following principles in the *Codex Working Principles for Risk Analysis for Food Safety for Application Governments (2007)* are particularly relevant to the issues discussed in this report:

- *risk analysis should be: applied consistently; open, transparent and documented (para. 6)*
- *[...] it is recognised that risk analysis is an iterative process, and interaction between risk managers and risk assessors is essential for practical application (para. 11)*
- *the degree of uncertainty and variability in the available scientific information should be explicitly considered in the risk analysis. The assumptions used for the risk assessment and risk management options selected should reflect the degree of uncertainty and the characteristics of the hazard (para. 12)*
- *unjustified differences in the measures selected to address similar risks in different situations should be avoided (para. 30)*
- *the [risk management] decisions should be based on risk assessment, and should be proportionate to the assessed risk, taking into account, where appropriate, other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade (para. 32)... Risk management should take into account the economic consequences... of risk management options (para. 34)*
- ***the risk management process should be transparent, consistent and fully documented. Decisions on risk management should be documented so as to facilitate a wider understanding of the risk management process by all interested parties (para. 35)***
- *risk communication should... provide a sound basis for understanding the risk management decisions proposed;... foster public understanding of the process, so as to enhance trust and confidence in the safety of the food supply (para. 40)*
- *risk communication should...promote consistency and transparency in formulating risk management options/recommendation ... include a transparent explanation of the risk assessment policy and of the assessment of risk, including the uncertainty... The decisions taken and the procedures followed to reach them, including how uncertainty was dealt with, should also be clearly explained (para. 43)*



3.3 The procedures for performing risk assessment (including peer review) are well established, with globally defined and accepted process steps. This facilitates acceptable levels of transparency and rigour, in accordance with the Codex Working Principles, notwithstanding that there is sometimes a significant degree of uncertainty related to specific subjects.

3.4 The WG considers that ***the principal challenge is for risk management to develop and promote transparency and rigour in the decision-making process comparable to that in the risk assessment process, so that the basis for risk management and the information and analysis used in this is clear.*** It is important to acknowledge that risk management is also an expert process, in which scientific and other forms of information, expertise and analysis should form a part, again in a clear and transparent manner.

3.5 The recommendations below focus on these aspects.

#### 4. HOW CAN WE DEVELOP AND SUPPORT GOOD PRACTICE?

4.1 The WG makes a number of recommendations to the HoA which would help to develop and support good practice in the transparent use of risk assessment in decision making.

##### **Reaffirming our commitment to established principles**

4.2 The key principles are clear from Codex (see 3.2). There is no need to revisit or revise them.

***Recommendation 1: The HoA should reaffirm their commitment to the Codex principles and should support, promote and communicate their use by risk assessors and risk managers.***

##### **Increasing transparency in the risk management process**

***Recommendation 2: Risk managers should develop and promote greater transparency in the risk management process, in discussion with risk assessors and stakeholders.***

4.3 Roles, responsibilities and procedures need to be clear, and their operation in practice and their communication need to be open and transparent, in ways comparable to those that apply to risk assessment. In particular, risk managers need to be clearer and more consistent in setting out how the other legitimate factors besides risk assessment have been taken into account, and (where relevant) the rationale for invoking the precautionary principle. These aspects are discussed in more detail in paragraphs 4.10 to 4.18, below.

4.4 The basic principles governing roles, responsibilities and transparency are given in the Codex principles. Frameworks for risk management can be helpful in building on these general principles, providing a clear, agreed view on how the process should work, while transparency in operation allows scrutiny and challenge on how things actually work in practice.

4.5 Risk assessors and stakeholders can provide useful insights into what such frameworks should address, and how, from the perspective of the scientific aspects and of what information stakeholders want and find useful. Many stakeholders will have an interest and the WG has not tried to list them all, but they would include sector organisations, consumer and interest groups, citizens, and others involved in decision-making at national and international level.

4.6 In Germany, the BfR publishes an *EU Food Safety Almanac* that describes for each of the EU member States and eight neighbouring countries the structure of governmental authorities and a detailed description of tasks and responsibilities of each institution.<sup>1</sup> This shows which authorities in each state are responsible for the assessment of plant protection products, health claims or zoonoses, which ministries in the Member States are responsible for the management in which areas, how risks are communicated and to what extent risk assessment and risk management are institutionally separated.

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<sup>1</sup> [http://www.bfr.bund.de/en/press\\_information/2011/33/food\\_safety\\_in\\_europe\\_who\\_is\\_responsible\\_for\\_what\\_-\\_127285.html](http://www.bfr.bund.de/en/press_information/2011/33/food_safety_in_europe_who_is_responsible_for_what_-_127285.html).

## Dialogue and iteration between risk assessors and risk managers

***Recommendation 3: Dialogue and iteration between risk assessors and risk managers should be developed, in a transparent manner that respects their distinct roles and responsibilities.***

4.7 Dialogue between risk managers and risk assessors (and other stakeholders if appropriate) should take place throughout the process of risk analysis, but has particular benefits at the beginning and the end. At the beginning of the process it can contribute to the following benefits:

- risk assessors are aware of the context of the request being put to them by the risk managers
- the question being put to the risk assessors is clear, comprehensive and appropriate –this in turn helps to ensure that the outputs of risk assessment will be useful for the risk management decision, in terms of addressing fully and correctly all of the issues that form part of the risk assessment
- risk assessors are not asked, and do not attempt, to address issues that are not properly part of risk assessment – for example the acceptability of a risk and the selection of a risk management option is a matter for decision-makers, and not of risk-assessors (risk assessment may discuss the options available for risk assessment and the relative risks and benefits associated with these)
- the factors that the risk manager will need to consider in weighing up their decision can be identified at the outset, and appropriate means selected to address them: issues for risk assessment are then carried out by the risk assessment appropriate body (and if more than one is relevant, they can each plan to carry out their respective tasks in a co-ordinated way); other factors can be addressed through other processes including, as far as possible, by other types of evidence-based analysis (e.g. economic analysis).

4.8 At the later stages, dialogue and iteration can contribute to the following benefits:

- risk assessors can help to identify and assess the risks associated with different risk management options (for example, if new options arise or develop since the original mandate for risk assessment was defined, or if new or unintended consequences of different risk management options emerge)
- it helps to ensure that the risk assessment is understood by the risk managers, and used accurately in developing and weighing risk management options, and in communicating these to stakeholders
- it provides feedback for both sides that can help to improve procedures and practices for the risk assessment and for risk management, including communication.
- it allows risk assessors to understand how their work has been used to inform policy
- it contributes to evaluation of risk management decisions and of their impact, and helps to identify whether any further work or revision is necessary to improve the analysis process.

4.9 Examples of approaches to develop dialogue and iteration between risk assessors and risk management include:

- i. In the UK FSA, the Chair of the independent scientific advisory committee that has carried out a risk assessment will attend the meeting of the FSA's Board which makes the risk management decision on the issue that the risk assessment informs. The Committee Chair will not take part in the decision on risk management, but they can answer questions and comment on the risk assessment; this helps to ensure that the risk assessment advice is properly understood by the risk managers, and provides assurance that the risk assessment is reflected accurately in the risk management options presented for discussion. FSA Board meetings are open and all papers are published, which also contributes to transparency.
- ii. In Sweden, the National Food Agency (NFA) has devised a form with an instruction for the commissioning of risk assessment issues, which risk managers fill out together with risk assessors at the risk- and benefit department (see Annex B1). Experience with this recent procedure are very positive in terms of mutual and clear understanding of the issues, formulation of risk assessment questions, time frames, traceability and documentation of the process. This illustrates that sometimes fairly simple measures can improve the risk analysis process. This early dialogue between assessors and managers will also clarify for the managers if the question/issue cannot be answered based only on a health based risk-benefit assessment, but if a parallel process, e.g. involving other legitimate factors, is necessary for reaching a management decision.
- iii. In addition, the NFA in Sweden has recently established a new 'Risk analysis group', with the role of considering whether and if so how different food related questions/problems should be dealt with by the NFA. The group consists of assessors, managers and communicators. The group has several criteria to follow, including both risk/benefit assessments and other legitimate factors. The group is intended to evaluate and weigh these categories, and deliver a proposal (including the rationale) for decisions by heads at different departments/director general.
- iv. In Belgium, risk assessors address an 'evaluation' survey to risk managers 1 to 2 years after recommendations have been put forward in the scientific opinions, to measure the impact of risk assessment on risk management decisions and to inform both parties about their mutual collaboration results.

## Use of other legitimate factors

***Recommendation 4: Risk managers need to be clearer and more consistent in setting out how the other legitimate factors besides risk assessment (such as economic or political considerations) have been taken into account, including the contribution and reasoning behind the consideration of other factors and the supporting evidence and/or expert analysis.***

4.10 Development of formal frameworks for transparent, structured and documented risk management processes would support risk managers in achieving such a goal. One such framework has been developed in the Netherlands.<sup>2</sup> The original report is in Dutch but an unofficial translation of selected sections is provided in Annex B (B4).

4.11 In Sweden, the National Food Agency (NFA) in connection with work on revising advice on food for infants and small children formalised the procedure by introducing the requirement for two separate reports. The first report was a risk-benefit assessment which was developed based on the terms of reference agreed upon following interaction between risk managers and risk assessors (Annex B2). In this work an earlier version than the present template (Annex B1) was used. The second report was the risk-benefit management which describes how the risk assessment results were used and other considerations that were taken in reaching the decisions. An example from the risk management report concerning advice on bisphenol A is shown in Annex B3. Experience with this procedure are very positive in terms of mutual and clear understanding of the issues, formulation of risk assessment questions, time frames, traceability (B2) and documentation of the risk/benefit management process (B3). Health care professionals, NGOs and consumers have also expressed their satisfaction, especially with the risk management report, where any decision not to give advice is also documented.

***Recommendation 5: (i) national agencies should exchange, through HoA, experiences on developing and using frameworks for risk management, and promote their development at national level; and (ii) the HoA should write to the Commission (SANCO) requesting they initiate discussions with Member States on the potential to develop such a framework at EU level.***

4.12 While the legitimate other factors are not considered in the risk assessment, it is possible, at least in principle, to assess and evaluate them, and to weigh the impacts of different factors against each other, using structured, evidence-based approaches (for example: economic analysis; impact analysis; structured evidence on consumer concerns; risk-benefit analysis, multi-criteria decision analysis). Such methods could help to increase consistency, objectivity and transparency in the consideration of these other factors. This is by no means straightforward, but some useful work has been done, and other work is underway, towards developing robust procedures in a number of areas.

<sup>2</sup> Bakker, E. de, H. Bouwmeester, M. Bracke, A. van der Sluis, M. van der Spiegel, D. Stijnen, L. Temme en H. van der Voet. *Transparant afwegen; Waarden en risico's beoordelen van voedselkwaliteit. Rapport 2009-020; ISBN/EAN: 978-90-8615-320-6, April 2009, LEI-DLO The Hague (Dutch Language)*

4.13 For instance, in Canada, management frameworks acknowledging that risk management decisions are multi-criteria decisions have been developed and their use illustrated for problems involving selecting food safety interventions<sup>3</sup> and prioritizing between foodborne pathogens.<sup>4</sup> In these studies, methods from the field of decision analysis are used and they show how the risk management frameworks vary depending on the type of decision in terms of which other legitimate factors that are included. Other examples illustrating the application of multi-criteria decision analysis in different fields and employing different criteria can be found in the scientific literature which can serve as a basis for a discussion of general risk management frameworks.

4.14 The European Commission has also recently consulted on possible improvements to the risk assessment process for its three non-food Committees, including the potential to develop multi-factor/multi-criteria assessments across different factors.<sup>5</sup>

***Recommendation 6: The HoA should maintain awareness of and support efforts to explore the potential for and the development of methods for robust, evidence-based analysis of other factors. HoA should seek engagement from the Commission (SANCO) in these discussions.***

4.15 The use of legitimate other factors is covered in national and international agreements and Codes, including in the Codex Procedural Manual<sup>6</sup> and the General Food Law (Regulation (EC) No 178/2002). This is a complex field in which legal and trade issues come into play, and it is beyond the remit and competence of the WG to offer expert analysis or detailed advice in this area. However, the WG does consider that risk managers may in some cases believe these constraints to be greater than they actually are. Further, risk managers may overstate the constraints arising from these rules, in order to avoid being clear about the role and use of other factors (such as economics, ethics, consumer perception, enforcement, good agricultural practice, etc.). Risk managers, and other stakeholders, may be more comfortable discussing decisions in the context of scientific risk assessment, with its associations with neutrality and objectivity.

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<sup>3</sup> Fazil et al, 2008, *Journal of Food Protection*, 71:11, 2323-33, *Choices, Choices: The Application of Multi-Criteria Decision Analysis to a Food Safety Decision-making Problem*

<sup>4</sup> Ruzante et al., 2010, *Risk Analysis*, 30:5, 724-42, *A Multifactorial Risk Prioritization Framework for Foodborne Pathogens*

<sup>5</sup> [http://ec.europa.eu/health/scientific\\_committees/consultations/public\\_consultations/scher\\_consultation\\_07\\_en.htm](http://ec.europa.eu/health/scientific_committees/consultations/public_consultations/scher_consultation_07_en.htm)

<sup>6</sup> *Codex procedural manual, 20th edition, Appendices: Statements of principle concerning the role of science in the Codex decision-making process and the extent to which other factors are taken into account* )

4.16 The use of other legitimate factors is due to be discussed in the coming months and years in the context of Codex. The national food Agencies in Europe, and the HoA group collectively, will need to consider how to input to these discussions, working with the European Commission. From the perspective of the WG, these discussions offer an opportunity to promote more transparent and consistent use of other legitimate factors in decision making.

***Recommendation 7: There needs to be more clarity on the extent to which treaties and legal measures at global, EU and national level allow or limit the use of other factors in decision making.***

### **Use of the precautionary principle**

***Recommendation 8: Risk managers need to be clearer and more consistent in setting out the basis for applying the precautionary principle and in particular the uncertainties and gaps in evidence, and what would be needed to address these.***

4.17 As with other legitimate factors, principles for the application of the precautionary principle are set out in the General Food Law (Article 7) and in more detail in the Commission Communication on the Precautionary Principle (COM (2000) 1).

4.18 These make clear, among many other things, that the precautionary principle should not be confused with the element of caution that scientists apply in their assessment of data, and that measures based on the precautionary principle should be:

- subject to review, in light of new scientific data
- capable of assigning responsibility for producing the scientific evidence necessary for a more comprehensive assessment.

### **Communication**

4.19 Clear, open communication is an essential component throughout all stages of risk analysis, as is made clear in the Codex principles. It is important for procedures and frameworks for risk assessment and for risk management are clear on who is responsible for communicating on which issues and aspects, at which stages of the process.

4.20 Clear communication on risk assessment has been helped by development of agreed procedures and, to some extent, agreed terminology of the main elements of the process. This is more of a challenge for risk management, given that it encompasses factors which can have significant political, cultural and social aspects, which vary across different contexts. Development of frameworks and templates for the risk management process and for its communication, and dialogue between risk assessors and risk managers (as discussed above), can help to build common understanding and clear communication.

## 5. CONCLUSIONS AND RECOMMENDATIONS

5.1 The WG has made eight recommendations, which are discussed above, and summarised in the box below. ***The WG invites the HoA to endorse these and to discuss their implementation.*** These are listed below in the order in which they are presented in the discussion. The HoA will wish to consider the order in which the recommendations should be addressed.

### ***Summary of recommendations:***

***1: The HoA should reaffirm their commitment to the Codex principles and should support, promote and communicate their use by risk assessors and risk managers.***

***2: Risk managers should develop and promote greater transparency in the risk management process, in discussion with risk assessors and other stakeholders.***

***3: Dialogue and iteration between risk assessors and risk managers should be developed, in a transparent manner that respects their distinct roles and responsibilities.***

***4: Risk managers need to be clearer and more consistent in setting out how the other legitimate factors besides risk assessment (such as economic, social or political considerations) have been taken into account, including the contribution and reasoning behind the consideration of other factors and the supporting evidence and/or expert analysis.***

***5: (i) national agencies should exchange, through HoA, experiences on developing and using frameworks for risk management, and promote their development at national level; and (ii) the HoA should write to the Commission (SANCO) requesting they initiate discussions with Member States on the potential to develop such a framework at EU level.***

***6: The HoA should maintain awareness of and support efforts to explore the potential for and the development of methods for robust, evidence-based analysis of other factors. HoA should seek engagement from the Commission (SANCO) in these discussions.***

***7: There needs to be more clarity on the extent to which treaties and legal measures at global, EU and national level allow or limit the use of other factors in decision making.***

***8: Risk managers need to be clearer and more consistent in setting out the basis for applying the precautionary principle and in particular the uncertainties and gaps in evidence, and what would be needed to address these.***

5.2 The WG has also considered the risks arising from implementing these recommendations. For example, greater dialogue and iteration between risk assessors and risk managers could be perceived as undermining the independence of the risk assessment process. Clearly, any development of good practice in this area must respect the distinct roles and operations of risk assessment and risk management. The WG believes that independence can only be enhanced by increasing openness and transparency of the risk management process. Commitment to agreed principles, and clear frameworks setting out roles and processes would help to support this.



5.3 Risk managers may foresee risk in the recommendation to be clearer and more consistent in setting out how the other legitimate factors besides risk assessment have been taken into account in decisions. Other factors can be highly contentious, and difficult to assess objectively. It may be more comfortable debating in the apparently more neutral and objective space of scientific risk assessment – where there is consensus at least that consumers safety is a legitimate and primary consideration. Greater clarity on the use of other factors may lead to more challenge in international fora. Even so, the WG believes that a lack of transparency and consistency carries far greater risks, as set out in section 2.

5.4 Overall, the WG believes that implementation of these recommendations will help to strengthen risk assessment and risk management, thereby helping to protect and to enhance the trust and credibility of food regulation and the wider food system. It will contribute to realising the benefits identified in 2.3 and to avoiding the negative impacts outlined in 2.4.

5.5 As the WG is advocating transparency as a key underpinning principle for good practice, it intends to follow this practice itself, and to publish its report.

## **ANNEX A Terms of Reference and membership of the Heads of Agencies Working Group on Transparent Use of Risk Assessment in Decision Making**

Final Version, reflecting discussion at the Working Group's meeting on 23 November

### **Background**

At their meeting on 30 June 2011, Heads of Agencies (HoA) discussed a paper from the UK Food Standards Agency on *Transparent Use of Risk Assessment in Decision Making*. The meeting agreed to establish a Working Group (WG) to discuss the issues raised in the paper and to report back to a future meeting with a more detailed paper. The UK FSA was tasked with drafting Terms of Reference for the Working Group.

Terms of Reference were prepared by the UK FSA, amended in light of comments by the WG, and agreed at the WG meeting on 23 November 2011.

### **Purpose and objectives**

The **objective** of the Working Group is to develop recommendations for the Heads of Agencies (HoA) on how to ensure consistent and transparent application of the principles of good risk policy set out in the *Codex Working Principles for Risk Analysis for Food Safety for Application Governments (2007)*, in risk management decisions that affect food safety in the EU. It will do this with particular reference to the principles that relate to transparency in the use of risk assessment and uncertainty, and of other factors, in risk management decisions.<sup>7</sup> The WG may also refer to relevant provisions within other guidance and measures, including the General Food Law (Regulation (EC) 178/2002) and the Commission Communication on the Precautionary Principle.

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<sup>7</sup> Relevant principles in the Codex document include:

- *risk analysis should be: applied consistently; open, transparent and documented (para. 6)*
- *the degree of uncertainty and variability in the available scientific information should be explicitly considered in the risk analysis. The assumptions used for the risk assessment and risk management options selected should reflect the degree of uncertainty and the characteristics of the hazard (para. 12)*
- *unjustified differences in the measures selected to address similar risks in different situations should be avoided (para. 30)*
- *the [risk management] decisions should be based on risk assessment, and should be proportionate to the assessed risk, taking into account, where appropriate, other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade (para. 32)... Risk management should take into account the economic consequences... of risk management options (para. 34)*
- *the risk management process should be transparent, consistent and fully documented. Decisions on risk management should be documented so as to facilitate a wider understanding of the risk management process by all interested parties (para. 35)*
- *risk communication should... provide a sound basis for understanding the risk management decisions proposed;... foster public understanding of the process, so as to enhance trust and confidence in the safety of the food supply (para. 40)*
- *risk communication... should include a transparent explanation of the risk assessment policy and of the assessment of risk, including the uncertainty. The decisions taken and the procedures followed to reach them, including how uncertainty was dealt with, should also be clearly explained (para. 43)*

The WG will:

- i. discuss the issues highlighted in the paper from the UK FSA on *Transparent Use of Risk Assessment in Decision Making*,
- ii. develop a more detailed report for a future HoA meeting, to include consideration of:
  - confirming the key principles, with reference to the *Codex* principles referred to above, for the HoA to endorse and reaffirm
  - illustrative examples that highlight challenges to transparent use of RA and/or risks and benefits of different approaches
  - good practice and other relevant activities at national/international level
  - what helps good practice and what makes it more challenging
  - recommendations for actions.

### **Guiding principles**

The WG has agreed the following guiding principles:

- (i) The WG will focus on identifying how to ensure that the established principles for good risk policy, as set out in the *Codex Working Principles for Risk Analysis for Food Safety for Application Governments (2007)* can be met consistently. It will not attempt to review these principles of good risk policy, which are supported across Europe and globally.
- (ii) The WG may consider case studies or illustrative examples in order to highlight general lessons on what helps good practice or makes it more difficult. However, it will not take a view on whether specific decisions are 'right' or 'wrong'.

### **Process and timing**

Key steps and timings are as follows (some timings depend on scheduling of HoA meetings):

- i. Exchange of views by correspondence on TOR, ways of working, membership and key issues (August – September 2011)
- ii. One-day workshop meeting (23 November 2011), to discuss:
  - issues, principles, roles and responsibilities, challenges, good practice and actions to support transparent use of risk assessment in decision-making
  - concrete actions or recommendations
  - format/content of report
- iii. Report back to HoA meeting with summary WG report (7-8 December 2011)
- iv. Draft and agree final report and send to the HoA, by 30 April 2012, for discussion at the first plenary meeting of HoA in 2012 (date to be confirmed).
- v. Copy final report to Commission (SANCO) and EFSA and publish the report.

### **Co-ordination and support**

The UK FSA will provide Secretariat support, and, subject to the agreement of other WG members, will undertake to present to results of the WG's work back to the HoA group.

## Membership

Six countries have volunteered to participate: Belgium, Germany, Netherlands, Norway, Sweden and UK (see table). The WG agreed to keep an invitation open to other Agencies to take part. EFSA and the Commission (DG SANCO) were invited to contribute comments and to participate if they wish as invited observers.

Country	Member
Belgium	Dr Xavier Van Huffel Director of the staff direction for risk assessment Federal Agency for the Safety of the Food Chain (FAVV)
Germany	Mr Klaus J. Henning Head of section "Clearing, EFSA Focal Point and Committees" Department Risk Communication Federal Institute for Risk Assessment (BfR)
Netherlands	Dr. Hub P.J.M. Noteborn Head Unit Integrated Risk Assessment Office for Risk Assessment and Research Netherlands Food and Consumer Product Safety Authority (NVWA)
Norway	Gisken Beate Thoen Head of Staff Department of Legislation NFSA
Sweden	Dr Rickard Bjerselius Adviser/Toxicologist Guidance Division NATIONAL FOOD AGENCY
	Dr Roland Lindqvist Chief Microbiologist Risk Benefit Assessment Department NATIONAL FOOD AGENCY
UK	Dr Andrew Wadge Chief Scientist Food Standards Agency <i>Note: Dr Wadge acted as Chair for the WG's meeting</i>
	Dr Patrick Miller Chief Scientist Team Food Standards Agency <i>Note: Dr Miller acted as Secretary to the WG</i>

Note: all members participated in the Group's meeting on 23 November 2011.

Mr Jalal Ahmed, Chief Scientist Team, UK Food Standards Agency, provided Secretariat support to the Group's meeting.

## ANNEX B Examples of frameworks to support transparent risk management

Note, the documents in this annex are unofficial translations into English, made by Working Group members, of extracts from documents published in national authorities' national languages.

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Annex B1 National Food Agency, Sweden  
Question to Risk- and Benefit Department

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### Question to Risk- and Benefit Department

Send to NN, Assisting Head of R/B-Department (NN@slv.se)

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Name of risk manager:

Department/Unit:

Registration number (the responsibility of the risk manager):

Overall objective:

Specific issues to address (E.g. risk groups, unit of risk/benefit):

The response will be used for/target audience (for what and to whom is the report intended, e.g. EFSA, Department of Control):

The responses will be presented as (type of oral/written delivery):

Time frame

Starting Date:

Final Date (when is the response needed):

Resources (e.g. account number for showing time and debiting):

---

#### **Filled in by Risk- and Benefit Department:**

Internal id (E.g RN001/2011):

Person responsible:

Date when task given:

Level of Quality Assurance: Traceability, transparency, review (Colleague, Co-authors, Internal reference group, External expert(s), Peer review):

Delivery of response

Date response delivered:

Response delivered in writing as a:

Feedback from risk manager:

Finalised/approved/publicised:

Signature of person in charge:.....

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**Annex B2 National Food Agency, Sweden**  
**Template for terms of reference for scientific risk/benefit report**

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National Food Agency	<b>Frame for Terms of reference for scientific risk/benefit report</b>	20
Department Name	2009-xx-xx	(31)
	<b>Appendix 1</b>	

***Terms of reference to the Risk/benefit department regarding scientific report for revision of advice on food for infants and small children***

**1. Background**

*The NFA consumer advice 'Food for children and infants' was published 1999 and 2002. Since then, new scientific results have been published. In addition, NFA has conducted food questionnaires for children, giving new results regarding children consumer behaviour. NFA has therefore started to revise the advice to children and infants.*

*The identification of the need has been done through a review of the present advice versus the present scientific documentation. Within this "pre-work", risk managers has also contacted professionals in the child health care sector in Sweden, expert groups and parents, to find out what are the present needs regarding consumer advices.*

*The present request is a part of the initial work, consisting of a review and/or update of the **scientific background** for the consumer advices.*

**2. Aim**

*The specific aim with this request is to review the scientific basis for the consumer advice regarding - \_\_\_\_\_ (e.g. pesticides) in baby food. The report will be used as a part of the ongoing work to revise the consumer advice for small children and infants. The scientific report will be published, and will be one of several reports (i.e. risk/benefit assessment report, risk management report, report to health care professionals and brochures to the parents).*

**3. Methodology**

*If the present NFA risk/benefit assessment report is considered relevant, it can be used for the request. If not, other scientific reports/articles should be the base for the report. If such documentation is lacking, a systematic literature review needs to be conducted. The method should follow the work outlined according to "Risk assessment" in "The Codex principles of risk analysis"*

#### **4. Scope**

##### **Scope of the opinion:**

- answer the following specific questions
  - 
  - 
  -
- Description of how the work has been conducted
- A summary of the result
- Conclusions
- Summary in English and Swedish
- References

#### **5. Limitations of the Terms of reference**

*The present request should not formulate any advice or in any other way anticipate/forestall the risk/benefit management process of how to manage eventual risks/benefits.*

#### **6. Quality assurance**

*The opinion will be quality assured by\_\_\_\_\_ (NFA, other expert agency, expert group, expert etc.).*

#### **7. Delivery**

*The opinion should be written according to NFA frame work for such reports and delivered no later than\_\_\_\_\_ (year-month-day).*

## Risk/benefit management report

### – Consumer advice for children aged 0 -5 years

#### Introduction

The review of consumer advice concerning foods for infants and small children is based on independent scientific risk- benefit assessments (according to annex 2 and/or 3). With the scientific opinions as a basis, adjustments have been made, where also other relevant factors have been included in the decision making process ending in consumer advice for infants and small children.

In this risk/benefit management report, a summary of the risk- benefit assessment report, together with an evaluation of other relevant factors is documented, resulting in NFA consumer advice for infants and small children.

The emphasis in the management report is on clarifying the rationale for the decisions when and which advice to formulate. The rationale for not issuing advice is also documented.

*[Translators note: for each and every advice that was included in the reports, both a risk/benefit assessment report and a risk management document was published. Below you have the very simple frame that the risk managers used for their task. The final risk/benefit opinion consists of 281 pages and the risk management report of 121 pages. ]*

#### This consumer advice is about

e.g. bisphenol A - specifically risks with bisphenol A in food contact materials for infants and small children

#### Consumer Advice (final decision)

e.g. No advice

#### Rationale for the consumer advice

a) *Risk- and/or benefit assessment*

A short summary of the main conclusions from the risk benefit assessment opinion that are needed to formulate the conclusion, i.e. decision making, e.g. EFSA opinion stating that the existing TDI is valid to protect the consumers.

b) *Other relevant factors that have influenced the decision*

e.g. existing maximum limits in EU regulation 2002/72/EG, and banning of BPA in baby bottles, 2011/8/EU

c) *Conclusion*

e.g. NFA decide that it is not relevant to give a consumer advice to avoid these food contact materials intended for infants or small children because of BPA content.

#### References for the risk management process

e.g. EU legislation, Risk assessment reports (EFSA, NFA)



**Annex B4 Netherlands**  
**Transparent consideration framework (TRAK)**

This is an abridged, unofficial English translation of a Dutch official and public report (Bakker, E. de, H. Bouwmeester, M. Bracke, A. van der Sluis, M. van der Spiegel, D. Stijnen, L. Temme en H. van der Voet. **Transparant afwegen; Waarden en risico's beoordelen van voedselkwaliteit.** Rapport 2009-020; ISBN/EAN: 978-90-8615-320-6, April 2009, LEI-DLO The Hague)

Transparent policy decisions and broader risk assessments seem to be crucial for fulfilling the social aspirations established by the Ministry of Agriculture, Nature and Food Quality with regard to food quality. However, the use of instruments which support such decision making seems to be encountering problems. This report discusses the application of a Transparent Consideration Framework (TRansparant AfwegingsKader, TRAK). This instrument certainly offers potential, but successful implementation will take time and energy in view of the problems facing them.

**Summary**

**Transparent considerations applied; Broad policy decisions and risk assessments in food quality**

The Ministry of Agriculture, Nature and Food Quality (LNV) wants to improve the transparency of decision making in food policy (i.e. risk management). An important question is how different values and risks relating to food quality should be compared to each other. In 2006 and 2007, the Ministry commissioned the development of two instruments which could help answer this question: the Transparent Consideration Framework (TRAK) and the Broad Risk Assessment (BRB). TRAK focuses on transparent policy decisions, if possible linked to an open stakeholders' dialogue, or the promotion of this. In its own way, TRAK constitutes a methodical response to the challenges of knowledge uncertainty and lack of social consensus which confronts policy makers (risk managers) in the domain of agriculture and food today.

Although the instrument is very different with regard to existing risk management methodology, there is potential for combined applications on policy dossiers including risk assessments. However, as we saw during the course of 2008, the implementation of TRAK (and BRB) faces a number of problems. Besides practical and organisational problems, there are also obstacles related to a departmental 'policy culture'. When weighing up the pros and cons, based on our experiences we see that application of TRAK (and BRB) has both strengths and weaknesses (Table 1).

<b>Table 1: Strengths and weaknesses TRAK and BRB</b>	
<b>Strengths</b>	<b>Weaknesses</b>
<ol style="list-style-type: none"> <li>1. Open dialogue, insight into concerns and motivation</li> <li>2. Flexible application opportunities</li> <li>3. Time saved through mutual understanding based on insight and transparency</li> <li>4. Better coordination between generic policy and practical policy interpretation</li> <li>5. Can be used for new policy assignments (e.g. the new precautionary principal)</li> </ol>	<ol style="list-style-type: none"> <li>1. Requires initial time investment</li> <li>2. Timing is difficult</li> <li>3. Depends on representativeness of relevant stakeholders and availability of data</li> <li>4. Strategic action and opportunism dossier holders</li> <li>5. Policy culture in which integral considerations are secondary (compartmentalisation)</li> </ol>

The problems involved in implementing TRAK are a cause for concern. Transparent policy decisions (risk management) and broader risk assessments seem to be crucial for fulfilling the social aspirations established by the Ministry of Agriculture, Nature and Food Quality with regard to food quality, including safety. The lack of integral considerations which do justice to the broad pallet of food quality values could even undermine the administrative legitimacy of the Ministry. In this context, TRAK has strong characteristics and certainly has potential, but successful implementation will take time and energy in view of the weaknesses and threats facing them. In order to promote implementation of TRAK, we make the following recommendations to the Ministry of Agriculture, Nature and Food Quality.

### **TRAK**

- Emphasise the fact that the policy officials will not be required to do extra work, that it can save time and that it is legitimate to hire in external expertise for more integral policy decision making.
- Point to the policy principle of 'remote governance' (the modern motto) and the resulting need for procedural and process(oriented working in policy processes.
- Emphasise the fact that clear rules can be formulated for the use of TRAK in order to share responsibilities.
- Consider a gradual introduction of the method. Use it initially for planning and taking stock related to broader decision(making and set modest goals.
- See this as a step towards more intensive and complete applications.

See also Addendum 1 and 2.

## **Addendum 1**

### **TRAK (TRAnsparant Consideration Framework)**

#### **Background**

A general objective of the Ministry of Agriculture, Nature and Food Quality (LNV) is to stimulate consumer confidence in the policy on food quality (including safety). Transparent and understandable trade-offs by risk management between different values of food (such as economics, product quality, food safety, health, nature, environment, animal welfare or justice) can be an important basis for consumer confidence. In practice, policy (risk management) trade-offs between different values of food quality appear often implicit or incomplete, making these considerations of an opaque character and, therefore may raise trust problems. The methodology TRAK focuses on a broad and transparent balancing of values and criteria around food quality and is based on an open form of multi-criteria analysis (MCA). Upon the development of the methodology by Bakker et al, (2009) it was found that an open MCA variant offers most perspective for application in risk management because it is suitable for (1) trade-offs regarding food quality/safety as well as for (2) dialogue and social transparency in the context of interactive policy-making or risk management decisions (for a detailed description of the development, the operational steps and the roadmap of TRAK, see Beekman et al, 2007 and Bracke et al, 2008)

#### *References:*

*Beekman, V., D. Stijnen, E. de Bakker, M. Bracke, J. Teeuw, M. van der Spiegel, I. de Jong en K. Jansson, Evenwichtskunst. Op zoek naar een beleidsafwegingskader rond voedselkwaliteit. LEI Wageningen UR, Den Haag. 2007 (Dutch Language).*

*Bracke, M., E. de Bakker, V. Beekman, K. Jansson en R. de Graaff, TRAK: Voedselkwaliteit op het spoor. Op weg naar een transparant afwegingskader. LEI Wageningen UR, Den Haag. 2008 (Dutch Language)*

#### **Purpose of TRAK**

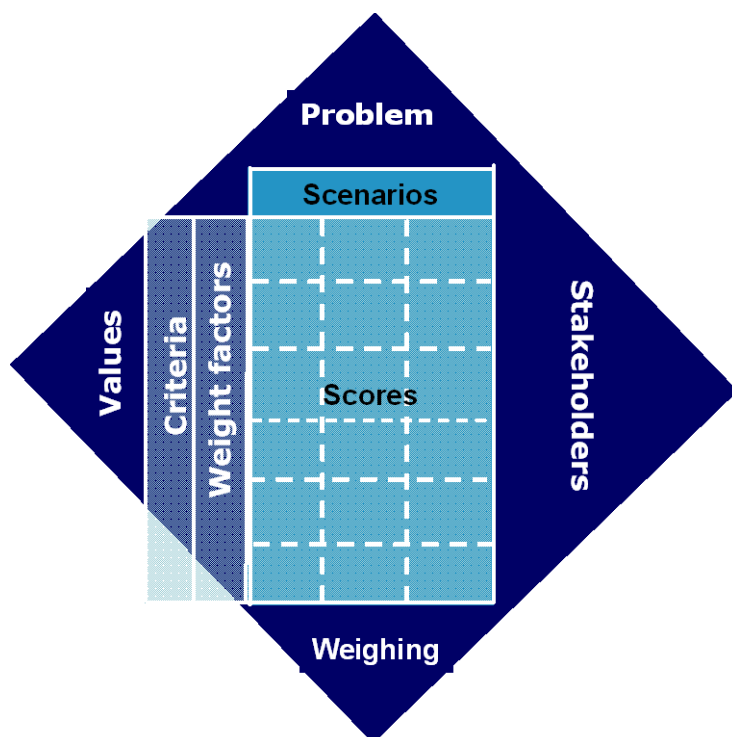
Focus is to support and achieve more transparent policy/risk management considerations. With a methodical roadmap policy-makers (risk managers) can be assisted with a tool to provide them a means to substantiate their choices for a given policy alternative. This is done by the trade-offs between different values of food in order to clarify the policymaking process and, regarding certain aspects of risk management, to make the decision more or less quantitatively explicit and understandable for stakeholders including the public at large. Although application of TRAK can lead to an increase involvement of stakeholders, this method is not primarily intended as a tool to create more support for risk management policies. This could be an important secondary effect, but it is not the main goal of applying TRAK.

#### **Core of the methodology**

Central to TRAK is a table of scores for criteria (rows) for a number of scenarios (columns). Criteria can have different weight factors. The process of building this table with criteria, weight factors and scenarios is the core of the TRAK methodology and functional for an exchange of arguments between various stakeholders. Below, figure 1 illustrates a schematic outline of the balancing (trade off) method

The result is a matrix which can also be displayed as graphic data. The core is, however, as indicated below, the process of consultation to achieve a final managerial result. This could be done in a workshop with stakeholders, where the matrix (Figure 1) is incrementally compiled, discussed and completed. The process of preparing and completing the matrix is of utmost importance as a better picture is obtained of the justifications that lie behind the considerations of relevant stakeholders.

Figure 1. Methodology TRAK



### Selection of participants

An important step is the selection of participants (stakeholders) within the framework of the consultation. TRAK delivers no definite rules, but the approach is limited to some rules of thumb and principles. As a rule of thumb would be, for example, to determine carefully in advance which stakeholders will be involved in the different scenarios and to aim for a good representation of stakeholders including their societal positions. From a practical standpoint, there are pros and cons of involving a larger or smaller number of participants to be consulted, because they may have an influence on group processes and their positions of power may disrupt an open, transparent and interactive process.

### Results

If the policy (risk management) decision is taken on the basis of the methodology of TRAK, it balances the different values of food quality in a (more) transparent manner. And the report (public communication) in which the process of decision is described can be regarded as a public recognition. Furthermore, the methodology proposed delivers the building blocks for assessing new scenarios, to systematically search for new solutions and to smoothly structure discussions between various stakeholders.

### Overview roadmap

The method comprises a number of steps divided into three phases:

#### Phase 1 Preparation

- a. Challenge
- b. Scenarios
- c. Values
- d. Criteria
- e. Scale
- f. Process
- g. Participants

## **Phase 2 Consultation**

- h. Agenda
- i. Aggregation
- j. Discussion
- k. Balancing
- l. Improvement
- m. Evaluation

## **Phase 3 Effect (outcome)**

- n. Reporting
- o. Implementation

The phases 1 to 3 are distinguished on the basis of who is involved. The above steps should not be construed as a fixed procedure where a return to a previous step is not possible, but as a totally iterative process. This means that information of later stages should always allow for an updating of previous choices. Moreover, a narrower interpretation (process flow) of the TRAK roadmap is always possible.

## **Application variants of TRAK**

TRAK can be applied in different ways depending on the policy (risk management) phase and working procedure selected. See also addendum 2:

### **1) External workshop**

An external workshop with stakeholders can be used to provide information about the subject (risk assessment) at stake, to substantiate an intended decision, or to involve stakeholders in policy making;

### **2) Independently by a policy/decision maker (risk manager)**

For example, can be done in situations in which sufficient information has been delivered by, for instance, risk assessors (or scientists), or when there is a high time pressure to consult stakeholders. The disadvantage is that no transparent interaction between stakeholders and the policy maker/risk manager exists. In principle, it is however, possible that an engaged and well informed risk manager can apply TRAK on an A4 in half an hour depending on the case at stake and under the condition that there is sufficiently experience with the integrated assessment framework and the underlying (moral and rational) principles;

### **3) Independently by a risk manager and bilaterally with different stakeholders**

Bilateral deliberations may be an alternative when it is not possible to invite all the required stakeholders to the consultation round in order to collect their views and information on the subject stake in order to substantiate a managerial decision, or to involve stakeholders in the process of policy making. The disadvantage is that there exists no open interaction between all the stakeholders and the risk manager(s);

### **4) Sounding Board**

An internal or external advisory group of experts can be used on the short term involving few people to get a feedback or to perform an inventory of different visions. The disadvantage is that the vision of a number of stakeholders has indirectly been obtained.

To summarize, the type of TRAK application (see above) further depends on the sensitivity of the subject (i.e. risk assessment), time available, amount of information available, expected long term effects and the experience of the policy maker (risk manager).

## Addendum 2 Major rules of responsibilities TRAK

<b>Table 1: Use of TRAK without external stakeholders</b>		
<b>Activity</b>	<b>Who</b>	<b>Responsibilities</b>
Preparation phase	Independent by risk manager or with external support	<p>Policy officer (risk manager) completes the table of figure 1 based on own file(s) or his/her experience (or asks for support of external experts). The completed table has a provisional status.</p> <p>Any allocation of weight factors has a preliminary or exploratory function.</p>
Consultation phase	Internal (closed) workshop	<p>Policy officer (risk manager) discusses the policy challenges and provisionally completes the table of figure 1 and, if required, adjusts its contents.</p> <p>They (risk managers) decide together whether (a) it is possible to allocate weight factors for advice based on current policy (risk management) priorities or (b) that this should be left entirely presented to the political leaders.</p> <p>In the case of (a), the weight factors are an indicative allocation only that subsequently needs to be approved at the political level</p>
Effect (follow up) phase	Internal policy procedure and discussion	<p>In consultation with higher management or political directors it will be decided whether and how to balancing of the risk management policy (decision) will be made public.</p> <p>After consulting political management or directors it shall be decided to what extent a further involvement of external stakeholders is required and what actions require any knowledge gap filling (e.g. additional investigation, etc.)</p>

<b>Table 2: Use of TRAK with external stakeholders</b>		
<b>Activity</b>	<b>Who</b>	<b>Responsibilities</b>
Preparation phase	Independent by risk manager or with external support	<p>Policy officer (risk manager) fills table of figure 1 based on its own file(s) or experience (or asks support of external experts). When completed, this table has a provisional status.</p> <p>Any assignment of weight factors has a preliminary or exploratory function.</p>
Consultation phase	External (open) workshop with stakeholders	<p>Policy officers (risk managers) and external stakeholders discuss policy challenges and provisionally complete the table and adjust figures (information) where required.</p> <p>In advance of the stakeholder consultation it is decided whether either (a) the workshop is limited to an inventory of scenarios, values and criteria or (b) that participants will also be asked to assign weight factors to the different values and criteria.</p> <p>In the case of (b) emphasizes that this is an exercise where stakeholders cannot derive any administrative political consequences, but which is intended to provide the best possible understanding of the different motives and arguments.</p>
Effect (follow up) phase	Internal policy procedure and public communication	<p>In consultation with higher (risk) management or political directors it shall be decided whether and to what extent risk management will deviate from the stated policy of balancing by the invited stakeholders. It can also be decided to conduct further investigation or involvement of additional external stakeholders in the consideration.</p> <p>In the after-care and public communication phase risk management explains on what eventual weight factors their arguments for the decision were made. It examines also all motives and arguments that have been put forward upon the consultation phase.</p>