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

Second report to the Heads of Agencies

September 2014

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SUMMARY

The Working Group's first report on transparency in decision making identified a challenge 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 Heads of Agencies (HoA) agreed this report and its recommendations in December 2012, and tasked the WG to develop an Action Plan to support implementation of the recommendations. The Action Plan was agreed in 2013.

In this second report, the Working Group discusses and sets out recommendations to the HoA for frameworks and approaches to the risk management process that would help to ensure the transparency of the resulting decisions and their rationale and justification. This addresses the key action in the Action Plan.

The WG considers that it is not feasible or appropriate to recommend a single framework for use across the HoA network. Approaches need to be flexible and to be adapted to the specific contexts of the country and of the issues being considered. Instead, the WG proposes a set of common objectives and features that any approach should seek to meet, and some conclusions on the factors to be considered in decisions and the scope of application of these approaches. HoA member organisations should now pilot the use of frameworks, to see which work best in meeting the overall principles in their countries and in different circumstances. National food agencies and the HoA as a group should work with others, and particularly with risk managers, at national and European level, in order to develop this work to the next stage.

The recommendations from this report are summarised below:

Recommendation 1 The HoA individually and as a group should agree the WG's 2nd report and endorse the proposed objectives and features that frameworks and approaches to transparency in risk management decisions should meet.

Recommendation 2 HoA should champion the development and application of approaches as described in the WG's report, and engage more widely to promote their wider development and use, including with national risk managers, the European Commission and Codex.

Recommendation 3 As a first step, national agencies should bring the WG report to the attention of relevant national bodies responsible for risk management decisions and for their enforcement, and initiate a discussion on how the recommendation should be developed and tested in practice.

Recommendation 4 HoA member organisations should commit to developing and piloting the use of frameworks, to see which work best in meeting the overall principles in their countries and in different circumstances, and report back to HoA.

1 INTRODUCTION

1.1 In 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* and 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 Working Group's first report, in 2012,¹ discussed transparency in decision making and identified, as a principal challenge for risk management, the need 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 report made a number of recommendations to HoA for how this could be done. The HoA agreed the report and recommendations in December 2012, and tasked the WG to develop an Action Plan to support their recommendations. The Action Plan was agreed in 2013 and the HoA has received an update on progress at each of its subsequent meetings. The WG recommendations and Action Plan are at Annex A.

1.3 In this second report, the WG discusses experiences since its first report, and considers the principles and key features necessary for approaches to risk management to ensure transparency of the resulting decisions and their rationale and justification. It makes a number of recommendations to the HoA on these points and on actions to support their development and implementation.

1.4 The membership of the WG for this second report is at Annex B. The WG met once, on 25 June 2014 at the UK FSA in London, to discuss the issues and the structure and content of its report. The Working Group also received a report from Dr Volkert Beekman (LEI Wageningen, Netherlands) on his experiences with the TRAK methodology and of developing this and other tools for transparent risk management in practice. The Working Group would like to thank Dr Beekman for his input.

¹ <http://www.food.gov.uk/science/sci-gov/decision-making>

2. REVIEW OF THE 'LANDSCAPE' SINCE THE WORKING GROUP'S FIRST REPORT

2.1 The WG reviewed relevant activities and experiences in their own countries, and elsewhere, to identify any examples which could inform the WG's report, with regard to the 'state of the art', positive experiences or features of approaches and potential challenges and potential barriers. This overview is set out below. It is not intended to be an authoritative review of work in the area; rather it aims to summarise some relevant experiences and some lessons that emerge from this.

Summary of relevant experiences and examples since the WG's first report

Belgium

2.2 Currently the Scientific Committee of the Belgian Food Safety Agency is preparing an opinion on a scientific and transparent approach for recall of food in case of short term exposure of consumers to foodstuffs (highly) contaminated with arsenic, cadmium, mercury, methylmercury, lead or nitrates. This opinion which is due for the end of 2014 will help risk managers to make transparent decisions in case of contamination of food with the cited chemicals.

Netherlands

2.3 In the Netherlands, the Ministry of Economic Affairs (EZ), previously 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 the risk assessment and different values relating to food quality should be compared to each other in an open way. The Transparent Consideration Framework (TRAK)² – a participatory multi-criteria analysis (pMCA) for transparent risk management - focuses on transparent policy decisions via a quick-scan by an individual risk manager, and if possible or indicated linked to an open stakeholders' dialogue (participatory session), or the promotion of this. In its own way, TRAK constitutes a transparent framework for mapping and balancing food quality values beyond economic cost-benefit analysis and environmental and health risk – benefit assessment including the challenges of knowledge uncertainty and lack of social consensus which confronts risk managers in the domain of agriculture and food today. Experiences from pilot studies (e.g. health risk of outbreaks of Avian Influenza, Q-fever, Mad Cow disease) show that risk managers and involved stakeholders are able to reach agreement fairly quickly with regard to changing,

² Beekman, V., E. De Bakker and R. de Graaff (2007) Standing on the shoulders of a giant: The promise of multi-criteria mapping as a decision-support framework in food ethics. In: W. Zollitsch, C. Winkler, S. Waiblinger and A. Haslberger (eds.) Sustainable food production and ethics. Preprints of the 7th Congress of the European Society for Agricultural and Food Ethics, Wageningen Academic Publishers 95-100.

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modifying and adding scenarios, values/criteria and interpretation of risk assessments. Experiences also demonstrate that the structure of a multi-criteria mapping approach forces broader and more rational ways of thinking, and that the associated dialogue between risk managers and stakeholders contributes to better mutual understanding of the content and scope of the risk assessment among the various interested parties. Finally, experiences show that multi-criteria mapping (TRAK) gives risk managers a clear view about the convergence and divergence in their considerations about and priorities with respect to the mapped values in the issue (i.e. risk assessment) at stake. Although the instrument (TRAK) is very different with regard to existing risk management methodology, there is potential for combined applications on policy dossiers relating to risk assessments. It is a promising decision-support framework in food safety and quality that is able to meet the double challenge of providing methodological guidance in both mapping and balancing the relevant values in the issue at hand. It offers a structured and transparent process of opinion-formation and provides a foothold in decision-support with respect to mapping and balancing the risk assessment versus various other values. Moreover, this decision-support framework includes a participatory dimension.

Norway

2.4 It is well known that the first stage in the risk analysis process, the formulation of the request and mandate for a risk assessment, is of great importance for the applicability of the results in the subsequent risk management.

2.5 The use of an open hearing process inviting comments to a draft request for new risk assessment tasks has been seen to be very beneficial in Norway. The hearing is an element in risk communication and increases the transparency of the work by informing all interested parties about the planned risk assessment at an early stage. At the same time the hearing opens up to process to valuable input of information and points of view, which may be important when formulating the final risk assessment request or mandate. Possible implications for later risk management actions may also be identified as a result of the hearing. The hearing can be organised as an open meeting or as an invitation to send written comments.

2.6 In Norway risk assessment and risk management are separated. The Norwegian Scientific Committee for Food Safety (VKM) is responsible for risk assessments, while risk management, including the requests for risk assessment, is administered by the Norwegian Food Safety Authority (NFSA). In many countries the whole risk analysis is conducted within one authority. We would expect a public hearing of the mandate for planned risk assessments to be no less important for the transparency of risk management in these countries.

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Sweden

2.7 The Swedish NFA has two ongoing projects to further develop the transparency of risk management. The one is similar to the German (BfR) risk assessment profile, and Swedish NFA has been in contact with BfR regarding the project. In addition to the BfR risk profile concept, the NFA will try to add also a risk management perspective to the 'pure' risk assessment profile. The rationale for this is to make it understandable and transparent also for e.g. consumers and stakeholders how the risk managers value different risks. The work is ongoing and no decisions have been taken, but one suggestion is that the work might end up in a "Risk thermometer".

2.8 A second project is a work to establish a 'risk assessment based' risk classification of different contaminants in food. The idea is to use present health-based reference values (e.g. Tolerable Daily Intake, TDI; Acceptable Daily Intake, ADI; No Observed Adverse Effect Level, NOAEL; Bench Mark Dose Level, BMDL; Reference point, RP) as guiding criteria for which contaminants to prioritise in control for in official Swedish control programs. To do this, we use Swedish dietary surveys results and contaminant levels in different food categories from market basket surveys for exposure assessments for the contaminants in question. Based on this, we get a result showing which contaminants the Swedish population has a large or small margin of exposure to the health based reference values. The result is meant to guide the official control program in prioritizing the decisions of official control, and make sure it is risk based.

2.9 Since the last report, NFA has published one more risk management report, *"Consumption of red and processed meats in relation to colorectal cancer – risk and benefit management report"*. In the report we documented not only the risks and the benefits with red meat, but included also "other relevant factors". Relevant factors considered in this risk and benefit management report are: environment; animal protection; antibiotic resistance; Swedish food culture and traditions; as well as trade consequences. Other relevant factors taken into account are whether the consequences of the action taken are proportionate in relation to the possible risk or benefit it is estimated to make and/or if an action is practically viable and judged to be effective. The risk management action decided was consumer advice to limit the consumption of red and processed meat. The purpose of the report is to clearly state how the National Food Agency justifies its recommendation. The public and media interest was big and the report was well received, so far.

United Kingdom

GACS/SSRC Working Group on Use of Evidence

2.10 Two of the independent scientific advisory committees that advise the UK FSA, the General Advisory Committee on Science and the Social Science Research Committee, have set up a joint Working Group to look at how to capture the nature of evidence informing a decision

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across different types of consideration, and how this information is combined in the final decision, in a more structured and transparent way. It is doing this through the concepts of balance of evidence (what the evidence is telling us overall) and strength of evidence (quality and confidence in the evidence and its interpretation), and how these can be captured consistently across different types of assessment or evidence (health risk-benefit; costs, societal, feasibility/impact, etc.). As well as strength and balance, the Group is also looking at how to capture the 'dynamics' of evidence, which is more about the implications for decision/action, including: how a change in evidence/assumption might affect the decision; what might trigger a review; where key gaps exist what might be done about them and with what priority.

GCSA report on risk, innovation and regulation

2.11 The UK Government Chief Scientific Adviser, Sir Mark Walport, is working with a group of experts to produce an authoritative report on Risk, Regulation and Innovation. UK FSA has been feeding into development of this report. The report will highlight, among other things, the importance of transparency and consistency in use of evidence in decision-making. This illustrates the wider interest and discussion at a senior level on the need for transparent and evidence-based treatment of other factors besides risk assessment in decisions.

Germany

2.12 The BfR in Germany has produced a BfR risk assessment profile,³ which is a tool for communicating key features of a risk assessment in a simple and consistent framework. A number of other countries are looking at this tool to see whether and how it might be adapted and expanded to include useful summary information on risk management, as well as on risk assessment.

International

FAO workshop: Evidence-informed Food Safety Policies and Risk Management Decisions

2.13 The FAO organised an expert workshop on 18-22 November 2013 on *Evidence-informed Food Safety Policies and Risk Management Decisions*. This was part of a project funded by the EU, looking at existing practice and the potential to develop principles, guidance and tools for using different strands of evidence (or risk assessment and other factors, in the language of the HoA WG) inform food policy and risk management. UK FSA took part, alongside participants

³ http://www.bfr.bund.de/en/bfr_risk_profile-186391.html

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from across the globe, and gave a presentation on the WG's work. The workshop agreed on a number of principles which align closely with the WG recommendations:

- The need to respect and build on Codex and WTO framework particularly Codex Principles for Risk Analysis
- Scientific risk assessment should have primacy in policies and decisions
- Other factors will need to be considered and this should be evidence-based and transparent, as should the weighting between factors

Paris Risk Group

2.14 The Paris Risk Group aims to bring together experts and policy makers to develop and promote good practice in the use of social sciences in policy and risk management for food, which is relevant the WG's recommendations on more structured and transparent handling of risk assessment and of 'other factors' in risk management. The UK hosted the 2nd meeting of this Group, in March 2014.

Work at EU level

2.15 The EU CSA, Professor Anne Glover, has spoken on various occasions on the use of evidence in decisions including the need for politicians and risk managers to be open about how they have taken other factors into account, and to set out the evidence and rationale behind decisions. She has also initiated a project to look at the use of the Precautionary Principle.

Conclusions from review of the landscape

Positive features

2.16 The examples above illustrate some positive experiences in introducing frameworks for transparency and engagement in different parts of the decision-making process, particularly in showing how the risk assessment had informed a decision. This helps to identify some of the benefits of these approaches, and the features which can help to deliver these benefits.

2.17 In all cases, the risk assessment of potential effects (risk and benefits) on human health is a 'starting point' for a decision, with other factors also taken into account. While the selection and weighting of other factors will differ between countries and cases, the common principle and benefit is to achieve clarity on what factors are considered, and why, and how they are assessed and used to reach the final decision.

2.18 As well as transparency, other benefits observed, or aimed for, across these examples include greater consistency and a clearer structure for decisions. Among other things, this helps

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clarify and make more explicit the thinking behind decisions - on evidence, but also on values, uncertainties, assumptions etc. Making this explicit is helpful for those involved in making decisions, those who may need to act on the decision, and those who want to understand how the decision was made.

2.19 Dialogue and participatory methods can add value in terms of broadening inputs and building common understanding on issues, evidence and decisions. They can also help to identify why differences in opinions and interpretation arise, and sometimes to move towards a consensus. These methods (particularly fully participative methods) can take time, so are best suited to cases where the nature of the issue and the decision allows for this, and the benefits merit the time and resource involved.

2.20 More generally, it is useful to have approaches that can achieve the same overall objectives of transparency on the decision and its basis, which can be applied where there is very little time and information for a decision, or where a decision is not complex, as well as where there is more time and information, and the issues and inputs needed are more complex.

Links to other work

2.21 The overview highlights potential links to wider work on similar issues, at national, HoA, European and international levels - including the Commission, FAO, Codex, USA, Canada, Australia and New Zealand.

2.22 The same issues and benefits that arise for transparency in risk management decisions on specific food issues also arise in other types of decision, for example risk ranking, prioritisation and benchmarking of performance. Transparency, structure, consistency and clear use of evidence and analysis are all relevant and beneficial in these areas as well. The WG has focused its discussion on risk management decisions on food issues, but highlights the potential to link this work and to extend its application to related types of decision-making.

Challenges, barriers and risks

2.23 This review has also highlighted a number of challenges that will need to be addressed in developing recommendations and taking this work forward. In particular, experience suggests, perhaps not unexpectedly, that while there are several positive examples of transparency in how risk assessment has been used in risk management, it is more challenging to achieve full transparency in respect of the overall decision-making part of the process, across all the other factors that influence the decision. Similarly, it is not always easy to engage risk managers and decision-makers at the political level and secure their support for adopting more consistent, transparent, evidence-based approaches in practice. This does not mean that we should diverge from our objective of developing and implementing such approaches, but it may

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suggest that it could be easier in doing this to start at a more 'local' level and broaden out progressively to higher decision-making levels.

2.24 The fact that risk assessment and risk management (or at least the final decision-making stage) are often done in separate organisations contributes to these challenges. It is therefore important that risk managers as well as risk assessors (and other stakeholders) are involved in further development of approaches.

2.25 The expertise needed to carry out evidence-based assessments of other factors (for example: costs/economics, social sciences, regulatory impact assessment, etc.) may not exist within the risk assessment (or the risk management) body. It will be important to consider how to bring in relevant expertise into the assessment of 'other factors' alongside risk assessment, both in developing and in implementing new approaches. This will need to address how to provide the relevant evidence and expertise for assessment, and how to deliver appropriate peer review or quality assurance on the work.

2.26 As noted in the WG's first report, there are potential risks associated with bringing greater transparency into decision making. Exposing the decision-making process to greater scrutiny may result in greater challenge; and creating an expectation of transparency in decisions and their basis may lead to a demand for similar information in different contexts (for example through 'Freedom of Information' requests). On the other hand, explaining up front how and on what basis a decision is made should reduce the need to respond to requests for this information which inevitably arise if the process is not transparent.

2.27 Complete transparency for all information and all stakeholders may not always be appropriate in all circumstances, or at all stages of a decision - for example in an early scoping stage, where an issue is subject to high uncertainty, or in a rapidly-moving emergency situation. However, approaches should be able to provide transparency at least at the stages where a decision is made that needs to be communicated to or acted on by the public, industry or other stakeholders.

3. PROPOSED FEATURES OF A FRAMEWORK AND APPROACH

3.1 The WG considers that it is not feasible or appropriate to try to develop and recommend a single framework for use across the HoA network. Approaches need to be flexible and to be adapted to the specific contexts of the country and of the issues being considered. Instead, the WG has identified the key outcomes and features that any framework or approach should aim to meet, as far as possible.

3.2 The WG wishes to emphasise that this approach is not demanding anything fundamentally new, in that consideration of risk and of other factors, assessing the evidence or information for each, and weighing these up in a decision, are all part of decision making, even if this is not always explicit. The WG is proposing ways to make this process more structured, consistent and transparent.

3.3 In order to communicate the risk management decisions resulting from the application of this transparent process, it could be helpful to develop a simple tool to summarise the key points of the decision, in a similar way to how the BfR template aims to capture the key points of a risk assessment.

Key outcomes and features of transparent approaches to risk-management decisions

| Table 1 Key outcomes of transparent approaches to decision making | |
|--|--|
| Transparency | This is the key overarching outcome: to ensure transparency on the process and its outcomes and rationale. This includes: <ul style="list-style-type: none"> – the context and nature of the decision and its basis and rationale – the issue(s) to be addressed and options considered – the factors considered, the main evidence and analysis for each and how these were used in decision; uncertainties and gaps, how these were addressed. <p>It is also important to be transparent that a decision has been made.</p> |
| Clear structure and process | The approach should provide a clear structure and process for decisions, including the desired results, the timeline, inputs (people and information), the stage at which the decision will have an impact, and what comes next. |
| Consistency | The process and outcome should be consistent for similar issues and contexts - and where there are differences, it should be clear why. |
| Sound understanding of evidence and analysis | The approach should achieve a clear, sound understanding of the evidence and analysis needed and used in the decision, across all factors. This includes the main conclusions from the evidence, key uncertainties and gaps and their impact on the decisions, and, where possible, how new information or assumptions might change the decision, to inform review. |
| Openness | The process should allow for stakeholders to engage with and contribute to the process, to the extent that the nature of the issue and the time and resource available allow. This will not always be appropriate, but the process should ensure the approach to openness is considered and the rationale for the selected approach is clear. |

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| Table 2 Key features of transparent approaches to decision making | |
|--|---|
| Flexible | The approach should be able to adapt to reflect the context of the country/body making the decision and the nature of the issue, while aiming to achieve the key principles in all cases, as far as possible. |
| Proportionate | The information, resource and time involved should be proportionate to the importance and complexity of issue and of the decision, and to the time and resource available. |
| Scalable | <p>The approach should be capable of operating at a simple level but also to be 'scaled up' to bring in more extensive and complex approaches where the nature of the issue and available information and resource allow or require.</p> <p>It should be clear how the scale of approach is selected and there should be appropriate supporting tools for each level⁴</p> <p>An initial, 'framing' stage to decide the initial level of approach could be a common a step across all decisions. In some cases, no further development would be needed, while for others this would set out the next stages for more extensive consideration.</p> |
| Participation, iteration and dialogue | <p>There should be a clear approach to deciding who participates and for their involvement. The process should support dialogue between different parties, based on iteration rather than linear/compartmentalised approaches, while respecting the distinct roles of different parties (such those of risk assessors and risk managers; and of decision-makers and stakeholders).</p> <p>The process should involve those responsible for implementing the final decision wherever possible.</p> <p>The extent and scale of stakeholder participation will depend on the nature and importance of the issue and the time/resource available.</p> |
| Review and reflection | The process should have a clear approach to review, and should operate in a way that facilitates review at the appropriate point. This includes having clear objectives, analysis and reasons for the decision, identifying any needs for collection of data on baselines for and changes in key parameters, and understanding how a change in evidence or assumption might change the outcome. |

⁴ Note- an example is given in the paper on the TRAK methodology included in the WG's 1st report, which discusses how the approach can follow a simple or more detailed path depending on context while meeting the same common objectives. See also paragraph 2.3 above.

Factors to be considered

3.4 Assessment of effects on human health (risks and benefits) will always be part of a decision on food risk management, and its starting point. It is not possible to set out a definitive list of other factors that should be considered, or of how these should be assessed and weighted in the decision, although there are a number which are likely to be relevant in many cases, such as: effectiveness in terms of impact in practice on public health risk/benefit; cost; impact on industry; public views; political considerations; and legal, ethical, and environmental impacts. The key point is that any approach should be capable of clearly identifying the relevant factors and the information and approach needed to assess them, and to show transparently how they were assessed and used in the final decision.

3.5 The WG wishes to underline the importance of considering the practical implications and feasibility of possible risk management options (such as legislation and its enforcement), and their effectiveness in practice (and how these can be evaluated) among the factors considered in decision-making. This should include considering potential unintended consequences.

Scope

3.6 These approaches can be applied across the whole of the decision-making process, from initiating/framing questions to decision-making and review. The detail of the approach and the information and analysis needed may vary at each stage, but the overall outcomes and features outlined above would still apply.

3.7 As noted in part 2, the WG believes that these principles could also be applied, and would be beneficial, for prioritisation across a range of food issues including for risk ranking. The same principles, outcomes and features would apply, but there would be differences in the criteria and the supporting tools; the process might be simpler in some respects in the case of high-level prioritisation, which might be based on broad categories such as High-Medium-Low or Red-Amber-Green.

Supporting tools and approaches

3.8 Although the WG is not recommending a specific tool or approach there are a number of features of existing or potential tools that could be helpful to inform and support the development and implementation of approaches that meet the above principles. One example is the experience with the use of the TRAK methodology in the Netherlands.

3.9 There are many decision-support tools that might be adapted to the specific context of food risk management decisions, in line with the principles above. Many of these use

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templates or other forms of prompt and checklists to ensure the necessary clarity and structure and consistency; these may be supported by guidance and worked examples.

3.10 Many of these tools are based on some form of Multi-Criteria Decision Analysis (MCDA) or on approaches which, if not 'formal' MCDA, attempt to achieve the same outcomes in terms of clear structure for capturing the factors considered and combining them in a consistent way. There is a tendency in MCDA approaches to adopt numerical systems for scoring individual factors and in scoring/ranking options. While this can be helpful, it is important not to introduce too much complexity in this part of the process, as there is a risk of losing the benefit of simplicity and transparency in how a decision is made. More complex approaches can be resource intensive and can suggest a precision in the analysis and the outcome which is not justified by the available evidence. The WG considers that both numerical and other approaches can be useful, and should be explored in developing and testing approaches. Non-numerical approaches would include qualitative rankings or categories such as Low-Medium-High, Red-Amber-Green, etc., or even narrative approaches that capture information according to standard headings - which might be appropriate for example in a very basic/quick approach or where there is very little time or information.

3.11 In developing approaches, national agencies should draw on useful material and examples from other bodies' experience with capturing and communicating key elements of assessment. For example, several bodies (such as the IPCC, to name one) have developed frameworks for describing key elements of evidence and analysis in common categories and terms - for example type and scale of effect, confidence, likelihood, uncertainty etc.

3.12 Finally it is important to be clear that a decision that uses a simple process to capture and communicate its conclusions can still be informed and supported by complex information and analysis (for example in the risk assessment) to arrive at the conclusion summarised in the 'simple' framework.

4. CONCLUSIONS AND RECOMMENDATIONS

4.1 Given that the organisations in the HoA network are responsible for risk assessment but generally not for (all aspects of) risk management, the national food agencies and the HoA as a group will need to work with others, and particularly with risk managers, at national and European level, in order to develop this work to the next stage.

4.2 The WG has proposed a set of common objectives and features that any approach should seek to meet, and some conclusions on the factors to be considered in decisions and the scope of application of these approaches. **The HoA should now commit to developing this work further and the WG makes the following recommendations to this end.**

Recommendation 1 The HoA individually and as a group should agree the WG's 2nd report and endorse the proposed objectives and features that frameworks and approaches to transparency in risk management decisions should meet.

Recommendation 2 HoA should champion the development and application of approaches as described in the WG's report, and engage more widely to promote their wider development and use, including with national risk managers, the European Commission and Codex.

Recommendation 3 As a first step, national agencies should bring the WG report to the attention of relevant national bodies responsible for risk management decisions and for their enforcement, and initiate a discussion on how the recommendation should be developed and tested in practice.

Recommendation 4 HoA member organisations should commit to developing and pilot the use of frameworks, to see which work best in meeting the overall principles in their countries and in different circumstances, and report back to HoA.

Implementing the recommendations

4.3 Pilots should aim to explore different approaches and test them on different types of issue and decision (in terms of scale, time, complexity), and report back on what works, any problems and barriers; how well they meet the principles, and other conclusions with regard to experience, ease of use and other impacts and benefits. It may be best to start with risk management decisions on specific issues but consider scope to expand to risk ranking and other types of decisions.

4.4 It is suggested that national agencies inform the WG Secretariat of their plans for pilots and on their progress and outcomes, with a view to reporting back to the HoA in 12-18 months.

4.5 Piloting and testing will need to involve others, including risk managers and probably wider experts relevant to the assessment of other factors. It may be easier to carry out pilots at a national level, at least at first, although it could be done jointly between countries (and/or with the Commission) if this is thought feasible.

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ANNEX A: Membership of the Working Group for preparation of its 2nd report

For the second phase of its work, five countries participated in the Working Group: Belgium, Netherlands, Norway, Sweden and UK (see table). The WG invited other Agencies to take part or to contribute to the preparation of this 2nd report.

| 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) |
| 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 |
| UK | Dr Patrick Miller Chief Scientist Team Food Standards Agency <i>Note: Dr Miller acted as Chair for the 2nd meeting</i> |

Note: BfR (Germany) is also a member of the WG, but did not nominate a participant for the second phase of the work following the retirement of Klaus Henning in 2013]

Dr Volkert Beekman (LEI Wageningen, Netherlands) provided input to the WG drawing on his experience of developing frameworks for transparency in risk management and in applying them in practice.

Ms Suzanne Fred, UK FSA, provided Secretariat support to the Group's 2nd meeting.

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ANNEX B: Summary of recommendations from the WG's 1st report (April 2012) and Action Plan to support their implementation

Summary of recommendations from WG report

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.

ACTION PLAN

(i) Work by HoA to promote and implement the report and recommendations

1. Each plenary HoA meeting to include update reports
 - (i) from the WG on its activities
 - (ii) from members of the HoA on any activities at national level to promote and implement the report and its recommendations.
2. HoA to act as a forum to share experiences and for discussion of issues, acting collectively as a supportive community and a critical friend:
 - Regular discussion as standing item on agenda of HoA meetings
 - HoA to share information on national approaches and experiences with frameworks etc., via WG (UK happy to continue to co-ordinate WG)
 - Discussion between meetings of approaches and individual cases through email (or online forum if practical)

FINAL

3. HoA WG to consider in more detail work to develop and apply methods for robust, evidence-based analysis for other factors, including through seeking views from EFSA and SANCO, and identifying and discussing with other relevant experts (legal, social sciences, etc.)
 - Invite HoA to share information/experience of relevant work and on lessons learned – both what worked well and areas to be improved
 - WG to develop proposals for a framework for how the risk management process could be executed, to ensure transparency of the resulting decisions and their rationale and justification.
4. Reflect on experience with 1 to 3 after 6-12 months and discuss at first meeting in 2014; review progress and action plan.
5. Outputs from 4 to inform a written approach to the Commission in line with recommendation 5(ii) in the report.

(ii) Wider engagement to promote debate and development of tools and approaches

6. Promote wider debate through publication and discussion of the WG report in the scientific literature
7. HoA WG to organise discussion (e.g. in a workshop/seminar) of the report in the wider context of risk communication and management, with researchers in these fields, to further develop the scientific bases for and approaches to risk management.
8. Engage with the European Parliament informal Working Group on Risk to share information and identify opportunities/actions to promote and develop tools and approaches:
 - WG to Circulate information on the EP Working Group to HoA
 - HoA to invite a representative of the EP WG to a future meeting of HoA to describe the work and discuss collaboration with HoA.
9. HoA to reflect principles in approach to Codex discussions nationally and in input to the formulation of EU position.
10. HoA WG to engage with third countries to publicise HoA report, share experience on issues and approaches and identify opportunities to develop further.
 - Initial suggestions for contact: EFSA, Codex, national agencies in Australia, New Zealand, USA, Canada
 - Invite HoA to suggest further contacts and/or highlight any relevant work in other countries

Co-ordination

The WG will help to co-ordinate the different activities and sharing of information, take a lead on engagement more widely, and where necessary discuss specific issues in more detail before reporting back to HoA.