ACM/1049

ADVISORY COMMITTEE ON THE MICROBIOLOGICAL SAFETY OF FOOD

ACMSF APPROACHES TO MICROBIOLOGICAL RISK ASSESSMENT: PROPOSED FRAMEWORK FOR FUTURE WORKING

Introduction

1. At the last ACMSF meeting members expressed an interest in clarifying the committee's approach to risk assessment and to consider whether a more formal process was needed to assist the committee in conducting its work in this area. The accompanying paper ACM/1049a provides background information on the way in which the committee considers technical issues and the situations where risk assessment is currently used. The present paper sets out proposals to address some of the issues concerning risk assessment policy highlighted in the background paper.

2. The Committee's views are sought on whether the following framework offers a way forward for future working in this area and to comment on any other risk assessment issues which remain to be resolved and are likely to impact on future work of the committee. As indicated in the background paper the FSA is updating its Science Checklist and the Good Practice Guidelines for SACs and is also planning to produce a statement to clarify the Agency's approach to risk assessment and risk management. This is scheduled for discussion by GACS in March 2012 and by the FSA Board in July 2012. The committee will be kept informed about the outcome of these discussions.

3. The committee's main activities are producing or reviewing work and this includes risk assessment as well other technical reports and studies. It is proposed that technical assessments undertaken by the committee including some working group reports, surveys, reviews and ad hoc requests should continue to be undertaken as they are now unless the request is specifically to assess the level of risk.

4. Key considerations for risk assessment policy covering the committee's work are

    a) ensuring clarity around the framing of risk assessment questions
    b) undertaking risk assessments according to a framework and,
    c) ensuring clarity in the way that outputs of risk assessment are presented.

    To ensure consistency it is anticipated that the same approach should apply whenever a risk assessment is undertaken. .

Risk assessment questions

5. The interface between risk assessment and risk management is important. This is particularly so in the framing of questions including the statement of purpose for risk assessors and in ensuring that there is a common understanding about how the outputs of a assessment will be presented. Whenever a risk assessment is to be undertaken by the committee, a working group or an *ad hoc* group or the

risk assessment is to be presented to the committee by FSA scientists or another body then the question should be discussed with the appropriate risk managers to ensure that there is clarity and common understanding before any work begins. When the committee, working group or *ad hoc* group is asked to undertake a risk assessment, then the risk manager will usually be the FSA or another body. In the case of the FSA presenting a risk assessment to the committee, working group or *ad hoc* group for comment or endorsement, then the risk manager will usually be policy colleagues or incident managers in the FSA.

Risk assessment framework

6. The recent paper on *M.bovis* (ACM/1047a,b) was well received by the committee as a structured approach to setting out a formal risk assessment by addressing the key elements of the risk assessment process namely hazard identification, exposure assessment, hazard characterisation and risk characterisation (EC1998; CAC 1999). The tabular format (unpopulated) is presented in Annex A with the descriptors slightly amended from the version in the *M.bovis* paper. It is proposed that the committee adopts this approach for future work when a risk assessment is being undertaken by the committee, working group or ad hoc group. It should also be followed when a risk assessment is prepared by the FSA or another body for consideration by ACMSF. Whilst the nature of each risk assessment will be different with respect to scope, available information and whether the assessment is qualitative, semi-quantitative or quantitative, adopting this framework will ensure a greater consistency of approach in assessing risk.

Risk assessment outputs

7. The types of risk assessment output (qualitative descriptors, semi-quantitative, quantitative) and the way in which these are presented are important considerations for those involved in risk assessment, risk management and risk communication. Variability, uncertainty and assumptions should be recognised in any risk assessment and should be taken into account in the risk assessment output.

Next steps

8. Further consideration needs to be given as to how risk estimates are described and presented and it is proposed that a paper on this topic be presented to the committee at a future meeting to inform the approach in this area.

References

Codex Alimentarius Commission (1999). Principles and guidelines for the conduct of microbiological risk assessment, CAC/GL 30-1999.

European Commission (1998). Principles for the development of risk assessment of microbiological hazards under directive 93/43/EEC concerning the hygiene of foodstuffs. Office for official publications of the European Communities. ISBN 92-828-1871-3.

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Annex A. Proposed tabular framework to follow for microbiological risk assessments prepared for or produced by ACMSF. Adapted from EC (1998) and CAC (1999).

1.0	**Statement of purpose** (*The specific purpose of the risk assessment*)
2.0	**Hazard Identification** (*A description of the nature of the hazard e.g. microorganism/toxin/trait capable of causing adverse health effects and the food(s) of concern*)
3.0	**Hazard Characterisation** (*A description of the qualitative and /or quantitative evaluation of potential adverse health effects attributable to the specific hazard, the mechanisms by which it exerts its effects, and the associated dose-response relationship*)
4.0	**Exposure Assessment** (*the qualitative and/or quantitative evaluation of the likely intake of the hazard via food*)
5.0	**Risk Characterisation** (*The process of determining the qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on information from the hazard identification, exposure assessment and hazard characterisation*)

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BACKGROUND PAPER

Purpose

1. This background paper seeks to provide an overview of the way in which scientific issues are currently examined by the committee together with wider aspects concerning the application of risk assessment. The paper does not propose a definitive framework for how the committee should undertake risk assessment or how risk estimates and attendant uncertainties should be presented. These aspects are considered further in ACM/1049 as part of a proposed framework for future risk assessment work by the committee.

Scope

2. The paper briefly considers the components of microbiological risk assessment, the relationship to risk management and risk communication and examples of risk assessment being application internationally. The committee's terms of reference (TOR) is considered, how it relates to assessing risk and how it compares to other Scientific Advisory Committees (SACs). The paper provides examples of the different situations in which technical issues are presented to or developed by ACMSF (e.g. committee, working group, ad hoc requests) and the extent to which these involve risk assessment. The role of the General Advisory Committee on Science (GACS) is considered in relation to the provision of guidance in this area for SACs and finally the resource considerations in relation to undertaking risk assessment. These areas should be considered together with the proposals in ACM/1049.

Microbiological Risk Assessment (MRA)

3. Risk assessment is one of the three components of risk analysis the others being risk management and risk communication (CAC 2007a). Whilst it is expected that there should be a functional separation between risk assessment and risk management, interaction between these processes is essential for framing risk assessment questions, interpreting the outputs of risk assessment and in assessing the impact of different risk management options on risk (FAO/WHO 2006). Risk communication in the formal sense usually relates to the presentation of the risk assessment outputs (risk estimate, uncertainties) with the risk management option(s) such as in public messages. However, communication in the broad sense should run seamlessly throughout the risk assessment and risk management processes encompassing evidence gathering, stakeholder engagement as well as in presenting outputs and reviewing and updating risk assessments.

4. Assessing risk is a key function of many scientific committees both nationally (SACs) and internationally (EFSA, WHO/FAO) but the approach taken can vary. Risk assessment is a scientific process usually comprising the four stages of

hazard identification, hazard characterisation, exposure assessment and risk characterisation (CAC 2007a). In the food safety area these have been clearly defined and set out in formal structures at the international level through activities and publications by bodies such as the European Commission, Codex Alimentarius Commission, the Food and Agriculture Organisation and World Health Organisation (EC 1998; CAC 1999; 2007a, b).

5. The Codex documents on microbiological risk assessment and microbiological risk management illustrate the complexity of these processes and articulate the frameworks within which these processes operate (CAC 1999; 2007b). There are an increasing number of microbiological risk assessments conducted at the international level and many using the Codex framework. In the food microbiology area examples of international risk assessments include the FAO/WHO series undertaken by the Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment (JEMRA). These began in 2000 in response to requests from the Codex Alimentarius Commission and FAO and WHO Member Countries and the increasing need for risk based scientific advice on microbiological food safety issues to inform the development of risk management (http://www.fao.org/ag/agn/agns/jemra_index_en.asp).

6. Like ACMSF working group reports the risk assessments in this area tend to be longer term pieces of work running over many months to several years. An important consideration is how risk assessment can be addressed where the timescale is shorter whilst ensuring that the risk assessment is robust and fit for purpose.

7. The term risk profile is often used in the food microbiology area but it is not always clear what is intended by this term or how a risk profile should be undertaken or used. Within the Codex Alimentarius Commission a microbiological risk profile is a concise description of a food safety problem and its context including potential risk management options and the food safety context (CAC 2007b). Within the Codex process a risk profile is often used as part of the supporting evidence for commissioning a microbiological risk assessment and is perhaps akin to undertaking a pilot study.

Terms of reference

8. The terms of reference (TOR) is important in framing the scope of a committee's work area and in the context of the current paper the extent to which it covers risk assessment. The current TOR of ACMSF is "*to assess the risk to humans of microorganisms which are used, or occur, in or on food, and to advise the Food Standards Agency on any matters relating to the microbiological safety of food.*" Apart from reporting changes, the TOR has changed very little from when the committee was established in 1990. Assessing risk is clearly a core part of the committee's' work but the TOR also recognises that the committee will provide advice on "*any matters relating to the microbiological safety of food".* This is helpful as it enables the committee to comment on a wide range of microbiological safety issues on which the FSA seeks a technical view. These issues have probably formed the bulk of the committee's work over the past 20 years.

9. Whilst risk assessment is seen as the main task of the Agency's SACs the level of detail in the TOR with respect to assessing risk varies between SACs. For example, the Committee on Toxicology (COT) has a detailed TOR concerning its role in risk assessment "*To assess and advise on the toxic risk to man of substances…."* and setting out the types of substance and situations on which it will provides an assessment. Contrastingly the Advisory Committee on Animal Feedingstuffs (ACAF) has adopted a shorter TOR "to *advise….on the safety and use of animal feeds and feeding practices, with particular emphasis on protecting human health and with reference to new technical developments*"

10. If the ACMSF wishes to adopt a more formalised approach to assessing risk then a clear framework as to how such assessments should be undertaken and proposal for this are addressed in paper ACM/1049. In this respect it may be timely for the Committee's TOR to be revisited to make sure that they fully reflect the nature of the committee's work going forward.

Risk assessments presented to the committee by the FSA

11. The work presented to ACMSF from the FSA takes many forms ranging from commenting on FSA funded research and surveys, raising the awareness of the committee to new or ongoing issues, specific requests for an opinion on an issue concerning microbiological safety or seeking a view on an assessment made by another body. Where specific risk assessments are undertaken a key aspect has been to focus the outputs of the risk assessment more clearly both in terms of articulating the right language and acknowledging assumptions and attendant uncertainties associated with the assessment. The purpose of the *Mycobacterium bovis* risk assessment (ACM/1047a,b) recently considered by the committee was:

    - To assess the potential for unpasteurised milk and milk products contaminated with *Mycobacterium bovis* to enter the food chain

    - To assess the risk to consumers associated with these products

    - To assess whether the risk has changed in light of the increase in *M. bovis* infection in cattle in the UK

12. The format followed the classical risk assessment format in a tabular layout addressing hazard identification, exposure assessment, hazard characterisation and risk characterisation. Such a format helps to convey the extent of the available information (or lack of it) and any assumptions or uncertainties associated with the estimate or components contributing to it. Whilst the format has worked well with the *M.bovis* example, the approach needs to be tried with different hazard/food combinations. In addition there are important resource considerations recognising that the approach may not be appropriate where there are significant time constraints in providing an assessment of risk.

Risk assessments presented to the committee by bodies other than the FSA

13. Whilst many of the papers presented to the committee are prepared by the FSA other organisations (e.g. DEFRA, HPA, and WRAP) have also presented papers

to the committee. In many cases these have been for information. Not all of have been intended to focus specifically on assessing risk but where they do, they may be framed in a different way to that which the committee is used to. One option is that organisations presenting a paper on an issue for which an assessment or peer review of risk is being requested should follow a standard format wherever possible. Paper ACM/1049 seeks to address this by bringing such assessment into line through adopting a common framework.

ACMSF working groups and reports

14. An important part of the Committee's work is undertaken by working groups which have addressed a diverse range of issues over the past 20 years. Most of these working groups have been ad hoc in nature conducting their work over a few months up to several years depending on the topic. The Committee also has ongoing working groups covering food surveillance and emerging pathogens. The membership of working groups is drawn from the committee and supplemented with co-opted members who tend to be specialists in the topic under consideration.

15. The outputs of the working groups form a core area of business for the committee and the reports produced over the years have been well received with working groups addressing relatively narrow topics (e.g. cooking of burgers, botulism in cattle) as well as much broader subject areas (*Campylobacter*, antibiotic resistance). The reports produced often cover the topic under consideration in a comprehensive way but essentially are scientific assessments of the situation or risk profiles (e.g. *Toxoplasma*) rather than risk assessments *per se,* at least in the formal sense. Some of these reports have included, refer to or recommend more formal elements of risk assessment (e.g. second report on *Salmonella* in eggs, minimally processed baby foods).

16. The terms of reference for working groups have an important role in defining the anticipated outputs. Whilst these may include key elements which relate to assessing risk, many of the reports have touched on risk management issues including through the framing of some conclusions and recommendations. Such recommendations have helped to set the committees work in a wider context as well as aiding risk managers in prioritising and selecting risk management options.

17. The recent shift by the committee to place a greater emphasis on risk assessment suggests that the approach taken to tasks considered by working groups may need to be reviewed to ensure that they meet the needs of the committee. The TOR of the working group should be agreed by the main committee before the work starts. This should include a critical look at the framing of the working group TOR as this will have an impact on the anticipated outcome, which the main committee will need to consider towards the end of the work. The way in which the working group approaches the task should also be considered together with the nature and format of the outputs and attendant uncertainties.

Ad hoc requests

18. The FSA deal with a large number of microbiological incidents each year (271 in 2010) and whilst these vary considerably in scale and complexity, in most cases they are dealt with without the need to seek an independent view on the science. However, on a couple of occasions over the past 6 years the ACMSF has been asked by the FSA to comment on technical aspects to help inform an assessment of the situation. Whilst the nature of what the committee is asked to examine will vary, key elements are the robustness of the information provided and the extent to which it informs an assessment of the level of risk. .

19. Examples have included various data relating to an incident involving *Salmonella* contamination of chocolate in 2006 and a case control study of *E.coli* O157 PT8 infection in people in 2011. In both cases the timing was such that the issue needed to be addressed quickly by a small group of committee members including the chair. In the case of the *Salmonella* and chocolate incident an ACMSF *Salmonella* contact group was established and an *ad hoc* meeting was held at short notice to consider the information and provide timely feedback to the FSA. For consideration of the *E.coli* O157 PT8 case control study participating members communicated via E-mail.

20. It is envisaged that the FSA may need to consult the committee more frequently with such *ad hoc* requests in the future. Because of the *ad hoc* nature and potential urgency of requests it may not always be feasible to involve the entire committee. It is anticipated that the chair would always be involved in dealing with *ad hoc* requests. They would be consulted on the composition of any *ad hoc* group, taking into account the nature of the issue and the type of expertise required. Subject to the status of any ongoing investigations the intention is for the full committee to be informed about the outcome or progress with the work at the next plenary meeting of the Committee. With respect to the work undertaken by *ad hoc* groups this will mostly involve commenting on the robustness of technical information or reviewing a risk assessment or aspects of it. It is envisaged that risk assessment work will fall under the framework in ACM/1049.

Aspects of the committee's work not explicitly assessing risk

21. The committee receives regular updates from the FSA and is requested to comment on a wide range of issues within the interests of the committee. These include updates from the Epidemiology of Foodborne Infections Group, research findings from FSA funded work, reports of FSA funded surveys, reports of other scientific committees and significant outbreaks or incidents. From time to time the committee is also asked to comment on strategic issues such as the foodborne disease reduction work in support of the FSA's strategic plan 2010-2015. Although these topics do not specifically request an assessment of risk, information gleaned from them does assist the committee as part of an overall situation assessment and horizon scanning. An important consideration is the extent to which any comments made by the committee in these areas might be interpreted as risk management options or recommendations. If information from such activities leads to the need for a risk assessment being identified then the proposed framework suggested in ACM/1049 should be followed.

Advice on governance of risk assessment and risk management from the General Advisory Committee on Science (GACS)

22. The GACS provides independent challenge and advice to the FSA on the FSA's governance and use of science. At its fourth meeting GACS agreed to set up a working group on risk assessment/risk management to:

    a) consider the extent to which the policies and guidance on risk assessment are clear to the Scientific Advisory Committees (SACs) in advising the FSA, and to other stakeholders

    b) consider the extent to which they are observed consistently in practice by the SACs in advising the FSA, and by the FSA in using that advice

    c) recommend to the FSA any changes needed to guidance or procedures

23. GACS considered the working group's final report in March 2011. A copy of the report is provided at Annex A for information. It includes recommendations for the FSA to take into account in reviewing and revising its procedures and guidance in relation to SACs, which GACS endorsed. These include a recommendation that the FSA continues to promote/adopt the principles laid out in the Royal Society/FSA Report (2006) on risk assessment, and that reviews of SACs include an assessment of adherence to those principles. The five principles are that:

    ■ stakeholders and the public (where appropriate) should be consulted on the framing of questions to be put to expert scientific advisory committees;

    ■ a cyclical and iterative process to inform risk assessment, management and communication should be developed;

    ■ assumptions and uncertainty in risk assessment should be acknowledged

    ■ public and stakeholder engagement should be broadened at the different stages of the process, particularly on issues of controversy or high uncertainty; and

    ■ it is important to be clear about your audiences and communicate the things that matter to them

24. GACS also recommended more extensive interchange of information between risk assessors and risk managers; as a minimum, the FSA should ensure that risk assessors should always begin their task with an understanding of the risk management decisions that their assessments will inform.

25. GACS discussed the role of SACs in providing risk management advice. It considered that it could be appropriate for SACs in some circumstances to

advise on issues related to risk management that are within their remit and expertise[1]. For example, and SAC might legitimately be asked to assess the risks associated with different risk management options (including unintended consequences), in what might be a more iterative process.

26. While SAC members also had views in other areas, care was needed in such dialogue not to blur boundaries between the remits of risk assessment and of risk management, or to attach special importance to views of SAC members outside their sphere of expertise.

27. Following this advice, the FSA is updating its Science Checklist and the Good Practice Guidelines for SACs[2] and is also planning to produce a statement to clarify the Agency's approach to risk assessment and risk management. This is scheduled for discussion by GACS in March 2012 and by the FSA Board in July 2012. This will be important information for SACs and will help to ensure a consistent approach in how risk is assessed and its relationship to risk management.

Resource considerations

28. The approach taken to risk assessment can have significant resource implications for the Committee and FSA which can impact on the comprehensiveness, precision and time taken to put the risk assessment together as well as the timeliness of the outcome and its communication. Getting the balance right is important for all those concerned with the risk assessment, risk management and risk communication.

29. Whilst the principles and frameworks for undertaking microbiological risk assessments have been set out, the actual approaches taken may vary depending on the way in which the question is framed and resources available to undertake the assessment. Time considerations can be a key driver with urgency influencing the approach taken. In an incident or crisis situation an assessment may be required in hours or days, committee outputs generally tend to be months to years whereas strategic commissioned risk assessments can take several years to come to fruition.

30. Whilst it is prudent to have a functional separation between risk assessment and risk management interaction between risk assessors and risk managers is clearly important and hence the need for an element of flexibility in the processes involved in these steps. The recent GACS working group on risk assessment/risk management (see Annex A) has suggested that that there should be a more extensive exchange of information between risk assessors and risk managers including providing clarity to risk assessors at the outset of their work about the risk management decision(s) that their risk assessment will inform. This point is highlighted in paper ACM/1049.

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[1] http://gacs.food.gov.uk/gacsmeets/gacs2011/3march11/gacsmins110303
[2] http://www.food.gov.uk/science/researchpolicy/commswork/goodpracticeforsacs

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Annex A

Report from the GACS Working Group on Risk Assessment (RA) and Risk Management (RM) February 2011