GENERAL ADVISORY COMMITTEE ON SCIENCE

PAPER GACS 7-6 For discussion

Agenda item 8 3 March 2011

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

Issue

This paper provides an update from the GACS Working Group on Risk Assessment (RA) and Risk Management (RM) on its work to date.

The Committee is asked to:

- **Consider** the report, and
- **Consider** the conclusions and recommendations set out on page 7

Origin of paper

GACS work plan

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Background

Risk assessment (RA) entails identification and characterisation of the risks associated with a situation or course of action, and of the attendant uncertainties. It is essentially a scientific activity.

Risk management (RM) is the process of deciding between two or more possible courses of action, taking into account the associated risks, costs and benefits and the uncertainties in their assessment. This process requires judgements on the possible outcomes, and it has been argued that such judgements should reflect, or at least take into account, the values of the parties who will be affected by the decision.

There can be advantages in separating RA from RM:

- If the same persons are responsible for both RA and RM in any one instance, their selection and interpretation of scientific evidence in the RA may be coloured by their responsibilities as risk manager with the result that the rationale for the risk management decision is misrepresented. For example, a risk manager who attached great weight to the protection of children from dental caries through fluoridation of drinking water might be more inclined to dismiss or undervalue evidence suggesting a risk of adverse effects from fluoride. As a consequence a decision to fluoridate might appear to be driven simply by weight of scientific evidence when in fact it owed more to the values of the risk manager.
- Scientists who have the expertise to assess the risks associated with a course of action may not be qualified to form judgements also on its benefits and costs.
- The value judgements of scientists who carry out risk assessments may not adequately represent those of the people who will be affected by risk management decisions.

In practice, however, it is impossible entirely to separate RA from RM:-

- It may not be practical to convey accurately all of the detailed nuances of a complex RA to risk managers.
- RA that is conducted without an understanding of the risk managers' perspective may be inefficient (for example, unnecessary effort may be invested in refining estimates of risk to a degree that will not have any bearing on the risk management decision).
- Elements of RM may be implicit in what appears to be a RA activity. For example, judgements as to whether a higher tier of scientific evidence is needed to reduce uncertainties require an understanding of the science, but are essentially risk management decisions.

In September 2009 GACS established a Working Group to undertake a preliminary investigation into the extent to which the distinction between RA and RM was clear in the work of the SACs that advise the Food Standards Agency, and how it was observed in practice.

Terms of Reference of the Working Group

The WG's terms of reference were to consider:-

- The extent to which the policies and guidance on risk assessment are clear to the SACs in advising the Agency and to other stakeholders
- The extent to which they are observed consistently in practice by the SACs in advising the Agency, and by the Agency in using that advice
- To recommend to the Agency any changes needed to guidance or procedures

Pilot Study
The first task was to achieve a sense of the way in which key players interpreted the terms "Risk Assessment (RA)" and "Risk Management (RM)". The main purpose in so doing was to uncover and begin to detail similarities/differences between those interpretations, i.e. appreciate the potential diversity/variety.

A pilot investigation was undertaken comprising a series of audio-recorded interviews with (a) those who chair SACs (b) those who service them (c) members of the WG.

Procedure
The topics listed for inclusion in the interviews were kept to a minimum: definitions/ interpretations of each of RA and RM distinctions between RA and RM, and any difficulties with putting RA and RM into practice.

As is good practice, interviews were to be conducted in stages. Briefly, after completing a small number of interviews, they are transcribed verbatim (the best option), or listened to and summarised if verbatim transcription is not possible. Scrutiny of the first group's content then informs the next batch of interviews, and the procedure is repeated as needed.

Interviews with four key players were completed – amounting to nearly three hours of interview time in total. They were transcribed verbatim/near-verbatim. All details of interviewees were withheld in order to preserve anonymity. However, as arranged from the outset and agreed by those interviewed, the WG had access to the transcripts. Presented below is a brief digest of these four interviews.

Four interviews – a digest
Assembled as a "composite portrait", the interview material is presented to highlight similarities/ differences in interpretations of RA and RM.

Definitions/ interpretations of RA and RM
The following definition of RA, from an early point in one interview, was not contradicted across the interview material:

> '*RA is assessing the likelihood of the risk occurring, so it is a fairly scientific and... involves some level of quantification*.'

While nowhere else was quantification mentioned specifically, in a second definition the concept was enlarged by stressing that RA was tantamount to 'scientific risk assessment.' A more elaborate version began with requiring sufficiently full examination of all aspects of a hazard to make it possible '*to assess the risk associated with that hazard*.'

However, in a yet more developed characterisation it was stated that '*it is situational*' and the definition of RA was approached by referring to the initial question/problem. Thus RA depended on

> *'a well formulated problem – with one or more adverse events or outcomes. The hazard is usually a specific agent or experience, exposure or lack of exposure to which is associated with one or more adverse events: the definition and the practice of hazard characterisation and risk characterisation, incorporating an assessment of potential exposure to a hazard within the general, or specific populations may vary between agencies and advisory bodies both nationally and internationally. However this overall process of Risk Assessment is routinely developed to inform Risk Management. In other words an outcome that might have one or multiple sources or might actually relate to possible outcomes from exposure or lack of exposure to one particular experience or ingredient.*'

RA is a term known to be used in various circumstances. Two examples were mentioned of risk assessments deemed amenable to a '*box ticking exercise*' such as the assessment that might be completed by the Fire Officer inspecting a building or the decision to send staff abroad by an organisation. These contrast with work such as the Agency's in that neither was held to need '*underlying sciences*' to provide

the answers and, correspondingly, neither required any particular training/expertise.

By contrast, no mention was made about expertise required for RM. As with RA, there was, at one level, no contradiction across the interview material about RM, in that it is held to be both based on, and go wider than RA. RM entails taking the results of RA and then deciding whether the risk at issue is acceptable or not. RM may also entail making further decisions, such as limiting the product or item to certain population groups, or to certain circumstances or only if labelled in a certain way. All the information gathered in the RA stage is to be

> '*used by the risk managers in conjunction with other factors they have to take into account to decide what the policy should be in relation to something.*'

'Other factors' mentioned include: the principle of consumer choice; community feeling; proportionality ('*is it a sledgehammer to crack a walnut?*'); priority in relation to other responsibilities; cost; and, procedurally, the inclusion of stakeholders. Dealing with insufficient or outdated data at the RA stage was a special issue for RM, introducing recourse to the precautionary principle. It was, however, noted in one instance that budget constraints meant that '*we can't afford to put any more precautionary effort into (example under discussion).*' Though such factors can be presented in a simple list, discussions implied that '*risk management... can itself also be quite complicated in developing policy and practice*.'

Distinctions between RA and RM

Although it is possible, as in the previous section, to select separate definitions of RA and RM from the material, in practice interviewees talking about one tended to include talking about the other. For instance, when asked to talk about RM, one interviewee replied

> *'risk management would really involve the testing the practicality and applicability of the advice that has come from... the risk assessors. Engaging with the risk assessors to discuss what their information means'*

There remained an undercurrent of a sort of "compare and contrast" with some aspects of the various distinctions drawn between RA and RM arising in passing. One, for instance, was that ethics was deemed part of RM rather than RA. And, contrary to what one interviewee had recently heard, risk communication (RC) was not to be thought of as a synonym for RM but one option available to those responsible for RM. Another interviewee agreed RC is to be distinguished from RM, adding that

> '*Risk management really does require an engagement with all of whom are likely to be affected by any management decision; i.e. all the stakeholders including manufacturers and consumers (with attention where necessary to those whose interests might need championing and where equality issues might be important). Thus this activity, as well as informing the risk management decisions, should also enable effective strategies for risk communication and implementation of risk management.'*

A further view was that having RM clearly based on RA is held to signal '*that we're at the forefront of scientific knowledge*' a view implicitly predicated on a distinction between them. And a clear separation between RA and RM is underscored in one interpretation, by the former being hard-headed and unemotional, whereas opinion and personal viewpoints can enter into the latter.

Organizational aspects of the way the Agency operates were also raised. When asked, given that many say RA and RM are to be kept separate, how possible and how easy it was in practice, one interviewee declared that it was '*very difficult*.' Dealing with incidents constituted an example where both RA and providing advice to local authorities on management go together. It may not be exactly the same person, but those involved are members of the same team, so '*building up a science*' and '*managing the risks*' takes place at the same time.

However, other reasons for distinguishing between RA and RM were explicitly prescriptive rather than simply descriptive, holding that the two should be kept firmly apart. For instance

> '*Because RA should be something that can be repeated... ask(ing) scientist A and scientist B should come up with*

same answer. RM can't put it to RM A or RM B because... can't get same answer... (so you need to) keep RA and RM separate because people who manage the risks have to be able to be held to account.'

Another reason was to avoid those with a commercial interest being unduly close to policy-making, notably in those instances where the science associated with RA is either funded, or undertaken, by industry. This was considered to be especially the case in the US where

'*decisions about food safety... were heavily driven... by the food industry not politicians, so you can't prevent the RA being done sometimes by industry... they are the ones who fund PhDs in Harvard about the specific subject, have all the scientists working for them... so we wanted to make sure that OK if they are involved in the RA... then at least let's keep them out of the RM, because that would be conflict of interest.*'

Since some agencies are international, having to cater for differences in funding and in other arrangements between nations, keeping to a firm distinction between RA and RM takes on particular significance.

At the same time, even though distinctions between RA and RM are identifiable across the material and their retention considered necessary, an interrelation between the two was also necessary – and the boundary between them described as '*fuzzy*', partly as a result of procedural requirements (e.g. the submission of draft RA for stakeholder scrutiny), partly as a matter of achieving smooth working. There appeared to be agreement across the interviews that the topic for any RA work is to be presented by those responsible for RM (future enquiry would need to check that this is held always to be the case). Indeed, success in RA and RM work was thought to stem from a well-formulated question/problem – one that needed to be set by those responsible for RM since it was they who had to make the decisions at a later stage. Thus, asked whether a lot hangs on the nature of the question, the reply was

'yes I think some people get confused about their role and stray into RM because the questions they have been asked in the beginning haven't been that clear and that leads to misunderstandings as to what their respective roles are. If the risk assessors do want to offer a view maybe there's some value in hearing that view but it shouldn't then be formulated as under the heading of RA...

As part of avoiding the conflict of interest already noted, the science is to be kept independent, which is '*another reason for questions that have to be answered shouldn't be set by risk assessors*

That questions were typically set by those responsible for RM was held not to preclude questions arising from SACs. Some by the nature of their field were considered to some extent to be '*self- starting.*' Equally, it was also held to be important that those responsible for RM '*really should interact with the risk assessors in formulating the problem from the outset*' – a feature considered to be '*often overlooked.*'

So the interrelation is held to require more than a simple, '*linear*' handover to RA followed by another back to RM. '*(T)here has to be a flow backwards and forwards'* which did not always happen. For instance, reporting an observed compartmentalisation (the adverse consequences of persisting '*silo-working*' was also mentioned elsewhere in the material) resulted in one SAC left without knowing – except by chance or with extra effort – what RM decisions had been made on the RA advice they had provided. Underscoring the need for the process to be circular is the additional observation

'...I do believe that once a decision's been made, that information should go back into the risk assessment if necessary. 'Cos sometimes the effect of risk management making a decision based on the data will actually affect that data.'

Once again, though a firm line is drawn between RA and RM, it is still deemed necessary that an engaged working relationship is sustained across it. So even after those responsible for RM have posed a suitably formulated question and the RA has been developed

'*risk management would really involve testing the practicality and applicability of the advice that has come from... the risk assessors. Engaging with the risk assessors to discuss what their information means – and this is really*

coming back to what I was saying just now because if the risk assessors have thought of some of the risk management issues they would be able to talk intelligently about that.'

In effect, those responsible for RA are to know enough, and be able to imagine the issues facing those responsible for RM, as a way of ensuring successful communication between them.

Any difficulties in putting RA and RM into practice

Some difficulties are noted above, but there are others. For instance, asked whether the relation between and RA and RM looks different in different circumstances (ranging, for instance from the situation in which the science is well developed, or RA is implemented in a routine fashion, to those like BSE in which there is insufficient scientific evidence and more work is needed), one interviewee was clear that it does:

'RM decisions will be much harder to make if you've got gaps in your knowledge, gaps in your RA, RM decisions will be harder and... you may be less sure what RM decisions to take because of that lack of knowledge'

Possibly the difficulty mentioned most emphatically across all the interview material revolves around scientists' views and their own position vis à vis RM. Those responsible for RA were held to act in two opposing ways – both of which came in for criticism. In one interview scientists were thought to shy away from anything to do with RM – deemed unhelpful given the need for that flow backwards and forwards. In other interviews reference was made to their going beyond their remit, and not liking to be reminded that they had no responsibility for RM. For instance, when introducing the precautionary principle (and noting that this is an important feature of the whole discussion) an interviewee observed that it is

'*one term that makes people run away. That is really part of RM that's saying we don't know enough about this that this is safe, so we're not going to allow it... better safe than sorry. Again that's I think that's why so many scientists have a problem with that concept because it makes it clear that the ultimate decision isn't theirs...*'

There was also a suggestion that the RA/RM distinction worked best in the case of food safety, essentially a toxicological model, but was harder to put into practice in other fields relevant to the Agency.

Discussion

Our findings echo those of a previous Workshop held jointly by the Royal Society and the Food Standards Agency in 2005.[1] At that Workshop, which involved scientific experts and leading social scientists, two case studies exploring risk assessment were examined. They were the transmission of bovine spongiform encephalopathy (BSE) and the consumption of fish.

To enable more effective risk assessment, and related management and communications processes it was recommended 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.*"

Our pilot study suggests that there remains variation in the extent to which these recommendations have been implemented.

Conclusions and recommendations

Given that it is unrealistic to separate risk assessment from risk management completely, the aim should be to optimise the degree of separation according to circumstances.

The best outcomes require more extensive interchange of information between risk assessors and risk managers. As a minimum, the Food Standards Agency should ensure that risk assessors should always begin their task with a good understanding of the risk management decisions that their assessments will inform.

We recommend that the Food Standards Agency continues to promote/adopt the principles laid out in the Royal Society Report and that the quinquennial reviews of Scientific Advisory Committees should include an assessment of adherence to those principles.

Reference

1. The Royal Society/Food Standards Agency (2006). Social science insights for risk assessment: findings of a workshop held by the Royal Society and the Food Standards Agency on 30 September 2005. Available at <http://royalsociety.org/uploadedFiles/Royal_Society_Content/Influencing_Policy/Themes_and_Projects/Themes/Governance/fsa_final.pdf> Accessed 14 February 2011.

GACS Working Group on RA and RM
February 2011