Presenting scientific advice on GMOs: Reporting uncertainty and assumptions

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Decision making about genetically modified (GM) organisms has been intensely controversial in Europe. One dimension of the debate has been about the adequacy of scientific information available to inform risk assessments and another the level of risk considered acceptable. This contested nature of the risk assessment of GMOs reflects similar conflicts and pressures on scientific advice in other areas, including BSE, chemicals and climate change. Gaps in knowledge and uncertainty about what is known inevitably leaves judgements to be made about what is and is not acceptable. Because such judgements are not purely scientific, valid questioning arises including about the level of protection desired as well as social and economic issues.

Policy makers in Europe and elsewhere are seeking ways to separate, where possible, political decisions and scientific advice. By doing this, it is hoped that decision making will be improved and public confidence increased, because scientific advice will no longer be considered to be biased towards one interest or another and political responsibility lie properly with the decision makers. To facilitate such a separation, there have been recommendations for scientific advice to be collected and presented differently including by being more transparent, explicit about uncertainties and gaps in knowledge, and open to divergent opinions. These new requirements for how scientific advice should be presented are being implemented through new policy guidelines at national and international level. For example, the UK (which suffered most from mistakes in scientific advice and its interpretation in relation to BSE) now has guidelines on scientific analysis in policy making[1] and a code of practice for scientific advisory committees.[2] The European Union also has a White Paper on EU governance which address the issue and principles and guidance of the collection of expert evidence.[3]

The precautionary principle

In addition, Europe has adopted the precautionary principle to underpin decisions about environmental and human health risks[4] and this has been included in the regulations governing the safety of GMOs - the Food and Feed Regulation (1829/2003) and the Deliberate Release Directive (2001/18). Under the precautionary principle, where serious harm may arise, lack of evidence of harm should not preclude action to prevent harm. Within this, there are judgements to be made about what constitutes a risk of *serious* harm and the amount and quality of data required to make such a decision.

The European Food Safety Authority and GMO risk opinions

The creation of the European Food Safety Authority (EFSA)[5] as an independent source of scientific advice on food matters, including GM food, is intended to address the problems that have arisen over food risks in the past. The EFSA web site (www.efsa.eu.int) describes its mission as being: '.*the keystone of European Union*

(EU) risk assessment regarding food and feed safety. In close collaboration with national authorities and in open consultation with its stakeholders, EFSA provides independent scientific advice and clear communication on existing and emerging risks'. To undertake this task, the EFSA has established a series of scientific advisory panels to provide opinions for the EC, including the Panel on genetically modified organisms, known as the 'GMO panel'.

How well does the GMO panel present its scientific opinions in relation to making uncertainty, gaps in knowledge and assumptions explicit – the fundamental requirements for transparency and efforts to separate the scientific from the political?

The EFSA GMO panel presents its scientific opinions on requests to market GMOs[6] in the same general format which is largely based on the approach to risk assessment laid down in the legislation including:

- *Molecular characterisation* – to establish the stability of the genetic modification, the exact details of the insert, copy number and site of insertion. This is to help determine whether there may be changes in the behaviour of the GMO over time.
- *Comparative analysis* – to establish whether the chemical composition of the GMO is the same as that of a non-GM equivalent. This is used to determine whether there may have been any unintended changes to the GMO as a result of the genetic modification.
- *Food/feed safety assessment* – to determine, for example, whether any new allergens or toxins are present that would harm animals or people eating the GMO.
- *Environmental risk assessment* – to determine whether there may be short or long-term, direct or indirect adverse effects on the environment from, for example, gene flow to wild species, effects on non-target species or biodiversity changes resulting from altered management practices.
- *Post-market environmental monitoring plans* – which covers case-specific monitoring to test assumptions made in the risk assessment and general surveillance for unintended effects.

In each section of the opinion, there is an evaluation of what are determined to be the 'relevant' scientific data and from these the opinion makes conclusions and recommendations. The opinions rely on the risk assessment conducted by the applicant together with any other relevant scientific information the GMO Panel consider relevant.

The EFSA's guidelines to applicants[7] emphasise the need to consider uncertainty and state assumptions. For example, the guidance states that*: 'Risk assessment can be described as "a process of evaluation including the identification of the attendant uncertainties, of the likelihood and severity of an adverse effect(s)/event(s) occurring to man or the environment following exposure under defined conditions to a risk source(s).."'* (p17); and '*The final risk characterisation should result in informed qualitative, and if possible quantitative, guidance to risk managers. It should explain clearly what assumptions have been made during the risk assessment, and what is the nature and magnitude of uncertainties associated with establishing these risks.' (p51)*

Examples of uncertainties in a risk assessment of a GM crop may include:

⇒ the extent to which testing systems to identify allergens are reliable;

⇒ whether all relevant non-target species have been tested for sensitivity to an introduced toxin;
⇒ if data on crop performance covers all the environments that it is likely to be grown in.

Assumptions which might be made include that:
⇒ farmers will identify and report any unexpected findings promptly;
⇒ volunteer weeds will be controlled effectively;
⇒ a certain crop does not support significant levels of biodiversity and so any changes will not be biologically important.

However, in the twenty opinions published in relation to the risk assessments for applications to market GMOs published since August 2004, there is not a single reference to 'uncertainty' or 'uncertainties'.[8] There are occasional references to 'assume' or 'assumptions', usually when making reference to the requirement for these to be addressed in monitoring plans under Directive 2001/18, but not in any systematic or substantial way.

Therefore, in presenting their advice to decision makers, the EFSA GMO panel is failing to make any information available about their views of the uncertainties and assumptions inherent in the risk assessment and the implications of them. It is possible that the GMO Panel has made its own internal assessment of the uncertainties and validity of the assumptions, but because this is not included in the opinion, the process is far from transparent and decisions about the acceptability of risk may be being made in a manner that is not acceptable to member states.

A new approach – making uncertainties and assumptions clear
In preparing its opinions, the EFSA GMO Panel is using an approach that has been the norm in the past. So while it is disappointing, it is not surprising that uncertainty and assumptions are not being made explicit. However, GeneWatch believes that a new format for the preparation of the GMO panel's opinions is possible that draws on the model adopted in the UK's GM Science Review Panel's report in 2003 as part of the national debate on GM.[9] Here the framework for the review included:

- the range of views and quality of evidence;
- whether there is general scientific agreement;
- whether there are gaps in our knowledge or scientific uncertainties and how these are important;
- the potential way forward where there is recognised scientific uncertainty (such as more research or management methods)

This approach could be adapted and applied to the opinions of the GMO panel by adopting the following format under each section (molecular chacterisation; comparative analysis etc):

- A review of the information and its quality including:
  ⇒ methodological issues (such as whether data arise from field or laboratory studies and the statistical power - could the experiment actually detect the effect it is seeking to find?);
  ⇒ identification of where disagreement arises together with a review of why it has arisen and its implications.
- What uncertainties and gaps in knowledge exist together with an explanation of their importance and whether or not they could be, or need to be, the subject of further research.

- The panel's view of the overall risk in each area including an explanation of the assumptions and reasoning used in coming to their conclusion. This should include assumptions and reasoning made about physical environments (e.g. that acquisition of a gene will not give a competitive advantage in the anticipated environments) and also individual and institutional behaviour (e.g. that farmers will identify adverse effects) in relation to compliance with regulations and guidelines.
- Recommended risk management measures and monitoring to prevent possible adverse effects arising, verify assumptions and improve knowledge.

If such a system were adopted, the advice that would be provided to decision makers would be much more scientifically rigorous and transparent about the inevitable uncertainties and assumptions. As a result, following its use, there would be greater clarity about how scientific evidence and assumptions had inform political decisions about the risks involved.

References

[1] HM Government (2005) Guidelines on scientific analysis in policy making. http://www.ost.gov.uk/policy/advice/guidelines_2005.htm

[2] Office of Science and Technology (2001) Code of practice for scientific advisory committees. Department of Trade and Industry: London. http://www.ost.gov.uk/policy/advice/copsac/index.htm

[3] Commission of the European Communities (2002) Communication from the Commission on the collection and use of expertise by the commission: principles and guidelines. COM(2002) 713 final. http://europa.eu.int/eur-lex/en/com/cnc/2002/com2002_0713en01.pdf

[4] Commission of the European Communities (2001) European governance. A white paper. COM(2001) 428 final. http://europa.eu.int/eur-lex/en/com/cnc/2001/com2001_0428en01.pdf

[5] Regulation (EC) No 178/2002 of the European Parliament and of the Council, 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

[6] Opinions of the Scientific Panel on genetically modified organisms [GMO]. http://www.efsa.eu.int/science/gmo/gmo_opinions/catindex_en.html

[7] Guidance document of the scientific panel on genetically modified organisms for the risk assessment of genetically modified plants and derived food and feed. November 2004 http://www.efsa.eu.int/science/gmo/gmo_guidance/660/guidance_docfinal1.pdf

[8] Searches were conducted of each opinion using the Adobe Acrobat document search function.

[9] GM Science Review Panel (2003) GM science review. First report. http://www.gmsciencedebate.org.uk/report/default.htm

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