



GM FOOD SAFETY: FACTS, UNCERTAINTIES, AND ASSESSMENT

*The OECD Edinburgh Conference on the Scientific and Health*

*Aspects of Genetically Modified Foods*

*28 February - 1 March 2000*

## **RAPPORTEURS' SUMMARY**

LA SÉCURITÉ DES ALIMENTS GÉNÉTIQUEMENT MODIFIÉS :

FAITS, INCERTITUDES ET ÉVALUATION

*Conférence OCDE d'Edimbourg sur les aspects scientifiques et sanitaires des  
aliments génétiquement modifiés*

*28 février - 1er mars 2000*



*This report reports the views of the two rapporteurs on common ground emerging during the conference, both on matters of substance and on how to move debate forward.*

1. The Conference drew together 400 participants from a variety of backgrounds. The aim was to identify common ground on whether and how applications of GM technologies in the food and crops sector serve the needs of society. This report concentrates on developing this common ground.
2. The focus is the safety of the tens of GM crops now in use for food. Environmental impacts, trade and developmental effects, ethical and societal concerns were not considered at length, but could not altogether be separated or hierarchically ordered. However, the various issues need to be addressed separately if they are to be analytically tractable.
3. The conference critically assessed – from the various perspectives represented – different approaches to assessment of the risks and benefits of GM food. A strong sense emerged that there was a need to take steps to rebuild trust among the various actors, particularly governments, industry, scientists, regulatory agencies and the public.

## **SUMMARY RESULTS OF THE CONFERENCE**

4. There were a significant number of points on which there was general agreement amongst the majority if not all of the participants. Unsurprisingly, there were also many issues where opposing views were put. In some cases, these were a result of different interpretations of the available evidence; in others, disagreement was more fundamental. Finally, there were points where there was neither clear agreement nor disagreement, since there is currently a lack of knowledge.

## **POINTS OF AGREEMENT**

- In considering how society deals with GM food, the circle of debate needs to be widened, including bringing in workers in laboratories, factories, farms, etc. The debate needs to become more open, transparent and inclusive. Openness and transparency are also required in the policy process. The general public – consumers and citizens – not only have the right to know, but they also have valid points of view, which need to be effectively voiced, understood, and given their due weight in the decision-making and policy process.
- Many consumers already eat GM foods, though they do not necessarily know they are doing so. No peer-reviewed scientific article has yet appeared which reports adverse effects on human health as a consequence of eating GM food.
- The concept and practice of assessment of risk – including a consistent international approach to the use of the concept of substantial equivalence and to a form of the precautionary approach – have been valuable tools, and should remain so – so long as they continue to be kept under regular open review.

- Benefits as well as risks posed by GM foods should be evaluated. GM foods have the clear potential to bring real benefits to developing countries. However, that potential has yet fully to be realised and will only be so if the technology is put to use under appropriate conditions. Population growth and poverty are real challenges for global food production, both in terms of quality and quantity of food. But GM biotechnology will not be the whole answer to increasing demands for food; it can only be a part of it.
- Consumers in industrialised countries have yet to appreciate benefits from the first generation of GM food products. Benefits might include reduced food prices and, in some cases, health benefits – for example, reduced rates of use of pesticides or carcinogenic compounds by farmers. There has, however, been no quantification of tangible benefits to consumers as yet. So-called “second generation” GM food products will offer more tangible potential health benefits. Past experience teaches important lessons on how to conduct the debate in the future.
- The continued use of antibiotic resistance marker genes in GM food crops is unnecessary given the existence of adequate alternatives, and should be phased out. There was broad consensus not to use technologies that deliberately render seeds sterile if farmers – particularly in least developed countries – do not have a realistic choice about which seed varieties they can use. However, the use of “terminator” genes for the purpose of genetic containment was widely acknowledged as a useful safety measure.
- Partnerships between the public and the private sector must develop further if the potential benefits of GM food are to be delivered to those who most need them. These should seek to combine public and private investment, technical know-how, technology transfer and local knowledge.
- Consumers need to be able to exercise choice; for this they need information on the way products have been manufactured. Almost all participants recognised the value of labelling in enabling consumer choice.

### **POINTS OF DISAGREEMENT**

- Some participants regard human health aspects of GM foods as inseparable from wider issues, like impact on the environment, trade and socio-economic factors and people’s belief systems. Others favour distinct and specific ways of assessing the various potential impacts.
- Some see genetic modification as part of a continuum in the development of tools for plant breeding. For them, GM is just another step in the process, albeit a powerful one. Others see genetic modification as a fundamental change in the way new crops are produced. For them, this fundamental difference necessitates new ways of assessing safety.
- There is disagreement whether GM foods in animal feed presents a problem either for animal or human health.

- There is no consensus as yet on the level of agency at which risks and benefits of GM food should be decided. While some would favour a global framework for developing, marketing and using GM technologies and the products based thereon, others adhere strongly to national sovereignty and to making their own judgements on risks and benefits. There is equally disagreement about whether GM crops have a role in global agriculture in the long term.
- There is as yet no agreement on the detailed process of assessing consumer concerns about GM foods.
- The need for traceability of GM material is controversial. Some consider it a necessary complement to *a priori* risk assessment. Others claim that risk assessment can be sufficiently improved so as to avoid post-market monitoring (the practicalities of which are uncertain).

### **CURRENT LACK OF KNOWLEDGE**

- While there seems to be agreement that the social process of risk handling needs to be “open, transparent and inclusive” and should clearly acknowledge scientific uncertainties and take into account the validity of social concerns, there is no consensus on how this should be done in practice.
- There remains uncertainty about the potential long-term effects of GM food on human health and on worker safety (as a result of exposure during production).
- Current methods for testing toxicity and allergenicity (for example the potential for unknown allergens to be transferred between species during genetic modification) leave some uncertainties and need to be improved.
- There is still uncertainty over long-term environmental effects, potential complex ecological interactions and impacts on biodiversity. The impact in tropical zones is particularly uncertain, as most field trials have been carried out in temperate zones.
- Though feeding trials in animals may in some cases offer supplementary safety guarantees, it is unclear whether for GM foods they will be applicable or useful.

### **A POSSIBLE WAY FORWARD**

5. To tease out the issues and present them in a coherent form, the key points raised are discussed under the following headings:

- **Benefits versus risks:** this describes the consensus emerging from the conference that the benefits of GM food needed to be considered as well as the risks.

- **Management of GM technologies:** this presents a synthesis of the participants' views on managing risks from GM foods.
- **The role of stakeholders:** this describes how stakeholders can move forward together.
- **An international programme** as a potential way forward.

### **Benefits versus risks: a first balance**

6. The trade-off between benefits and risks for any one GM food may vary across different regions of the world and between different economies – from least developed countries, to emerging economies, to countries in transition, and to fully industrialised countries. Within regions the balance may be different for different segments of the population. For the least developed countries in particular more food of improved nutritional quality will be needed as population growth continues. Distribution problems are real, as are post-harvest losses. But it is not realistic to assume that a strategy that does not incorporate increased local production of cheap food for consumers will work.

7. In judging new technologies one should also bear in mind that the potential of present-day agriculture to meet future demands is under strain. The area of available arable land is decreasing with urban development, and productivity growth is levelling off (partly due to the diminishing potential of “traditional” breeding technologies). GM technologies, if developed under appropriate conditions, offer the potential of providing solutions, though it should be clear that GM technologies, and biotechnology as such, can only be part of a range of answers to the problem of providing sufficient food of the necessary nutritional quality to the developing world. Policy measures are needed in a whole range of domains. GM technology should not take the place of efforts to eradicate the sources of poverty.

8. GM food-based oral vaccines and nutritional supplements offer potentially great benefits. Though other technologies may be available, biotechnology potentially offers more practical and affordable options for least developed countries in the short and medium term. To deliver on this may require a redirection of research and development efforts, so that the needs of developing countries are given a higher priority. This does not imply that on the individual or the societal level the judgements about what might constitute “acceptable” risks need be different. If developing countries are to choose to use GM technologies, strict safety procedures are in every way as necessary for them as for the industrialised world, and special efforts will be required by all countries to ensure the capacity exists for risk analysis to be carried out in the context of the countries using the GM product. But in the end the balance of benefits and risks may result in different decisions in various societies.

9. For highly industrialised countries the core issues are different. Producers are concerned with efficiency gains and corporate profits – but also with reduced environmental stress. However, tangible benefits to consumers, which should come through lower prices, reduced health risks (owing to less exposure to pesticides or carcinogenic chemicals) or improved health, are generally perceived to be small. The exception may be when GM foods address special dietary problems of specific segments of the population. The potential for developing nutrient-fortified foods and edible vaccines to increase the resistance of elderly people to infectious disease is a case in point. The question remains unanswered of how safety

of such products (e.g. “nutraceuticals”) should be assessed – in particular, whether this should be more akin to assessment of pharmaceuticals than of novel foods.

10. There was almost complete consensus that consumers in all parts of the world should (where possible) have the opportunity to exercise choice on whether or not to consume GM foods. Mandatory labelling was widely, but not comprehensively, supported as a means to help achieve this.

11. Though labelling might allow choice, it would not in itself help answer the question whether there were long-term impacts of GM food – beneficial or detrimental – on human health. Appropriate testing and monitoring measures would be necessary for this purpose. Further investigation is needed on the need for and the practicalities of tracing GM food products throughout the food chain.

12. A differentiated approach is also required to tease out the possible impacts of GM food and crops on the sustainability of ecosystems as well as more generally on societies and economies (including concerns about, for example, the structure of agriculture and the future of rural areas, or about market concentration in the biotechnology industry). Assessing impact on, in particular, the sustainability of ecosystems requires long-term data collection, which is not *per se* yet available. Meaningful comparisons need to be made with traditional varieties of crops. Impacts will by definition be different for different countries or regions. The issue does need to be studied further and would benefit from long-term study programmes.

### **Management of GM technologies**

13. We cannot rule out all risk for all eternity for any area of human activity. The challenge is to take a sufficiently precautionary approach to investigating scientifically risks that may occur. We need to communicate effectively in our societies about these assessments. We need to be clear about how we decide about acceptability. And we need systems in place, trusted by citizens, for managing risks that encompass those measures that become effective after decisions on acceptability have been taken.

14. There is, of course, a need to constantly remain vigilant. As every new technology is based on harnessing different aspects of nature in varying combinations, testing techniques and protocols need to be addressed regularly and developed further as appropriate. But, in making an assessment of risks and benefits, novel products and their production technologies should be compared with products of existing technologies and not just looked at in absolute terms.

15. The present situation can be summarised as follows. With regard to health issues, tests on toxicity and allergenicity have been and are being conducted. So far none has shown significant toxic or allergenic harm. No peer-reviewed article on clinical trials or epidemiological study reporting adverse effects on human health has yet appeared. Where there have been indications of potential unacceptable effects, the present mechanisms have enabled us to identify them and prevent such products coming to the market. Yet the example of the current uncertainty about whether genetic modification could lead to the transfer of unknown allergens demonstrates the need to be alert and continually to refine protocols.

16. It is recognised that a large number of field trials of GM crops have taken place without apparent adverse effects and this suggests that we may be able to manage the risks at least under the specific conditions encountered. However, though the majority of trials have been evaluated at least to some extent in terms of safety, evaluation has not followed identical protocols and most trials have been carried out in temperate zones. There is a need to improve the monitoring of such trials and to do more work on pre-release assessment of new as well as existing crops. This needs to be done in environments in which GM crops are to be grown.

17. Views differ as to whether modern GM technologies are simply yet another stage in the progress of approaches available for genetic transfer. Some see GM technology as the most recent point on the continuum of development from the earliest breeding technologies through breeding assisted by cellular techniques, to modern interventions at the molecular level. Others see GM technology as something fundamentally different from what has gone before. All agree, however, that open, transparent, inclusive systems of risk assessment, management and communication are essential.

18. The systems of risk assessment, management and communication<sup>1</sup> that countries have developed to deal with the safety aspects of food in general and how they are applied have recently come under increased scrutiny. This has not just focused on GM issues and it has been further complicated by the difficulties in disentangling public concerns focused on health and safety issues from environmental, socio-economic and ethical considerations.

19. Both specific assessment methods applied to GM foods and crops and the design of the overall system of assessing, managing and communicating risks have been criticised. Yet, even though there is consensus that risk handling systems need to be improved, evidence to date by way of the responses taken to deal with unexpected consequences showing up in trials and other experiments indicates that actual risk levels have not been increased. In general, experimenters have learnt how to better cope with them. Mechanisms have been developed which appear – so far as we can tell – to have addressed such emerging unexpected events and to have assigned responsibility for dealing with them. Responses have included referring a problem back to science, requiring further testing, and action for regulatory authorities. A case in point is the now general consensus to phase out the use of antibiotic resistance marker genes.

20. The challenge now is to monitor and adapt risk handling systems so that they are able not just to continue to respond to unexpected events and deal with scientific uncertainty, but to handle broader questions that emerge in society about GM foods and crops, in an effort to help to restore confidence in regulatory regimes.

21. If this is to be done, the methods used to appraise possible adverse effects on health and the environment will have to be regularly reviewed and judged to be adequate for their intended purposes. A number of proposals for concrete action came out of the conference:

- Much of the allergenicity and toxicity testing of GM products now done is based on gene products expressed in recombinant micro-organisms rather than in the target crop plant. There is a case for reviewing this practice, and for considering the applicability and usefulness of animal testing as a predictive tool.

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<sup>1</sup> It is generally agreed that these three aspects – assessment, management and communication – are essential for the way societies cope with risks. We use the term “the societal process of risk handling” or just “risk handling” to denote all these aspects.

- Immediate improvement can and should be made to the decision tree in use for testing against allergenicity (which is not specific for GM foods), so as to incorporate *in vivo* and *in vitro* tests.
- There is a need to review the principle of substantial equivalence. The OECD has carried out an ongoing review of the concept over its five years of use, but the conference was of the view that a more fundamental reassessment is necessary. The means for carrying out a transparent review – which should acknowledge the need to include the various interest groups – should be worked out between the various international bodies active in the field. Namely, the new Codex Alimentarius Task Force, the OECD, the FAO and the WHO. Ideally, the review process should be completed and the results widely disseminated within two years.
- The concept of a precautionary approach to risk assessment, recognised in the Cartagena Protocol on Biosafety, has the potential to be worked up into a practical way to accommodate the new approaches consumers, the public at large, special interest groups, and scientists request from a risk assessment and management system.

22. In developing the system of risk analysis, it would be useful to categorise risks according to likelihood. For example, risks might be assigned a probability (where empirical results allow such an estimate), or labelled as hypothetical (where they may exist in theory, but there is no data to assess probability), and designated speculative (where there is no convincing theoretical base, but where further R&D may be warranted).

23. Reviewing methods and principles used in safety assessment should not imply automatically more or tighter regulation. There was wide support for the conclusion that an assessment of the benefits is equally necessary to arrive at final judgements. Regulation should balance the potential risks and benefits of the technologies in the circumstances prevailing in countries or regions of use. It is a policy process in which the costs of regulation also must go into the equation.

24. Variations in health risk assessments may be substantially less than for the environment. Environmental risk/benefit assessment will almost always involve a strong regional or local component. Results may not be completely transferable between one environment and another. Health risk assessment is more universal – and is recognised as such in international approaches to medicine regulation allowing more sharing and consistency of results obtained in different countries. Though consumption patterns may differ significantly, and basic health and nutritional levels vary, in general the same food will have similar impacts on human beings regardless of location.

25. Finally on this issue, the conference concluded that risk analysis systems are only likely to generate public trust if based on transparency, provision of information (on monitoring, research results, etc.), and on greater inclusiveness of the various stakeholders. There then needs to be clarity about how stakeholders' perspectives are taken account of in the policy process.

## **The role of stakeholders**

26. Tackling the issues mentioned above demands a major commitment from governments. Focussing research and development priorities on longer-term domestic and global agricultural needs will be particularly challenging

27. So too will organising a more inclusive public debate on the risks and benefits of new GM technologies. The conference was clear that independent scientific advice – even if it is contrary to the generally accepted view – has a role to play in a fully open process.

28. Both governments and scientists should do more to provide the public with clear, understandable and relevant information. That does not necessarily mean that what scientists say must be taken at face value, or that scientific arguments are the only ones that count when the final decisions are made, but decisions – which are the politicians' business – must be informed by the best available scientific advice. It is also important that scientists work both on internal mechanisms in the scientific community and mechanisms that reach out to the wider public, in order to review the state of scientific knowledge at regular intervals, with the aim of reducing or specifying areas of uncertainty.

29. More open access to information will be essential to convince concerned consumers that there is nothing to hide in making safety assessments of GM foods. Data on safety assessments, on field monitoring, and on post-marketing assessment ought to be made much more widely and easily available than is presently perceived to be the case. This needs to include as much as possible of the extensive data sets held within the private sector. There is a real challenge for industry, academia and government to deliver on this.

30. Many good examples from a variety of countries and regions were put forward at the conference on how to involve the public – whether through interest groups or independently. This practical experience provides a basis for social and natural scientists working together to design better ways of building open, transparent and inclusive processes of analysis and decision-making that might restore public trust. Many groups have legitimate views and experience that should be drawn upon – farmers, for instance, have diverse approaches and concerns in the different global economies.

31. In promoting the public good, governments work routinely with industry. GM technologies in the agricultural domain are recognised as an area where there is much scope for enhanced public-private co-operation. The private sector needs to take part in the debates, as they play a major role in developing and marketing GM technologies. But, as not all development and dissemination of technology, including biotechnology, can or should be carried out under conditions of commercial profit, relying on the private sector alone will not be sufficient to harness the full potential of GM food. There is considerable scope for developing further public-private partnerships.

32. This is also true for risk assessment. Improved sharing of comparable data and risk assessments and co-operative international publicly funded research may contribute to reducing the overall cost burden of effective risk analysis. Rising costs could be expected to act as a driver for industry concentration.

33. For partnerships between the public and private sectors to serve effectively the multiple interests at stake, it will be important to develop a more subtle approach to ownership issues. For example the most appropriate balance between patent rights and plant variety protection rights continues to require careful assessment and consideration. Special exemptions on intellectual property rights protection for crops widely used by farmers and government agencies of developing countries, or more general policies of sharing GM technologies, have been proposed as part of a number of private/public ventures. Ongoing efforts by the appropriate bodies to review current arrangements in order to develop equitable solutions for these concerns should be strongly encouraged. They are essential for reducing the controversies around GM foods and crops. Similarly, issues of liability between companies, farmers, and breeders must be settled.

### **An International Programme as a way ahead**

34. This is an area in which there is already substantial activity by a number of international bodies, including the FAO, the WHO, the OECD, the CGIAR, the ILSI and others. Earlier this year, the Cartagena Protocol on Biosafety was agreed in Montreal. Any new international initiatives must offer added value and complementarity to what is and can be carried out effectively by existing parties and frameworks.

35. At the detailed level, a three-pronged international programme might show collective commitment to action:

- In the light of the urgency of the problem of producing food for a larger population in increasingly smaller areas, many participants referred to the alarming decline of conventional agricultural research. Any effort to harness the potential of GM crops should therefore include a fundamental reconsideration by governments of the level of funding of agricultural research through the existing international frameworks.
- A collaborative and comparative testing programme on health and environmental issues of GM technologies, involving all parties – including farmers – under appropriate conditions, could through its international visibility contribute to viable approaches that then could trickle down to national practices, without involving the transfer of autonomy. For such a programme it would be essential, and feasible given the prevailing consensus on the general framework to be used in the assessment of health effects, to start working on internationally agreed scientific protocols. The development of criteria for environmental risk assessment in different geographical zones is ongoing.
- Participation in such a programme could be linked to training possibilities for professionals and scientists in developing countries, the need for which was repeatedly stressed during the conference.

36. There remains, however, the persistent need for some sort of over-arching international initiative to knit all of these strands – ongoing and proposed – together if the global benefits of this technology are to be maximised and risks minimised.

37. At the very least, the international debate begun at this conference should be continued and broadened in an attempt to inform international policy making. The inherent scientific uncertainties, and the necessary involvement of actors from a broad range of disciplines seeking a way forward together, bears a strong resemblance to the current debate regarding climate change. In that context, the International Panel on Climate Change (IPCC) might provide a possible model.

38. In terms of immediate next steps, if there is political will, a feasibility study into creating an ongoing expert forum for debate of the issues around GM food might quickly be drawn together by the various international organisations and leading countries in this field.

**Edinburgh**  
**March 2000**