

SCIENCE TECHNOLOGY INDUSTRY

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## GENETICALLY MODIFIED FOODS

Widening the Debate on Health  
and Safety

The OECD Edinburgh Conference on the Scientific and  
Health Aspects of  
Genetically Modified Foods

OECD Consultation with  
Non-governmental Organisations on Biotechnology and  
Other Aspects of Food Safety

OECD 

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ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

## ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

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## FOREWORD

This publication contains the contributions of the OECD Directorate for Science, Technology and Industry (DSTI), prepared in response to the request of the G8 Heads of State and Government that the OECD “undertake a study of the implications of biotechnology and other aspects of food safety...” (G8 Summit in Cologne, June 1999).

These DSTI reports are part of the complete OECD response to the G8 request, whose precise terms of reference were defined by the OECD Council in late Autumn 1999. This response consists of five sets of reports, mostly written by committees of officials from Member countries, which were co-ordinated by the Environment Directorate and the Directorate for Food, Agriculture and Fisheries. Mr. Michael Osborne, Head of the Internal Co-ordination Group on Biotechnology, was in charge of overall co-ordination of the OECD response. The complete list of OECD documents submitted to the G8 summit in Okinawa (July 2000) is attached in Annex. The reports are also available on the Web site: [http://www.oecd.org/subject/biotech/g8\\_docs.htm](http://www.oecd.org/subject/biotech/g8_docs.htm).

DSTI responded to particular concerns of the Secretary-General of the OECD, Mr. Donald Johnston, as well as the Council, who recognised that communication with the public and representatives of the many concerned elements of civil society is crucial to promoting progress in the fields of biotechnology and food safety.

The reports published under this cover summarise two consultations with civil society (science, business, industry, agriculture, labour, consumers and environmental activists) as well as a number of developing countries.

The first, the OECD Consultation with Non-Governmental Organisations (NGOs) on Biotechnology and Other Aspects of Food Safety, was held at OECD on 20 November 1999, the second, larger one, the OECD Conference on the Scientific and Health Aspects of Genetically Modified Foods, was held from 28 February-1 March 2000 in Edinburgh, hosted and funded by the Government of the United Kingdom. While these reports (in contrast to the others developed at the OECD) do not necessarily represent the official views of Member

governments, they reflect broader and sometimes conflicting views of civil society, indicate areas of agreement and disagreement, and attempt to show a way forward towards resolving some of the controversies raised by genetically modified foods. The names of participants are shown on the respective Web sites <http://www.oecd.org/subject/biotech/ngoconsultation.htm> and <http://www.oecd.org/subject/biotech/edinburgh.htm>, along with broader information about each event.

Responsible for the programme and organisation of the Consultation with NGOs was Mr. Jean-Éric Aubert. Responsible for the programme and organisation of the Edinburgh Conference, in parallel to the United Kingdom authorities, was Mr. Salomon Wald, Head of the Biotechnology Unit, supported by Mr. Stefan Michalowski, Ms. Johanne Newstead, and others. Ms. Sonia Guiraud and her colleagues provided the indispensable administrative backing for both conferences.

The Chairman's Report on the Edinburgh Conference was written by Sir John Krebs, Oxford, the Rapporteurs' Summary of that conference by Mr. Iain Gillespie, London, and Mr. Peter Tindemans, The Hague.

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# THE OECD EDINBURGH CONFERENCE ON THE SCIENTIFIC AND HEALTH ASPECTS OF GENETICALLY MODIFIED FOODS

## CHAIRMAN'S REPORT

### Introduction

The conference was attended by about 400 invitees from more than 25 countries. Its aim was to be inclusive, and to encourage a wide diversity of views to be expressed both on the platform and in the audience. Each session was organised with short introductory presentations, followed by commentaries from panel discussants before opening the discussion to the audience.

The speakers and panellists were, in approximately equal numbers, proponents of GM, opponents, and those who were essentially neutral. The presenters came from a wide range of developing and developed countries. They were primarily scientists, regulators, NGOs and industry representatives.

The conference focused on GM food safety and human health. In my Introduction, I acknowledged that this was only one part of the debate about GM technology in food and agriculture, which in turn was only part of the debate about the future of biotechnology. Whilst the conference was focused on food safety, which was the primary public and NGO concern in the United Kingdom and elsewhere during the adverse public reaction to GM last year, I did not wish to exclude debate of other issues. These include ethics, environmental safety, economic development, and the ownership of intellectual property.

The conference also focused on the science (including the social science of consumer attitudes) of GM food safety, although I agreed that other non-scientific issues (*e.g.* values and beliefs) come into the debate, and should not be excluded.

The conference was not aimed at producing a simple consensus, but rather at identifying areas of greater agreement, of divergence of opinion, and of uncertainty due to lack of knowledge. Even the very basic question of whether



or not GM technology is fundamentally different from genetic modification through conventional breeding was one on which there was not a consensus amongst the participants.

The conference was divided into three sections:

- What is the science of GM and its potential risks and benefits for food and agriculture?
- What is the science of assessment of food safety, and what, if any, are the special problems posed by GM foods?
- What are the regulatory systems worldwide, and do these require adjusting because of special features of GM foods?

This short summary provides an account of my personal impressions of the conference. A more detailed summary is available in the rapporteurs' report. I have taken into account comments made in the concluding discussion, and afterwards by e-mail and by members of the Steering Committee.

## **Principal conclusions**

### ***Food safety***

Worldwide, many people are eating GM foods (especially in North America and China) with no adverse effects on human health having been reported in the peer-reviewed scientific literature.

There could, in theory, be long-term effects on human health that have not yet been detected because GM foods have been available for less than ten years.

### ***Decision making, assessment and choice***

In the future, policy decisions about GM foods, as well as the assessment of their safety, should be more inclusive and open than has typically been the case in the past. People want to know how decisions have been reached and to be consulted. This process will help to remove suspicion.

Having said this, there was no clear conclusion on how attitudes and beliefs that might become apparent as a result of consultation should be incorporated into the assessment and communication of GM food safety. For many, safety assessment remains an essentially technical and scientific process.

Consumers should be allowed to choose. Labelling of GM foods is important, although there was no agreement on how far this should extend

(e.g. to GM derivatives? To animals fed on GM?). It is important also to note that the labelling applies to the process by which organisms are created and not the food product, which in many cases is identical to its conventional counterpart.

### ***The assessment of GM food safety***

The assessment of the safety of any novel foods, including GM food, involves a variety of kinds of evidence. One commonly used tool is the concept of “substantial equivalence”. The essence of this idea is that a comparison between the novel food and one already in the diet provides the basis for asking questions about the safety of the novel product. Substantial equivalence is not a quantitative criterion or a hurdle, but a framework for thinking. It is continually modified and updated, but it is timely now, after six years of using the tool, to undertake a more detailed review.

On two more technical issues: *i*) there is no clear agreement about the importance of animal feeding trials (other than toxicity trials) in assessing the safety of novel foods, including GM foods; and *ii*) the methods for testing toxicity and allergenicity of GM foods need re-examination.

Existing international bodies are working to achieve consistent standards and criteria for the assessment of food safety, and this is to be applauded. The “precautionary principle” is now beginning to be discussed internationally in relation to food safety, but it has not yet been translated into an agreed operational form.

### ***GM technology in developing and developed countries***

The majority of speakers from developing countries stressed the crucial importance of GM technology as part of the armoury for feeding their population in the future. In China, with 20% of the world’s population and 7% of the land surface, GM is already playing a major role in food production, and its importance was also emphasised by speakers from Africa and Latin America. However, the view was also expressed that the future application of GM technology in developing countries should be more explicitly tuned to the needs of local people rather than of multinational corporations.

In light of this last comment, GM technology for the developing world should be carried forward through a mixture of public and private funding.

Whilst it is essential that standards of safety assessment should be consistent and high throughout the world, the strongly expressed demand for

GM technology in developing countries casts substantial doubt on proposals for a worldwide moratorium made by some participants.

The first generation of GM crops and foods are perceived as having brought little direct benefit to consumers in developed countries, but this may well change as new products appear with direct quality, health or price benefits.

### ***Concerns about GM other than food safety***

The principal concerns of the opponents of GM related less to food safety than to the broader question of why GM food is being produced at all. Most developing country speakers argued forcefully that GM technology is an essential part of their future food production, but this was rejected by some NGO speakers from Europe and North America. They argued, instead, for solving world food shortage by redistribution, better prevention of loss during storage and so on. They also pointed out, as did some developing country participants, that citizen engagement in decision making and discussion should be improved in developing countries.

A second concern about GM agriculture was the potential environmental impact. Although there have been many field trials and, in some parts of the world, large-scale commercial planting of GM crops, there has been insufficient work to fully assess environmental impacts, especially in the biodiversity-rich tropics.

### **The way forward**

The most significant aspect of the Edinburgh Conference was that it included all sides of the debate surrounding GM foods and nevertheless identified certain areas of agreement. It also succeeded in identifying issues in which there is disagreement or uncertainty due to lack of knowledge, and in separating out issues which are subject to scientific analysis and those which are related to political factors, beliefs and values. Further detail is available in the rapporteurs' report.

The conference represents a new start in the global debate about GM food and agriculture: a more inclusive approach in which the protagonists discussed some of the key issues with each other. There was support for continuation of this process to deal with other parts of the debate.

I therefore recommend that an *international forum* be set up to continue the process started in Edinburgh. The aim of such a forum would be to provide

governments with a state of the art assessment of scientific knowledge about GM technology, and to set this assessment in the context of broader concerns of society.

A model for such a global assessment is the IPCC (Intergovernmental Panel on Climate Change). This Panel allows governments to draw on worldwide expertise in climate science. It informs but does not make policy and it acknowledges the minority scientific views as well as the current majority view. It also updates its reports at intervals.

The forum I propose would have similarities to the IPCC, but it would include not only scientists but also other stakeholders.

The following suggestions indicate how the forum might be developed:

- It should build on and interact with, rather than duplicate or replace, the work of existing international groups such as Codex Alimentarius.
- It should be global in scope and not restricted to G8 countries or a subset thereof. In particular, a key message of the Edinburgh conference was the role of developing countries where application of the technology is proceeding rapidly.
- It should be led by the world's best scientific experts, but include a wider range of expertise and opinion than scientists.
- Two initial themes for the forum would be food safety and environmental safety of GM in agriculture and food production.
- There would be two kinds of outputs: *i*) scientific assessments in the form of reports that inform policy; and *ii*) an inclusive and global debate about the relationship between GM technology and society. It will be essential that governments take ownership of the forum and its reports.
- The reports should be produced in a timely way so as to facilitate the assessment of rapidly emerging technologies.

## Summary

In summary, this proposed forum could serve two important functions by enabling a global debate and assessment of GM technology in food and agriculture.

First, it will allow the best scientific analysis of the risks and benefits of the new technology, as it develops, to be carried out in order to provide governments worldwide with appropriate expert advice. This advice will acknowledge the range of scientific opinion and uncertainties, as well as indicating the current majority opinion.

Second, it could create a better understanding of the relationship between technological developments, policy, and the concerns and aspirations of citizens. This would be achieved by widening the forum beyond purely scientific analysis, to include the broader issues that I have referred to in relation to the Edinburgh Conference.

There is more than one way of achieving these twin objectives. One approach would be to have an expert panel, led by scientists but including other stakeholders, to carry out the scientific assessments. Draft reports of this expert panel could be used as the basis for discussion by a broader forum, along the lines of the Edinburgh meeting, in which the non-science issues are brought into the debate. The expert panel might choose to revise its report in light of this broader discussion.

I have deliberately left the details of implementation to others, because I want to sketch out the vision rather than the detailed mechanisms.

John Krebs  
Oxford  
March 2000

# **THE OECD EDINBURGH CONFERENCE ON THE SCIENTIFIC AND HEALTH ASPECTS OF GENETICALLY MODIFIED FOODS**

## **RAPPORTEURS' SUMMARY**

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

The Edinburgh 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.

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.

The conference critically reviewed – 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**

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 – as 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 to be fully 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 present 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**

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***

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.

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.

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.

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.

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.

Though labelling might allow choice, it would not in itself help answer the question of 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.

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***

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.

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.

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.

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.

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.

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

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1. 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.

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.

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.

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.

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.
- 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.

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).

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.

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.

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 into account in the policy process.

## *The role of stakeholders*

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

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.

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.

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.

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.

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 it plays 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.

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.

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*

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.

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 could then 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.

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.

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.

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.

Iain Gillespie  
Peter Tindemans  
Edinburgh  
March 2000

# THE OECD EDINBURGH CONFERENCE ON THE SCIENTIFIC AND HEALTH ASPECTS OF GENETICALLY MODIFIED FOODS

## CONFERENCE PROGRAMME

28 February - 1 March 2000

**Location:** Edinburgh International Conference Centre

**Attendance:** By invitation only, limited to approximately 400 participants from around the world, including experts from academia, consumer and other interest groups, industry, international organisations, OECD government representatives, and the Press.

**Purpose:**

The purpose of the conference is to bring together a diverse group of participants for a constructive dialogue on the safety of GM food, with an emphasis on the underlying science and on human health. Through a comprehensive and balanced set of presentations, and through a frank exchange of views, answers will be sought to the following questions:

- ◆ What is the current state of scientific understanding of the genetic modification of foods, and what are the areas in which scientific uncertainty exists? What are the current trends and future prospects? What are the potential benefits and risks?
- ◆ How do the natural and social sciences help us understand and ensure the safety of GM foods (*e.g.* by comparing the health risks associated with GM and conventional foods)? How do consumers perceive food safety risks?
- ◆ How is GM food safety assessed within existing regulatory frameworks?
- ◆ Is further international co-operation on scientific GM food safety issues required?

The genetic modification of food, while currently a matter of concern for members of the public and governments, is just one of a set of interrelated issues connected with practical applications of advances in genetics, molecular biology and related fields. The impact of GM food on human health is the principal subject of this conference, and it is closely linked to other important issues, for example: effects on the environment and on national economies, international trade, as well as cultural and ethical concerns. Whilst these topics will not be excluded from the conference, it is hoped that an emphasis on human health will lead to a focused, constructive debate and a useful outcome.

The event is part of a programme of work at the OECD to review and report on selected aspects of biotechnology and food safety in response to mandates from OECD Ministers, and to a request from leaders of the Group of Eight (G8) industrial countries. The report of the Conference will be submitted to the G8 representatives this year.

**Format:**

Presentations and discussions will focus on three principal themes: “Genetic Modification and Food Production”, “GM Food and Human Health” and “Regulatory Frameworks and Consumer Involvement”. In each session there will be a panel response and a plenary discussion.

The final day will see the conference working towards conclusions. The rapporteurs will present their summaries of the key points arising from each session; this will be followed by an opportunity for conference participants to further discuss these issues. The Chairman's overall report of the conference will be made available on the OECD Web site at: [www.oecd.org/subject/biotech/edinburgh.htm](http://www.oecd.org/subject/biotech/edinburgh.htm).

## DAY 1 - MONDAY, 28 FEBRUARY 2000

### WELCOMING ADDRESS AND OPENING REMARKS

Welcoming Addresses:

Susan Deacon MSP, Minister for Health and Community Care, Scottish Executive  
The Rt. Hon. Dr. Mo Mowlam, Minister for the Cabinet Office, United Kingdom  
The Hon. Donald J Johnston, Secretary-General, OECD

Opening Remarks - The GM Debate: Towards a New Dialogue:

**Conference Chairman:** Sir John Krebs, Professor of Zoology, Oxford University

### SESSION 1: GENETIC MODIFICATION AND FOOD PRODUCTION

**Chair:** Professor Francisco Bolívar Zapata (President, National Academy of Sciences, Mexico)

*The session will review the history and development of genetic modification of food. It will provide an opportunity for a wide-ranging general discussion of concerns, risks and benefits, as well as the role for GM food in meeting global needs.*

Introduction by Chair

Presentation 1.1. Research Trends in Crop Genetics and Transgenics

Professor Charles Arntzen (President and CEO, Boyce Institute for Plant Research Inc., United States)

Presentation 1.2. Areas of Concern with Respect to GM Crops

Dr Suman Sahai (President, Gene Campaign, India)

Presentation 1.3. Transgenic Food: Need and Safety

Professor Zhangliang Chen (Vice-President, Beijing University, China)

Presentation 1.4. Crop Biotechnology: Benefits, Risks and Ownership

Professor Gordon Conway (President, Rockefeller Foundation, United States)

#### Panel and Plenary Discussion 1

Panel Members: Mr Benedikt Haerlin (Greenpeace International)

Mrs Marilena Lazzarini (CEO, Institute for Consumer Defense, Brazil)

Dr Andreas Seiter (Vice President, External Relations, Novartis, Germany)

### SESSION 2: GM FOOD AND HUMAN HEALTH

**Chair:** Professor Goran Hansson (Professor of Cardiovascular Research, Karolinska Institute and Hospital, Sweden)

*The session will provide both a historical perspective on food safety and the effects on human health, and a forward look at changing patterns of diet and their implications. It will address both the potential of GM food to improve human health and the possible health risks.*

Introduction by Chair

Presentation 2.1. An Overview of Food Safety - Impacts of Diet and Nutrition on Health

Professor Ambroise Martin (Professor of Nutrition and Biochemistry, Medical School, University of Lyon, France)

Presentation 2.2. GM Foods: Opportunities to Improve Human Health

Professor Marc Weksler (Professor of Geriatric Medicine, Weill Medical College, Cornell University, United States)

Presentation 2.3. Possible Health Risks of GM Foods

Professor Hans Günter Gassen (Professor of Biochemistry, Darmstadt Technical University, Germany)

Presentation 2.4. Food Allergy and GMOs

Professor Carsten Bindslev-Jensen (Head of Allergy Centre, Odense University Hospital, Denmark)

### **Panel and Plenary Discussion 2**

Panel Members: Dr Arpad Pusztai (Private Consultant, United Kingdom)

Professor Zhangliang Chen (Vice-President, Beijing University, China)

Professor Alan McHughen (Professor and Senior Research Scientist, University of Saskatchewan)

Mr Pete Riley (Senior Food and Biotechnology Campaigner, Friends of the Earth, United Kingdom)

Dr James Maryanski (Senior Scientist, Centre for Food Safety and Applied Nutrition, US Food and Drug Administration)

**Reception** All Conference Participants

Hosted by Ross Finnie MSP, Minister for Rural Affairs, Scottish Executive

## **DAY 2 - TUESDAY, 29 FEBRUARY 2000**

### **SESSION 3A: REGULATORY FRAMEWORKS AND CONSUMER INVOLVEMENT**

**Chair:** Dr Harry Kuiper (Head, Department of Food Safety and Health, RIKILT Wageningen University and Research Centre, the Netherlands)

*In this session the fundamental regulatory principles involved in protecting human health with regard to food safety will be reviewed. There will be an opportunity to compare regulatory oversight in OECD and developing countries, including examining the implications of globalisation, and the work of international bodies. The contribution of the social sciences to understanding and dealing with consumer concerns will be addressed.*

Introduction by Chair

Presentation 3.1. Prevention, Precaution, Consumer Involvement: Which Model for Food Safety in the Future?

Professor Bernard Chevassus-au-Louis (President of the Board, French Health and Food Safety Agency)

Presentation 3.2. Food Safety Assessment and Regulatory Oversight in OECD Countries

Dr Peter Kearns (OECD)

Presentation 3.3. Biotechnology Regulations in South Africa

Professor Jennifer Thomson (University of Cape Town, Department of Microbiology, South Africa)

Presentation 3.4. The Work of the Codex Alimentarius Commission

Dr Alan Randell (Codex Alimentarius, Food and Agriculture Organisation, FAO)

Presentation 3.5. Widening the Circle: Engaging the Public in Policy Making for GM Food  
Professor John Durant (Head of Science Communication, Science Museum, United Kingdom)

Presentation 3.6. Less Risk, More Choice: A Consumer's Perspective  
Mr Julian Edwards (Director General, Consumers International)

**Panel and Plenary Discussion 3A**

Panel Members: Dr Val Giddings (Vice-President for Food and Agriculture, Biotechnology Industry Organisation, BIO, United States)

Dr Michael Hansen (Consumers Union, United States)

Mr Joseph Muchabaiwa Gopo (Biotechnology Institute of SIRDC)

Mr Martin van Zwanenberg (ex-Divisional Director, Food Technology, Marks & Spencer, United Kingdom)

**SESSION 3B: REGULATORY FRAMEWORKS AND CONSUMER INVOLVEMENT**  
(continued)

Presentation 3.7. Codex Alimentarius Commission: Perspective on Labelling of Food and Food Ingredients Obtained Through Modern Biotechnology

Dr Anne MacKenzie (Chair, Codex Committee on Food Labelling)

**Panel and Plenary Discussion 3B**

Panel Members: Mme Marion Guillou (Director for Food, Ministry of Agriculture and Fisheries, France)

Ms Gwenn Straszburger (Senior Adviser, Euro Coop, Brussels)

Ms Lisa Katic (Director of Scientific and Nutrition Policy, Grocery Manufacturers of America)

## **DAY 3 – WEDNESDAY, 1 MARCH 2000**

### **SESSION 4: WORKING TOWARDS A COMMON VISION**

**Chair:** Sir John Krebs

Introduction by Chair

Keynote Speech: Benign Biotechnology: Harnessing the Best of Science for the Public Good  
Dr Ismail Serageldin (Vice President, World Bank and Chairman, Consultative Group of International Agricultural Research)

**Rapporteurs:** Dr Peter Tindemans (The Netherlands)  
Dr Iain Gillespie (United Kingdom)

*The rapporteurs will present the draft summaries of the three individual sessions, with an emphasis on four areas: factual information reported, areas where substantial consensus exists, main areas of disagreement, and topics for further scientific investigation. Following the Conference, a Chairman's report will be made available to the public.*

Plenary Discussion

Closing Remarks: Sir John Krebs

Conference Close

Press Conference

**THE OECD EDINBURGH CONFERENCE ON THE SCIENTIFIC AND  
HEALTH ASPECTS OF GENETICALLY MODIFIED FOODS**

**MEMBERS OF THE STEERING COMMITTEE**

*Ex Officio*

Professor Sir John Krebs (Chairman)  
Professor and Behavioral Ecologist  
Department of Zoology, University of Oxford

Dr. Michael Osborne  
Deputy Director  
Directorate for Industry, Science and Technology  
OECD

*Chairs of OECD Committees*

Dr. David Harper  
Chief Scientist  
UK Department of Health

Dr. Paul Mayers  
Director  
Bureau of Microbial Hazards  
Food Directorate  
Health Protection Branch  
Health Canada

Professor P. Werrij  
Director of International Co-operation  
Dutch Ministry of Agriculture, Nature Management and Fisheries  
Agricultural Research Department

### ***Independent and Government Scientists***

Professor Charles Arntzen  
President and CEO  
Boyce Thompson Institute for Plant Research Inc. at Cornell University

Dr. Francisco Bolívar Zapata  
President  
Mexican Academy of Sciences and  
Director, Biotechnology Institute, UNAM

Prof. Bernard Chevassus-au-Louis  
Président du Conseil d'Administration  
Agence Française pour la Sécurité Sanitaire des Aliments

Professor Zhangliang Chen  
Vice President  
Beijing University and  
Director of the National Laboratory of Plant Genetic Engineering

### ***Representatives of NGOs***

Mr. Graham Wynne  
President  
The Royal Society for the Protection of Birds

Ms. Anna Fielder  
Director  
Office for Developed and Transitional Economies  
Consumers International

# **OECD CONSULTATION WITH NON-GOVERNMENTAL ORGANISATIONS ON BIOTECHNOLOGY AND OTHER ASPECTS OF FOOD SAFETY**

## **SUMMARY**

The OECD held a meeting with over 50 non-governmental organisations on 20 November 1999 in its Paris headquarters. I believe it was a successful use of this international forum to hear and to understand the views of NGOs on biotechnology and other aspects of food safety. Business, trade union representatives and scientists also participated. The government representatives who chair the five committees of the OECD dealing with these issues were present, as were the diplomatic representatives of a number of OECD Member countries who had come to observe the debate.

The majority of the NGOs present were not critical of developments in biotechnology *per se*, but wanted to see more careful oversight and monitoring of the processes and products derived from modern biotechnological techniques. Many NGOs said they did not believe science has at this point satisfactorily addressed their concerns over GMO effects on human health or the environment. Business and scientific groups held a number of different views.

Some of the general conclusions I would draw from the meeting were:

- Scientists themselves are not promoting GMOs one way or the other. They recognise that all science, all progress, carries risks or hazards and that historically this has always been the case. Modern science produces sophisticated technologies that require analysis and action in terms of assessing “probabilities” and improving risk management tools. Some participants considered that it is also necessary to apply a “precautionary principle” when dealing with such new technologies.



- Farmers are excited about the prospects these new technologies present for reducing costs and increasing production yields. However, they wish to have the choice of whether or not to use GMO seeded crops on their farms. They are also concerned about intellectual property rights belonging to a few multinational companies which could lead to the exercise of monopolistic power worldwide. A number of participants challenged the right to patent “living” beings such as plants. Farmers also wished to know the international trading rules on GM foods before cultivating crops that may not be saleable abroad.
- Consumers are not uniformly lined up in opposition to GMOs, but they are adamant about the “right to choose” food in their local markets. They feel that consumers have the right to know what they are eating, no matter what their reasons may be – health, ethical, religious or other. This raises the issue of mandatory labelling and related questions such as the thresholds for traceability of GMOs, or the standards for labelling.
- Some proponents of GMOs took the view that the issue is whether particular products can be demonstrated to be safe for human consumption, and they pointed to the United States where GM food has been consumed for more than ten years with no ill effects. They argued that labelling is irrelevant because the product – whether GMO or non GMO – is the same from a safety viewpoint.
- Environmentalists strongly disagreed, arguing that it is necessary to regulate the very processes of modern biotechnology in order to avoid unforeseen longer-term impacts on the environment and human health. Product regulation is too short-term and insufficient for these groups.
- Proponents of GMO crops claimed that they provide demonstrable environmental benefits. GMO crop plants combined with the use of new herbicide products enable, they claimed, only one application of a herbicide instead of multiple doses of different varieties. In the developing world, increased production through the use of GMOs might mean preservation of rain forest and this is very much in the interest of the global environment.
- Many environmentalists rejected these positions, noting that single dose herbicides must be even more toxic if only one application is required. The further intensification of farming through GMOs was presented as a serious negative for biodiversity, and doubts were raised about rain forest-cultivated land trade-off arguments.

- Some proponents argue that GMO technology is necessary to feed fast-growing populations in the developing countries. This is a central issue since the OECD countries already produce food surpluses, while many in the developing world are hungry. Do developing countries need GM crops to feed themselves? GMO opponents vigorously deny this need, arguing that traditional agriculture will suffice if properly managed and that, in any case, hunger in developing countries is more a problem of inadequate income, faulty distribution of existing food stocks and technology transfer bottlenecks.

The following individual session summaries give fuller details of the rich debate and exchange of ideas that took place.

### **Session 1 – Consumer Concerns**

There was general agreement that consumer questions and concerns regarding food quality and safety are both universal and personal. While particular aspects of this complex topic are likely to vary – from country to country, from North to South, from developed to developing societies – the principal issues that attract attention are likely to be the same. Several participants cited national and international surveys that seem to indicate there is much greater public concern in European and Asian countries than in the United States over food safety issues, but some participants noted a rise in concern over these issues in the United States recently. It was stated in both lead presentations – by Consumers Union (US), on behalf of Consumers International, and Euro Coop – that people want to learn about possible added health benefits, or health risks, of genetically engineered food; that they are sensitive to environmental impacts and ethical issues; and that they feel manufacturers should be obliged to make truthful claims in this regard, claims that are in no way misleading. It was recognised that developing countries, while sharing these concerns with developed countries, show great interest in technologies that can improve the yield and nutritional value of foods and feeds currently available. For better or worse, however, these technologies have yet to make their way to developing country markets.

#### ***Consumers are concerned about the increasing commercialisation of GM foods ...***

Consumer representatives said that consumers question outright the benefits of genetically engineered foods as opposed to traditional foodstuffs, and are concerned by the possibility of transfer of known and unknown allergens and toxins via novel foods and feeds. Genetically engineered foods

and feeds are, they said, perceived as intrinsically different and as offering no added benefits. Current products are as expensive as their conventional counterparts and do not appear to be more environment-friendly. It was pointed out that ordinary consumers want the fullest possible risk/benefit information; they have a fundamental right to eat what they choose, and to choose what they eat. Those with expert knowledge about quality and safety of foods on the markets must therefore share their knowledge with the public – through labelling, broadly based public education programmes on food issues, or other means.

### ***Many consumers want to see labelling requirements ...***

Several consumer organisations present demanded responsible international oversight and international guidelines on labelling. They felt that labelling is essential for ascertaining the origin of foods, and in particular for separating GM from non-GM foods; for monitoring possible adverse effects of ingredients; and for the security of the public in the long term. In the view of these organisations, many national governments need to develop stricter regulatory and surveillance systems, and should, accordingly, apply the “precautionary principle” as a fundamental part of risk assessment. Governments must develop mandatory approval systems and clear criteria, and consumers should be entitled to a central role in the policy-making process. Rules for product labelling and advertising must, according to these organisations, be backed by sound monitoring and reporting, with provision for reviews and appeals of decisions related to permits and licensing. It was stated that GM food safety cannot be a field for voluntary guidelines, and that safety measures should not be left to companies. A number of participants felt that governments therefore have a clear role in developing risk management tools such as mandatory labelling, transparent approval processes for novel foods, and regular, systematic environmental impact analyses as part of risk assessment. It was suggested that GM food should be subjected to the same requirements as pharmaceutical products.

### ***Science is perceived by many consumers to have limits ...***

Many consumer representatives thought that one of the greatest challenges is to define the scientific principles by which governments make food policy. A number of NGOs felt that sound science and a transparent and predictable regulatory process are essential if an approval system is to have legitimacy in the eyes of the public. Information derived from risk assessments should be made available and translated into commonly understood language. According to some of the groups present, however, science should not be considered as the only basis for decision, for two reasons.

First, science has limits. It can provide answers only in probability terms – it cannot offer absolute certainties. It is essential to acknowledge what we don't know and the tentative nature of some things we do know. This could even be an incentive to develop a more solid scientific basis to address the safety of GM foods and feeds.

Representatives of the scientific community replied that the fact that science has limits should not be taken as a reason for a standstill on science or on the approval of GM foods and feeds. Had scientific certainty been required, surgery and anaesthetics would never have been introduced into medical practice and air transport would not exist – to cite just a few examples. But progress based on science has been possible, because science makes a distinction between the concept of hazard (danger) and that of risk (the probability that the danger will be realised). The scientific approach can systematically identify hazards, as well as the critical control points and monitoring methods that will help us avoid risks associated with those hazards.

The second reason given for the inadequacy of a purely scientific approach was that food policy decisions require subjective choices derived from social values, not merely scientific facts. Many consumers today believe that GM foods are different because the process of genetic modification of crops which produce the food is fundamentally new and different – and therefore untested. They request that the process be identified in the label of all commercial goods derived from GMOs. Yet, scientists and regulators argued that the process itself does not tell us much about the safety of the final product. This is the reason why in most current legislation, the emphasis is on regulating the product rather than the process.

### ***There is a convergence of interests with trade unions ...***

Finally, the concerns of consumer organisations and those of trade unions appeared to converge on the question of the health and safety of workers involved in food production and distribution. Both groups of organisations seemed to agree that these issues should be treated as part of any public health monitoring or research programme. Specific research is needed to assess occupational hazards related to the development, production and processing of new foods and GMOs. Workers' rights to information about products or processes that may affect their well-being must be guaranteed, and the right to refuse work that poses a threat to the public's well-being must be enshrined in legislation.

## **Session 2 – Environmental Concerns**

The lead presentations of NGOs concerned with protection of the environment emphasised the risks associated with GMO-based agriculture. The discussion centred around a few main themes which can be categorised as: the benefits and drawbacks of the technology; regulatory assessment issues; and the future management of biotechnology.

At the heart of each aspect of this discussion was a debate over whether the applications of biotechnology and genetic modification, especially in agriculture, represent something new, or whether these applications are simply extensions of traditional agriculture and plant breeding. Both these very different views were expressed.

### ***A number of NGOs present felt there are real risks to the environment ...***

Environmental NGOs emphasised the fact that risks associated with GMOs cannot be evaluated in probability terms given the current state of knowledge. We cannot apply what we know about traditional plants to the evaluation of transgenic plants. Nor, in the view of these groups, can the concepts of “familiarity” or “substantial equivalence”, as developed by the OECD, be applied.

Environmental NGOs also emphasised that the long-term effects of GMOs on nature are relatively unknown. They are concerned with the serious possibility of genetic mutations and the uncontrollable developments that could ensue. They called for more in-depth studies, and a strict application of the “precautionary principle”.

Finally, they pointed out that with GM crops there is an inherent risk of reducing biodiversity. They cited the negative impacts on both flora and fauna, recorded notably in OECD countries, when traditional agriculture has been intensified.

### ***But some underlined potential benefits for the environment ...***

The current and potential benefits in the use of products of biotechnology were emphasised by a number of participants, especially industry groups from a number of regions. Representatives of farmers, especially from the United States where genetically modified crops are now commonplace, stressed the value to them of planting genetically modified crops. A specific case cited was the use of herbicide tolerant crops which some producers said allows them to have more efficient weed control and has actually led to a decreased use of herbicides. Similarly, the use of crops which are resistant to pests has led to a

lower use of pesticides. These developments were said to be examples of benefits to the environment.

In terms of the future benefits, a number of participants argued that genetically modified crops will lead to a more efficient agriculture which will equally benefit producers and consumers in developing countries as well as those in the developed world. This should assist in world food production.

***However, this optimism was questioned ...***

This optimism was questioned by a number of environmental NGOs. There were varying degrees of scepticism, with some saying they were not opposed to GM crops *per se*, while others were strongly opposed. Many seemed unconvinced of the current or future benefits that were claimed. In the specific case of herbicide-tolerant crops, a number of NGOs raised the concern that this would lead to an increasing dependence on herbicides. Others were worried that the use of genetically modified crops, which involve patented genes, might shift the balance away from traditional forms of agriculture, with farmers being unable to plant seeds they had saved from their crops. They argued that this would lead to an increased dependence on the products of multinational companies that could have a deleterious impact on agriculture especially as practised in developing countries. As a general point, a number of environmental NGOs were highly sceptical of the claim that biotechnology can “help feed the world”. They stated that other factors, such as poverty, were of much greater relevance (see Session 3 – Agro-food Sector Concerns.)

***Regulatory practices were also questioned ...***

Environmental NGOs outlined a number of criticisms on the current regulation of products of biotechnology. Some believed that there is a presumption by regulators that genetic modification is, in general, a good thing. A number called for a wide range of expertise to be involved in regulatory assessment, including (among other things) experts in ecology, socio-economics as well as public-interest groups.

Many participants made reference to the regulation of biotechnology and genetic modification. This discussion did not focus in detail on any specific national regulatory system – although there was some brief mention of the role of the FDA, USDA and EPA as regulatory agencies in the United States. A number of participants from industry expressed confidence in that system. A further suggestion, especially from industry representatives, was that there was a need for increased efforts in regulatory harmonisation so that regulators in different countries could share information more closely.

### ***Is the development of biotechnology well managed ...?***

Finally, there was much discussion on issues related to the future management of biotechnology and genetically modified organisms. A number of participants stressed that this technology was based on very recent scientific developments – it could even be called an infant technology. They felt that these developments had taken place very quickly and that it was still too early to predict the impacts on the environment and society as a whole. Some stated that many citizens are simply uncomfortable with the use of GMOs – regardless of the current state of science; they argue that scientists do not necessarily know best. This rationale led a number of participants to call for a moratorium on the use of GMOs in agriculture until more research could be undertaken. Others were content for field trials to take place, while favouring a moratorium on commercialised products. Many stressed the need for management tools to be in place, such as mechanisms for labelling GM products as well as methods for ensuring traceability of GMOs in products. Most environmental NGOs invoked the “precautionary principle” as a means of giving a “breathing space” while the long-term impacts of GMOs were more closely assessed.

On the other hand, a number of participants, especially from industry, argued that biotechnology was simply one more tool that could contribute to an increasingly efficient agriculture. It had a role, for example, in integrated pest management. It could even lead to better conservation of biodiversity by limiting agricultural exploitation. Without it, future developments in agriculture could suffer. An inappropriate level of assessment and management could inhibit the development of technology. In this context, it was argued that labelling was only of value where there was a clearly defined need, such as an identified hazard. The “precautionary principle” was also criticised if it meant that one needed to demonstrate zero-risk in order to proceed with the general release of genetically modified organisms in food.

### **Session 3 – Agro-Food Sector Concerns**

The session on the agro-food sector focused on the biotechnology and food safety concerns of agricultural producers and related upstream (seeds, agrochemicals) and downstream (food processors, wholesalers, retailers) industries. A wide range of issues was discussed, reflecting the diverse interests of business and of different regions. Nevertheless, a certain degree of convergence appeared to emerge in the discussion. At all levels of the food chain, industry representatives stressed that they share many of the same concerns expressed by the consumer and environmental groups.

### ***Improve risk assessment and risk management ...***

Opinions were divided over the extent to which current food safety assessment regulations were adequate, especially with respect to GM foods. There was general agreement that risk assessment should be science-based and transparent; that governments rather than industry should set regulations; that such regulations should be mandatory where human, animal or environmental safety were in question; and that regulatory agencies should be independent. However, rules alone are not sufficient unless enforcement and compliance are assured. Harmonisation or mutual recognition of regulations was seen as a means of reducing costs to industry and consumers while increasing trade. Many participants considered that GM foods, by definition, are substantially different from non-GM foods and suggested, in consequence, that each should be subjected to a full safety assessment on a case-by-case basis. In terms of risk management, “better safe than sorry” was the common approach but there was no agreement on the definition of precaution or how it should be applied. Labelling regulations and consequent identity preservation systems for GM foods were seen as a way to permit consumers to make informed choices. Information on such regulations and systems would also allow farmers to engage in more efficient decision making regarding their choice of crops.

### ***The issue is more than health and safety ...***

Concerns over biotechnology and food safety go beyond the matter of human health and safety. There are economic, social and ethical issues. Effects on food quality, animal welfare and biodiversity were just some of the areas where many felt that information was inadequate. Many participants questioned if, and how, the “non-scientific” concerns should be addressed in the context of national and international regulatory frameworks. Maintenance of national sovereignty in the area of food safety and quality was seen as essential but working towards harmonisation of standards is equally important. There was general agreement that it was useful to separate the safety and non-safety issues as the problems and possible solutions were quite different. For farmers, the significant concentration of the biotech industry could mean excessive dependence on products and techniques controlled by a handful of multinationals.

### ***A framework of sustainable development ...***

Many agreed with the sentiment that new biotechnologies need to be assessed within a framework of sustainable agriculture, encompassing both economic and resource sustainability. There was considerable discussion about the actual benefits of biotechnology and genetically modified (GM) crops in particular. Anecdotal evidence and scientific studies were referenced both



supporting and questioning the benefits in terms of yields, costs and environmental impacts. Producer groups generally reported favourable results but experience is not widespread and local climatic conditions may make a difference. Organic farmers, who represent a small but rapidly growing segment of agriculture, expressed concerns about potential damage from GM crops to neighbouring farms and raised questions about measures of protection and liability. Farm groups felt they should be protected by legislation against liability for any damage caused by GM products if codes of practice are followed.

### ***Food safety is also a trade issue ...***

It was pointed out that different food safety regulations reflecting different national evaluations of acceptable risk can be accommodated in international trade agreements so long as such regulations are based only on scientific risk assessment. However, several groups argued that science is not able to assess unquantifiable risks and, consequently, they urged precaution. The possibility of trade disputes increases when economic, social and ethical considerations are superimposed on the science-based approach, but at the same time the concerns of consumers must be respected. Countries should seek consensus on regulatory approaches by working through international bodies. It was suggested by some that the WTO take a lead role in addressing these issues by updating the Sanitary and Phytosanitary Agreement (SPS), including a clarification of the “precautionary principle”. Others felt strongly that many of these issues were best dealt with under the Biosafety Protocol initiative. There were also those who do not want the SPS or Technical Barriers to Trade (TBT) agreements to be tampered with for fear of an increase in non-tariff barriers to trade.

### ***Greater focus on developing countries ...***

While most saw modern biotechnology as an important tool in assuring increased food supplies for the world’s growing populations, no-one considered it as the only, or even the most important, avenue for achieving greater food security. Such technologies are seldom designed for or accessible to, the small landholders in developing countries. Poverty, political conflict, production inefficiencies and imbalances in the world trade system were viewed as greater constraints on food security. However, experiences from Mexico, for example, suggested that there is a potential for modern biotechnology to contribute to sustainable agricultural systems while improving international competitiveness. The seeds industry indicated that technology transfer to the South is occurring to some extent but many participants agreed that greater effort is required to enhance traditional crops, protect indigenous plant varieties and foster local knowledge of farmers in developing countries, as these could contribute to long-term economic and environmental sustainability.

### ***Research must continue ...***

Virtually all participants agreed that research in modern biotechnology should continue. However, concerns were expressed about the shift in both basic and applied research from the public to the private sector as well as the privatisation of public research. Many called for greater government or non-profit organisation involvement in research on agricultural applications of biotechnology. A major issue is the introduction of such crops and products into the food chain and the environment. It was suggested that research should increase but only under carefully controlled conditions with regular monitoring. And not all research was seen as beneficial. For example, development of the terminator gene uniquely for patent protection reasons was strongly rejected by the majority of participants. In reference to patenting and plant breeders' rights, it was recognised that firms need some assurance of a reasonable return on large investments in research. However, the rights of farmers to reuse seed from their own crops must also be respected. The possibility of patenting life forms was also a point of debate, with no clear-cut consensus emerging. In advanced countries, the development of non-food uses of crops, such as biodegradable plastics and biofuels, could breathe new economic life into rural communities. Some suggested that the industrial uses of agricultural biotechnology would be quite important in the not-too-distant future.

### ***More information, more dialogue ...***

Greater emphasis on sound science was seen as critical for risk assessment, risk management and communication. Too often, unsubstantiated claims, anecdotal stories and biased reporting have served only to cloud the issues. Scientific studies should always be subject to peer review prior to public release. Governments, industry and NGOs all have a responsibility to get the facts straight and make this information available to the general public. The scientific community stressed that there was still much that was unknown and much research to be done. All stakeholders want to be consulted in the regulatory process from planning to implementation. This process must be analytically sound, objective, credible, transparent and accountable if it is to instil public confidence.

These summaries are available on the OECD Web site at <http://www.oecd.org/subject/biotech/ngoconsultation.htm>.

Donald Johnston  
Secretary-General of the OECD  
Paris



**OECD CONSULTATION WITH NON-GOVERNMENTAL  
ORGANISATIONS ON BIOTECHNOLOGY AND OTHER ASPECTS  
OF FOOD SAFETY**

**CONSULTATION PROGRAMME  
20 November 1999**

- **Welcome**
- **Introduction by Mr. Donald Johnston, Secretary-General of the OECD**

**Session I: Consumer Concerns**

*Chair: Mme Marie-Odile Monchicourt (France Info)*

*Lead presentations*

- Dr. Michael Hansen, Consumers International
- Ms. Gwenn Strasburger, Consumer Cooperative International/ Euro Coop

*Interventions and reactions*

**Session II: Environmental Concerns**

*Chair: Mr. Stephen Moore (The Wall Street Journal Europe)*

*Lead presentations*

- Mr. Benedikt Haerlin, Greenpeace International
- Mr. Etienne Vernet, Ecoropa (France)
- Dr. Mark Avery, Royal Society for the Protection of Birds (United Kingdom)
- Mr. Mario Rodriguez Montero, Pulsar International (Mexico)/BIAC

*Interventions and reactions*

**Session III: Agro-food Sector Concerns**

*Chair: Mr. Guy Faulkner (Agra-Europe)*

*Lead presentations*

- Mr. Bernard Le Buanec, Fédération Internationale du Commerce des Semences and Association Internationale des Sélectionneurs
- Mr. David King, International Federation of Agricultural Producers
- Mr. Raymond Destin, Confédération des Industries Agro-alimentaires de l'Union Européenne

*Interventions and reactions*

**Media Views and Wrap up**

*Chair: OECD Secretary-General*

## **Proposed Issues for Discussion**

### **Session I: Consumer Concerns**

#### ***Consumer concerns in general***

- What are the consumer's concerns? Why have they grown so significantly in recent times?
- How far do they extend beyond personal health and touch on the environment?
- Are there important differences between the OECD regions (Europe, North America, Asia-Pacific)?
- Do the concerns vary with the consumer profile (age, sex, education level, level of income)?
- How should consumer interests be protected?

#### ***Consumer information***

- What information should be included in product labelling?
- Why should we buy GM food (benefits, price, gains)?
- How safe is "safe"?

#### ***Consumer confidence***

- To what extent do consumers trust the scientists? Or the government? Or the food industry? Or the media?
- What can be done to boost confidence in the sources of information?

#### ***Consumer associations***

- What roles have such associations played?
- Should their status be reinforced in the policy debates? If so, through what procedures or mechanisms?

### **Session II: Environmental Concerns**

#### ***Environmental safety assessment***

- Is genetic modification essentially different from conventional plant-breeding practices?
- What are the effects on the environment – product by product?
- Are environmental safety assessments carried out in an adequate way?
- How can we correctly evaluate the long-term environmental impacts?

#### ***Changes in agricultural practices***

- What are the impacts of GMOs on agricultural practices (*e.g.* production, pesticide use)?
- What benefits and concerns are identified for specific GMOs?
- What can be considered appropriate GMO management practices?
- What new developments can be expected in the near future?

#### ***Impacts on biodiversity***

- Is there gene transfer from GMOs to natural flora, and to what extent does such a transfer pose a problem?
- Are GMOs able to survive as weeds in nature?
- What are the specific concerns regarding the international movement of GMOs?

### ***Information-sharing regarding environmental considerations***

- Is information-sharing sufficient with regard to environmental concerns?
- What information should be shared nationally and internationally?
- How can we establish an information-sharing structure?

## **Session III: Agro-food Sector Concerns**

### ***Research and development***

- What new products are in the pipeline? What are their benefits for farmers? For consumers?
- Are monitoring and control sufficient?
- What are the implications of the shift from public to private research?
- How are these new products brought to market?

### ***Structural adjustment***

- What is the impact on commodity and processed product markets?
- How are farming systems adjusting?
- Are there greater pressures towards vertical integration and industry concentration?
- What are the implications for market power? For price setting? For competitive markets?

### ***Developing countries***

- Are new biotechnologies suitable for developing countries?
- How can modern technology be made available to small, low-cost producers?
- What are the implications of modern biotechnology for food security? For sustainable agriculture? For biodiversity?
- Can developing countries comply with highly technical food safety standards?
- What is the role of the public sector?

### ***Regulation***

- Are existing food safety regulations adequate for products derived from modern biotechnology?
- Is the regulation process efficient? Transparent? Effective? Are regulations enforceable?
- Is there a role for private industry standards? A role for labelling?
- What are the costs/benefits to industry? To consumers?
- How can international harmonisation and mutual recognition be enhanced?

### ***Trade implications***

- How can food safety be assured without creating technical barriers to trade?
- What changes in intellectual property rights are required?
- Can international agreements accommodate cultural, ethical and moral differences?
- Can domestic sovereignty over food safety and quality be maintained?

*Annex*

**LIST OF OECD DOCUMENTS SUBMITTED TO THE G8 SUMMIT IN  
OKINAWA (JULY 2000)**

Report of the Task Force for the Safety of Novel Food and Feeds

Report of the Working Group for the Harmonisation of Regulatory Oversight of Biotechnology

Report of the Ad hoc Group on Food Safety, which includes:

- Overview of Food Safety Systems and Activities: Executive Summary
- Overview of National Food Safety Systems and Activities
- Overview of International Organisations with Food Safety Activities
- Compendium of International Organisations with Food Safety Activities
- Compendium of National Food Safety Systems and Activities

Chairman's Report and Rapporteurs' Summary on the OECD Edinburgh Conference on the Scientific and Health Aspects of Genetically Modified Foods *GM Food Safety: Facts, Uncertainties and Assessment*, 28 February-1 March 2000

Summary Report of the OECD Consultation with Non-Governmental Organisations (NGOs), 20 November 1999

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