



A Framework for Sustainability

2020 Vision Seminar Report



Genetic Modification and Sustainability: Working Towards Consensus

A Report on a Dialogue about the Place of GMOs in a Sustainable Future, Wednesday 28th April 1999

Dr Mark Everard, Director of Science, The Natural Step UK

Diana Ray, Facilitator, The Natural Step UK

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Summary

GMO (genetically modified organism) technology is an important issue and a source of concern for the Environment Agency, industry, retailers, academics, other regulators, NGOs and the general public. This **2020 Vision** publication reports on the process and outcomes of a seminar held in April 1999 to explore the diverse issues connected with the debate about GMOs.

The Natural Step (TNS) was used as a helpful "systems thinking" approach and an appropriate framework to structure this debate in the context of the place of GMOs in a future sustainable world. Consensus about this point is of value to investors (who will want to know how to invest wisely), regulators, agricultural and industrial interests, NGOs, and the general public. The process of informed and inclusive debate, based on sound scientific principles, is also important to rebuild public confidence in science. The Environment Agency has a key role to play in this, both as an arbiter and wise manager on behalf of the environment and wider community, as well as informing its own policy decisions.

The workshop comprised a closed meeting of invited experts, engaging in dialogue leading towards consensus positions about the role of GMOs in a sustainable world, and the things that could be done today to work towards realising it. Delegates included Environment Agency staff and people from various organisations with interests and expertise related to GMOs. The group explored the implications of GM technology for society and nature, with the focus on their place in a more sustainable future.

The workshop was initiated by a series of expert presentations, aimed at *information-sharing*, and providing a baseline of factual information covering all of the diverse implications of GMO technology. The process of the day was towards *consensus-building* about the role of GMOs in a sustainable future. The focus on consensus encouraged conflicting views and opinions to be aired, structured by the holistic framework of sustainability of TNS, without encouraging people to establish polarised positions. Consensus took the form of:

- Identifying knowledge gaps and questions remaining;
- Determining points of agreement; and
- Agreeing on ways forward.

The **Points of Agreement**, outlined in detail in section 3 of this report, included the following key issues:

- This is a radical technology, the consequences of which are not yet fully understood;
- There is a need to monitor impacts on biodiversity;
- We lack an adequate framework to regulate its development internationally;
- We need more effectively to include public concerns into the regulatory process;
- A need to increase public understanding of the science behind the GMO debate;
- A two-way flow of understanding between scientists and the public is required;
- GM issues as only one alternative in the wider debate on sustainable agriculture, and considerably more work is needed to determine what comprises truly sustainable agriculture;
- We need a multi-disciplinary approach, including the public, to shape the direction of GM technology. This will entail a more consensus-based approach;
- Further exploration is required of the implications of GMOs as a development technology (particularly in overcoming poverty).

Consideration of Next Steps, also outlined in detail in section 3 of this report, included a range of possible actions:

- Insights from this event should be disseminated;
- Participants to help others access the ideas and understanding;
- We need an independent body to take a lead in stimulating further debate;
- Broadening the base of discussion, and developing tools for public communication;
- Involving other stakeholders in linking GM issues to sustainability;
- Involving all sectors of society in decision-making about the technology; and
- Engaging all major players, and encouraging dialogue between them.

This review document is part of the continuing consensus-building process. However, it is recognised that the views and needs of a wider range of stakeholders must be tapped as a basis for assessing and managing the technology in a wise way that takes into account the elements of a sustainable future. Whilst scientists have a key role in predicting the scientific implications of the technologies, they are not always best placed to propose policy and best practice to take account of the wider needs of society and a sustainable future. For this reason, a more inclusive approach to policy-making is required.

The ideas and findings in the report show that there are many reservations about GM technology and GMOs. Numerous potential benefits are also perceived, although in many cases the associated risks have yet to be determined. In no sense did the participants give unreserved support to pursuing the technology incautiously. Grave concerns were raised about the potential impacts of the technology upon the environment, biodiversity, and ownership of genetic resources, and how these might conflict with the public interest.

1. Background to the 2020 Vision Seminar on GMOs

1.1 The 2020 Vision Seminars

The 2020 Vision series of seminars and publications provides information about a range of contentious issues, many of which may have featured in the media. The Environment Agency, together with The Natural Step, has started running a series of 2020 Vision Seminars, involving an invited expert audience, to share information and to debate the place of these issues in a future, more sustainable world. This publication reports on one such seminar, outlining the key issues of agreement about GMOs, and perhaps more importantly also identifying the gaps in our present knowledge, the research priorities, and what can be done today about the issues raised.

The series is sponsored by the **Environment Agency**, which has wide-ranging powers and duties relating to water management, environmental protection and pollution control across England and Wales. Its principal aim is to exercise them so as to contribute to sustainable development. The Agency therefore has strong interests in the application of science to decision-making — both its own and that of other sectors of society — as an important part of its contribution towards the achievement of sustainable development. The "2020 Vision" process started internally within the Agency as a mechanism to envisage the kind of environment that the Agency wished to work towards. The 2020 Vision series of seminars and publications has stemmed from this aspiration, and provides an expert analysis of the place that a range of contentious issues occupy in a future sustainable world.

The Natural Step (TNS) was developed in Sweden some years ago to help determine in scientific terms what sustainability actually means, and what can be done about it in practice. The Natural Step has been operating in the UK as a charity, led by the well-known environmentalist Jonathon Porritt, since the beginning of 1997. It has already been successful in helping a range of large companies address sustainable development as a strategic issue. The science-based model of a sustainable world, that lies at the heart of TNS, can also be used as an "intellectual round table" around which to address the various social, environmental and economic aspects of contentious issues. Together with a range of other specialist tools, TNS therefore provides a framework for the building of consensus about the place of these issues in a future more sustainable world. The Natural Step, which is supported by the Environment Agency, is a partner of the Agency in the 2020 Vision series of seminars and publications

1.2 The GMO Debate

The public profile and media interest in GMO issues have steadily increased in recent months. In the current climate of debate, it is timely for the Environment Agency to be determining the issues and implications of GMO in a measured and balanced way. Though not a primary regulator of GMOs, the Environment Agency's environmental protection roles inevitably involve it in consideration of the wider implications of GMO use. It is also likely to be a focus of public attention on the issue, because of the public perceptions about the Environment Agency as an arbiter and source of sound advice on behalf of the environment and the public interest.

The focus of public debate has tended to be about risks and potential opportunities in the intentional releases into the environment where GMOs are used in crops, in animal production, and human genetic manipulation. Less public attention is focused on the increasing uses of GM technology in industrial processes (food industries, and many others) and the potential for accidental or inadvertent releases into the air, water or land resources through waste disposal or leakage. However, these are also issues of concern for the Environment Agency.

In order for any organisation to find a way through the plethora of information and conflicting opinions, there is a need for:

- a scientifically rigorous framework to assess GMO issues, enabling the development of a long term view in the context of a more sustainable future that does not see "the environment" in isolation, but integrates it with society (locally and globally); and
- ways of working that establish credibility and acceptance enabling them to work
 with others to form opinions and develop understanding in a constructive way, so that
 the decisions and actions taken have wide ownership and acceptance.

A great deal of jargon has become attached to the GMO debate. To help the reader through this, a glossary of technical terms used in this report is attached at Annex 1.

1.3 New Thinking And Effective Ways Of Working For A Sustainable Future

There is increasing recognition in society that:

• The rationales and justifications driving pure research and applied science, and the development of technology, need to undergo change. This is to take account of a more inclusive process, in which the views of the whole of society are represented, looking towards a sustainable future and taking account of the wellbeing of the planet and of human society. New skills and planning frameworks are needed for this to happen.

• New ways are needed for working out choices and best options with the future in mind. Processes to bring diverse people and professional fields together, based on dialogue, and facilitation of active participation are proving more effective than "top down" approaches.

The challenges for the Environment Agency raised by the introduction of GM technology are that it requires:

- awareness of whole system implications dealing with complexity;
- dealing wisely with the unknown;
- not just "the environment" but also interests of society (local and global), and economic issues (commercial pressures, true cost awareness) to be taken into account. These diverse factors reflect an increasing emphasis on sustainability;
- bringing together different professional fields and stakeholders, and creating understanding and consensus so that decisions can be taken with confidence;
- shifting from short-termism to taking responsibility for long-term implications, and how actions today can potentially affect the future;
- sensitivity and transparency to the public scepticism about scientists, industry and regulatory agencies in the wake of the BSE saga; and
- implementing local regulation in the context of national, European and international legislation and agreements which potentially conflict. For example, international targets for biodiversity and emissions are under challenge from trading agreements and practices.

The GMO isue is far from unique in this regard. Climate change, new technologies, and new combinations of materials in the environment and other changes in the pipeline provide similar challenges to the Agency. A consensus-based approach, arranged on the intellectual framework of the conditions for a sustainable future, is recommended for dealing with these complex multi-dimensional issues.

1.4 Consensus-building

Consensus requires recognition of what is agreed and what is in dispute; it does not deny disagreement and uncertainty. Whereas other decision-making processes can override minority and opposed views, consensus-building approaches work with these and look for their underlying value. Consensus-building takes more than a one-day event and requires representation and participation by stakeholders from across the whole system.

Signs of meaningful consensus would be that a range of key players would agree, own the decisions made, and abide by the decisions and actions agreed.

1.5 The Natural Step and Consensus-building

The Natural Step UK (TNS UK) has been operating The Natural Step process and tools in the UK since the beginning of 1997. Details of the derivation and mechanics of TNS are provided at Annex 2.

Rooted in robust scientific principles, The Natural Step has been helpful to businesses and others seeking to get to grips with sustainable development in pragmatic terms. Another helpful aspect of TNS is that the science-based model at its heart, and the system conditions that derive from this model, can be used as an "intellectual round table" around which to hang debate. This framework enables consensus-based dialogue about the various environmental, social and economic issues associated with the place of contentious topics in a sustainable future. From this holistic and robust framework, the polarisation so common in traditional debate about contentious issues can be avoided by suspending judgements and providing a context in which to fit the breadth of issues involved.

Although the four system conditions of The Natural Step are articulated, together with their derivations, in Annex 2, they are repeated here for reference:

- 1. Substances from the Earth's crust must not systematically increase in nature.
 - In a sustainable society, fossil fuels, metals and other materials are not extracted at a faster pace than their slow redeposit and reintegration into the Earth's crust.
- 2. Substances produced by society must not systematically increase in nature.
 - In a sustainable society, substances are not produced at a faster pace than they can be broken down in nature or deposited into the Earth's crust.
- 3. The physical basis for the productivity and diversity of nature must not be systematically diminished.
 - In a sustainable society, the productive surfaces of nature, including their biological diversity and the processes that ecosystems perform, are not diminished in quality or quantity. We must not harvest more from nature than can be recreated and renewed, nor seriously compromise the processes performed by natural systems.
- 4. We must be fair and efficient in meeting basic human needs.

In a sustainable society, basic human needs must be met with the most resource-efficient methods possible, including equitable resource utilisation and distribution. This system condition differs from the former three in that it relates less to the underlying science and more to the promotion of social justice.

The Natural Step provided the intellectual framework for the 2020 Vision Seminar on GMOs, helping to address the question:

"What is the place of GMOs in a future sustainable world?"

This consensus-based approach takes the debate away from polarised views and into evaluation of the contribution GMOs may or may not make. The TNS approach has consensus-building potential around issues relating to the environment and society because it provides:

- a framework for sustainability that is:
 - inclusive of the needs of the whole of society;
 - a science-based approach which bridges traditional science to social aspects, and helps scientists connect with other views and wider questions;
 - understandable by most people which therefore helps create a level playing field whereby scientific and technological information can be evaluated in a wider context without lack of expert knowledge being a barrier to dialogue;
 - a helpful unifying context for all to understand, and to record, the risks and the opportunities benefits;
 - a holistic model taking account of resources, biodiversity and social aspects;
- clarification of the terms of application of the precautionary principle;
- the vision for those with vested financial interests to determine how they could invest more wisely in aspects of the technology that may have a place in the future;
- an holistic context from which to identify aspects about which we currently know too little to make informed judgements;
- a metaphor of the "Funnel", which helps identify the reasons why sustainability is a big issue for all sectors of society and helps people with future scenario planning;
- the methods used with the framework help links to be made between cause and effect and this helps people agree on next steps and key issues;

- a way of mapping opinions and ideas that may be opposing or apparently incongruent, thus suspending argument by fitting apparently opposing points within a wider context. This enables ideas to be worked through in a positive way; and
- a framework to set out clearly the under-pinning knowledge, values and perceptions which are the basis for the "win-win" of consensus.

1.6 Just the Start of the Process

It is important at this stage to recognise that a single workshop event is not of itself adequate to truly deliver consensus. The process of this 2020 Vision Seminar has started dialogue, with interim conclusions and consensus views on a range of issues, that continues through four principal route:

- 1. Dialogue promoted in the 2020 Seminar itself, and in the review and finalisation of this report;
- 2. Ownership of actions by participants in the dialogue;
- 3. The establishment of a network of participants who might progress key issues of mutual concern collectively; and
- 4. Acknowledgement of, and action upon, points of consensus by other bodies (government departments, regulatory agencies, etc).

2. The Process of the 2020 Vision Seminar

2.1 A Consensus Process

The thrust of the day was to work from information-sharing, through dialogue, to points of consensus. The audience comprised 26 invited experts, including Environment Agency staff from a range of policy areas, active researchers, interested parties, members of voluntary groups and others. It was recognised at the outset that not all stakeholder groups were represented, and that further events of this type would be helpful in taking the consensus process forwards. The format of the event was essentially that of a closed dialogue. Delegates are listed in Annex 3.

The Natural Step's approach provided not merely the systems thinking and the intellectual framework (the four system conditions) around which to hang the debate, but also the dialogue and consensus-building tools to lead towards the desired outcomes. The TNS framework and tools gave structure to the debate, but were not used in an intrusive way. The emphasis was on bringing out the issues and ideas rather than excessive deliberation and training on the TNS system conditions. This enabled the participants to use them in a relaxed way rather than sticking to a purist view on which system condition to choose for a particular issue.

2.2 Guidelines for the Day

The workshop was designed to encourage participation and sharing of ideas from the outset. During the informal period prior to the meeting starting in earnest, participants wrote up their interests in GM issues, and their hopes and concerns for the day. At the start of the workshop, a set of guidelines for the day were agreed to establish the way of working:

- listening to others and helping others be heard;
- seeking constructive and positive ideas and next steps;
- treating the views of others with respect and accepting that everyone's perspectives are valid and useful; and
- confidentiality concerning the discussions in groups(the event report will not attribute ideas and findings to individuals, other than acknowledging the authors of the prepared papers in Annex 4).

2.3 The Three Phases of the Workshop

The three phases of the workshop were:

2.3.1 Updating and Information-sharing

The morning session was dedicated towards sharing information through brief presentations by invited experts across the breadth of topics affected by GMOs. Speakers had been briefed that they were essentially *imparting information* and then joining freely into debate, without necessarily *defending a position*. Most presenters had, as requested, prepared papers prior to the meeting, and these had been circulated and were read by delegates prior to the meeting to ensure a consistent and high level of information-sharing. Questioning of speakers was restricted to points of fact — not of opinion or interpretation. The prepared papers, attached at Annex 4, were:

- GMOs: the debate so far and the way ahead (Mark Everard, TNS UK)
- Implications for the Environment Agency (Richard Howell, Environment Agency)
- Genetic engineering or natural law? (Mark Griffiths)
- The impact of GMOs on resource use (Suzy Hodgson)
- The regulatory framework for GMOs (Paul Burrows, DETR)
- GMOs: an industrial perspective crops and other uses (Marie Janson, CEST)
- Resource use and biodiversity (Brian Johnson, English Nature)
- Public perception (Robin Grove-White, Lancaster University)
- Notes on ethical implications (Clare Twigger-Ross, Environment Agency)

During this morning session, all participants were asked to pick out key points, issues and questions, and to record these on yellow stickers. Delegates placed all yellow stickers on one of four boards, each corresponding to one of the four TNS system conditions. The comments on the yellow stickers provided the material upon which the future phases of the workshop would be based.

2.3.2 Group Discussion and Enquiry

Following lunch, delegates broke into four groups to consider the papers from the morning. Further issues and concerns arising from this session were recorded on additional yellow stickers and attached to the four system condition boards. All comments, structured around the four system conditions, are therefore copied in Annex 5.

Once it was felt that most of the substantive points had been identified and captured, the four working groups then circulated between "sticker boards", reviewing and discussing the findings.

2.3.3 Basis for Consensus

The next phase of the process entailed each of the four syndicate groups debating the key issues recorded on one of the four boards. Ideas arising were recorded on more yellow stickers, either as **Knowledge Gaps** or **Questions Remaining** on a further pair of boards. The four groups circulated around the four system conditions boards to ensure a mixing of views. The knowledge gaps and questions remaining are recorded in Annex 6.

In the concluding stages, the groups were reorganised to create four new working groups, each comprising representatives from each of the previous discussion groups. This helped people to capture the flavour and diversity of discussion from each group, and then draw out **Points of Agreement**. These points of agreement were subsequently discussed in a final plenary session involving the whole group.

The event ended with participants proposing Next Steps, indicating aspects that they personally would put effort into, and selecting priority issues.

The Points of Agreement and the Next Steps therefore represented the culmination of the consensus-based process of the workshop, and are captured in the Outcomes section, which comprises Part 3 of this report.

3. Outcomes

The process of the day was one of moving from information-sharing amongst participants, through consensus-building steps using TNS tools as a framework for the debate, and leading towards three main outcomes:

- Points of Agreement
- Next Steps
- Ways Forward

3.1 Points of Agreement

The final outcomes of the workshop were a set of **points of agreement**, which were evolved during the day by inclusive dialogue, and presented and discussed in the concluding plenary session. These points of agreement – which were unusually numerous and diverse when compared to typical debates about GMOS - are listed below under a range of sub-headings:

3.1.1 Concern for nature

- GM is a radical technology, going beyond traditional selective breeding and hybridisation and by-passing natural "filters" to the transfer of DNA between species. The full implications of this transfer of genetic material have not yet been determined. This includes the full implications of:
 - □ The target genes transferred between species; and
 - Bacterial and viral "promoters" used to insert new DNA into recipient organisms.
- There is a need carefully to monitor impacts on biodiversity (including long-term effects).
- The mechanics, frequency and implications of "genetic drift" of genes, by crosspollination and other means, to wild plants and non-transgenic crops remain to be explored in detail.

3.1.2 Regulatory framework concerns

- This is a radical technology without an adequate framework to regulate its development internationally.
- The regulation of GMOs should be reviewed in the light of current debate and public concern, with particular emphasis on the appropriate application of the precautionary principles where knowledge is lacking or inadequate.

3.1.3 Need quality information (two-way) with public interest a priority

- There is a need for comprehensive, balanced and widely-available scientific information, targeted to increase public understanding of the GMO debate.
- We need to find ways of bridging the gulf of knowledge and understanding between scientists and the public, and providing a two-way flow of concerns and appropriate information.
- We need to define what constitutes a "sustainable agricultural/health/etc. system".
- We also need parallel baseline information for non-transgenic crops, against which to evaluate differences with the transgenic crops.
- We need to be clear on how much "knowledge" we need before translating "science" into technology.
- 3.1.4 Democracy and public involvement are crucial it is not just a matter for "the experts"
- We can not leave it to "experts"; the public must have a more active role in shaping the direction of GM technology.
- A multidisciplinary framework is required to bring <u>all</u> groups, issues and concerns together.
- It will take radical institutional changes to generate consensus and capture the benefits.
- This is an important development technology it will not blow away because it is already here now.

• The important test is how we manage the knowledge and know-how.

3.1.5 Seeking solutions to poverty

- Poverty is a major obstacle to meeting real human needs we should do something about it. There is widespread scepticism about the way commercial enterprises are matching their claims to "feed the world" with applications of GM technology.
- If GMOs are a potential solution to poverty in a sustainable manner, we must pursue them. However, this should not be just a "techno-fix". For example, land reform and participation are also key issues that must be addressed.
- The current debate is not taking in the "global/poverty" context.
- There should be recognition that the parameters governing uptake of GMOs in developing countries are different from those in industrialised countries. Issues such as the patenting of life forms and of tradition crops, or the industrialisation of agriculture for the apparent benefit of multinationals, remain to be explored.

3.1.6 Agriculture and farming systems

- GM issues are only part of a wider debate on sustainable agriculture.
- Can we have a sustainable agricultural system without GMOs? If not, how would/should they fit in?
- There is a need to re-assess the role of GMOs in agriculture and identify the possibility of developing new agricultural systems.

3.2 Next Steps

During the final plenary session, delegates proposed next steps to take the debate forward in the light of the issues raised during this one-day workshop. Again, the issues raised are divided between category sub-headings.

3.2.1 Information

Insights from this event should be disseminated.

• Help others access the ideas and understanding.

3.2.2 Independent debate

- There is a need to find a body, or bodies, to take a lead in stimulating truly independent debate. Who would be acceptable to all sides? Perhaps a government agency, with partners such the RASE and/or an NGO (for example RSPB, FoE, or the Genetics Forum who publish Splice magazine)?
- There was support for broadening the base of discussion, and developing tools and vocabulary for public disclosure. This should take the form of an *imaginative* catalyst, using non-traditional techniques, through LA21, events, festivals, plays, public awareness of science and engineering (PAWS), etc.

3.2.3 Stakeholder involvement and connections

- Other stakeholders need to be involved in linking GM issues to sustainability (this includes in particular industry, organisations representing developing countries and particularly indigenous communities and the poor, NGOs representing specific interests, etc).
- There is a need to identify and involve in the wider public debate those who are making decisions about food, deliberate release, contained use, etc.
- There is also a need to engage all major players (it was disappointing, for example, that MAFF was unable to send a representative to the event).
- The Environment Agency and the Health and Safety Executive need to discuss the contained use of GMOs.

3.3 Ways Forward

The 2020 Vision Seminar on 28th April 1999 was a constructive and enriching experience for those who took part. It was also successful in bringing out a wide range of points of agreement and airing the issues. However, for the **points of agreement** and **next steps** to move forwards, further actions are required such as:

3.3.1 Continuing to build consensus and awareness of GMO issues relating to a sustainable future through further work with the participants, and through widening the process to include others from within the Environment Agency. This could include circulating ideas generated on the day and

running further events designed to make progress on the issues raised for the Environment Agency;

- 3.3.2 Exploring ways of taking forward the ideas and options raised on the day with other decision-makers, researchers and GMO regulators, in conjunction with other key stakeholders representing wider society and ordinary peoples' interests;
- 3.3.3 Seeking collaborators (e.g. other UK government and European agencies, and non-government agencies) to develop rigorous regulatory guidelines and frameworks. These could include development of protocols for the justification and management of research and pre-market trials, to take into account the implications of striving for a sustainable future; and
- 3.3.4 Developing a stakeholder analysis to elucidate ways for dialogue and consensus to build around the issue. Ideally this would include bringing together the widest possible cross section to explore the issues in an informed way.

3.4 Concluding Notes About Workshop Outcomes

It is important to note that the ideas and findings in the report show that there are many reservations about GM technology and GMOs. There is also recognition of a number of potential benefits, through the risks associated with them have yet to be determined.

In no sense did the participants give unreserved support to pursuing the technology incautiously. Grave concerns were raised about the potential impacts of the technology upon the environment, biodiversity, and ownership of genetic resources, conflicting with the public interest.

In conclusion, it is important to recognise that consensus-building takes more than a one-day event. However, there was a general perception amongst delegates that this event had taken the debate forwards.

4. Feedback from Participants

Feedback from participants, both informally and through a more formal evaluation questionnaire, indicated that they had found the discussion useful and helpful. On the whole they were satisfied with the day but felt that it was not an end in itself. There was a strong sense that actions should be taken to involve other stakeholders. In addition, they identified areas of interest to take forwards for themselves. Some found the focus on sustainability and the future helpful, and wanted more exploration of scenarios; others felt more immediate knowledge gaps and regulatory issues should be tackled as a priority.

Annex 1: Glossary

ACRE Advisory Committee on Releases to the Environment

Biotechnolog

y

The use of biological organisms for human purposes. This includes fields as diverse as selective breeding of crops and livestock, brewing, drug fermentation, etc. Although often used synonymously with GM in the media, this term covers not just organisms produced by genetic modification, but also those produced in natural strains, selective breeding and hybridisation.

BSE Bovine Spongiform Encephalopathy

Bt A natural insecticidal toxin released by the bacterium Bacillus thuringiensis,

encoded in a gene that is inserted into crop plants to confer insect resistance.

DETR Department of the Environment, Transport and the Regions

GM Genetically Modified - one aspect of biotechnology, relating to the transfer of

genetic material between different species, permanently modifying the recipient organism. Alteration of the genetic material of an organism in a way that does not occur by mating or natural recombination or both. It involves the random

insertion of single genes from unrelated organisms.

GMOs Genetically Modified Organisms

HSE Health and Safety Executive

LA21 Local Agenda 21

MAFF Ministry of Agriculture, Fisheries and Food

Marker Genetic material added to the genome which have "no known effect" such as

the so called "green markers" and antibiotic resistance markers

RASE The Royal Agricultural Society of England

SSSI Sites of Special Scientific Interest

TNS UK The Natural Step UK

crops

Transgenic Crops derived from GM technology, which have modifications to the DNA

(genetic material) in all of their cells.

End of Annex 1

Annex 2: Outline of The Natural Step

This annex is provided to help delegates understand the background to The Natural Step, and how it can be used as an holistic framework of sustainability against which to assess the future place of GMOs (and other issues) in a future sustainable world. The article below, titled "The Longest of Journeys Begins...", appeared on pages 14-15 of the November 1998 edition of the journal Industrial Environmental Management. It is reproduced here by kind permission of Matt MacAllan, Assistant Editor.

"The Longest of Journeys Begins..."

Sustainable development is a sound, necessary and widely-supported concept. But how does one move from concept to practice, and begin applying it in the messy world in which we live? Dr Mark Everard, Director of Science, The Natural Step UK - launched last month - strides out.

Let's be clear, sustainable development goes way beyond mere compliance with basic environmental and social obligations, and is substantially different to "greening" (peripheral "end-of-pipe", "end-of-field", process optimisation, mitigation, or reputation-building measures). Although sustainability has been the subject of myriad definitions, and seemingly interminable debate about detail, the concept is really quite simple. A sustainable system is one that can continue indefinitely. A sustainable society is one that does not impair or overload the life-support systems that provide for its needs. A sustainable business or other enterprise is one that respects nature's limits and the rights of those with whom it interacts, however remotely, and that can thereby be sustained indefinitely. It is that basic and, at the same time, that remote from what we do today!

How then can one get to grips with sustainable development in the gritty reality of day-to-day decision-making? The first step is a realisation that a commitment to sustainable development is about far more than altruism. A more sustainable business or activity will be less disrupted by resource scarcities, reduced environmental "headroom", adverse public opinion, more stringent environmental and social regulations, etc, in a future world in which population is set to increase and environmental resources to diminish. In short, a more sustainable enterprise is one that will preempt future pressures and future markets, and will thereby be more competitive.

High-level Principles

Net-working and shared learning with those upon whom we depend, and who depend upon us, is also essential since sustainable development touches all aspects of human life and is therefore not something we can ever hope to achieve in isolation. And, since the application of sustainable development pervades all sectors of society, a set of high-level

principles are therefore required to offer a generic, yet robust and science-based, framework for the development of a shared vision, and for wise decision-making.

The Natural Step (TNS) was developed in Sweden some nine years ago to address this gap between the idea and its widespread practice. It has proved highly successful in influencing decision-making across Swedish society - in business, in local and central government, in education and in the home. And it is now beginning to spread across the world.

TNS addresses the scientific underpinnings of the sustainable cycles of nature, upon which not only our health and survival but also the totality of human interests ultimately depend. Using a systems thinking approach, it addresses the biosphere as a holistic dynamic system, and from the scientific laws that govern this system it derives a set of first-order principles governing how a sustainable society would need to operate. The basic TNS model is illustrated in Figure 1.

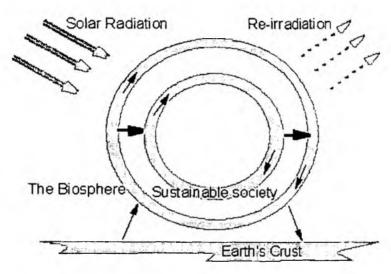


Figure 1: A sustainable society exists within the "rules" of nature's solar-powered cycles. An unsustainable society is one that offends these "rules", and which will inevitably contribute towards the breakdown of the support systems upon which it depends.

Nature's Cyclic Flows

Our present developed society, for example, relies substantially upon linear ("mine-use-dispose") resource flows. Linear resource flows inevitably cause problems since, being alien to nature's cyclic flows of matter, wastes build up in the biosphere in the longer or

shorter term, even if we put them "out of sight and out of mind" in the seas, in landfill or into the air. Using the systems-oriented TNS model, it is possible to determine, in simple yet scientifically well-founded terms, the primary ways in which human practices can contribute to an unsustainable world. The four "system conditions" are first-order principles derived from the TNS model, and define the behaviours that a sustainable society would have to observe. These four system conditions are indicated in Figure 2, and described below.

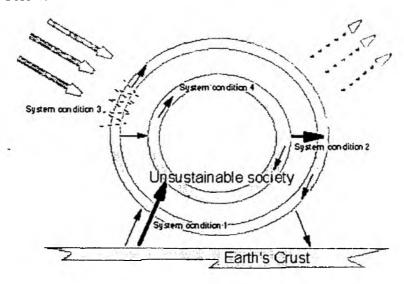


Figure 2: The four system conditions, illustrated by breaches caused by an unsustainable society.

System condition 1 - "Substances from the Earth's crust must not systematically increase in nature" - relates to those substances immobilised in the lithosphere (the "rocky" and largely inert parts of the planet) by billions of years of slow sedimentation and biomineralisation. Clearly, modern developed industrial and agricultural processes breach this system condition extensively, relying on inputs of cheap and abundant energy unlocked from fossil fuels, nutrient substances added to soils, and extraction of metals and radioactive substances. The associated problems of climate change, eutrophication, and increasing soil and water contamination are, however, also well known, resulting from production of wastes at rates exceeding nature's reintegration and deposition processes. As wastes tend systematically to rise in concentration, potentially adverse and unpredictable impacts upon nature and climate also harm the economic and social values deriving from them.

System condition 2 - "Substances produced by society must not systematically increase in nature" - relates to man-made substances. Substances new to nature are processed inefficiently, if at all, by biochemical systems that have evolved over 4.5 billion years in their absence. Breakdown and reintegration of the estimated 100,000 such substances currently in production is therefore slow, leading to systematic accumulations in the

biosphere. Predicting tolerable limits, particularly in mixtures and in complex ecosystems, is difficult given our largely incomplete knowledge of their toxicity. We also know that there is a possibility of unforeseen effects revealing themselves in the future - a very recent example is the discovery of endocrine disruption - and it is for this reason that the Swedish Government is considering phasing out persistent bioaccumulative substances, regardless of toxicological data.

System condition 3 - "The physical basis for the productivity and diversity of nature must not be systematically diminished" - addresses the extent and diversity of nature's productive surfaces. The natural processes and productive capacity of nature are the "engines" of biospheric processing, equipped throughout millennia of evolution with diverse ecosystems providing adaptable and efficient pathways. The consequences of over-harvesting natural resources are well-know from the collapse of the world's major marine fisheries, from the scarcity of hardwoods, and from the ever-extending list of extinct and critically endangered species, yet over-harvesting still continues. Equally, we are beginning to become aware of the massive scale of the life support "services" provided collectively by earth's ecosystems, which we diminish or impoverish at our peril.

Social Considerations

System condition 4 - "We must be fair and efficient in meeting basic human needs" - highlights the social considerations permitting compliance with sustainable resource use. Primarily it addresses issues of resource efficiency and equity. Whilst the need for improved resource efficiency is already accepted (Factor 4, Factor 10, etc), we are less responsive to the international dimension of environmental problems, and the contribution of injustices and inequities to social instability.

TNS as a Tool for Sustainability

TNS is a generic, science-based tool to support more sustainable decision-making on a society-wide basis, and as such is applicable across a range of scales. The TNS model is based on nature's sustainable cycle, and the four system conditions define how a sustainable society must act "ecocyclically". As such, it provides a readily-understandable framework to get to grips with the practicalities of sustainable development, to predict future pressures, to communicate complex ideas within a business environment, to share these concepts with partners and across social sectors, and to make strategic judgements about the steps we need to take now towards a more sustainable future. It helps us address the fact that we can not realistically hope to achieve sustainability immediately in a world that is far from sustainable, but enables us to "navigate" increasingly towards sustainability through incremental decisions.

The Natural Step is now operating in the UK as a part of Forum for the Future, the charity established by Jonathon Porritt to promote practical commitment to sustainable development across UK society, and the scientific work of TNS UK is kindly supported by the Environment Agency. There is clearly a great deal more to The Natural Step than it is possible to convey in this brief article. We believe that TNS offers a unique tool for getting to grips with sustainable development, for putting it into practice within enterprises, and for doing so as a matter of "enlightened self-interest".

Annex 3: List of Workshop Participants

From the Natural Step	9 Imperial Square, Cheltenham,
_	Gloucestershire GL50 1QB
	Tel: 01242-262744 Fax 01242-524445
Dr Mark Everard (Chair)	E-mail: mark.everard@environment-agency.gov.uk
Director of Science	
David Cook	E-mail: david.cook@tnsuk.demon.co.uk
Chief Executive	
Professor Steve Martin	E-mail: steve.martin@tnsuk.demon.co.uk
Director of Learning	
Diana Ray	E-mail: diana.ray@btinternet.com
TNS Facilitator	Tel: 01451-820274
From the Environment Agency Board	Environment Agency, Rio House
	Waterside Drive, Aztec West
×	Almondsbury, Bristol BS32 4UD
10.0	Tel: 01454-624400
Nigel Haigh	Rio House (see above)
Prof Jacqui McGlade	Rio House (see above)
Prof Donald Ritchie	Rio House (see above)
Tony Rodgers	Rio House (see above)
Environment Agency Staff	
Dave Bird	Rio House (see above)
Research and Development	
Stefan Carlyle	Rio House (see above)
Head of SATIS	
Liz Greenland	Rio House (see above)
Science and Data Exploitation Manager	
Emma Hayes	Environment Agency
	National Centre for Environmental data and Sureveillance, Bath
Richard Howell	Rio House (see above)
Biodiversity Manager	
Rob Robinson	Rio House (see above)
Rural Land Use	,
Beatrice Rose	Rio House (see above)
Sustainable Development Unit	, ,
(Forum for the Future Scholar)	<u></u>

Clare Twigger-Ross	NCRAOA	

Social Issues Office	Steel House
	11 Tothill Street
	London SW1 9NS
	Tel 0171-664-6705
Other invited participants	10.01/1.004.0/03
Paul Burrows	DETR
_ = = = = = = = = = = = = = = = = = = =	2 Marsham Street
	London SW1P 3EB
	Tel: 0171-890-3000 x5285
	E-mail: paul burrows@detr.gsi.gov.uk
Mark Griffiths	75 Fairfield Road
*	Winchester SO22 6SG
	Tel: 01962-842233 (work)
	E-mail: griffiths@writeme.com
Robin Grove-White	Centre for Study of Environmental Change
	Lancaster University
	Lancaster LA1 4YT
	Tel: 01524-65201
<u> </u>	E-mail: grovewhite@lancaster.ac.uk
Suzy B Hodgson	Centre for Environmental Strategy
Programme Director	University of Surrey
	Guildford
	Surrey GU2 5XH
	Tel 01483-259073 (direct) Tel 01483-259047 (office)
	Fax 01483-259394
	E mail: S.Hodgson@surrev.ac.uk
Anna Hope	English Nature
	Somerset & Avon Team
	Roughmoor
	Bishops Hull
	Taunton
	Somerset TA1 5AA
	Tel 01823-283211
Professor Roger Hull	John Innes Centre
Associate	Norwich Research Park
	Colney
	Norwich NR4 7UH
Dr Marie Janson	CEST Programme Ltd
	5 Berners Road
	Islington
	London N1 0PW
	Tel 0171 354 9942

Dr Brian Johnson	English Nature
	Somerset & Avon Team
	Roughmoor
	Bishops Hull
	Taunton
İ	Somerset TA1 5AA
	Tel 01823-283211
Sue Mayer	Genewatch
	The Courtyard
	Whitecross Road
	Tydeswell
	Buxton
	Derbyshire SK17 8NY
	Tel/Fax 01298-871898
Dr Andy Swash	FRCA
	Room 346
	Nobel House
	17 Smith Square
	London SW1P 3JR
Dr John R Witcombe	CAZS
	University of Wales at Bangor
	Bangor
- 9	Gwynedd LL57 2UW
	Tel 01248-351151 (department)
	Tel 01248-382922 (direct) E mail dfid.psp@bangor.ac.uk
L	L man unu.psp(w)vangor.ac.uk

Annex 4: Papers Presented at the Workshop

The following papers were presented by delegates at the workshop, and are reproduced here for information with the permission of their authors:

- GMOs: the debate so far and the way ahead (Mark Everard, TNS)
- Implications for the Environment Agency (Richard Howell, Environment Agency)
- Genetic engineering or natural law? (Mark Griffiths)
- The impact of GMOs on resource use (Suzy Hodgson)
- The regulatory framework for GMOs (Paul Burrows, DETR)
- GMOs: an industrial perspective crops and other uses (Marie Janson, CEST)
- Resource use and biodiversity (Brian Johnson, English Nature)
- Public perception (Robin Grove-White, Lancaster University)
- Notes on ethical implications (Clare Twigger- Ross, Environment Agency)

Annex 4 continued...

GMOs: The Debate so Far, and the Way Ahead

Dr Mark Everard, Director of Science, The Natural Step

A Brief History of the GMO Debate in the UK

The history of the debate about GMOs in the UK to date has been largely one of entrenched views, with little true consensual light emerging amidst the heat of argument. What appears lacking is an holistic appraisal, taking on board the breadth of scientific ideas, the full implications of either the claimed benefits or the claimed disbenefits, the weight of public concern, and a balanced risk assessment. And this appears almost wholly lacking whether one looks to big businesses with interests in GM technology, the UK Government or the European Commission, the opponents of GM foods and GM releases, or the media.

Without going into great depth, this papers seeks to introduce some of the ideas promoted by the extremes of the debate, the features confounding enlightened debate and consensus-building, and then to explore the middle way towards forming a balanced and enquiring view. This central path is based on the consensus-forming capacity of The Natural Step.

The Potential Benefits of GMOs

Proponents of GM food technology claim, in advertising materials and in the media, that many benefits will arise from widespread application of the technology. For example, it is claimed that it will:

- ! Result in reduced energy and fertiliser inputs
- ! Require the use of less pesticides
- ! Reduce tillage, compaction and erosion
- ! Adapt crops for optimum productivity in poor soils
- ! Decrease pressures on biodiversity
- ! Improve food quality
- ! Produce more food with a lower Afootprint≅ for a growing global population

The Potential Disbenefits of GMOs

Conversely, opponents of the technology make counterclaims that GMOs will instead:

- ! Result in increased energy and fertiliser intensity
- ! Increase pesticide use
- ! Result in increased tillage of marginal land not previously brought into cultivation
- ! Effectively sterilise farm land, further threatening biodiversity
- ! Allow genes to Adrift into wild plant an animal species
- ! Replace traditional crops and foods, and environmentally benign agricultural practices
- ! Disenfranchise local people by centralising economic power into a few multinationals

Confounding Features

In the heat of debate, it is often forgotten that:

- ! The benefits claimed, if substantiated, would be a significant contribution to sustainability
- ! Even if the potential benefits are proven, this does not invalidate the disbenefits
- ! Therefore, points raised by all parties have critically to be examined
- ! Generic claims are often raised about issues related to specific GM crops
- ! Confusions over terminology mislead
- ! The debate polarises, with little common ground nor a clear way ahead

An AIntellectual Round Table≅to Help Form Consensus

The Natural Step (TNS) is based on a systems model, built up from the principles governing the sustainable and cyclic biogeochemical processes of planet Earth. Since humans too are part of nature, although we often overlook this and act in stark denial, then this same model indicates to us the conditions under which a sustainable society would have to operate. Natural processes, after all, provide the totality of life-support services upon which we depend, and from which our health, economic activities and Aquality of life= ultimately derive. Further, though still brief, details of TNS are attached in the paper AThe Longest of Journeys Begins... (Everard, 1998).

As an holistic systems model, from which are derived four fundamental and non-overlapping Asystem conditions, TNS provides a helpful Aintellectual round table around which to hang the differing points of the debate. This provides a number of advantages:

- ! Implicit is the question about the place, if any, of GMOs in a sustainable future
- ! It places the debate onto a solid and science-based framework
- ! It enables consensus to be achieved on claims, without negating the counterposition
- ! It explores the diversity of issues: material/energy intensity, biodiversity, ethics, etc
- ! It highlights the questions that would need to be addressed to produce a balanced view
- ! It provides a mechanism for all to have their say
- ! The TNS model is so readily-understood that all can see where their arguments fit
- ! Consensus on issues, questions and a way ahead can be explored

TNS has already proven extremely successful in Sweden, where it originated in the late 1980s, in building consensus about contentious topics such as sustainable agriculture, forestry, nuclear power, etc. This workshop utilises this potential in the UK.

The achievement of a consensus view about GMOs is in everyone=s interests:

- Business wants to know where best to invest (and where to avoid) for the future
- ∀ Environmentalists/ethicists want to explore how best to meet the world=s growing needs
- ∀ Regulators/government want a framework for thinking about this complex issue

Annex 4 continued...

Genetically Modified Organisms: Implications for the Environment Agency

Richard Howell

(Conservation & Biodiversity Policy Co-ordinator, Environmental Strategy Directorate, Environment Agency)

Background

The Environment Agency has wide ranging powers and duties relating to water management, environmental protection and pollution control. Its principal aim is to exercise them so as to contribute to sustainable development, and it is required, in doing so, to have regard for, or further, conservation.

The Agency has no direct regulatory role in respect of GMOs, though they may impact on its activities in a number of ways. On behalf of the DETR the Agency currently makes available, via its regional offices, the public register of GMO releases to the environment.

The Agency's Position

The Agency endorses the need for a precautionary approach, as provided by the current regulatory regime and advocated by English Nature, involving a properly conducted programme of vigorous research and testing into the use of GMOs. One of the principal aims of such a programme should be to ensure environmental safety.

The Agency is interested in the use of GMOs for the following reasons

- the safe regulation of GMOs by the Health and Safety Executive and the DETR so their use in industrial processes do not present a threat to the environment via discharges or emissions which the Agency regulates
- the safeguarding of the aquatic environment as a result of growing GMO crops for food; and
- possible GMO applications which the Agency itself may wish to use, for example in respect of the decontamination of land or as environmental tracers.

In recognising the need for sound regulatory systems covering the media of land, air and water, the Agency will continue to make its scientific and regulatory expertise available to the Government and other interested bodies.

Implications for the Agency

In order to inform our own decision making at both a policy and operational level and to ensure our interests are properly taken into account in the overall regulatory process, the Agency needs to build on and develop its overall understanding of GM related issues. We need to consider:

- how the environmental issues in which we have a specific interest fit into the overall balance of risks and benefits associated with a particular GM products or application;
- the extent to our interests have been (or are being) taken into account by the principal regulators;
- the adequacy of existing controls, in the widest sense;
- potential and likely new developments and applications, and their environmental consequences; and
- public perception of the risks presented by GMOs.

Specific Issues

Arising from GM development and use, an initial list of issues for the Agency to consider includes:

Agriculture

Changes in:

- the uptake of water, nutrients etc.
- overall patterns of land use
- application of polluting materials (e.g. agro-chemicals, fertilisers)
- agronomic practices (minimum tillage, timing of operations)
- "upstream" and "downstream" activities (e.g transport, processing)

Industry

- changes in use of finite raw materials
- changes in overall pollution burden
- disposal of waste material

Environment

- bio-remediation and clean up technologies
- pollution tracing
- pollution reduction

Regulatory Process

- what do Agency inspection staff need to know
- efficacy of existing procedures and controls
- The Agency's role in respect of public registers.

We hope the Natural Step workshop will help initiate discussions and move us forward on many of the above issues, some of which we have already taken steps to address.

Annex 4 continued...

The Millennium Choice - Genetic Engineering or Natural Law?

Mark Griffiths BSc FRICS FAAV

(Environment Spokesman, Natural Law Party (UK))

The development of human civilisation in recent centuries has been shaped to a large degree through the discoveries of modern science. Science has provided an objective, systematic means to understand the laws of nature and to apply the knowledge it provides for the benefit of both individuals and communities.

Agriculture and food production have been major participants in this process. Up until now two key technologies which have produced profound agricultural revolutions have been the mechanisation of farming which began in the 19th century and the chemical based paradigm which developed chiefly after the second world war.

Both technologies represent interventions by man in the 'natural order of things', but do so at quite different levels of natural law. The chemical approach acts at a level which is considerably more complex than the mechanical, and as a result requires a much more extensive breadth of knowledge for it to be applied without creating unintentional lifedamaging effects.

Few people question the value of the mechanisation of agriculture. However, over the years hindsight has required the withdrawal of various agro-chemical products from use because of their damage to health or the environment, and even now the true effect of those that remain in use is not fully understood. These difficulties arise because the technology is applied at a level of nature's functioning in respect of which science's own knowledge base is inadequate. Additionally errors made at the chemical level are much more pervasive and insidious than those made at a mechanical level.

Now, as we arrive at the beginning of the third millennium, we find sections of the scientific community (in conjunction with powerful commercial interests) presenting genetic engineering as the next and most desirable step in our ability to transform our systems of agricultural production. Higher yields, production from otherwise unproductive land, reduced chemical usage, improved nutritional content of food and many other hoped for benefits are the goal of this new technology.

But genetic engineering operates on the basis of manipulating and controlling the DNA of living organisms. This involves intervention at a level of natural law infinitely more

complex than any previous technology applied in the field of food and agriculture, and in respect of which there are few reliable science-based predictive models.

By contrast after three hundred years or more of theoretical and empirical progress physics is a highly developed science. It is able to tell us almost everything there is to know about the nature of non-living matter from sub-atomic particles through to the behaviour of stars. It even reveals that the behaviour of such diverse microscopic and macroscopic systems are related and connected - something which would have been inconceivable at the time of Newton and certainly before the development of the unified field theories of the twentieth century.

Above all what the new physics has told us is that to understand the functioning of any natural system it is not sufficient to have knowledge of its components, it is also necessary to understand relationships within the system. And so we have found that at nearly the most profound level of physical functioning - the nuclear level - powerful forces are involved which man does not have the capacity to contain with any degree of long term reliability.

As with genetic engineering today, nuclear technology was presented by its proponents as having the potential to solve vital world resource problems. Nuclear energy would be so cheap and efficient that it would not be necessary to meter electricity supplies. That was the promise, but today we know better. The German government now has a commitment, however vague, to phase out nuclear power and in the UK the nuclear energy industry is the only public utility the government is unable to privatise because no one is willing to take on the costs of its long term liabilities.

In relative terms the science underpinning genetic engineering finds itself where physics sat three hundred years ago. Certainly the vast majority of genetic components and relationships are nowhere near being identified, let alone understood.

Physics is already highly developed because it has had the task of integrating only a handful of fundamental components and forces, all of which ultimately are derived from a common source. In genetic engineering the number of components and relationships is almost infinite.

Even in simple biological organisms like bacteria, the total potential interactions between genetic components run into many millions. These relationships have until now been managed by the intelligence of the organism's own DNA. It is now proposed that these relationships should be 'controlled' by the same species whose own limited intelligence has mistakenly and irretrievably peppered the globe with unmanageable nuclear wasteman.

In traditional plant breeding it is the highly sophisticated discriminatory intelligence of the plant which ultimately determines which genes may be accepted as part of the newly created organism, and it is that same intelligence which determines their placement and functioning within it. This process is driven by the information and knowledge contained within the DNA of the plant itself and exercised as an integral part of the natural sexual breeding process.

With genetic engineering this process is completely bypassed. Single genes are selected by the 'scientist' and randomly inserted into the genome of the host organism. The scientist has no control over their placement. In fact the plant geneticist has little or no knowledge as to where the new genes should be placed in any case; and usually he does not know where they have actually lodged even after his work has been completed. He simply "hopes for the best." Furthermore the inserted genes will frequently be taken from totally unrelated species.

Because of the limitations of the technology, in most cases the process will also necessarily involve the insertion of genetic material from at least one foreign pathogen, the most common of which (the 35S promoter) is taken from a virus which is very similar to Hepatitis B and related to HIV [1,2,3]. The consequences of using such elements have even been questioned by researchers at the John Innes Institute, one of the UK's premier research establishments in the field of agricultural genetic engineering [4]. Despite this, routine use of such pathogen-derived elements continues.

After only 20 years or so of development genetic engineering still involves processes which are random and 'trial and error' in nature, and in that sense they are imprecise and unscientific. The biotechnologist has little or no prior predictive power as to how a new gene will behave in the host organism. Without demonstrable predictive power it is inappropriate to refer to any process as 'engineering' or 'science-based'. As Einstein himself once said: "If we knew what it was we were doing, it would not be called research, would it?".

Let us be absolutely clear about this - genetic engineering is only just at the most basic and primitive stage of its own research.

If this somewhat alarming analysis is correct, then given the rapid introduction of genetically engineered crops and related technologies in the United States and elsewhere, we would expect things to be going wrong already - and indeed they are. Things are going badly wrong even after supposedly rigorous statutory testing and approval procedures. Here are some examples of the 'successes' of post-approval genetic engineering to date:

- in 1989 Showa Denko marketed an amino-acid food supplement manufactured using a genetically modified bacteria which produced an acutely poisonous new toxin. 37 people died and 1500 people were left permanently disabled in the US, resulting in claims of over \$2 billion.
- milk currently produced on a widespread basis in the US utilising a genetically engineered drug (rBST) manufactured by Monsanto is known to contain an insulin-

like growth hormone at levels associated with breast, prostate and intestinal cancer. Approval for the product was granted in 1993 despite evidence of toxic effects on rats submitted to (but not reported by) the Food and Drug Administration by the manufacturers. This issue is now subject to parliamentary hearings in Canada, and calls by American Senators for an investigation into the drug's earlier approval in the US.

- Calgene's Flavr Savr tomato was heralded as a breakthrough in genetic engineering in 1994. However, the delayed ripening characteristics engineered into the tomato were also accompanied by an unintended susceptibility to bruising. This forced farmers and processors to spend millions of dollars re-equipping their harvesting and handling systems, and eventually to abandon the product.
- despite claims from the biotechnology industry that genetic engineering is necessary to
 feed the world and to provide more renewable resources, yields from genetically
 engineered soya, cotton, oilseed rape and sugar beet since 1996 have proved to be
 lower than from traditional varieties. Some US farmers are now starting to pull out of
 these crops. Some herbicide resistant crops are also in practice requiring multiple
 applications of herbicide, rather than the single application originally envisaged.
- despite being deemed 'substantially equivalent' to traditional varieties by the regulatory authorities, genetically modified soya has been shown to produce biochemical changes in the milk of cows to which it is fed. It is possible that these may reflect raised estrogen levels in the beans as a result of their treatment by the glyphosphate herbicide with which they are engineered to be used. Elevated levels of estrogen are known to be damaging to animal and human health.
- in 1997 and 1998 farmers in at least four states in the US have been experiencing special problems with Monsanto's herbicide resistant cotton. These range from the cotton bolls falling off the plant prior to harvest to root deformation and plant collapse. Some farmers have experienced total crop losses and Monsanto have paid out millions of dollars in compensation.
- in 1998 Canadian farmers have reported the arrival by cross-pollination of genetically engineered herbicide resistant oilseed rape plants as weeds on fields where none had been sown. In order to control them farmers are having to widen the range of chemicals used on their farms because the new weeds are resistant to Monsanto's Roundup herbicide. AgrEvo has also acknowledged that a similar scenario is likely to emerge in relation to its own herbicide resistant products. Effects of this type are now the subject of farmer-manufacturer litigation in Canada.
- in 1998 Novartis began offering financial incentives to US farmers who agree to plant up to 40% of their maize crops in non-genetically modified varieties. This is because the effectiveness of their genetically engineered Bt pesticide maize (in controlling the European Corn Borer) is collapsing almost immediately after its commercial launch.
- in 1998 Swiss research also revealed that Novartis's genetically modified Bt maize can produce toxic effects in non-target beneficial insects.
- since the 1980s doctors throughout the world have been transferring people with diabetes from porcine insulin onto genetically engineered so-called 'human' insulin. Thousands of diabetics have since suffered serious adverse effects from this product,

including up to 50 suspected deaths. This is despite the fact that far stricter rules than those which apply to genetically engineered agricultural and food products govern the testing and approval of genetically engineered drugs. The genetically engineered insulin was claimed by one of its manufacturers to be 'one hundred percent a safe drug'.

What these experiences tell us is that with genetic engineering we are moving from so-called 'science' to applied technology in a way which is invasive almost beyond imagination, and with only a tiny fragment of the knowledge necessary to predict the results. The chief executive of Monsanto has himself described the effects of genetic engineering as "unknown, and to some degree unknowable"; and yet we are proposing to use this technology to irrevocably change the fundamental molecular structure of the world's food supply utilising un-recallable, self-replicating organisms.

What little science there is already tells us that gene placement and inter-chromosomal relationships between genes are important, and yet even many of the genes themselves within the plants that we are currently modifying have yet to be identified. There is not a single agricultural plant which has had its gene map completed.

Even before properly establishing this elementary information, we are then proceeding to randomly insert into our food foreign genetic material from viruses and bacteria which have never been an integral part of the human diet. In the words of Professor Philip James, the principal advisor to the UK government on the establishment of the proposed Food Standards Agency: "The perception that everything is totally straightforward and safe is utterly naive. I don't think we fully understand the dimensions of what we're getting into."

This scenario is far from encouraging. The scale and penetration of what is proposed is almost beyond belief. It is estimated by some that the majority of the world's food supply will be genetically engineered within 5-10 years if what currently sits in the corporate pipeline is allowed to go ahead.

What this astonishing situation reveals is not simply a problem concerning the 'science' of genetic engineering itself, or even of the health of the relationship between science, commercial interests, regulatory authorities, and government. What it demonstrates is a problem of our own consciousness. It is essentially a problem of the way we think, both as individuals and collectively as a society. And what it particularly demonstrates is our inability to learn from experience and to think and act holistically.

As such the debate about genetic engineering raises questions not simply about the use of the technology itself, but about the very nature of the society that we are trying to create at the end of the twentieth century. Do we wish to build a society which harnesses natural law, or one that violates it; one that nurtures life (including our own) or one that destroys it?

These are questions of immense importance, and they are ones not to be considered on an exclusive basis solely by senior scientific, commercial and political professionals. These are questions to be considered by every man and every woman, and particularly by those who are most directly responsible for the thought processes and values of our society as we enter the new millennium - our teachers and educators.

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(The Natural Law Party does not consider the risks posed by genetically engineered crops and food to be realistically containable, and is active in over 80 countries in seeking a permanent global ban. More information on these risks is available at www.btinternet.com/~nlpwessex .)

Notes on the Impact of GMOs on Resource Use

Suzy Hodgson (CES, University of Surrey)

1. Putting issue in context - scientific, historical, industrial, cultural/ethical

1.

Genetic modification is not new - Cross-breeding. We've been conducting genetic experiments for some time since 60s.- producing new organisms which nature would not have produced. There is lots of literature on recombinant techniques, including both good and bad results:

- Dalmatians with spot-gene also associated with blindness (10-15% born blind)
- plum + peach = nectarine
- polio vaccines
- 2. Defining boundaries around issues defining scale of issue
 - biotechnology vs. other technologies synthesis of new pesticides -
 - any genetic modification
 - introduction of certain genes (e.g. anti-biotic resistance)
 - intra vs. inter species, plant vs. animal vs., human cloning
- 3. Methods for studying issue
 - risk assessment what is hazard?
 - What are set of circumstances which would allow hazard to happen?
 - hypothetical or empirically-based?
 - risk pathways ingestion in foodchain, waterborne, airborne
 - What is the likelihood/probability?
 - uncertainty, level of acceptance
 - interpretation of data bias, vested interests of studies/sites, etc.
 - need for independent verification
 - risk perception
 - what degree of separation can be maintained between so-called natural species and GMOs?
- ⇒ risks vs. benefits Do benefits outweigh risks?
 - life cycle assessment
 - o compare resource burdens of different agricultural systems
 - □ GM crop vs conventional crop

- □ GM measure inputs/outputs
- How is crop defined?
 - □ What is functional unit equivalency of use?
 - □ Define boundaries of study site?
 - □ Field boundaries, time periods one harvesting cycle?
- Can effects be reliably measured?
 - □ food chain; and
 - ecosystem effects (e.g. impacts on biodiverisity)
- are there enough monitoring data from trial fields to make study statistically valid?
- need for consensus on parameters and assumptions of assessments joint factfinding
- possibilities for crops which do bring real societal benefits
 - of or example, drought resistant crops for drought prone areas
 - □ need more research

Annex 4 continued...

Forenote:

The paper below is not the one that Paul Burrows had initially tabled at the consensus-building workshop in April 1999. Paul has updated it since then to reflect subsequent developments in GMO policy and the implications of devolution. These useful additions make the paper more relevant today.

Deliberate release of genetically modified organisms: the UK regulatory framework

Paul Burrows

Department of the Environment, Transport and the Regions, Ashdown House, 123 Victoria Street, London SW1E 6DE, UK

This paper outlines the operation of the regulations covering the release of genetically modified organisms (GMOs) in the UK. The process described is that prior to 1 July 1999 when devolution transferred regulatory responsibility to Scotland and Wales in respect of their own territory. Post-devolution the regulatory process will remain broadly the same but there is likely to be a number of key operational differences that recognise the new powers of the devolved administrations to grant or refuse release consent. The details of these are still under discussion and are not dealt with here.

Summary

The regulatory framework controlling the deliberate release of GMOs aims to prevent or minimise damage to the environment by establishing a statutory system of risk assessment and prior consent, before any GMO can be released or marketed. Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms does much to harmonise the release of GMOs across the European Community. The Directive recognises two classes of release depending of the purpose; Part B releases for research and development and Part C releases for placing on the market. In the UK, no GMOs may be released without the express consent of the Secretary of State¹. All UK applications for Part B releases are submitted to the Department of the Environment Transport and the Regions, and the Advisory Committee on the Releases to the Environment (ACRE) advise whether the release should be allowed. In issuing consent the Secretary of State will also take account of views expressed by other Government Departments, the Statutory Nature Conservation Bodies

¹ Prior to devolution, the power to grant or refuse consent rested with the Secretary of State for the Environment, Transport and the Regions. After 1 July this power was transferred to Scotland and Wales with respect to their own territories. See note above.

and the general public. Applications for Part C consent follow a different procedure and are submitted initially to any one of the 15 Member States, which then reviews the application and forms an opinion. The other 14 States then evaluate the application. If there are no objections the lead Member State issues the marketing consent which applies throughout the European Community. If one or more State objects to the application then it falls to the Commission and Council to resolve.

Introduction

Judging from the presentation of GM issues over the last 12 months by the national media, it would be easy to believe that GM crops and food are being forced upon the market with scant regard to safety. It comes as a surprise then to many genuinely concerned observers that we do in fact have a rigorous and effective safety based regulatory system in the UK. The regulations enforce several layers of risk assessment and safety testing that cover the development GMOs right from initial research and development in the laboratory through to testing in the environment and finally placing a product on the market.

This paper outlines briefly the regulatory framework in the UK² in as far as it controls the deliberate release of GMOs. The emphasis is placed on the *process* whereby the regulations are put into action and explains how consent may be obtained to release GMOs either for experimental purposes or for placing on the market.

Development of the Deliberate Release Regulations

The regulation of genetic modification has its roots in the early 1970s when scientists working at the forefront of the emerging technology recognised its potential power and called for a 'moratorium' until a number of safety concerns had been considered. In 1976, the Genetic Manipulation Advisory Group (GMAG)³ was set up to consider proposals for work involving genetic manipulation. Soon afterwards, the *Health and Safety (Genetic Manipulation) Regulations 1978* came into force and required that any activity involving genetic manipulation [modification] should be notified to the Health and Safety Executive (HSE). These regulations only covered GM work in containment⁴, and at this time the release of GMOs to the environment was controlled by a voluntary code of practice overseen by HSE.

The first specific controls over the environmental release of GMOs in the UK were provided by Part IV of the Environmental Protection Act 1990. At the same time, the

² The UK regulatory framework is intimately linked to the wider European Community controls over GMOs

³ GMAG latter became the Advisory Committee on Genetic Modification (ACGM) which still advises Government today on the contained use of GMOs

⁴ Contained Use of GMO refers to activities in, for example, research laboratories and industrial facilities

Environmental Protection Act was being drafted the European Commission was also preparing community legislation to control deliberate release, this later emerged as the now familiar Council Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms. Directive 90/220 was implemented in the UK by the Genetically Modified Organisms (Deliberate Release) Regulations 19925 (amended 1995 and 1997) and came into force on 1 February 1993.

Aims and Provisions of the Regulations

The regulatory framework provided by these various statutory instruments aims to prevent or minimise damage to the environment by establishing a statutory system of 'prior informed consent' before any GMO may be released or marketed. In the UK, this means that no GMOs may be released without the express consent of the Secretary of State. The regulations set out prescribed information (see below and Box 1) which must be supplied in an application for consent to conduct a deliberate release. Central to the approval process is an *environmental risk assessment* which considers the potential risk to human health and the environment posed by releasing a particular GMO and, where necessary, identifies risk management procedures to avoid or minimise any damage. The regulations are framed in such a way that if it can be shown, to the best of current scientific understanding, that a release poses a low or negligible risk to the environment then it should be given the necessary consent to proceed. Potential benefit or scientific value of the proposed release are not factors that the regulations allow to be taken into account – only the safety.

Directive 90/220 recognises two broad categories for the deliberate release of GMOs⁶ depending on the proposed purpose:

- 1. releases for research and development, which are made under Part B of the Directive, cover a number of activities but, in particular, are used mostly for conducting experimental field trials with GM crops.
- 2. releases for *placing on the market* which are made under *Part C* of the Directive. Part C consent is necessary before a GMO may be used commercially or marketed within the European Community.

The principal procedural difference between these two categories of release is that Part B consents are granted at the national level on an individual Member State by Member State basis, whereas Part C consents are granted at the European Community level. Once issued, Part C consents apply across all Member States.

⁵ These regulations also gave effect to the substantive provisions in Part VI of the Environmental Protection Act 1990

⁶ Which are also reflected in our national deliberate release regulations

The Regulatory Process: Putting The Regulations Into Action

Although Directive 90/220 does much to harmonise the deliberate release of GMOs across the European Community, there are nevertheless differences between the individual Member States in the ways in which the Directive has been implemented and the national procedures followed to obtain release consent. By way of illustration, the following section describes the process in the UK whereby Part B and Part C consent may be obtained. The example of seeking approval to release a GM plant will be used, but the process is essentially the same for all GMOs covered by the Directive.

Part B Consent - Releases for Research and Development

Applicants wishing to conduct an experimental field trial in the UK with GM crops must first apply to the Secretary of State for consent to conduct the deliberate release. The application is submitted to the Biotechnology Safety Unit of the Department of the Environment, Transport and the Regions (DETR). Applications consist of a dossier of information substantially composed of the responses to 41 prescribed questions (Box 1) which are set out in schedule 1 to the 1995 regulations⁷. Taken together, the questions and answers build up a detailed description of the GM plant, how it has been modified and the conditions of the proposed release. Importantly, each application dossier also contains a detailed environmental risk assessment that considers the potential harm that may be caused to human health and the environment and identifies ways in which the risks may be avoided or minimised.

On receipt of the application dossier, it is initially reviewed by specialist scientists (case officers) in the DETR Biotechnology Safety Unit who copy it for comment to other Government Departments which also have an interest. These Departments are the Ministry of Agriculture Fisheries and Food, the Health and Safety Executive, the Scottish Office⁸ and the Welsh Office⁹. Details of each application and the environment risk assessment are also copied to English Nature, which in GMO matters represents the statutory Nature Conservation Agencies¹⁰.

The deliberate release regulations also specify certain information¹¹ about each application which is required to be placed on a statutory public register¹² within 12 days of receipt of the application by DETR. This information includes, among other things, a

⁷ Genetically Modified Organisms (Deliberate Release) Regulations 1995

⁸ If a release is to take place in Scotland. See opening statement (above) about devolution

⁹ If a release is to take place in Wales. See opening statement (above) about devolution

¹⁰ English Nature, The Country Commission for Wales and Scottish National Heritage

¹¹ Information prescribed under Part VI section 17 of the Genetically Modified Organisms (Deliberate Release) Regulations 1992

¹² Held at DETR in London. Copies of the register are also held at regional offices of the Environment Agency and at the Scottish Office in Edinburgh

summary of the application written in non-technical language, the location at which the release will take place and the environmental risk assessment. In practice, DETR goes much further than is required by law and makes all of each application available to the public, excluding the names of private individuals and any information agreed to be 'commercial in confidence'.

To aid transparency in the regulatory process, the applicants are required to place an announcement of the proposed release in a newspaper circulating in the area where the release is planned. The announcement must be placed within 10 days of submitting the application to DETR and it gives concerned or curious members of the public the opportunity to write the Secretary of State to object or to seek further information about the release.

Most applications when they are first submitted to DETR contain inadequate or ambiguous information and the case officer has the statutory power to request more information from applicants or clarify specific points. Once the case officer is content that the application contains sufficient detail and is compliant with the regulations then the dossier is put before the statutory Advisory Committee on Releases to the Environment (ACRE). ACRE is a scientific and technical committee made up of leading experts in subjects such as ecology, farming, nature conservation, plant breeding, microbiology, plant and animal molecular biology and toxicology. The Committee advises the Government on the potential risks to human health and the environment from the release of genetically modified organisms. Members are appointed on the basis of their technical and scientific expertise. They do not represent any particular stakeholder interests such as the biotechnology industry or environmental pressure groups.

ACRE reviews critically all of the information in applications put before it with particular emphasis on the risk assessment and any proposed risk management procedures. Gene flow is always an important part of the risk assessment where both the potential for gene flow and its consequences are considered. Often, the Committee will advise that the risk management is not sufficient and indicate what must be done to make it acceptable. Similarly the Committee may instruct the Secretariat (provided by DETR Biotechnology Safety Unit) to seek more information from applicants. When ACRE is content that the proposed release poses a low risk to human health and the environment, then the Committee will advise Ministers that the consent may be granted. In reaching a final decision on whether or not to issues consent the Secretary of State will also take into account views expressed by other Government Departments, English Nature and any letters received from the general public in response to the initial Public Notice placed in a local newspaper. If ACRE have expressed a favourable opinion and there are no scientific objections from the other parties then consent will be granted.

The granting of a Consent is not the end of the regulatory process. All consents carry statutory requirements for monitoring of release sites while the GM trials are in progress and after the release is terminated. Monitoring sometimes extends for two or three years after the trial. The monitoring looks out for unexpected effects (none have ever been

found in the UK) and seeks to confirm the assumptions made in the risk assessment. DETR is sent copies of all monitoring reports. There is additionally a system of inspection and enforcement in operation in the UK, whereby GM trials are examined by a specialist HSE inspector to ensure that they are in accordance with the conditions and specifications set out in the consent. Where non-compliance is detected, the regulatory power exists to take enforcement action and, if necessary, prosecute consents holders.

Part C Consent - For Placing on the Market

Marketing applications (which are more correctly called Part C notifications) are submitted initially to any one of the 15 Member States. The selected country then takes the regulatory lead on that particular application. The lead Member State has 90 days in which to form an opinion on the application. During this time additional information may be requested from the applicants and the clock is stopped while this is supplied. Marketing notifications that come to the UK, as the lead competent authority, go through the same strict evaluation process outlined for the Part B releases above, in that information is placed on the statutory public register and the dossiers are copied to other Government Departments (including Northern Ireland in the case of marketing) and English Nature. ACRE is asked to advise the Secretary of State whether the proposed marketing of a particular GMO poses a risk to human health and the environment.

In the case of part C notifications, ACRE pays particularly attention to the implications of the scale of the potential releases. Part C consent can allow the widespread cultivation of a GM crop on a landscape scale. This clearly has greater potential for environmental impact on, for example, farmland wildlife and biodiversity than does a small scale experimental field trial.

After reviewing the dossier, if the lead competent authority is content for the GMO to be placed on the market in the European Community then the application dossier is forwarded to the Commission with a favourable opinion. The Commission must then circulate the dossier to the other 14 Member States who have 60 days in which to comment. During the 60 days Member States can request further information but there is no opportunity to stop the clock. If none of the Member States object to the application then the Commission instructs the lead country to issue the marketing consent, which then applies across all Members States.

If however one or more Member States objects then it falls to the Commission to make the decision¹³. In practice, to do this the Commission seeks advice from the Scientific Committee on Plants (SCP) which serves a purpose much the same as ACRE. If the SCP reaches a favourable opinion on the Part C notification the Commission will propose that it is given a consent, and asks Member States to participate in a qualified majority vote (QMV). If the QMV is in favour then the original lead Member State issues the consent.

¹³ According to procedures in Article 21 of Directive 90/220/EEC

If there is no QM for placing the product on the market, i.e. the Member States do not agree with the Commission's proposal, then the final decision is referred to the Council of Ministers. The Council has 90 days to reach a decision but at this stage according to the comitology it can only block the GMO from getting Part C consent by a unanimous decision. Otherwise the Commission's proposal is accepted and the product is given consent.

The Deliberate Release Regulations: Future Developments

With the current scepticism and mistrust of GM in Europe, it is unlikely that there will be any major effort, at least in the near future, to deregulate GMOs - even if increasing experience world wide of releasing and using GMOs begins to indicate that our worst fears are unfounded. Nevertheless, there is scope to make the existing regulations work even better.

The current Directive 90/220 has been in operation for several years and has attracted some criticism mainly because the procedures for getting marketing consent are slow and lack transparency. Furthermore, like all legalisation of this sort it is only when it has been operating for some time that areas where there is room for improvement are revealed. The Directive is currently under review based on a text put forward by the Commission in February 1998. Political agreement on the revised text was reached in June 1999. The main elements of the proposed changes include clarification of risk assessment procedures, post market monitoring, time-limited consents and a tough new labelling regime. The revisions will respond to public concerns about protection of human health and the environment and also provide a more transparent and predictable system for industry.

Other Changes

When Directive 90/220/EEC was first produced it covered the environmental release of all GMOs, but over the past few years the primary regulatory responsibility for some GMOs has been removed. GM medicines and vaccines¹⁴ and novel foods¹⁵ consisting of or containing GMOs are now covered by separate regulations. There are future plans to remove responsibility for other GMOs such as GM seeds, forestry products and animal feed containing GMOs.

^{14 2309/93 (}OJ L25 (2 February 1993) p 18))

¹⁵ Novel foods and novel food ingredients regulation No. 258/97 (OJ L43 (14 february 1997) pp 1-7

Concluding Remarks

The deliberate release of GMOs is tightly regulated in the UK and firmly linked to the wider European Community. It is accepted that there may be scope for improvement in the regulations, but despite what is claimed in sensationalised reports the regulations do in fact provide a very effective safeguard for human health and the environment.

We have a science based regulatory system in the UK and science/safety decisions must not be based on emotional grounds. That said, science alone can not address all of the concerns of society over genetic modification and there is a good argument for a wider debate on ethics and acceptability of GM and, more generally, on what our society wants from agriculture. For this reason the Government has established the new Agricultural and Environment Biotechnology Commission (AEBC). The AEBC will take forward and discuss some of the wider issues that go beyond pure sciences and safety. Such questions have not been easily addressed in the advisory system 'til now.

It is often said that we do not know the long-term consequences of releasing GMOs. This is true, but no field of human endeavour is absolutely free from risk, nor can all long-term consequences ever be foreseen at the outset. This is as much true for new advances in engineering or medicine as it is for agriculture. Given that there will always be some uncertainty, then the long-term unpredictability of a new technology should not be used as a reason for not taking the first cautious steps. Genetic modification may bring great benefits for the environment but we must recognise that there is also potential for harm. The challenge is to realise the potential benefits without the harm.

BOX 1. Information required under Schedule 1 of the 1995 Regulations for the Deliberate Release of Genetically Modified higher plants

General information

- 1. The name and address of the applicant.
- 2. The title of the project.

Information relating to the parental or recipient plant

- 3. The full name of the plant: family, genus, species, subspecies, cultivar.
- 4. Information on reproduction of plant: mode, generation time and the sexual compatibility with other cultivated or wild plant species.
- 5. Information on the survivability of plant: survival structures, dormancy, etc.
- 6. Information concerning dissemination of plant: means, extent and factors affecting dissemination.
- 7. The geographical distribution of the plant.
- 8. If the plant species is not normally grown in Member States, describe the natural habitat.
- Information on any significant interactions of the plant with organisms other than plants in the ecosystem where it is usually grown, including toxicity to humans, animals and other organisms.

Information relating to the genetic modification

- 10. A description of the methods used for the genetic modification.
- 11. The nature and source of the vector used.
- 12. The size, function and donor organism(s) of each DNA sequence intended for insertion.

Information relating to the genetically modified plant

- 13. A description of the trait(s) and characteristics of the GM plant which have been modified.
- 14. Information on sequences inserted or deleted size/structure, copy number of insert, information on any vector sequences or foreign DNA remaining in the GM plant. The size/function of any deleted regions. Cellular location of insertion (e.g. chromosomal, mitochondria, chloroplast etc.).
- 15. Information on the expression of the insert: expression and parts of the plant where expressed.
- 16. How does GM plant differ from the recipient plant in: mode/rate of reproduction, dissemination, survivability.
- 17. The genetic stability of the insert.
- 18. The potential for transfer of genetic material from the GM plants to other organisms.
- 19. Information on any toxic/harmful effects on human health and the environment arising from the genetic modification.
- 20. The mechanism of interaction between the genetically modified plants and target organisms.
- 21. Any potentially significant interactions with non-target organisms.

- 22. A description of detection and identification techniques for the genetically modified plants.
- 23. Information about previous releases of the genetically modified plants.

Information relating to the site of release

- 24. The location and size of the release site or sites.
- 25. A description of the release site ecosystem, including climate, flora and fauna.
- 26. Details of any sexually compatible wild relatives or cultivated plants present at the release sites.
- 27. The proximity of the release sites to officially recognized biotopes or protected areas.

Information relating to the release

- 28. The purpose of the release.
- 29. The foreseen dates and duration of the release.
- 30. The method by which the genetically modified plants will be released.
- 31. The method for preparing and managing the release site, prior to, during and after the release.
- 32. The approximate number of genetically modified plants (or plants per m²) to be released.

Information on control, monitoring, post-release plans and waste treatment plans

- 33. A description of any precautions to minimize or prevent pollen or seed dispersal from GM plant.
- 34. A description of the methods for post-release treatment of the site or sites.
- 35. A description of post-release treatment methods for the GM plant material including wastes.
- 36. A description of monitoring plans and techniques.
- 37. A description of any emergency plans.

Information on potential environmental impact of the release of the genetically modified plants

- 38. The likelihood of the GM plant becoming more persistent or invasive than recipient plants.
- 39. Any selective advantage or disadvantage conferred to other sexually compatible plants species, which may result from genetic transfer from the genetically modified plant.
- 40. Potential environmental impact of the interaction between the GM plant and target organisms.
- 41. Any possible environmental impact resulting from potential interactions with non-target organisms.

End of Box 1

Annex 4 continued...

Experience from Stakeholder Debate on GMO in the Food Chain

Dr Marie Janson (Centre for Exploitation of Science and Technology)

Background

CEST, Centre for Exploitation of Science and Technology, was founded 11 years ago as a private-public sector partnership by the then British Government to support exploitation and uptake of new science and technology.

During the autumn of 1998 CEST started the a European GMO forum to provide an open discussion group as well as to provide a learning forum for the participants over a series of workshops. CEST had identified that many players in the food industry would be working with GM-food or their business would be affected by the introduction of GMO-products in Europe. However, many were struggling with trying to understand the consequences and developing strategies without understanding the technology or some of the issues surrounding it. Because CEST is a charitable organisation with no vested interests in GMOs, it is well positioned to act as an unbiased facilitator, helping organisation to plan to address the opportunities and risks associated with this new technology and food products derived from it.

For this stakeholder forum CEST combined three elements:

- Stakeholder representatives from along and adjacent to the food chain from various parts of Europe
- Scenario planning
- Outside input from speaker to highlight particular elements as requested by the participants

Stakeholder representatives:

The aim of this forum was to stimulate a genuine discussion along the food chain of what GM-food might mean, and for the participants to learn about and understand what the implication of it might be for the different players. Participating in this group are representatives from seed providers and the agro-chemicals industry, food manufacturers, food distributors or wholesalers, retailers and consumer representatives among others. Organisations from seven different countries are taking part.

Scenario planning:

To open up the debate as well as to prevent the discussions from becoming too focused on temporary issues, CEST decided to use scenario planning as a tool to stimulate the discussions and to provide a range of potential strategies.

The Forward Studies Unit, at the European Commission has developed five complete future scenarios for Europe 2010 for the European President, covering political, technical and socio-economic developments, which they very generously let us use for this purpose. These formed the basis for our discussions. For each scenario, the participants would analyse and discuss how agriculture and food industry would look like, and how GM would map onto this world.

Onto these five very different scenarios were mapped, over a series of meetings, types of GM products, drivers and barricades, types of consumers and their interests, likely legislation and regulation, business climate and types of business likely to survive, level of environmental concerns etc.

This also provided the participants with a portfolio of futures, to be used as planning tools for their respective organisations.

Outside input

Particular issues of interest to participants were identified and outside speaker found that could provide unbiased expertise. Examples of topics covered were:

- Consumer attitudes to science and technology
- Stakeholder dialogue on GMO in Holland
- EU-validated methods for testing for GM-presence
- European consumer concerns regarding GMOs
- The biotechnology debate in Switzerland before and during the referendum

Conclusions

To establish a genuine stakeholder debate in this forum, certain conditions have to apply:

- Chatham House rules
- Participants have to be in sending as well as receiving mode
- Freedom to express views without direct commitment
- Respect for different values, and willingness to discuss these values and their consequences
- Well informed participants

Benefits to the group of stakeholders have been:

- Peer group learning process
- The opportunity to have a dialogue with different players in the food chain, and gain some understanding of different viewpoints
- Experience the difference of attitudes across Europe regarding GMOs
- The opportunity to explore issues freely and creatively
- Networking
- Factual as well as "soft" information to bring back to the organisation to help them to understand the problems and in developing strategies

Examples of concerns raised by the group have been:

- Any longer term development being lost in a short term crisis
- How to progress the discussion forward in a constructive way
- How to answer environmental concerns
- Players being coerced into making "impossible" claims
- Consumer benefits, either present or future, are lost

Annex 4 continued...

Briefing Paper: English Nature=s Concerns Over GMOs and the Need for a Moratorium on Commercial Release

Dr Brian Johnson (English Nature)

Summary

There is much good scientific evidence of declines in arable flora, insects and birds as a result of agricultural intensification over the last 30 years. An 78% drop in grey partridge numbers between 1972 and 1996 has been linked directly to pesticide use, whilst a further 18 species of farmland birds are also in serious decline. The skylark, for example, has declined by 75% over this period and is listed in RSPB=s Red List and the UK Biodiversity Action Plan. Conserving our farmland biodiversity is essential if the terms of the Rio Convention are to be delivered in the UK. English Nature fears that crop management systems associated with herbicide tolerant and some insect resistant GM crops, which we call the >indirect= effects of GMOs, are likely to intensify agriculture even more, exacerbating declines in wildlife.

English Nature is not opposed to genetic modification. We recognise that the use of genetically modified crops may have potential benefits for farmland wildlife, particularly if their use results in better targeted or lower usage of agrochemicals. However, there is no scientific evidence that such benefits are being realised and English Nature therefore advocates the precautionary principle (as described in the *Rio Declaration*, Principle 15: "Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.") where commercial releases are proposed. We recommend that there should be a >breathing space= in which proper assessment is made of the potential effects of GMOs which are nearing marketing consent, primarily herbicide tolerant beet and oilseed rape, and insect resistant and herbicide tolerant maize. Our reasons for recommending this moratorium are outlined briefly below.

- 1. Lack of scientific evidence of the direct and indirect effects of GMOs
- Many research projects currently in progress will contribute essential knowledge of GMOs, but are not due to report until at least 2000. In the interests of scientific scrutiny and public confidence, further time is also needed for the results to be distributed, peer reviewed and evaluated.
- The chief trend in current research is to examine specific direct effects of individual

GMOs and additional research to examine indirect effects is needed. We suggest that this research should initially focus on cumulative effects on biodiversity of crop management systems associated with generic modifications, such as herbicide tolerance. Such projects, if initiated in 1999, could be expected to report by 2002 at the earliest.

- Gene escape is the chief topic of research on direct effects. Gene escape is now considered inevitable from the crops currently being considered for marketing in the UK. However, evidence is not available on the likely impact of gene escape on native ecosystems. For example it is not clear whether escaped genes will confer a competitive advantage to hybrids. If they do, the effects on biodiversity and the management of protected wildlife sites could be profound. However, there is very little research on the effects of gene transfer on native biodiversity overall.
- We also lack basic understanding of the function of soil ecosystems, for example, to be able to make decisions now about potential effects of GM crop management systems.
- We consider that all research and development on modification of native plants, especially forage grasses, should be put on hold. The ecological risks of releasing these GMOs (for example high yield herbicide tolerant grasses, which can outcross to native species), are currently unacceptable. An ethical Code of Practice developed with the industry could guide future research away from environmentally unacceptable areas.
- We want much more research to be done on the effects of the cultivation of GM crops on native biodiversity, especially comparing the effects of GM cultivation with conventional intensive systems.
- 2. The regulations and the advisory system require amendment
- The regulatory system needs to be extended so that consideration of impacts on biodiversity is properly covered by statute and operated effectively. Responsibility must lie with the developer to do the necessary research and present the results to the regulatory authority for assessment.
- EC Directive 90/220, under which GMOs are released, is weak on the management of GM crops and the potential impacts on biodiversity, and does not require high quality information on this issue within risk assessments. In our view the Directive should be amended to address these issues.
- Problems with the current advisory process for releases to the environment have been highlighted by the Royal Society and Parliamentary Office of Science and Technology, among others. We believe the scope, operation, remit and membership of ACRE should be reviewed and the value of a separate, accountable and

environmentally represented body, with a remit which includes examining generic effects of GMOs, should be considered.

- 3. The risk assessment process requires improvement
- We would like the regulatory system to ensure, before release is authorised, that the GMO is at least environmentally benign. Better risk assessments will be necessary before the regulatory system could make such a judgement. The risk assessments currently submitted by biotechnology companies are qualitative and generally poor quality when addressing the issue of risks to biodiversity.
- Companies could address current failings in risk assessments now, by providing better information from academic research, in sections which deal with effects on other organisms. Examples of what could be covered are: direct and indirect impacts on target species and the food web; effects on biodiversity of changes to husbandry practices; the capability to bring marginal land of wildlife interest into productive use.
- 4. Mechanisms for control of GMOs on farm and post-release monitoring should be put in place
- Mechanisms should be developed for regulation of GM crop management systems beneficial to biodiversity. A regulatory system, similar to the UK pesticides regulations, could be put in place to ensure that these systems are used on the farm. These regimes might attract incentive subsidy, making the system more profitable.
- The value of cross-compliance should also be investigated. For example, consent to grow GM seed could be attached to conditions for crop management, such as leaving weeds uncleared or managing an equivalent area of the farm without pesticides.
- 5. Public confidence must be secured
- If potential benefits to biodiversity of GM crops are to be realised, public confidence will need to be restored. We believe that showing that certain GM crops have demonstrable environmental benefits relative to conventional agriculture would go some way towards achieving this.

English Nature maintains that the existing timescales for commercial release will not be sufficient to allow the above issues to be addressed. We have therefore recommended a 5 year moratorium on the commercial release of herbicide tolerant and some insect resistant crops.

Annex 4 continued...

Public Perception and GMOs

Robin Grove-White (Centre for the Study of Environmental Change, Lancaster University)

Key Questions

- 1. What is known about public perceptions of GMOs in UK?
- 2. How reasonable ('rational') are such perceptions?
- 3. How responsive is the political/regulatory framework to such dimensions?
- 1. Public Perceptions: Some Recent Studies
- Fiddes (1995). Green Alliance-CSEC-ESRC (1995).

 Anthropological/sociological. Pointed to limitations of existing GM crop/food regulatory framework for assessing emerging 'wider' ethical and 'need' issues.
- Frewer, Howard, & Shepherd (1996). Psychological/psychometric. Highlighted public ambivalences about genetically modified foods.
- CSEC (1997). Qualitative social-psychological/sociological. Identified growing public unease, fatalism, and concern about food 'tampering' and cross-species transfers. But also important public discriminations in favour of medical GMO uses. Highlighted glaring mismatch between nature of (broad, analytically-elusive) public concerns about trajectories and unknowns, and reductionist product-by product approach of official food/crop regulatory framework.
- Eurobarometer (1997). Quantitative psychometrically-grounded attitude survey analysis. Suggested centrality of public *ethical* concerns, more than concerns about physical *risks* to health or environment. Confirmed public ambivalences and mistrust of current regulatory arrangements.
- MAFF/Sheffield (1998). Qualitative-quantitative public attitude analysis. Confirmed strong public anxieties about GMO foods and crops, in context of wider concerns about increasing 'unnatural' farming and food processing practices. Also confirmed perceived inadequacy of regulatory frameworks for addressing key concerns. Found inverse relation between levels of *knowledge* of GMO processes and confidence in official regulation.

Overall Picture

A consistent picture appears to emerge from these and other studies. Public perceptions of GM foods and crops arise within a broader set of concerns about recent trends in industrialisation of food and agricultural processes, and experience (BSE etc) of (officially unacknowledged) limitations of dominant regulatory cultures. There are substantial concerns about the propriety and cumulative implications of 'unnatural' crossing of species boundaries, and doubts about the adequacy of present knowledge. There is also mistrust of the motives of those developing and promoting the technology, and lack of confidence in the adequacy (even the integrity) of political/regulatory oversight. Indeed, the more people know, the greater their apparent concern and suspicion. At the same time, people are discriminating about particular uses of GMOs (eg in the horticultural or *medical* spheres).

2. Reasonable or Not?

Though all of the above public perception studies were undertaken before the February 1999 GMO media brouhahas, and pointed to the depth of latent concerns, the over response of Ministers and key advisers has been to imply that most of such concerns are ungrounded, and hence largely products of media mischief. The implication appears to be that, beyond a limited range of food safety concerns (claimed to be fully addressed by the existing regulatory framework) and ecological issues (now claimed to be being examined through new research studies), adverse public perceptions of GMOs are essentially unreasonable.

However, month by month, specialist journals such as *Nature* and *ENDS* are reporting growing indications of limitations, uncertainties, and unknowns in current understanding of aspects of GM food and crop behaviours. It has to be said that such reports appear to give substance to significant dimensions of the public concerns found in the studies referred to above.

3. Responsiveness of the Regulatory System?

Evidence from the above research - for example CSEC (1997) - suggests that the gaps between recent official reassurances about GMO safety (by, for example, the Government's Chief Scientific Adviser and the Prime Minister) and the extensive scope of 'reasonable' public concerns risk intensifying public mistrust of the regulatory framework currently in place. A body of social research from other environmental risk domains, such as nuclear power and pesticides, tends to confirm this likelihood.

The current spate of 'consultations' and inquiries by Select Committees of both Houses, the Office of Science and Technology (OST), and other bodies appears to be aimed at addressing the gap.

A key issue is the need to align the scope of scientific and other assessments within the GMO regulatory system more closely with the scope of public concerns - particularly concerning the weight to be attached to areas of scientific ignorance or uncertainty in the setting of standards for authorisation purposes.

Comments and recommendations in the recent 21st Report of the Royal Commission on Environmental Pollution (RCEP 1998) may be especially relevant in this connection, particularly chapters 7 and 8. More recently, both the RCEP and the Wellcome Foundation have suggested ways of strengthening public oversight of GMO developments, in their respective submissions to the OST's current 'consultation'.

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Annex 4 continued...

Notes on Ethical Implications of GM Crops

Clare Twigger- Ross (Social Issues Officer, National Centre for Risk Analysis and Options Appraisal, Environment Agency)

The aim of this brief presentation will be to highlight some of the main ethical arguments that have been voiced with respect to GM crops.

Controversy around the GM debate has, in recent months, become highly public and polarised. The development of this new technology has led to the wider issues of ethics, uncertainty and necessity being voiced. This has led to a wide range of reactions from individuals, organisations and governments, from accepting the principle of GM crops and continuing with experimentation, postponing experimentation, or completely banning (as in the case of the Austrian, Luxembourg, Greek and French governments).

The ethical arguments can be categorised into four related areas: health and consumer choice, environment and concepts of nature, developing countries, and multinationals.

Health and Consumer Choice

Concerns surrounding health issues are centred on the uncertainty of the possible consequences of eating food that contains GM ingredients, e.g. the possibility of disturbing the chemical functioning of food which might lead to new allergens and toxins. This is heightened by the fact that any introduction would be essentially irreversible.

This leads to the question of consumer choice and the right of consumer's to know what they are eating and drinking. Because much food is imported, and the ability to track genetic modification is beyond national control, it is much harder to know exactly what is the anatomy of an ingredient. US growers were reported as not segregating GM soya from non-GM soya because of the costs. In addition, any one country cannot refuse to import GE food because there are no safety grounds for doing so. Within the UK the National Farmer's Union has launched guidelines to ensure that GM food grown in the UK can be separated and labelled accordingly.

Around this issue choice is that of labelling. The Advisory Committee on Novel Foods and Processes is responsible for the safety of GM crops. The general objective of UK regulations with respect to novel foods and processes is that people should know when GM crops enter the environment and the food chain so that they can choose whether or not to consume those products. Given the problems outline above, labelling of GM foods has become a key issue. The issue of consumer choice and labelling has had a high

profile in the media with some (for example in the *Daily Mail*, 10th April) responding by producing guides to GM foods in supermarkets, indicating which foods could "quite likely", "possibly" and "not at all" contain GM ingredients. It is not clear where their information comes from.

Environment and Concepts of Nature

Ethical concerns and the environment centre around the issue of what is natural. That is, debates consider the extent to which GM crops are an extension of more "traditional" biotechnology to produce a specific plant/crop or represent a fundamentally different way of approaching plant husbandry. The speed at which genetic changes can be made using these new techniques, as well as the seemingly radical nature of those changes, are regarded as causes for concern as they seem to be happening "in a manner not controlled by natural selection" (English Nature, 1998, p 1). Further, there is concern that GM crops will alter non-GM crops in an uncontrollable manner.

Developing Countries and World Hunger

GM crops, because of the ability to produce, for example, drought-resistant or increased-yield crops, have been suggested to provide a solution to problems of famine in developing countries. However, it is not clear that developing countries would have access to the GM technology except through the purchase of hybrid seed. In addition, it is argued that the world already produces enough food, and questions about famine and malnutrition are answered more readily by socio-political and economic factors. GM crops have been developed for large-scale, intensive farming, not localised, sustainable economies typical of developing countries. Further, some seeds cannot reproduce themselves which would make countries dependent on companies to maintain their crop yields. There is still considerable debate around these issues and there is work being done not for profit using GM seeds and developing countries.

Multinationals and the Patenting of GM Technology

A final issue that is raised by GM crops is that of the role of large multinational corporations in the patenting of crops. Questions have been raised to what extent is it ethical to patent crops and plant DNA, stemming from the view that nature is part of our common inheritance and should not be owned by individuals. In addition, patents that have been filed by multinationals relating to plant species with long-established uses in developing countries have aroused opposition. These are regarded as unethical as they exploit the resources of those developing countries without adequate compensation.

End of Annex 4

Annex 5: GMO-related Issues and the System Conditions

Note: The emphasis of the day was to use the TNS processes and tools to structure the debate, rather than spending a large amount of time training the delegates rigorously in the Natural Step's principles. For this reason, delegates' perceptions, of which system conditions are most appropriate, may differ. This fitted with the thrust of the workshop which was to suspend fixed view points to allow for new insights and consensus-building.

Figure 1 below summarises some of the key issues arising on the four system condition "sticker boards", and comments are listed in full in the subsequent sections of this Annex.

Condition 1

Substances from the earth's crust must not systematically increase in nature

Potential reductions in fuel and inorganic fertilisers still to be proven

Condition 2

Substances produced by society must not systematically increase in nature

Concerns about regulatory approaches

Evidence and potential for systematic increase of pesticides and manufactured genetic materials

The precautionary principle and risk recognition
Information gaps

Alternatives to GM

The Place of GMOs in a Sustainable Future Monitoring of industrial GMOs and Environment Agency activities

Condition 3

The physical basis for the productivity and diversity of nature must not be systematically diminished

Risk

Biodiversity and nature

Unknown implications and sense of unease about the technology

Potential benefits

Agriculture and farming systems change

Regulatory frameworks and policy

Condition 4

We must be fair and efficient in meeting basic human needs.

Ownership of genetic resources and information

Risks to society

Motives and driving forces

Democracy and controls

Wider forum needed - not just vested interest

Regulatory frameworks

Agricultural risks

Information for wise decision-making

Meeting human needs

The precautionary principle

System Condition 1

Substances from the earth's crust must not systematically increase in nature

Potential reductions to be proven

- 1. Potential* for reducing the use of chemical fertilisers
- 2. Potential* for reducing energy consumption intensity potential reducing use of fossil fuels
- 3. Reducing use of phosphates
- 4. Will GMOs in practice reduce/ address problems of eutrophication
- 5. Will the finite use of raw materials for making fertilisers, pesticides go up or down?
- 6. Will GMOs deliver better/ easier Integrated Farming Systems or Minimum Tillage systems, which would have the potential to conserve nutrients etc. (thus less crust extraction required).
- * In the plenary discussion it was noted that <u>potential</u> is not the same as <u>actual</u> impacts and the evidence is not unequivocal

System Condition 2

Substances produced by society must not systematically increase in nature

Evidence and potential for systematic increase

- 1. Releases of GMO began in UK in 1980s under a voluntary code
- 2. DETR is making a case by case study but what about the impact of WIDE-SCALE commercial release and cumulative effects
- 3. Transfer to "relatives" of GM crops is happening in the natural environment. How can the technology be controlled?
- 4. Out crossing to "wild relatives" is occurring and expected
- 5. What if GMO materials do increase in nature (e.g. via pollen dispersal)?
- 6. Can pollen be contained (wind and insect transfer). DETR risk assessment accepts some pollen dispersal will and does happen.
- 7. Disabled GM crops (sterile) potentially would not increase in an uncontrolled way

Concerns on regulatory approaches

- 8. Crops of GMO are managed and regulated under a voluntary code
- 9. "Tip of the iceberg metaphor" how can the scale/ or use of GMO application in the longer term be controlled
- 10. "Contained Use" Regulations are being changed with removal of the requirement for physical containment of GMOs- this will result in discharges
- 11. How long should the research phase be (for individual GMO) before satisfactory and adequate evidence can be given to the public

Monitoring of industrial GMO and the Environment Agency activities

- 12. No monitoring takes place by HSE or the Environment Agency of industrial GMOs in industrial waste or aerosols
- 13. Where does waste from industrial GM processes go? What about secondary implications; for example, in sewage farms.
- 14. The Environment Agency has no data on use of GMOs in industrial processes
- 15. Should the Environment Agency be using GMOs as tracers in the environment?

Information gaps

- 16. Is there any independent scientific evidence that GMOs reduce use of pesticides and herbicides?
- 17. Can we have confirmation that No Part C releases have yet been authorised in Europe

The precautionary principle and risk recognition

- 18. Lessons from evolution and ecologically balanced fitness suggest respecting natural barriers is important and that testing of gene/environment/human interaction is required before wide dissemination
- 19. We need scenario planning to prepare for the unthinkable/impossible how would you/I react if GMO do increase in nature
- 20. Are the risks of using GMOs worth taking? How to evaluate <u>all</u> the risks posed by use of GMOs

Alternatives to GM

21. Are there alternatives to GM (e.g. blue green algae sequestering heavy metals)

System Condition 3

The physical basis for the productivity and diversity of nature must not be systematically diminished

Biodiversity and nature

- 1. Can "potential" advantages of GMOs be realised without disadvantages to biodiversity and to non-GMO based agriculture?
- 2. If we are encouraging agri-environmental measures, we need some confidence at least that the agricultural systems underpinning the delivery of these objectives are sustainable and sufficiently long term
- 3. Will increasing Bt resistance in the environment affect bio-geochemical cycling in soils?
- 4. Do we know enough about the long-term implications of inter-species gene transfer

- 5. The rapid widespread application in the environment is too hasty- this devalues science
- 6. Damage to SSSI (Sites of Special Scientific Interest)

Agriculture and farming systems

- 7. The impact of GMO on agricultural systems should be a fundamental concern the whole farm system may need to adapt to new crops
- 8. Is productivity in agriculture from GMO better? Why does English Nature NOT publish data on weeds in non-GM oilseed rape? Is it because there are hardly any?
- 9. "Life learns" -the benefits of GM crops breakdown in 2-5 years as pests, diseases and competitors adapt; herbicides and pesticides may have less and less impact on "escapes" and "weeds". A particular GMO may have say 3 years of productivity benefit then need to be replaced new variants will be needed regularly
- 10. Herbicide tolerance and resistance to disease and pests are <u>already</u> targets for conventional breeding <u>what</u> is the difference between this and GM approaches and impacts on ecosystems?
- 11. Conventional plant breeding has had many failed crops but it is still considered beneficial technology
- 12. Need to analyse what the differences might be between a) GMO crops and b) new variant crops produced by other means

Regulatory frameworks and policy

- 13. We need a regulatory framework /clear agricultural policy and vision for the future of our agricultural systems, whilst also taking account of concerns over new technologies
- 14. Is the regulatory framework aiming to prevent or minimise impact on the environment -there is a big difference
- 15. Does the case officer review take into account advice from other departments If so, what if they do not give the same message on advice conflicts
- 16. The regulatory system must address the whole farming system
- 17. Are ACRE (Advisory Committee on Releases to the Environment) guidelines adequate

Risk

- 18. Are costs to ecosystems (and rural communities) adequately addressed in risk and cost benefit assessment?
- 19. What are the hazards- in what conditions could risk happen. What are the paths in air, water and soil?
- 20. There is no such thing as zero risk
- 21. Deliberate release impacts are irreversible. The genetic component includes viruses (non-recoverable in perpetuity)

22. Cauliflower Mosaic Virus issues a) Many plants are infected naturally b) Interactions between 35S promoter and virus infections

Potential benefits

23. Will GM technologies actually reduce soil loss and require less tillage?

Unknown implications and sense of unease about the technology

- 24. There is public intuition that this technology is radical and will affect nature. We need joined up thinking about impacts on biodiversity and our global responsibility
- 25. Why are we not concerned about environmental damage from the "release" of conventionally bred crops?
- 26. Need to understand that genotypes are not unique. Different organisms have similar genes
- 27. Genetic manipulation technology has a long history in plant and animal breeding BUT cross species is a new tool
- 28. Where does our confidence come from?

System Condition 4

We must be fair and efficient in meeting basic human needs.

Ownership of resources

- 1. Who owns GMOs and who will pay the price?
- 2. How will world genetic resources be safeguarded from patenting by the rich
- 3. How will genetic resources of the poorest in the world be safeguarded from contamination, and decline?
- 4. Could there be benefits for human kind world wide? The potential benefits to the farmers should not be forgotten. Can these be developed wisely? Who will own the basis of production

Access

- 5. There is a gap -unfair access to knowledge and know how. Who will receive benefits? Who will be at risk? Different sectors of society get different benefits.
- 6. Access to independent information is needed for farmers They are being increasingly threatened financially and need to take advantages of new approaches

The precautionary principle

7. Why hurry? What about the precautionary approach? How much uncertainty should society be forced to accept by actions of a minority?

- 8. The greatest unknowns appear to be in environmental and biodiversity issues the basis for life
- 9. Ethical issues are raised for example: over riding natural selection

Motives and driving forces

- 10. There is mistrust of motives the explorer mentality of scientists profit focus. The "Brave New World" -public fear is caused by lack of trust in scientists/industry because they are non-democratic and motivated by profit.
- 11. Reduced <u>public</u> funding of science means important scientific issues for society as a whole are being neglected. For example, around patterns of GM development that would advance sustainability
- 12. Who is deciding what characteristics we are breeding into crops? This should not be dictated by industry
- 13. Who will fund the necessary research and call the shots? Changes in patterns of funding of scientists (from public to private sources is "contaminating" public view of scientists in the GM domain

Agricultural risks

- 14. Who will audit risk assessments to eliminate bias?
- 15. Who defines what is meant by environmental safety and risk assessment -what do the concepts mean (not just UK but globally)

Regulatory frameworks

- 16. Who monitors industry -so much is based on a voluntary code, trial sites are monitored by companies
- 17. Is the DETR capable is it "overloaded"- is it independent?
- 18. ACRE is "totally open and transparent in its working" how does ACRE liaise with other regulatory systems (pesticide use, Town and Country planning) to ensure the overall impact of GMOs is addressed
- 19. There seem to be substantial questions about the <u>rigour</u> of field trials- is this fair to society?
- 20. We need to learn from US experience and avoid making some of the same mistakes in Europe

Democracy and controls

- 21. Local control of a common inheritance will be lost to multinationals creating dependency not building self determination and empowerment. Farmers' visual inspection and indigenous knowledge eroded
- 22. Lack of overall control by democratically elected bodies. NGOs are seen as the most objective sources of information

- 23. Political and economic factors are a major force in food shortages GMOs are irrelevant (saying they will alleviate world hunger is an ill informed approach)
- 24. Democratic processes in the UK enable people to take action
- 25. GM issue a continuum. There are conflicting opinions about the possibility of GMOs being totally banned. Some favour the banning merely of obvious bad practice
- 26. Can all ministries and agencies get together? Stakeholders not just shareholders interests

Risks to society

- 27. Why don't we require proper trials of foods (eating GM materials in unavoidable) the food is the pesticide. The tryptophan story is concerning; there is no general concensus about the role of microbial DNA and the process of genetic manipulation in the expression of toxins though some scientific publications suggest a causal link
- 28. Lethal effects might be introduced into the gene pool by GMOs jeopardy for food security and vulnerable communities
- 29. Monoculture approach increases vulnerability to widespread crop failure.
- 30. UK novel foods committee concern on the potential transfer of antibiotic resistance in food to gut microbes this could result in untreatable illnesses

Information - wider forum

- 31. People have a right to be able to choose "safe" labelled foods (local and imported)
- 32. The press have a key role in the public perception of risk of the use of GMOs
- 33. "Scenarios" for the future could be used not only to simulate different political contexts but also specific environmental/agricultural/economic situations. For example, what will happen when/if one multinational is in charge of the whole world food chain; what if "super weeds" become a severe problem
- 34. International perspectives. Why are GMOs such an issue in UK not the USA? The decision making processes for permanent releases (i.e. non-experimental) is European. It is essential to understand the attitudes of other European countries.
- 35. We need a forum for the factual basis of the science to be promoted
- 36. A forum is needed not just for vested intérests government departments and advisers should be included on a regular basis
- 37. What would be needed for public perception and science management to be in harmony?

End of Annex 5

Annex 6: Knowledge Gaps and Questions Remaining

The following Knowledge Gaps and Questions Remaining were listed by participants during the process of moving from sharing information towards consensus on key issues and ways forward.

Knowledge Gaps

- 1. The knowledge gap is bigger than the knowledge. (We need to formally recognise this not act as if it was not so)
- 2. What knowledge there is is owned by different groups.
- 3. "Expert" knowledge is incomplete. Much information is not "Common" knowledgenot enough information and knowledge are with society and decision makers

Unknowns in the under pinning science / lack of comparative information

- 4. Incomplete understanding of genetic structure and functioning
- 5. Incomplete understanding of long term effects of GM technology
- 6. Biodiversity impacts are not understood
- 7. Possible effects of antibiotic resistant marker genes
- 8. Other markers added to the genome which have "no known effect" the so called "green markers"
- 9. Formal comparison between existing systems and GM systems
- 10. Difference between GMO and "natural" variants from conventional breeding (the sinister/non-sinister perception)

Risks and benefits - on whose terms

- 11. Base line comparisons are needed for benefits or detriments to be evaluated- what should GMOs be compared against
- 12. "Experts" see risk in a narrow context not all risks are assessed or considered, only site specific and immediate risks are considered, only quantitative and not qualitative risks are assessed

Public perceptions and public needs

- 13. What drives public perceptions?
- 14. Where can the public get robust information and have confidence?
- 15. Can a system be developed which really allows choice? For example, organic/GM free options maintained.

Policy and regulation

- 16. Criteria on which assessment is made
- 17. Where are we going? Lack of agriculture policy and vision for a sustainable agriculture system. How can we develop options?
- 18. Other European countries ideas and plans

Farming

- 19. Field verification is poor -are the "potential" benefits real?
- 20. What are the farming systems that can use GMOs- what is the best farming practice with GMOs (gaining integrated and reduced tillage system benefits)

Institutional and regulatory frameworks

- 21. What institutional frameworks do we need to handle new technology like GM technology, embryo rescue etc.
- 22. Is the current regulatory framework adequate
- 23. Is our knowledge of risk management adequate from our conventional plant breeding experience. The speed of change is higher and numbers are increased by a big factor.

Ecology

- 24. lack of predictive ecology
- 25. Baseline information on peri-agricultural ecology in the non-transgenic situation. Information is building on some aspects- but is there sufficient knowledge on aspects such as field edges and biodiversity?
- 26. lack of factual scientific knowledge
- 27. Seriousness of allowing gene flow to be unchecked

What drives industry?

28. Industry take a narrow view of cost/benefit in relation to profit. Society's issues and distribution and access issues in society are not considered

Questions Remaining

- 1. Why do we need GMOs (beyond profit making)?
- 2. Can we develop a sustainable society based on profit?
- 3. Do governments have power to regulate multinational companies?
- 4. Can they "feed everybody?" -Can it be demand led and responsive to local communities not primarily for industry profit?
- 5. If the facts presented by Mark Griffiths are correct (see paper in Annexe 4), why doesn't the GM crop market in the US collapse?
- 6. Can there be a consensus with vested interests and venture capital involved?
- 7. How do we take account of public sensibilities in giving real weight to what we do not know (the answer my friend is blowing in the wind)
- 8. Can Government carry out by further research and development to address public concerns?
- 9. How radically different is GM technology from conventional plant breeding?
- 10. How can long term effects be monitored?
- 11. How to develop an international framework against which to monitor?
- 12. Can GM culture be integrated with natural systems?

End of Annex 6

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A Framework for Sustainability

Scientific and Technical Information Service The Environment Agency Rio House Waterside Drive Aztec West Almondsbury Bristol BS32 4UD

Tel: 01454-624400 Fax: 01454-624409

E-mail:

stefan.carlvle@environment-agency.gov.uk

Environment Agency Web Site:

http://www.environment-agency.gov.uk

The Natural Step UK 9 Imperial Square Cheltenham Gloucestershire GL50 1QB

Tel: 01242-262744 Fax: 01242-524445

E-mail: info@tnsuk.demon.co.uk

The Natural Step is a Forum for the Future activity.

Charity Number 1040519

The Natural Step's Web Sites:

http://www.naturalstep.org.uk