Genetically Modified Plants

United Kingdom Environmental Law Association Seminar on
Environment Liability
For release of GMOs
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Summary

This presentation on GM plants will summarise the following issues:

a. The meaning of the terms 'GMOs' and 'gene flow'.
b. The meaning of the terms 'environment' and 'common goods'.
c. The current range of GMOs.
d. GMOs in the R&D pipeline.
e. Theoretical and actual technology-inherent and technology-transcending risks of GMOs.
f. The Precautionary Principle.
g. Ownership of GMOs.
h. Risk-benefit analyses.
i. Range and source of challenges (legal and illegal) to GMOs.
j. Potential challenges.
k. Existing and developing scientific, technological and procedural systems to help evaluate and reduce liabilities.

The issues are interlinked, complex and relate to dynamic, far-reaching science and technology.

Genetically Modified Organisms (GMOs) and Gene Flow

At the outset, we refer the reader to review articles in the SCRI Annual Report series, principally the Reports since 1996-1997; see also the SCRI website (http://www.scri.sari.ac.uk). Sections of five articles dealing with biotechnology are attached:

i. 1996-1997, pp 26-30;
ii. 1997-1998, pp 36-41, and
iii. 44-53;
iv. 1998-1999, pp38-54
v. 1999-2000, pp36-47.

The report by H Ross and D Tennant, *A Definitive Guide to GMOs, Genetically Modified and Novel Foods in the EU. The Law and Technology of GMOs in Europe,* Monitor Press, 2000 highlight the ill-…

conceived, piecemeal nature of EU legislation regulating GMO release, GM food and GM additions. Another useful review is *International Comparison of Regulatory Frameworks for Food Products of Biotechnology* prepared by D J MacKenzie for The Canadian Biotechnology Advisory Committee Project Steering Committee on the Regulation of Genetically Modified Foods.

Genetic modification is defined as the insertion into an organism, either by means of a natural vector (*e.g.* by particle gun bombardment), of heritable genetic material (*i.e.* DNA) prepared outside the organism. It also includes protoplast or cell fusion when the parents are plants from different botanical families, but not when they are from the same family. It does not include techniques such as mutagenesis or manipulation of ploidy unless the starting material has previously been genetically modified. A genetically modified organism (GMO) is an organism that has been produced by genetic modification as defined above, or an organism containing genetic material derived or inherited from such a modified organism. Thus, in addition to the original modified plant, any progeny plants derived from it through seed or vegetative propagation, or crosses bred from it, are considered to be GMOs. (Some refer to "LMOs", living modified organisms derived using biotechnology.)
Partial and complete genome analyses of humans, various plants, mammals, insects, nematodes, other animals, fungi, bacteria, and viruses *etc.* demonstrate that there are very similar gene sequences across all types of organism and organelles. In addition, the occurrence of spontaneous mutations, the widespread existence of retrotransposons, and conventional breeding and selection programmes that have produced huge variations in mammals such as the domestic dog and livestock, as well as in horticultural and agricultural crops, collectively make it challenging properly to define what is meant by the terms "species", "alien" genes, or even "GMOs". For example, cultivars of oilseed rape that are herbicide-resistant have been obtained by conventional breeding, and herbicide-resistance occurs spontaneously in weed populations. Conventional breeding systems can create intergeneric hybrids; successful crop varieties have been produced using ionising radiation and chemical mutagens. Moreover, because all habitats/ecosystems exhibit aspects of "gene flow" at various rates, and are not static, managed, semi-managed, or "natural" ecosystems can never be isolated. The atmosphere we breathe is replete with DNA-containing spores of various types. An apple contains about 40 billion genes; its consumption, as with all fresh fruit and vegetables, is rarely regarded as a method by which the consumer acquires interesting ancillary genetic characters. A significant portion of the protein and nucleic acid content of fruit and vegetables can

be viral in origin. Fortunately, the gut and lungs are designed to handle foreign genetic material.

The focus of present debates on GMOs has tended to be on the process rather than the product.

Environment and Common Goods

Biologists and other types of scientist define "environment" in various ways, from the sub-atomic to the intergalactic. Biotic and abiotic factors are considered in environmental analyses, hence the concepts of alleloinhibitory and allelomediatory organismal interactions. Gene expression is affected by a wide range of interacting environmental factors (temperature, humidity/moisture, atmosphere, day length, thermoperiod, gravity, spectral composition and radiant flux density *etc. etc.*), and there is some evidence to support the notion of the inheritance of acquired characteristics. Any organisms we see – the phenotype – is a result of the interplay between the environment (E) and its genetic constitution – the genotype (G). We speak of GxE interactions.

The concept and reality of "common goods" are dependent on philosophical, economic, political, scientific, engineering, and technological standpoints. Humans have modified the natural environment. They have eliminated species; introduced nearly 30,000 xenobiotic chemicals; altered the gaseous composition of the atmosphere; destroyed large tracts of land and ecosystems for roads, airports, recreation facilities, buildings, quarries and mines to extract natural resources or dump unwanted materials; and practiced large-scale agriculture, horticulture and managed forestry. The bulk of crops grown throughout the world are alien introductions. UK domestic horticulture is almost wholly dependent on alien species. Fresh and marine waters are polluted; fossil-water reservoirs are raided; the natural flora and fauna are interfered with; new types of organism are bred, selected and released; diseases are transmitted; visual amenity is affected; and noise, odour and light pollution can affect the lives of many. Many resources are not readily renewable. In agriculture, horticulture and forestry, monocultural systems have introduced specific selection pressures that have given rise to rapidly changing populations of pests and diseases. "Island biogeographic" effects are becoming manifest as once continuous stands of plants, or animal communities, have become discontinuous, and genetic erosion takes place. Our air, water, food, and environment are polluted by our neighbours. They spread infectious diseases such as colds and influenza with little redress!

The 1994-1995 UK Technology Foresight Sector Panel on Agriculture, Natural Resources and Environment reviewed wealth creation, quality of life and sustainability. We noted that wealth is created when resources are combined in such a way that society values the result more than it valued the resources in their existing uses. An industry can create wealth by changing the amount of resources it uses or by changing the way in which resources are used. Whether a change in activities represents a gain or a loss depends on how society values the situation before and after change. These values exist in the minds of those who make up society. They include the quality of what is produced, as well as its quantity. In this context, judgement of quality may include values that relate to the process of production (e.g. welfare, environmental impact) as well as to discernible differences in the product.

Established methods of ascribing economic costs are inadequate when applied to environmental resources, since they fail to take into account the loss of species or environmental quality, and other forms of environmental degradation. In order to steer policy, it is essential to have some means of assessing alternative patterns of resource use. A substantial part of economics has been concerned with how markets reveal society's values. In the simplest model of a market economy, price movements will ensure that the bundle of goods and services which is most highly valued will result - given satisfactory distribution of income, good knowledge of market opportunities among consumers, mobility of resources, and suitable conditions of competition. Much economic thinking has been concerned with elaborating ways in which the real world is likely to fall short of this `optimum' output. Policies may be adopted to improve the working of markets. For example, the Treaty of Rome includes rules of competition. In the UK, we attempt to achieve a more acceptable redistribution of income within society through tax and social security. Such actions are all concerned with raising the real level of wealth in society.

Environmental wealth escapes market mechanisms but greatly affects our quality of life. Economists talk about **externalities, costs or benefits** that the activity of one business creates for other individuals or businesses - e.g. the cleaning costs incurred by factories using river water polluted by other industrial plants or agricultural activities. Economists also draw attention to public goods or `non-rival' goods, enjoyment of which by one person does not lessen the benefits to others. Such goods cannot be priced in a market place but depend upon particular uses of resources that have to be funded if they are to continue. If such wealth is to be retained or created, then policies have to try to incorporate `externalities' in decision-takers' calculations and ensure that those who provide public goods are rewarded in proportion to the benefits to which their activities give rise.

Categories of goods that fall outside the market system give rise to serious problems of valuation. For example, the pursuit of pleasure has an environmental cost. These problems led to the development of economic methodologies such as production function, contingent valuation, hedonic pricing and travel cost. While such methods provide support to policy makers, only estimates of the value of production and function give similar authority to that which economists place on the operation of prices in a free market.

Two general approaches toward developing indicators of environment-economic performance have emerged, although much refinement is still required: "environmental satellite" accounts for natural resource, pollution emissions and expenditure on environmental protection, which are annually produced in addition to conventional GDP accounts; and "adjusted GDP" or "extended monetised" accounts.

The related issue of sustainable development is complex but important. It has been discussed widely in the context of the Brundtland concept, and the Precautionary Principle (see later). In the real world, the application of such concepts and principles needs to be set against the demands of economic development. The weight to be given to long-term sustainability and benefit to future generations has to be assessed against that to be given to wealth creation and jobs for the present generation. Sustainable development is the creation that endures over the long run, with due regard for the maintenance or enhancement of the quality of life. It is a multidimensional concept with socio-cultural, economic, political, environmental and moral dimensions. Economists define sustainable development in terms of non-decreasing levels of utility, income *per capita*, or real consumption *per capita* over time. In broad terms, sustainable development involves intergenerational equity - a bequest from the current generation to the next of an amount and quality of wealth at least equal to that inherited by the current generation. This requires stock of capital that does not decrease over time. The most publicised definition of sustainable development, credited to the World Commission on Environment and Development, included a criterion of intragenerational equity. Sustainability, therefore, requires development that allows for an increase in the well-being of the current generation (with particular emphasis on the welfare of the poorest members of society), while simultaneously avoiding uncompensated, `significant' costs (including costs of environmental damage) on future generations. A cost liability would reduce the `opportunities' for future generations to achieve a comparable level of well-being. Sustainable development is based on a long-term perspective, it incorporates a criterion for equity as well as for efficiency, and it may also emphasise the need to maintain a `healthy' global ecological system.

There is a spectrum of overlapping positions for sustainability, from very `weak' to very `strong'. `Weak' sustainability requires the maintenance through time of the total capital stock - composed of manufactured or reproducible capital, human capital, or the stock of knowledge and skills, and natural capital (exhaustible and renewable resources, together with environmental structures, functions and services). This approach has an implicit assumption that there are infinite possibilities to substitute between all forms of capital. The Hartwick Rule is also used to buttress the `weak' sustainability position by regulating intergenerational bequests of capital. This rule lays down that the rent obtained from the current generation, exploiting the natural capital stock, should be reinvested in the form of reproducible capital which forms future generations' inheritance. This transfer of inheritance should be at a sufficient level to guarantee well being (non-declining, real consumption) through time.

The implicit assumption that capital is substitutable underpins another contention - that **extensive scope exists over time for the decoupling of economic activity and environmental impact.** The decoupling process would be mediated by technical progress and innovation. Total decoupling is not possible. But with the important exception of cumulative pollution, society's use of resources can be made more efficient over time. Thus, if the amount of resources used per unit of GDP decreases faster than GDP itself goes up, the aggregate environmental impact should fall. From the perspective of `weak' sustainability, a key requirement will be increased knowledge properly embodied in people, technology and institutions.

From the perspective of `strong' sustainability, some elements of the natural stock of capital cannot be substituted (except on a very limited basis) by man-made capital. Therefore, there is a concern to avoid irreversible losses of environmental assets. Some of the functions and services of ecosystems, in combination with the non-biological environment, are essential to human survival as they are life-support services (*e.g.* biogeochemical cycles) and cannot be replaced. Other multi-functional ecological assets are at least essential to human well-being, if not exactly essential for human survival (e.g. landscape, space and relative peace and quiet). We might therefore designate those essential ecological assets as being `critical natural capital'. This would protect against changes in relative valuation over time. Supporters of the very strong sustainability position of `deep ecology' argue for a particular type of non-substitutability based on an ethical rejection of the trade-off between man-made and natural capital. Strong sustainability therefore requires that we, at least, protect critical natural capital and ensure that it is part of the capital bequest to future generations.

Restoration and conservation of natural resources and the environment are crucial to achieving sustainable development. Advocates of `strong' sustainability are led to adopt the precautionary principle by a combination of factors: the risk of irreversible environmental losses; a high degree of uncertainty surrounding past rates and future trends in resource degradation and loss; and growing appreciation of the full structural and functional value of ecosystems. The message is that environmental degradation and loss of natural resources represent one of the main ways in which today's generation is creating uncompensated costs for the future.

There are a number of rules for the sustainable utilisation of the natural capital stock (these fall some way short of a blueprint):

- Market and policy intervention failures, related to resource pricing and property rights, should be corrected.
- Resources should, wherever possible, be exploited, but at a rate equal to the creation of substitutes (including recycling).
- The regenerative capacity of renewable natural capital should be maintained: harvesting rates should not exceed regeneration rates, and wherever feasible, cumulative pollution which could threaten waste assimilation capacities and life-support systems, should be avoided.
- Technological changes should be steered *via* an indicative planning system so that switches from non-renewable to renewable natural capital are fostered; and efficiency-increasing technical progress should dominate technology that increases throughput.
- The overall scale of economic activity must be limited so that it remains within the carrying capacity of the remaining natural capital. Given the uncertainties, a precautionary approach should be adopted with a built-in safety margin.

From our review of sustainability, the emphasis on equity and social issues as well as on physical constraints is important. For development to be sustainable, it must incorporate the following under the `strong' sustainability view: non-depletion of natural capital; both <u>inter</u>generational and <u>intra</u>generational equity principles; and, in the latter context, it must be capable of providing sustainable livelihoods to those whose work primarily depends on natural resources. Agenda 21 sets out principles for sustainable development, without advocating any explicit definition of sustainability and with a tendency to focus on global issues which may not be of greatest concern to the world's poor. The implicit definition of sustainability within Agenda 21, however, would seem to be closely related to the concept of `strong' sustainability discussed above. But the lack of operational details and the prevailing obstacles to change mean that implementation of such an agenda represents a very formidable task. The Panel noted that the idea of sustainability would continue to be an important driver but did not take a view on the `strength' of sustainability that would be followed. This was a future uncertainty, which needed to be taken into account in assessing the robustness of future technological opportunities.

<u>GMOs – Current and in the Pipeline</u>

Until the most recent statements about GM livestock and the possibilities of GM humans, most attention has been directed towards GM crops, largely ignoring those GMOs used routinely in food processing, fermentation, and medicine. Coming through regulatory and patenting pipelines in various countries are three generations of GM crops. The first generation of crops is predominantly aimed at crop protection by resisting competition from weeds through the introduction of herbicide-tolerant genes, usually deploying a single gene trait, or by resisting the depredations of pests and diseases. This strategy is still under refinement, extending the range of crops and genes, and addressing a wide range of pests and diseases. With suitable safeguards, stacking and mixing of genes are being considered to overcome the possible build-up of resistance in the pest and pathogen populations.

Second-generation transgenic crops are aimed at improving directly yield efficiency and quality. Over the next five to ten years, large-scale crop introductions will probably focus on (i) modified carbohydrate quality for industrial feed stocks (binders, fillers, stabilisers and thickeners) and improved food processing, (ii) vegetable oil content and quality, (iii) amino acid balance, protein content, overall quality and nutritional value (iv) harvestable fibres with low lignin content, and coloured cellulosic fibres, (v) substrates for the bio-plastics industries, (vi) tolerance to biotic and abiotic stresses, (vii) better water- and nutrient-use efficiency, (viii) enhanced photosynthetic efficiency, (ix) reduction in the production of anti-nutritional and allergenic factors, (x) modified colours and shapes of fruit, vegetables and flower crops, (xi) easier-to-harvest crops (*e.g.* synchronised maturation, improved abscission) with improved shelf/storage life, and (xii) hybrid crop production.

Third-generation crops, which may be grown on a large scale in the longer term, are likely to focus on phytoremediation of contaminated land and water, and on the production of nutraceuticals and pharmaceuticals. Environmental monitoring and the slow, methodical approach used to carry out dietary and clinical trials will of necessity delay the introduction of these fascinating crops and platform technologies that are currently under investigation. The second- and third-generation crops will often have genes that are targeted at specific integration sites in the chromosomes; some will employ organelle transformation, switchable promoters, and eventually also gene-use restriction technology (*e.g.* the oft-derided 'Terminator technology'), which can not only protect the intellectual property by effectively preventing further propagation but can stop inadvertent spread of GM or other crops. The problems of gene silencing, random location of inserted genes in the genome, resistance breakdown, genetic instability and unexpected pleiotropic effects will continue to be addressed by screening in conventional trials, and by technological advances. Increasingly, gene expression is being confined to specific parts of plants, at specific stages of development. The destabilising and often misconceived arguments about GM crops and GM food are already influencing investment strategies and may deprive the UK of accessing and reaping the benefits of all branches of biotechnology.

Technology-Inherent and Technology-Transcending Risks of GMOs

Technology-inherent risks relate to biosafety issues in respect of health and the environment. Technology-transcending risks are not specific to the technology but where its deployment may carry certain risks (*e.g.* induce poverty, diminish biodiversity). Concerns over GM technology cover both inherent and transcending issues. Thus, concerns and scares have been raised over toxicity, carcinogenicity, food intolerances, use of antibiotic-resistance gene markers, potential allergies, and modification of nutritional value. After thousands of trials and a huge number of market releases, there are no clear cases of harmful effects whatsoever of authorised and released GM crops and food products derived from them, on human or livestock health. Likewise, there are no unique issues in the testing of GM crops for ecological and environmental risks as compared with conventional crops. It is the product rather than the process that should be evaluated. There is no evidence of any crop species, transgenic or conventional, having become invasive weeds because of plant breeding; indeed, the reverse situation is the norm. Commercially bred cultivars are poor competitors; the more persistent species such as certain types of oilseed rape are relatively undeveloped in terms of plant breeding. Fundamental to any gene-flow considerations is "so what?" Massive publicity over potential food-safety and environmental risks would often appear to be a veneer covering deep technology-transcending fears and suspicions. Ethical and moral opinions, beliefs and assertions; political standpoints over intellectual property (IP) rights; concerns over access by the poor to technology; attitudes that are anti-profit, anti-multinational and/or anti-American; genuine misunderstanding of science; wanton ignorance; antipathy to the pace of technological and scientific change, progress and complexity; and political opportunism, collectively present challenges that scientists find difficult to address. Perceptions are moulded by marketing, pressure groups, peer pressure *etc.*, but perceptions, no matter how wrong, represent stark market realities. Given the general state of knowledge about risks, there is acute vulnerability of the populace to media presentations engendering and parasitising fear of the unknown.

The Precautionary Principle

There is no agreed single definition of the Principle and how it should operate. All progress in science, engineering, technology and medicine would grind rapidly to a halt if research and development were suspended by measures to prevent the possibility of harm, even if the causal link between the activity or product and the possible harm has not been proven, or is so remote as to be insignificant. Supplementary to this is the view, often propounded by animal rights activists, that R&D must only have a utility rationale as opposed to the pursuit of knowledge (curiosity) *per se*. Defining "harm" itself is difficult, especially when the harm is largely one of unquantifiable perception; both the Advisory Committee on Releases to the Environment and the Agriculture and Environment Biotechnology Committee are trying better to define "harm".

Ownership of GMOs

Patents and plant variety rights (PVR) operate throughout nearly all the nations deemed to be More-Developed Countries (MDCs). Prospects of monopoly rights give the owner an opportunity to recoup R&D costs as well as legal (!), manufacturing, marketing and other overhead costs, and the opportunity to make a profit. These time-restricted rights come at the cost of public disclosure of the invention, or in respect of PVR, release of the cultivar for parental purposes to other plant breeders. Certain provisional patents in biotechnology do appear to be discoveries rather than inventions, and are therefore vulnerable to successful challenge. Nonetheless, GM plants, especially those that have been through selection processes would appear to be secure. It is not a matter of ownership of one or a few genes, but a whole phenotypic assemblage.

Risk-Benefit Analyses

All technologies pose risks and offer benefits; each society sets the acceptable boundaries. Few technological developments have faced such scrutiny from their inception as modern biotechnology.
Globally, most agricultural and life scientists in Less-Developed and MDCs favour the introduction of GMOs to address future food, manufacturing and environmental demands. The sheer potential of the technology is too profound to ignore. Compared with conventional and organic systems, GM cropping systems are subject to extensive and intensive quality and environmental monitoring. Until such techniques as specific target gene insertion, elimination of antibiotic resistance markers, robust prediction of gene expression patterns *etc.* become routine, all GM

crops will be subject to systematic gene-by-gene, crop-by-crop analyses. Fortunately, however, advances in genomics, proteomics, metabolomics, and bioinformatics will soon address the main questions, and will be applicable to non-GM crops, livestock and products derived from plants, animals and microbes. The marketplace will be the ultimate arbiter between success or failure of GMOs.

Challenges to GMOs

The interface of GM technology with morals, ethics and law is a nebulous area. Individuals and groups attached to one or more hand-wringing concerns carried in the technology-inherent and technology-transcending bandwagons will continue to test the legal robustness of ownership, release and marketing of GMOs. Illegal activities are likely, and pressures to disrupt (by whatever means) the introduction of GMOs will be aimed at organisations and individuals holding different views. Where inflexible attitudes are attached to market-sensitive activities (*e.g.* organic farming), even in a plural society, strong feelings will be expressed and will be provoked by opposing attitudes, especially if these are equally inflexible or lack sensitivity to concerns or views that the practitioners genuinely hold.

The release of GMOs into the environment is a relatively novel issue both in criminal law and the law of delict, but established legal principles relating to the control of dangerous goods, law of nuisance and land use are relevant. The Environmental Protection Act 1990 and appropriate consents are pivotal. There are differences between Scots Law and English Law *e.g.* civil liability at common law concerning dangerous goods. Of the various fascinating questions that can be posed about GMO releases, most can be answered by expert advice and adherence to government regulations, guidelines, Codes of Practice, maintaining appropriate insurance, and acting in accordance with current scientific norms. A general tightening-up of rules on GMO containment in R&D laboratories is underway. Issues such as natural variation, comparisons with non-GMOs, and challenging gross misrepresentation of the scientific literature, and unwarranted claims, come to the fore.

The destruction of GMO field trials raises interesting possibilities of reciprocal actions by those who genuinely regard certain types of agriculture and horticulture favoured by environmental activists (*i.e.* farming methods that are perceived to harbour weeds, pests, parasites, and diseases, endangering quality assurance schemes and phytosanitary schemes in neighbouring conventionally farmed enterprises) as a threat to their livelihoods.

Potential Challenges

All technologies have the potential for good and ill. Rigorous regulatory environments and sophisticated litigious democracies greatly diminish the risk of malevolent or negligent actions. Harmful GMOs can be envisaged, but we are reassured by the fact that it was the scientists involved who, themselves, voluntarily introduced biohazard controls in the first place. With some outstandingly able exceptions, law makers and those interpreting and operating the law are woefully scientifically and technologically inadequate.

Potential challenges of merit are most likely to arise between competing companies, or from customers failing to derive claimed benefits from GMOs. With regard to challenges based on the effects of gene flow, principally through the movement of pollen, recent information on gene-sequence occurrence will be somewhat undermining, especially when stacked up against the scale of other health-threatening and environmental risks. Likewise, the use of inbreeding, sexually incompatible or sterile crop species will severely limit the potential for challenge. As the results of several environmental monitoring research projects come to fruition, the scale and likely consequences of gene flow will become obvious. DNA movement in soil or in guts is perceived as a threat, despite no evidence to support this view, or even application of commonsense! Any release of potentially dangerous GMOs will be constrained by statutory processes; independent scientific advice from the Advisory Committee on Releases to the Environment, Advisory Committee on Animal Feedstuffs, and Advisory Committee on Novel Foods and Processes; the operation of the Food Standards Agency and public-sector laboratories; due diligence by retailers and food preparation companies; the international scientific community; and the threat of litigation. Even so, public perception is one of control by certain biotechnology companies and lack of independent scrutiny.

Anemophilous, outbreeding polycarpic GMOs may come under special scrutiny, particularly those yielding food as opposed to industrial products, but the newer scientific procedures offer reassurance.

Systems to Evaluate and Reduce Liabilities

Technological advances in gene sequence analysis, genome mapping, proteomics, metabolic profiling, feeding trials, predictive modelling *etc.* are providing essential tools to assess likely impacts of released GMOs. Statutory bodies, national and international Codes of Practice, multilateral environmental agreements such as the Convention on Biological Diversity and the Cartegena Protocol on Biosafety, regulatory

frameworks *etc.* help structure the systems of assessment, reducing liabilities, but not eliminating all risks, of course.
On 14 February 2001, the European Parliament finally adopted a joint text concerning the deliberate release into the environment of GMOs. The text, which revises the European Directive 90/220/EEC (which itself lays down regulations for commercial releases of GM crops into the environment), seeks to increase the transparency and efficiency of the decision-making process on GM crops and products in the EU. This in itself may improve public confidence. The revised Directive aims to promote a harmonisation of risk assessment, and to introduce clear labelling requirements for all GMOs placed on the market. There are proposals to introduce mandatory monitoring for GM products and mandate a time limitation (renewable) of ten years, maximum, for first-time consent. There are plans to introduce compulsory monitoring of GM crops after they have been placed on the market (although it is difficult to envisage how this would be effective), to provide for a common methodology to assess the risks associated with their release, and to include a mechanism to allow modification, suspension or termination of the release when new information on risks becomes available. Other important components of the evolving legislation include: a gradual elimination of antibiotic resistance markers in commercial GMOs by the end of 2004, and by 2008 for releases into the environment for experimental purposes; a plan to bring forward a legislative proposal on environmental liability before the end of 2001, also covering damage resulting from GMOs; public registers of GMOs released into the environment for experimental purposes; introduction of general rules on traceability and labelling of GMOs and products derived from them; mandatory monitoring after GMOs are placed on the market; mandatory consultation of the public concerning both experimental and commercial releases; the application of the Precautionary Principle when implementing the Directive; the opportunity for consulting Ethics Committee(s) on issues of general nature. A 1% maximum threshold is proposed for GM "contamination" of non-GM food materials. To obtain this will demand almost unachievably strict control of seed "purity" at harvest, which itself will be influenced by possible cross-pollination from neighbouring crops, rotational practices, weed control, and crop-separation distances. The EU Scientific Committee on Plants justifiably opined on 13 March 2001 that a zero level of unauthorised (adventitious) presence of GM seeds in conventional seeds is unattainable in practice, and when establishing levels of tolerance, a major constraint is the limit of analytical sensitivity of available detection methods. We would also add that there is the need for accessible and accurate databases on DNA insertions, but commercial confidentiality will need to be respected.

Finally, how does one acquire proof of adverse health or environmental effects? Appropriateness of the controls, validity of post-release surveillance exercises, sample size, psychosomatic symptoms, and demonstrable fact as opposed to opinion or belief, are all factors to be taken into account.

As traditional botany and zoology departments of universities have given way to new academic structures that do not readily accommodate field courses and traditional field ecology, there is a marked decline in the monitoring of the native flora and fauna, and maintaining long-term data-sets. Likewise, valuable sources of information are being lost with the decline of agricultural courses and the contraction of agricultural research institutes. Nonetheless, modern scientific technologies, including remote sensing, are starting to redress in part the reduction in traditional ecological monitoring.

New forms of agriculture will need to be introduced, regardless of the release of GMOs, encompassing refugia (reserves), dispersal corridors (*e.g.* hedgerows), modified rotations, new types of harvesters, recycling, multi-use crops, improved storage, monitoring of biodiversity, *in situ* genebanks, germplasm collections *etc.*

Major longer-term research needs to be focused on both the nutritional effects and rôles of all foodstuffs, and on the environmental consequences of releasing bred material and alien wild species. There are genuine concerns about conventional, organic, and subsistence agriculture; domestic and commercial horticulture; and forestry; all with potential liability implications beyond farm, garden and park gates.

Future GM releases may be of restored (currently lost) genotypes; GMOs that can restore polluted or damaged habitats; GMOs that can mop up greenhouse gases; GMOs that are so efficient as to diminish the need to encroach onto natural or amenity habitats; GMOs that produce valuable natural resources currently only available by raiding natural habitats.

There is much to learn about organism-environment interactions: the soil is a particularly complex topic, largely unexplored but of fundamental importance to most aspects of environmental releases. A similar situation exists for fresh and sea water (oceanic) systems, with the release of fish and other organisms able to be transported globally, and also for the atmosphere. Environmental releases do not respect political and legal boundaries.

It is a fact that, to date, with the possible exception of some GM fish, wild-type (*i.e.* naturally occurring) organisms, those optimised by competition in nature, out-compete organisms bred by mankind. This weakness can be enhanced by using GM technologies to construct GMOs with special vulnerabilities, if need be. Constant monitoring of new pathotypes of pests and diseases, especially using biotechnology, will ensure that humanity's unending battles to have high-quality efficient food and industrial feedstock supplies will not be jeopardised. Clearly, a strong regulatory framework is essential, one that has the confidence of the electorate yet does not drive away innovation, inspiration and wealth creation.

"Ambulance chasing" activities in which there is no real victim or perpetrator, the continuing susceptibility of the public to the utterances of unelected and intolerant pressure/special-interest groups, and publishing and broadcast media unable to analyse scientific issues, are all features of the current debate. Unfortunately, scientists in their pursuit of knowledge and understanding tend to operate by careful scrutiny of the literature, use specialist vocabularies, realise that there are few absolute answers, know that there are no risk-free human activities, and operate in a system where knowledge develops incrementally. Sound-bite-driven debates, especially those that endlessly go over the same material in an atmosphere of hostility, superficiality and misconception, are alien environments into which they are involuntarily released!