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The regulatory system in the EU and further afield

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Abstract

The regulation of modern biotechnology began almost as soon as the potential benefits and risks became clear. In some countries a decision was made to use current law to address the new technologies, arguing that the changes that are able to be introduced into new products are not substantially different from those introduced by other techniques. In other jurisdictions new law was enacted to ensure that the products are at least as safe (or as some would have it, safer) than those currently on the market.

New treaties that have attracted widespread support among 'consumer' countries and indifference or hostility among 'producer' countries have just come into force, requiring countries to address the regulation of biotechnology and assess the risks to biological diversity and to human health of introducing living modified organisms into their territory.

Public perception of genetic engineering has led to changes in the regulatory system, which may not be justified by the risks posed by this technology. In particular, the national and international requirements that have been currently agreed require an analysis of risk only rather than a balancing of risk with the benefits that may accrue.

Keywords: *biosafety, regulation of biotechnology, biosecurity, European biosafety*

THE CARTAGENA PROTOCOL

On 11th September, 2003, the Cartagena Protocol on Biosafety came into force. This new international treaty requires member countries to implement an effective regulatory regime primarily aimed at ensuring the safe transfer of living modified organisms[1] between countries. The Protocol is a free-standing addition to the Convention on Biological Diversity (CBD) – those joining the Protocol must be party to the CBD, but members of the CBD do not have to become party to the Protocol. The treaties are designed to address:

- the conservation of biological diversity;
- the sustainable use of its components; and
- the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources.

Hence the living modified organisms (LMOs) that are addressed in the Protocol are those that result 'from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health'.[2] Modern biotechnology is also tightly defined in the Protocol (Art. 3) to be

> the application of:
> a. *In vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or
> b. Fusion of cells beyond the taxonomic family,

that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

Definitions of genetic modification and LMOs (GMOs) differ widely in legislation, although many countries are moving to a systematic definition in line with the Protocol. Directive 2001/18 of

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the European Union, for example, defines a genetically modified organism (GMO) to mean 'an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination'.[3] The European Directive provides a means for inclusion of techniques not currently considered to be 'genetic modification' by their addition to a list in Annex IA, and the exclusion of techniques from those that would otherwise result in a genetically modified organism through listing in part 2 of Annex IA.

The Cartagena Protocol on Biosafety is now in force

Among the 66 parties[4] to the Cartagena Protocol is the European Commission; all of the member countries of the EU will eventually have to become party to the treaty (fewer than half of the 25 current and new members are presently parties[4]). The contained use of LMOs is excluded from most of the major requirements of the protocol and the emphasis is clearly on the protection of the environment.

The Convention on Biological Diversity (CBD) came into force in 1993 and has 188 parties, with the USA as the only major country that has chosen not to be party to the convention. Article 8(g) of the CBD is extremely important in relation to the regulation of LMOs:

> Each Contracting Party shall, as far as possible and as appropriate:
> . . . (g) Establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health . . .

Countries are required to institute structures to manage or control risks

Each of the member countries of the CBD has, therefore, to institute an internal, national system for regulating all uses of transgenic organisms that may have adverse effects on the environment and/or human health, including (where appropriate) contained or confined use. The Convention and the Protocol only require countries to institute regulatory systems for organisms that fall within this definition. Countries must determine the risk associated with LMOs and institute risk management procedures to minimise or prevent harm to biological diversity and to human health.[5]

In 2001 the United Nations Environment Programme (UNEP), financed by the Global Environment Facility (GEF), started a three year project to assist those developing countries that wanted to become party to the Protocol and that needed assistance in developing a 'Framework for Biosafety'. Countries participating in this project had to sign, ratify or accede to the Protocol, should not have taken part in a previous project funded by the GEF to assist in setting up such a framework (12 countries) and be eligible for GEF funding. The project aims at helping each participating country to set up a framework for the management of LMOs at the national level, allowing them to meet the requirements of the Cartagena Protocol. There are 122 countries currently involved in the project, each trying to identify a system for regulating the use of LMOs within their territory and ensuring that the systems are in place to permit the transfer of LMOs.[6] A major part of the project involves an examination of current legislation and guidelines that may impact on biosafety, an analysis of the gaps in the regulatory system and the identification of guidelines, regulations or even primary legislation that is indicated by that analysis. In addition the GEF is funding projects in a further 12 countries where efforts are being made to bring the understanding of needs for the regulation of LMOs into a full legislative framework.[7]

REGULATION OF MODERN BIOTECHNOLOGY: FOR SAFETY'S SAKE

When considering the regulation of modern biotechnology, either within the borders of an individual country or when

transferring such organisms between countries, we need first to ask 'why?' What makes transgenic organisms so different from those produced using other techniques, including radiation mutagenesis, that the former require special regulation and the latter do not?

We have systems in place in most countries to ensure that organisms or new food, feed or agricultural products are as safe as possible. There is an International Plant Protection Convention that allows for effective international action against plant pests and that requires the countries to undertake a 'pest risk analysis'.[8] The newest version of this treaty was agreed in 1997 and is now legally binding. The Sanitary and Phytosanitary Measures Agreement[9] (part of the Uruguay Round of the set of treaties that set up the World Trade Organization) permits countries to take safety into account when disallowing the introduction into their environment of organisms that may cause environmental damage or affect plant, animal or human health. There is an international treaty to protect endangered organisms – CITES (the Convention on International Trade in Endangered Species of Wild Fauna and Flora).[10] These all have major trade implications and are therefore often seen as more important than treaties that protect against possibly delayed and indirect effects on our environment.

There are many trade and environmental treaties that require assessment of risk

PRECAUTIONARY APPROACH

The precautionary approach is basic to both the Protocol and to the European Directive

The most important 'principle' that underlies both the Cartagena Protocol and the European Directive that applies to the release of LMOs is that called the 'precautionary approach'. In the General Obligations placed on member states of the EU in Directive 2001/18,

> Member States shall, in accordance with the precautionary principle, ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or the placing on the market of GMOs.

The Cartagena Protocol identifies the approach in its first Article – its objective:

> In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development [see note 11], the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.

There has been much disagreement about the precautionary principle (or approach) in relation to biosafety. Many have suggested that transgenic organisms should not be released into the environment until there is sufficient information that there will be no harm. Others believe that the precautionary principle requires that risk analysis should apply to each individual case in a particular environment, and that the approach should be 'step-by-step'. Recital 19 of the European Directive 2001/18 states:

> A case-by-case environmental risk assessment should always be carried out prior to a release. It should also take due account of potential cumulative long-term effects associated with the interaction with other GMOs and the environment.

Recital 24 defines the 'step-by-step' principle:

> This means that the containment of GMOs is reduced and the scale of release increased gradually, step by step, but only if evaluation of the earlier steps in terms of protection of human health and the environment

indicates that the next step can be taken.

Regulations and guidance on the use of GMOs have existed since 1975

Precaution goes back to the beginning of the use of modern biotechnology. Almost as soon as it became possible to specifically cut and paste pieces of DNA (using restriction enzymes), the potential advantages of moving DNA within and between organisms was recognised.[12] Although it was clear that there were enormous benefits that could be harnessed, the harm that could result was also recognised. A UK Government committee reported early in 1975 that genetic manipulation techniques would provide 'substantial though unpredictable benefits . . . application of the techniques might enable agricultural scientists to extend the climatic range of crops and to equip plants to secure their nitrogen supply from the air' – the benefits of the new technology far outweighed the risks if suitable precautions were put in place in the view of the Ashby Committee.[13]

Stop, think and then proceed with caution

In 1974, Paul Berg and others wrote a letter to *Nature*, *Science* and *Proceedings of the National Academy of Science*[14] calling for a self-imposed moratorium on the use of the technology until a meeting had been held to discuss the 'potential biohazards' among the scientific issues. The purpose of the meeting was 'to review the progress, opportunities, potential dangers and possible remedies associated with the construction and introduction of new recombinant DNA molecules into living cells'.[15] The meeting of scientists, lawyers and journalists that took place in Asilomar in California in February 1975 produced a set of guidelines for the use of biotechnology: the formal goals of the meeting included the need to identify the 'possible risks involved for the investigator and or others' and 'the measures that can be employed to test for and minimize the biohazards so that the work can go on'.[16] At the time it was only microorganisms that could be modified, and it was primarily the workplace – the laboratory – that needed to be considered. The guidelines introduced in the USA after the Asilomar meeting, and regulatory structures introduced in Britain and other European countries at about the same time were all biased towards ensuring the safe use of transgenic organisms in the laboratory – primarily the protection of those who might come into contact with the organisms. It was only in the late 1980s and early 1990s that release of organisms into the environment and hence a potential threat to the environment or to the health of ordinary people became a reality.

The 'Asilomar Meeting' was an early example of precaution, where scientists – conscious of the potential of their work – met others to consider how to ensure that that which was done with the new technology could be safely carried out. 'Asilomar remains an important scientific landmark, a rare if not unique instance of scientists independently questioning and successfully regulating their own cutting-edge work.'[17]

NEW REGULATORY SYSTEMS' INTEGRATION INTO EXISTING LEGAL AND ADMINISTRATIVE FRAMEWORKS

The regulatory systems that countries introduce to ensure the safety of modern biotechnology will depend on their current legislation, their legal systems and the administrative systems that are in place. Some countries, such as the USA, deliberately chose to use existing agencies and law. The EU chose to make major changes to law and have instituted new pan-European agencies whose major role is the assurance of safety of the products of modern biotechnology including novel food and feed. These are the extremes, and many countries have instituted systems that lie between these.

Immediately after the Asilomar meeting many countries introduced some form of regulation. In the USA, the National Institutes of Health produced guidelines that applied to all organisations that received funding from US Government.[18]

These NIH Guidelines remain the primary regulatory system for assuring safety in the USA where transgenic organisms are used in containment (or confinement).[19] Other countries were quick to introduce guidelines for research involving rDNA technology. In many countries this was soon supplanted by law in the form of regulations under existing legislation (as in the UK) or specific new law. There have been strict safety regulations controlling all contained use work with GMOs in the UK since 1978. The legislation has developed over the years, partly because of changing technology. Major changes in regulations can be made relatively quickly. The initial regulatory or guidance regimes applied only to work in the laboratory, and it was only about ten years later that first guidance and then regulations for release into the environment were elaborated.[20]

LEGISLATION IN THE USA AND EUROPE: A BRIEF OVERVIEW AND ANALYSIS

USA

The most important regulatory systems that have been introduced are those in Europe and in the USA, primarily as they are perceived as very different and because of their impact on world trade. In 1986 the USA introduced a coordinated framework for biotechnology that sought to use existing law to ensure safety. The framework described the 'comprehensive federal regulatory policy for ensuring the safety of biotechnology research and products':

In 1986 the USA instituted its Coordinated Framework for Biotechnology

> Existing statutes provide a basic network of agency jurisdiction over both research and products; this network forms the basis of this coordinated framework and helps assure reasonable safeguards for the public. This framework is expected to evolve in accord with the experiences of the industry and the agencies.[21]
>
> The underlying policy question was whether the regulatory framework that pertained to products developed by traditional genetic manipulation techniques was adequate for products obtained with the new techniques. A similar question arose regarding the sufficiency of the review process for research conducted for agricultural and environmental applications.. . . Upon examination of the existing laws available for the regulation of products developed by traditional genetic manipulation techniques, the working group concluded that, for the most part, these laws as currently implemented would address regulatory needs adequately. For certain microbial products, however, additional regulatory requirements, available under existing statutory authority, needed to be established.[22]

Europe

At that time there were no Europe-wide laws for the protection of human health or for the protection of the environment in relation to GMOs, yet it was perceived as necessary to institute a legal regime that could address the possible risks posed by products of this new technology. In 1990 Europe introduced legislation in the form of Directives to member states to ensure that the risks were considered, identified and minimised before the marketing of products produced using modern biotechnology. It was, however, recognised that product-specific legislation would become important in the future:

> Whereas the provisions of this Directive relating to placing on the market of products should not apply to products containing, or consisting of, GMOs covered by other Community legislation which provides for a specific environmental risk assessment similar to that laid down in this Directive . . .[23]

Since 1990 there have been numerous changes to the EU's system for overseeing the use of GMOs. The two Directives originally introduced (90/219/EEC relating to the Contained Use of Genetically Modified Micro-organisms

and 90/220/EEC relating to the Release into the Environment and the Marketing of GMOs) have been modified extensively and have now been replaced by Directives 98/81[24] and 2001/18.[3] In response to public disquiet the regulatory system has been changed to ensure that permits are granted for only a limited time, that monitoring of the effects on the environment is undertaken and that the public is consulted during the decision process. A new European Food Safety Authority has been set up.[25] Directive 98/81 substantially altered the system for handling GMOs (microorganisms) in containment, while Directive 2001/18 set out to modify the manner in which GMOs were either field tested or marketed within the EU. In particular, it introduced new procedures and principles for the environmental risk assessment. It requires countries to institute mandatory post-marketing monitoring, including monitoring of possible long-term effects on the environment. Countries have to provide information to the public, and an initial system was introduced for labelling and traceability at all stages of marketing. Under 90/220 permits for commercial use of GMOs in the environment could be withdrawn if new information came to light that suggested that the risk to the environment or to human health was too great. Now there is a requirement that initial approvals of GMOs be limited to a maximum of ten years. Controversially, there is an obligation to consult the European Parliament on decisions relating to the authorisation to release GMOs into the environment and there is a possibility that the Council of Ministers may adopt or reject a Commission Proposal for authorisation of a GMO by qualified majority.

During the 1990s the system appeared to work well, with many products being field tested in a range of European countries and foods that contained or were derived from transgenic organisms being approved in many European countries. In 1997 the EU introduced Regulation 258/97 relating to the introduction of novel foods into Europe. After that came into effect there were no approvals for novel foods consisting of, or containing, GMOs, much to the annoyance of the producers and producing countries. It took many years of negotiation before Directive 2001/18 was introduced and, although it should have become law in October 2002, few of the countries in the EU have yet introduced legislation implementing the Directive. The European Commission decided in July 2003 to refer France, Luxembourg, Belgium, Netherlands, Germany, Italy, Ireland, Greece, Spain, Austria and Finland to the European Court of Justice for failing to adopt (and notify that it had) legislation implementing Directive 2001/18 on the deliberate release of GMOs into the environment.[26]

One of the problems identified by a number of the member states was that they wanted a complete package of legislation, including that specifying labelling, in place before proceeding to enact the Directive. The EU has recently agreed two new regulations on 'Genetically modified food and feed' (European Parliament and Council Regulation 1829/2003)[27] and 'Traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms' (European Parliament and Council Regulation 1830/2003).[28] The new rules entered into force on 7th November, 2003, but there is a transitional period of six months for applying Regulation 1829/2003 and of three months for Regulation 1830/2003. European Regulations apply directly in European member states and do not need specific legislation in national parliaments to bring them into effect.

The new regulations replace Directive 2001/18 where they concern food and feed, and are not concerned primarily with the environmental impact of growing the foods or feeds. They apply to GMOs that are for food or feed, food or feed containing (or consisting of GMOs), food produced from or containing ingredients produced from GMOs and

feed produced from GMOs. Food (for human use) and feed (for animal use) are treated separately in the Regulation. These foods must not '(a) have adverse effects on human health, animal health or the environment; (b) mislead the consumer; or (c) differ from the food which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for the consumer.'[29]

The objectives of Directive 1829/2003 are to:

(a) provide the basis for ensuring a high level of protection of human life and health, animal health and welfare, environment and consumer interests in relation to genetically modified food and feed, whilst ensuring the effective functioning of the internal market;
(b) lay down Community procedures for the authorisation and supervision of genetically modified food and feed;
(c) lay down provisions for the labelling of genetically modified food and feed.

It specifies a system for introducing such foods and feeds onto the market. The second regulation relates to traceability and labelling. It applies to (a) products consisting of, or containing, GMOs; (b) food produced from GMOs; and (c) feed produced from GMOs:

> This Regulation provides a framework for the traceability of products consisting of or containing genetically modified organisms (GMOs), and food and feed produced from GMOs, with the objectives of facilitating accurate labelling, monitoring the effects on the environment and, where appropriate, on health, and the implementation of the appropriate risk management measures including, if necessary, withdrawal of products.

A further Regulation has been published to bring the Cartagena Protocol into effect in the EU.[30] A package now exists which, in theory, covers all the contingencies that have been raised by those member countries that were most opposed to the introduction of GMOs into their territories. The EU is desperately trying to bring its regulatory system into effective use. In the strategy document produced by the EU it is stated that:

> **Regulatory oversight** of biotechnology and focused **public research** must, first and foremost, ensure that the development and application of life sciences and biotechnology is safe for humans, animals and the environment (including biodiversity), taking into account all the other concerns to ensure the safe and socially acceptable development and application of life sciences and biotechnology.
>
> The scientific and technological revolution is a **global** reality which creates new opportunities and challenges for all countries in the world, rich or poor. Europe needs to develop its policies with a clear international perspective, contributing constructively to international cooperation while defending its own interests.[31]

A further insight into the approach taken in Europe is provided in 'Life sciences and biotechnology – A strategy for Europe'.[32] This strategy stresses the importance of biotechnology in Europe, and the need for its safe use to assist in European development.

Dispute between the EU and the USA/Argentina/Canada

There has been an effective moratorium on the commercial planting of GM plants and the importation of foods containing GM organisms into the EU since 1998. Until recently no foods or plants have been approved through the European system that was designed for protecting human health and the environment. The USA decided that they need to address the loss of income to their farmers, and

Even while an effective moratorium was in place in Europe, negotiations continued on revising the Directives introduced in 1990

together with Argentina and Canada have taken the dispute with the EU to a panel set up by the WTO. After conciliation had (in their view) failed, they asked, on 7th August, 2003, for a panel to be set up to adjudicate on the fact that the European systems appear to have been deliberately frustrated to effect a moratorium. A panel has been set up (29th August, 2003) to examine the issues raised by the USA, Argentina and Canada (and other countries that have joined the dispute). It was emphasised that the legislation in place was not the object of the complaint; rather it was the manner in which the system was not working. The USA argued that:

> [s]ince October 1998, the European Communities ('EC') has applied a moratorium on the approval of products of agricultural biotechnology ('biotech products'). Pursuant to the moratorium, the EC has suspended consideration of applications for, or granting of, approval of biotech products under the EC approval system. In particular, the EC has blocked in the approval process under EC legislation [see note 33] all applications for placing biotech products on the market, and has not considered any application for final approval. The approvals moratorium has restricted imports of agricultural and food products from the United States.[34]

Argentina added that agricultural products account for over half of Argentina's total exports, and that it is the second largest producer and exporter of biotech products in the world. Argentina said that the EC's 'behaviour' discourages the introduction of the biotech process, and that it is particularly detrimental because EC has the ability to influence other WTO members.[35]

The EC said that it had repeatedly made clear that the approval of GMOs and GM food was possible in the EU; that a number of applications were being examined; and that decisions would be taken shortly. The EC further pointed out that 18 GMOs and 15 food products derived from GMOs have been approved over the years and that these GM products are imported each year by the EC.[35] The EC emphasised that every country should be free to make its own decisions and to determine the appropriate level of protection for its citizens.

PROBLEMS WITH THE EUROPEAN REGULATORY REGIME

The regulatory regime in Europe is confusing and, worse, still not working effectively. Even if the products of this new technology were to be rejected completely, at least there would be certainty in the working of the system rather than the present 'suspended animation'. When it is working it should provide those using the technology with the structures that are needed to be able to advance in using the technology. Many, however, are concerned that the regulatory system is too complex; is designed primarily to stop the use of modern biotechnology, particularly in the environment; and will stop Europe properly realising the benefits that biotechnology should bring. If the legislation was solely concerned with safety, why are products that are just as likely to be 'unsafe' not addressed with the same urgency?

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