GENETICALLY MODIFIED ORGANISMS AND BIOSAFETY: THE GLOBAL REGULATORY ISSUES*

DR PETER DRAHOS
Herchel Smith Senior Fellow, Queen Mary Intellectual Property Research Institute, Centre for Commercial Law Studies, University of London

Scientists have had more than two decades of experience with recombinant DNA techniques. Despite this, the regulation of genetically modified organisms (GMOs) has become more controversial, more politicised and more global. This has happened because GMOs are no longer confined to the laboratory. GMOs are being tested in field trials. Some have been approved for use in agriculture and for use as food.[1] There have been over 15,000 releases of GMOs around the world into the environment.[2] Their control has become an issue in environmental regulation, agricultural regulation and the regulation of food standards and food labelling.

The trade regime has also become relevant to GMOs because most countries are both exporters and importers of food. The World Trade Organization (WTO) administers agreements in trade, food, agriculture, and intellectual property that are all potentially relevant to the regulation of GMOs. A GMO can be the object of individual ownership via an intellectual property right system such as the patent system or the plant variety rights system. The ownership of genetic material has raised a number of concerns including the impact of a property rights regime in genetic material on biodiversity.[3]

Biotechnology promises much. Within agriculture the advantages are said to include increased food security through the development of high yielding plant varieties, less expensive inputs, the creation of disease free plants, increasing efficiency of breeding and low-cost, effective vaccine production in animal husbandry.[4] Whether or not modern biotechnology lives up to its potential applications and whether these applications will be delivered to those parts of the world where they are most needed, will depend crucially on the extent to which emerging global regimes can be co-ordinated according to an agreed set of regulatory principles.

The article is structured in the following way. It begins by briefly examining the early days of biosafety regulation, and then looks at some of the important international initiatives including the proposed biosafety protocol to the Convention on Biological Diversity (CBD). It goes on to look at the intersection between WTO trade rules and biosafety, and then examines the principle of labelling in the context of biosafety. The final section proposes a set of regulatory principles for GMOs and suggests how those principles should be ranked.

Biosafety – From Containment to Products

After the publication of a model of DNA in 1953 by Watson and Crick, scientific research on genes began to accelerate. During the 1970s a new field of scientific research called recombinant DNA was firmly established. Using the 'cut and paste' techniques of recombinant DNA technology, scientists were able to create new DNA molecules. These molecules would never have arisen in nature through mutation or have been brought into existence by animal or plant breeders. Breeders could only produce a novel genome by observing the phenotypes of organisms and then selecting for useful traits by means of cross breeding. They could not directly re-engineer the DNA molecule.

In the early 1970s a discussion began within the scientific community about the dangers of recombinant DNA experiments. Genetically novel organisms, it was realised, might bring with them novel hazards to human health and the environment. It was also becoming clear that the scale of recombinant DNA work was set to grow, especially in the United States where the industrial research laboratories of

* An earlier version of this article was presented as a plenary lecture at the 25th Science and Technology Congress of Thailand, 21 October 1999, Pitsanuloke, Thailand. The author is grateful to the Science and Technology Congress of Thailand and the British Council for making his visit to Thailand possible.

1) An example of both is Monsanto's herbicide-tolerant 'Roundup ready' soybean. For details of other releases see Nuffield Council on Bioethics, 'Genetically Modified Crops: The Ethical and Social Issues', May 1999, paragraphs 242 to 245.

2) Guy Van Den Eede and Marnix Housen, *Quantitative Environmental Risk Assessment for Genetically Modified Organisms*, European Commission, DG Joint Research Centre, 1999, 4.

3) See, for example, Graham Dutfield, 'Can the TRIPs Agreement Protect Biological and Cultural Diversity?' *Biopolicy International Series*, African Centre for Technology Studies, Nairobi, Kenya, 1997.

4) Catherine L. Ives, Bruce M. Bedford and Karim M. Maredia, 'The Agricultural Biotechnology for Sustainable Productivity Project: a New Model in Collaborative Development', in Catherine L. Ives and Bruce M. Bedford (eds), *Agricultural Biotechnology in International Development*, CABI Publishing, Oxford-New York, 1-14, 2.

pharmaceutical companies and chemical companies were taking an increasing interest in the commercial possibilities of the technology. The need for some form of regulation of genetic engineering experiments within the laboratory became an issue. It did so, because members of the scientific community made it one. In the United States, members of the National Academy of Sciences proposed in 1974 a moratorium on certain kinds of DNA experiments until the scientific community had devised some form of safety regulation for the conduct of these experiments.[5] At an international gathering mainly of scientists in Asilomar, California in 1975, a set of recommendations to manage the safety of recombinant DNA experiments was produced. These recommendations became the basis of a set of voluntary guidelines that the National Institutes of Health published in the Federal Register in July of 1976.

The conference at Asilomar had not produced a universal consensus on the regulatory issues. But from this start, a model of voluntary self-regulation for recombinant DNA experiments began to develop. Essentially it was based on the circulation of guidelines issued by an expert committee at the national level to biosafety committees that were local to the organisation carrying out the recombinant DNA work. This committee was usually referred to as an Institutional Biosafety Committee (IBC). Typically, the guidelines distinguished between different kinds of DNA work on the basis of potential hazards and provided guidance on containment procedures. The committees were predominantly staffed by scientific experts. The IBC administered and monitored the guidelines that the national body developed. The guidelines did not have the force of law. Usually, however, the national expert committee was linked in some way to the funding of research. This put the threat of non-funding at its disposal.

This model of self-regulation became influential in most western states. The differences that emerged largely related to how necessary the law was thought to be in obtaining compliance with the basic structure. In the United Kingdom, the self-regulatory system for recombinant DNA work that was headed by the Genetic Manipulation Advisory Group (GMAG) was given the backing of law in the form of the Health and Safety (Genetic Manipulation) Regulations of 1978.[6] In Australia, the Genetic Manipulation Advisory Committee (GMAC), a non-statutory body, continues to use guidelines in its task of overseeing 'the development and use of innovative genetic manipulation techniques'.[7] In the United States, the Recombinant DNA Advisory Committee (RAC) was established in 1974. Under the terms of its charter RAC is to advise the Director of the National Institutes of Health 'concerning the current state of knowledge and technology regarding DNA recombinants, and recommend guidelines to be followed by investigators working with recombinant DNA'.[8]

The early history of biosafety regulation was primarily concerned with the appropriate safety procedures for recombinant DNA work within the laboratory. The emphasis was on ensuring that researchers were taking proper steps to contain organisms that potentially posed a risk to themselves, or human health generally. Over time, protection of the environment also became a goal of the guidelines. Essentially the objects of regulation were different kinds of experiments. Biosafety was primarily seen in terms of the risk management of experiments involving DNA molecules.[9]

This narrow conception of biosafety began to change as genetic engineering began to produce organisms that were useful as products. Novel DNA molecules became, in other words, useful micro-organisms, plants and animals that could be deployed in industrial, agricultural, medical and environmental contexts. Biosafety regulation now had to deal with the use of GMOs in markets. Each national system of biosafety developed its own response to what might be termed the 'product phase' of biosafety regulation. Many countries, the United States being an example, had highly developed regulatory systems for products that were medicines, that were seeds or that were intended for consumption as food. This product-oriented approach to regulation meant that the responsibility for regulating GMOs as products might be shared amongst a number of agencies. Overlapping responsibility by agencies remains a feature of US regulation of the products of recombinant DNA. So, for example, if the product is a food crop that has been engineered for viral resistance, the US Department of Agriculture (USDA),[10] which has responsibility for plant and plant pests, will assess it for agricultural safety, the Environmental Protection Agency (EPA) will assess it for environmental safety and the Food and Drug Administration (FDA) will check whether it is safe to eat.[11] Similarly, if an

5) See Yvonne M. Cripps, *Controlling Technology: Genetic Engineering and the Law*, Praeger Publishers, New York, 1980, at 24 to 25.

6) Ibid, at 48. In 1984 GMAG became the Advisory Committee on Genetic Modification. This Committee advises the Health and Safety Executive in the United Kingdom on the contained use of GMOs.

7) See Genetic Manipulation Advisory Committee, *Guidelines for the Deliberate Release of Genetically Manipulated Organisms (Field Trials and General Release)*, Commonwealth of Australia, 1998, 1. GMAC was formed in 1987 by the Federal Government. It succeeded the Recombinant DNA Monitoring Committee.

8) The Charter is available at the National Institutes of Health website: http://www.nih.gov/od/orda/charter.htm

9) The NIH Guidelines, for example, state that their purpose is to specify practices for constructing and handling DNA molecules or organisms containing them: see section 1-A. The Guidelines are available at http://www.nih.gov/od/orda/sect1.htm

10) The Animal and Plant Health Inspection Service of the USDA has responsibility for protecting US agriculture from pests and diseases.

11) This example and others are to be found at http://www.aphis.usda.gov./biotech/OECD/usregs.htm

ornamental crop has been modified for herbicide tolerance, the USDA will evaluate its agricultural suitability and the EPA will scrutinise its herbicidal implications. Before an agency in the United States can claim regulatory authority over a GMO product, the product must fall within the one of definitions of product for which the agency has responsibility.

An important principle of regulation in the US system is the principle of substantial equivalence or familiarity.[12] In the context of risk assessment, substantial equivalence or familiarity requires the risk assessor to ask whether the relevant organism can be said to have properties and behaviours that are already known.[13] Once a GMO is classified as familiar it can be treated under the procedures that have been employed for other such organisms in the past. The FDA, for example, treats GMOs in food as food additives 'if they are significantly different in structure, function, or amount than substances currently found in food'.[14] If such differences do not exist no pre-market approval for the food product is required. The principle of familiarity or substantial equivalence has gained widespread acceptance amongst countries in risk assessment procedures for biotechnology products.[15] One of its early sources was a report of the National Research Council (NRC) of the US National Academy of Sciences that proposed a framework for the introduction of GMOs.[16] The Organisation for Economic Co-operation and Development (OECD) has also endorsed the principle.[17] It has been described as 'central' to an evaluation framework for GMOs.[18]

In Australia, the product phase of biosafety regulation saw GMAC develop guidelines for the release of GMOs into the environment. Through its guidelines GMAC integrated its information flows with other regulatory authorities. Under the guidelines GMAC must publish a description of the proposed release in the *Commonwealth of Australia Government Notices Gazette* and send the description to relevant State and Commonwealth bodies.[19] If GMAC concludes that the proposal is likely to have significant environmental effects it can refer the matter to the Minister for Environment for an environmental impact statement.[20] Just as in the United States, the regulation of the products of biotechnology in Australia is a mix of overlapping or partial agency responsibility. Dissatisfaction with the ad hoc patchwork nature of this regulation has led one Australian committee to recommend the establishment of a Gene Technology Agency (GTA). This agency would have the power to schedule GMOs products and activities according to degree of risk and to require the compulsory notification of scheduled GMOs and activities to the GTA.[21]

The European Union has also developed regulatory procedures for GMOs in the research and product phases. The European Council Directive 90/219 harmonises procedures for the contained use of genetically modified micro-organisms (the Contained Release Directive).[22] The key directive that deals with the release phase of GMOs is the Council Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms.[23] There are two distinct notification procedures for the release of GMOs. One relates to the release of GMOs for the purpose of research and development and the other to their release onto the market as or in a product.[24] In the case of releases for the purpose of research and development the competent authority of the Member State has 90 days in which to decide whether the release can go ahead. Where the notification relates to GMOs to be placed on the market there are review procedures that allow other Member States to object to the approval that another competent authority is proposing to give to the release. Ultimately, if the matter cannot be resolved there is a procedure allowing for a decision by majority. The notification

12) For present purposes we shall treat the principles of familiarity and substantial equivalence as interchangeable. There are cases where they can be separated. For example, two organisms might be thought to be substantially equivalent, but not be treated under the principle of familiarity because the impact of the properties of both organisms in the environment remains unknown.

13) The principle of familiarity has been described as involving the following criterion: 'Are we familiar with the properties of the organism and the environment into which it may be introduced?' G.J. Persley, L.V. Giddings and C. Juma, *Biosafety: The Safe Application of Biotechnology in Agriculture and the Environment*, Research Report No. 5. ISNAR, The Hague, 1993, at 7. The concept of substantial equivalence 'holds that existing foods provide the basis against which to assess the safety of GM foods'. See Calestous Juma, 'Science, New Foods and Public Policy: Using the Concept of Substantial Equivalence', at http://www.cid.harvard.edu/cidtech/home.htm

14) See htt://www.aphis.usda.gov./biotech/OECD/usregs.htm

15) See OECD, 'Modern Biotechnology and the OECD', *Policy Brief*, June 1999, at 5.

16) *Field Testing Genetically Modified Organisms: Framework for Decisions*, National Research Council, National Academy Press, Washington DC, 1989.

17) See General Secretariat Internal Co-ordination Group for Biotechnology, 'Report of the OECD Workshop on the Toxicological and Nutritional Testing of Novel Foods, Aussois, France, 5–8 March 1997'.

18) G.J. Persley, L.V. Giddings and C. Juma, *Biosafety: The Safe Application of Biotechnology in Agriculture and the Environment*, Research Report No. 5. ISNAR, The Hague, 1993, at 8.

19) Genetic Manipulation Advisory Committee, *Guidelines for the Deliberate Release of Genetically Manipulated Organisms (Field Trials and General Release)*, Commonwealth of Australia, 1998, paragraph 2.6.1.

20) Ibid., at paragraph 2.6.6.

21) See Report to SCARM by the Working Group to Examine the Regulatory System for Genetically Modified Organisms (GMOs), July 1997.

22) An amended Directive on contained use was adopted by the Council of Ministers on 5 December 1998. See Council Directive 98/81/EC, OJ 1998 L330, 5 December. In addition, the Directive on the protection of workers from risks related to exposure of biological agents at work 90/679/EEC, OJ 1990 L374, 31 December is also relevant.

23) OJ 1990 L117, 8 May. Directive 90/220 is currently the subject of amendment by the EC. See Proposal for a European Parliament and Council Directive amending Directive 90/220/EEC on deliberate release into the environment of genetically modified organisms, 98/C 139/01COM (1998) 85 Final.

24) Product is defined in Article 2 of the Directive to mean 'a preparation consisting of, or containing, a GMO or a combination of GMOs, which is placed on the market'.

to the competent state authority must contain information about the GMO, the conditions of its release, the interaction between the GMO and the environment, monitoring, and emergency response plans. In the case of products intended for the market further information is required including the conditions of use of the product and the type of use. The notification for the release of GMOs as products also needs to provide information relating to the possible ecosystems that might be affected by the use of the product. This information serves as the basis for an assessment of the proposed release with a particular emphasis on environmental risk assessment and the safe use of the product. The Directive as it stands does not offer national authorities guidance as to the principles of risk assessment. Importantly, the proposed revision to the Directive begins the difficult task of harmonising the risk assessment process by including in Annex II a list of principles that must be taken into account when undertaking an environmental risk assessment for the purposes of the Directive. The principle of information exchange between parties is entrenched in Article 22 of the Directive. There is also a procedure that allows Member States to object to a product being put on the market in another Member State. Article 6 (5) of the Directive allows the competent authority to apply to the Commission for simplified release procedures if it considers that 'sufficient experience' has been obtained with releases of certain GMOs. This might be seen as the application of the principle of familiarity.

The regulatory schemes that have developed in response to the product phase of biotechnology have also seen the evolution of a broader conception of biosafety. In Australia, GMAC has cast the biosafety net widely by saying that its task is to consider all the risk factors that are raised by GMOs in relation to public health and safety, agricultural production and the quality of the environment. Similarly, Directive 90/220/EEC requires an assessment of the impact of GMOs on the environment and human health. For the purposes of performing the risk assessment exercise the Directive requires that information about the impact of the GMO on ecosystems be provided to the competent authority. The United States through its approach of product regulation controls the use of GMOs in the context of food and agricultural products and their release into the environment.

Global Regulation of Biosafety

One of the striking features of biosafety regulation has been the extent to which national systems have harmonised at the level of principles and procedures for regulating recombinant DNA work at the research stage. The work of the OECD has proved to be important in this regard. In 1986 it published a study containing recommendations for the safe use of GMOs in industry, agriculture and the environment.[25] The thrust of the recommendations was to encourage member countries to follow a principle of information exchange, to develop national regulation in ways that did not hinder the development of recombinant DNA technology and to develop risk assessment procedures for the industrial, agricultural and environmental applications of recombinant DNA techniques. The OECD continues to be an important force for harmonisation. It has established a Working Group on the Harmonisation of Regulatory Oversights in Biotechnology and a Task Force for the Safety of Novel Foods and Feeds. The goal of the OECD is harmonisation through the provision of 'technical information for use during regulatory assessment of products of biotechnology'.[26] Thus, as in other areas of international regulation, the OECD has constituted a science-based epistemic community that is providing a policy direction for biotechnology as well as technical information for the development of harmonised standards for its regulation.[27]

There have been other harmonising initiatives by international organisations of states. An expert working group comprised of representatives from the United Nations Industrial Development Organization, United Nations Development Programme, the World Health Organization and the Food and Agricultural Organization released in 1991 a voluntary code of conduct for the release of GMOs.[28] The most ambitious attempt to produce a globally harmonised regime for the biosafety has taken place under the CBD.[29] Article 19(3) of the CBD committed members to a protocol on biosafety 'in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology'. So far, the negotiations for a protocol have not produced an agreed text, but rather a draft negotiating text that contains various alternative versions of possible provisions.[30] At Cartagena in Colombia in February of 1999 negotiations

25) See *Recombinant DNA Safety Considerations*, OECD, Paris, 1986.

26) See the OECD website.

27) On the importance of the OECD to epistemic community formation, see John Braithwaite and Peter Drahos, *Global Business Regulation*, Cambridge University Press, Cambridge, 2000, at 486.

28) *Voluntary Code of Conduct for the Release of Organisms into the Environment*, United Nations Industrial Development Organization, Vienna, 1991.

29) There are in fact a large number of international instruments that relate to GMOs. For a useful survey see the Background Document on Existing International Agreements Related to Biosafety, Open-Ended Ad Hoc Working Group on Biosafety, UNEP/CBD/BSWG/2/3, 18 March 1997. Available at http://www.biodiv.org/biosafe. The survey concludes that the UNEP International Technical Guidelines on Biosafety in Biotechnology 1995 are the most useful in the context of the transboundary movement of GMOs. The basic problem that the survey identifies is that these instruments do not constitute an integrated system of international regulation for the transboundary movement of GMOs.

30) The draft text is available at http://www.biodiv.org/biosafe.bswg6/html/engl/6-2e.html

between states on the Biosafety Protocol became more polarised. The key issues that concerned states were the extent to which the Protocol applied to LMOs[31] as products, the role of the precautionary principle in risk assessment, the rights of countries importing LMOs (the Advanced Informed Agreement procedure), liability for harm caused by LMOs and the relationship between the Protocol and trade instruments. Reports of the negotiations at Cartagena suggested that the negotiations broke down because the South pushed for a strong Biosafety Protocol that a group of Northern states did not want.[32] Strong in this particular context means strong from the point of view of states importing LMOs into their territory. If the negotiations did fracture along these lines then it is puzzling. Some states of the South such as Malaysia are in fact developing strong biotechnology programmes that are in part directed to their interests as agricultural exporters.[33] Others, like Egypt, are looking to biotechnology to solve problems of diminishing agricultural productivity.[34]

If developed and developing states operate in a structural situation where they both import and export food, it makes little sense to tilt a biosafety regime in favour of either exporters or importers, or for that matter in ways that make it impossible for the citizens of a state to get the benefits of a genuinely safe biotechnology. The date palm, for example, is a strategic crop for about 8 million people in North Africa. It provides local farmers with income and is the foundation of a desert agriculture that sees it supporting livestock, agronomic crops as well as fruits and vegetables. Bayoud disease has caused serious losses to the date palm industry in Morocco and Algeria and is threatening the industry in Tunisia and Mauritania. Using modern biotechnology to engineer some form of disease resistance is thought to be the best way in which to avoid further serious losses to the industry in these countries.[35] Amongst other things, the long time it takes for date palms to mature makes the application of traditional plant breeding techniques of limited use. For the countries concerned, viewing the biosafety issues through trade lenses makes no sense. The key issues become scientific and risk management ones. Is it possible to develop a genetic resistance to the disease and what are the risks of such genes to health and the environment? This example suggests that developed and developing countries alike have mutual interests in basing their national biosafety regimes on the best available science. If there is a low-risk biotech solution to the problem of Bayoud disease, farmers of the date palm will want to know about it.

Biosafety and the WTO

The Final Act of the Uruguay Round brought into existence a number of agreements that may affect the regulation of GMOs as products. As agricultural or food products GMOs can be internationally traded. The General Agreement on Tariffs and Trade of 1994 (GATT 1994) remains fundamental to the WTO. It incorporates the previous GATT regime. The pillar of the GATT is the principle of non-discrimination. Under the most-favoured-nation principle (Article I) an advantage granted to one member must be granted to others. Under the national treatment principle (Article III) the imported products of one member 'shall be accorded treatment no less favourable than that accorded to like products of national origin'. A state that discriminated against a GMO product from another state (for example, a genetically engineered tomato) might be in breach of the GATT if the GMO and non-GMO product (a natural tomato) were regarded as like products.

A state, however, is not prevented from enacting measures that restrict trade if it brings itself within the general exceptions recognised by Article XX. This article would permit a measure that is 'necessary to protect human, animal or plant life or health' (paragraph b) or one that relates to the 'conservation of exhaustible natural resources if such measures are made effective in conjunction with restrictions on domestic production or consumption' (paragraph g).

The operation of the GATT has been complemented by the inclusion of two further agreements, the Agreement on Technical Barriers to Trade (TBT) and the Agreement on the Application of Sanitary and Phytosanitary Measures (SPM).[36] Both of these agreements are aimed at the problem of states using technical standards to discriminate against foreign exporters.[37] The TBT applies to all products (see Article 1.3). Clearly the TBT captures all products of biotechnology including GM crops such as GM soya and maize, as well as products containing those crops. There is one qualification to this. The TBT does not apply to sanitary and phytosanitary measures (Article 1.5). The consequence of this would seem

31) Defined as 'any living organism containing a novel combination of genetical material obtained through the use of modern biotechnology'.

32) See Kristin Dawkins, 'Unsafe in any seed: US obstructionism defeats adoption of an international biotechnology safety agreement', *Multinational Monitor*, 20(3), March 1999.

33) Malaysia has established a National Biotechnology Directorate to facilitate the commercialisation of biotechnology and to help make Malaysia a leading biotech centre. See http://nbd.mastic.gov.my/inform.html

34) See the chapters in Part I of *Agricultural Biotechnology in International Development*, Note 4 above.

35) See Mohamed Aaouine, 'The Application of Biotechnology to Date Palm', in Catherine L. Ives and Bruce M. Bedford (eds), Note 4 above, at 133 to 146.

36) The preamble to the TBT links the TBT to the objectives of GATT 1994 and the preamble to the SPM links the rules of SPM to GATT 1994 and in particular Article XX(b). The TBT and the SPM have to be read as serving the objectives of GATT 1994.

37) The preamble to the TBT refers to the desires of parties to ensure that technical standards and regulations 'do not create unnecessary obstacles to international trade'. The preamble to SPM refers to the desires of parties to establish a multilateral framework for sanitary and phytosanitary measures in order 'to minimise their negative effects on trade'.

to be that when states come to adopt technical regulations or standards for agricultural products that are not sanitary or phytosanitary measures they will still have to comply with the provisions of the TBT. In particular it would seem that those provisions of the TBT that deal with the process of standard setting (for example, Article 4) continue to apply to national standardising bodies that set sanitary or phytosanitary standards. When states enact measures that are sanitary or phytosanitary measures they will have to comply with the SPM agreement.

The TBT pushes members in the direction of adopting international standards or recognising as equivalent the technical regulations of other members (see Article 2.7). Article 2.4 obliges members to use international standards where they exist.[38] Members are exempt from this obligation where those international standards would be an ineffective or inappropriate means of fulfilling legitimate objectives. Legitimate objectives include 'protection of human health or safety, animal or plant life or health'. Despite the apparently broad nature of this exemption the thrust of the TBT is to place the onus of justification on states that choose not to adopt an international standard.[39] States that adopt regulations for legitimate purposes that are in accordance with international standards get the benefit of a rebuttable presumption that those regulations are not an unnecessary barrier to trade (see Article 2.5). Similarly governments must ensure that government standardising bodies comply with the Code of Good Practice for standard-making that is part of the TBT.[40] This code also directs standard-setting bodies towards international standards.

Essentially the purpose of the SPM is to harmonise sanitary and phytosanitary measures between members by requiring them to adopt international standards. The SPM is structured in such a way that states have positive incentives in the form of beneficial presumptions and deeming provisions to comply with it (see Articles 2.4 and 3.2), while non-compliance with its harmonising thrust means that states incur the costs of justification (see Articles 3.3 and 5).

The wide definition of a sanitary or phytosanitary measure in the SPM (see Annex A) would seem to give a state the option of enacting a measure that kept out a GMO on the basis that it was, for example, a pest that threatened plant life. However, whether a state could enact a measure that prevented the entry of a GMO into its borders would be dependent on the international standards that already existed. Even in those cases where no such international standards existed a state would not have carte blanche over its sanitary and phytosanitary measures. Article 2.3 of the SPM obliges a Member not to 'unjustifiably discriminate between Members where identical or similar conditions prevail' as well as not applying measures in a way that 'would constitute a disguised restriction on international trade'. Article 3.1 makes it mandatory for states to base their measures on international standards. For food standards the relevant standards are those established by the Codex Alimentarius Commission, for animal health they are the standards of the International Office of Epizootics and for plant health the standards developed within the framework of the International Plant Convention (see Annex A). Members that enact measures that are based on standards that are higher than existing international standards bear the burden of justification. They must show that the measure has a 'scientific justification' (see Article 3.3). When enacting measures they must have taken account of internationally recognised risk assessment techniques (see Article 5.1). States, in other words, cannot simply conjure up risk assessment techniques to suit their purpose. Even if members can justify their standard on the basis of risk assessment the measure they impose must 'take into account the objective of minimising negative trade effects' (Article 5.4).

Read together, the TBT and the SPM suggest that states which wish to discriminate against GMO products by means of national regulations bear a heavy burden of justification. States without the capacity to produce scientific evidence or risk assessment analysis that is persuasive for scientists in other countries have very little chance of discharging the burden of justification. The decision of the WTO Appellate Body in the beef hormone case may be a signpost to a future of trade regimes in which scientific experts will become valuable pawns in the trade games that states play.[41] The states that can mobilise the most scientific expertise will retain the strength to set up barriers to trade. They will also be able to discipline states with less expertise by means of the WTO dispute resolution process. Scientific knowledge will lie behind a new form of trade power.

But there is another, less pessimistic, analysis that can be developed here. The citizens of all states have an interest in

38) The term 'international standard' is not defined, but 'international body' or system is defined as one whose membership is open to the relevant bodies of at least all members (see Annex 1 of the TBT). A standard (also defined) set by an international body becomes an international standard for the purposes of the TBT.

39) See Articles 2.5 and 2.9.

40) See Annex 3.

41) EC Measures Concerning Meat and Meat Products (Hormones); complaint by the United States (WT/DS26); Appellate Body Report and Panel Report adopted by the DBS 13 February 1998. The ban on hormone-treated beef by the EU was found to breach Articles 3.3 and 5.1 of the SPM. It is clear from this case that much more than consumer concerns or scientific conjecture is required before a state can discharge the burden of justification it bears under the SPM. See Wybe Th. Douma, 'The Beef Hormones Dispute and the Use of National Standards under WTO Law', 1999 *European Environmental Law Review*, at 137 to 144.

scientific truth. If growth hormones in beef turn out to be dangerous for European consumers they will be equally dangerous for US consumers. By requiring states to adopt international standards, the TBT and the SPM shift, in effect, the responsibility for scientific truth onto international standard setting organisations. There is merit in this because international organisations like the Codex Alimentarius are chartered to deliver what are public goods – international standards of food safety in the case of the Codex. It is true that, as with any organisation, the problem of regulatory capture remains. But it may actually be more difficult to capture an international organisation, which usually has many interested state and non-state actors gathered around its tables, than a national standards body which has far fewer actors and operates under lower levels of transparency.

What of the case where the national standards body develops through good science a standard that is higher than the international standard that is mandated by the TBT or the SPM? There are two observations to make about this situation. First, nothing in the TBT or SPM formally prevents a state from adopting its standard if it can justify it. Second, if the science is persuasive there is nothing to stop an international body from adopting it as the international standard. There is nothing in the TBT or the SPM that says national standards cannot become international standards. Moreover, sometimes the same scientists that have been involved in the setting of the higher national standard will be players in the international body. They will have an opportunity to persuade their counterparts on the international body. Whether or not international standard organisations will end up promoting the scientifically best standards will in large part depend on the way that scientists approach their task as a community. Here it is worth remembering that science is a language that can cross trade and political barriers:

> *Aerodynamics is aerodynamics. We were always able to talk to the Russians in the old communist days because science is science. Good scientific analyses are the same everywhere and that's the language we talk.*[42]

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) is the last WTO agreement that needs discussion. TRIPs sets minimum standards of protection for intellectual property. Membership of the WTO carries with it an obligation to comply with TRIPs. A GMO can be the subject of a number of intellectual property rights. If it is an invention it can be patented. It can also be the subject of a plant variety right or a trade secret. TRIPs in its Preamble recognises intellectual property rights as private property rights. The fact that GMOs can be privately owned under a set of intellectual property rights that have been globalised through inclusion in the trade regime raises a set of complex moral, economic and regulatory issues. For example, many patented GMOs are closely based on naturally occurring organisms that could be described as existing in some kind of intellectual commons or under the stewardship of an indigenous group. In either case, a collective asset has fallen into private hands. This raises both equity and access issues. The existence of these issues was recognised during the course of the negotiations that produced the CBD. Through the CBD the international community committed itself to a set of open-ended principles that would pattern the development of national regulation aimed at the 'fair and equitable sharing of benefits arising out of the utilisation of genetic resources'.[43] These principles include a principle of prior informed consent to govern access to genetic resources (Article 15.5), a principle of benefit-sharing to deal with the commercial exploitation of a community's biological resources (Article 15.7) and a principle of recognition of indigenous intellectual property (Article 8(j)). The absence of a recognition of these principles in TRIPs has led to debate about whether the CBD and TRIPs are consistent. The Working Party of the Nuffield Council on Bioethics in its report on GMOs recognised that there was a tension between the CBD and TRIPs. It recommended that the United Kingdom lead a WTO initiative to report on the extent of the conflict between the two regimes and how it might be resolved.[44]

The debate over the interaction between TRIPs and the CBD is part of a deeper problem that the international community will have to face. TRIPs offers multinational life sciences companies more security of investment in biotechnological research than ever before. Countries like India, which in the past set limits on the patenting of medicines and food by excluding product patents on such things, now have to recognise product patents in these areas. The markets in biotechnology products have been expanded by TRIPs. Whether or not the markets in biological information that have been constituted through TRIPs serve the CBD's goal of the conservation and sustainable use of biological diversity is an open and difficult empirical question. For example, in the United Kingdom it has been suggested that the introduction of GM herbicide-tolerant and insect-resistant crops (usually the objects of intellectual property rights) will reduce the food supply for farmland birds leading to a serious loss of biodiversity.[45] Another example relates to the fact that

42) US Federal Aviation Administration Official quoted in John Braithwaite and Peter Drahos, *Global Business Regulation*, Note 27 above, at 462.

43) See Article 1 of the CBD.

44) See Nuffield Council on Bioethics, Note 1 above, at paragraph 4.73.

45) Ibid., at paragraphs 6.35 to 6.37.

patenting in the field of biotechnology is characterised by the grant of very broad patents as well as patents over basic research tools.[46] Researchers in biotechnology are increasingly finding that the technologies they need to carry out their research are under private control. Flows of information between researchers are increasingly dependent on licence permissions. This is proving to be an important problem for public institutions, because often they are not in a position to bargain for access to proprietary technologies. Even more importantly, decisions about the future development of biotechnology are placed in the hands of markets rather than institutions that have traditionally provided biotechnology research and products as a public good. In the Consultative Group on International Agricultural Research one viewpoint is that the ever increasing application of intellectual property rights to agriculture will accelerate 'the replacement of diversity-based farming systems, and eco-social contexts in which they survive'.[47]

Biosafety and the Principle of Labelling

The principle of labelling has been slow to make an appearance in the context of the regulation of GMOs as products. In the United States the practice has been to allow GMO products onto the market unlabelled once they have cleared the relevant regulatory agencies. The application of the principle of familiarity has helped to facilitate this clearance process. The justification for this approach has been that consumers are not in a position to evaluate the information on the label. Rational choice by consumers, on this view, is not facilitated by labelling.[48] In Europe consumer resistance to biotechnology and its products has seen policy-makers begin to embrace the principle of labelling in an effort to win back the trust of consumers. Directive 90/220 did not impose labelling requirements on GMOs for release as products. The approval of the release of genetically modified soya and maize in 1996 and 1997 by the Commission without a requirement of labelling saw some European States such as Denmark and France adopt their own labelling requirements. The European Commission in June 1997 amended Directive 90/220 to provide for the mandatory labelling of GMOs.[49] Aside from the Directive, the Council and European Parliament adopted in January 1997 the Novel Foods Regulation.[50] The purpose of the Regulation is to establish a European regulatory system for the marketing of novel foods and food ingredients. Article 8(1)(d) of the Regulation requires that consumers be informed of whether foodstuffs contain 'the presence of an organism genetically modified by techniques of genetic modification'. In September 1997 the Commission adopted a Regulation that brought foods and food ingredients which used genetically modified soya and maize within the scope of operation of Article 8.[51]

The recognition of the principle of labelling for GMO foods is only the beginning of the debate and policy arguments in Europe. There are varying views on how strongly the principle is to apply and how it is to be implemented. Threshold limits below which a product containing modified genes would not have to be labelled are seen by some as consistent with the principle.[52] The European Commission, the UK Government and some expert bodies have taken the view that labelling should only occur where the product in question contains modified genes. In those cases where the product does not contain modified genes it should not be labelled. This applies even if it was produced by a process involving the use of modified genes.[53] This process/product distinction prevents the full application of the principle of labelling. Two things might be said about the distinction. First, it ignores consumer preferences that are based on values. Within secular societies there is a case to make for the fact that governments should be neutral as to such preferences. Second, some consumers will almost certainly be willing to pay a premium for products that provide them with information about their processes of origin. If governments fail to require the provision of that information it would seem to be a case of interfering in the operation of the price mechanism.

The Global Regulatory Principles for GMOs

The preceding discussion suggests that the following regulatory principles are emerging for the regulation of GMOs:

- The principle of risk assessment (SPS, TBT, OECD, Directive 90/220/EEC);
- The principle of information exchange (CBD, Directive 90/220/EEC, OECD);

46) John H. Barton, 'Patents and Antitrust: A Rethinking in Light of Patent Breadth and Sequential Innovation', (1997) 65 *Antitrust Law Journal* 449.

47) Report of the CGIAR Panel on Proprietary Science and Technology, Technical Advisory Committee Secretariat, Food and Agricultural Organization of the United Nations, April 1998 at 17.

48) See Select Committee on European Communities, House of Lords, 1998, paragraph 135. There are signs that US regulatory authorities are undergoing a change of heart on the labelling issue. The US FDA is reported to be considering the development of a voluntary labelling scheme for GMO products. See http://policy.voxcap.com/. More recently a bill requiring the labelling of GM food was introduced into the US Congress. For the time being at least it has little chance of becoming law. See *The Guardian*, 11 November 1999, at 20.

49) See Directive 97/35/EC, OJ 1997 L169, 27 June.

50) Novel Foods and Novel Food Ingredients Regulation, No. 258/97, OJ 1997 L43, 14 February.

51) Regulation 1813/97, OJ 1997 L257, 20 September.

52) See Select Committee on European Communities, House of Lords, 1998, paragraph 142.

53) Ibid., at paragraph 137. The Working Party of the Nuffield Council on Bioethics in its Report recommended that more work be done on the issue of providing information to consumers: see paragraph 5.52.

- The principle of familiarity or substantial equivalence (NRC, OECD);
- The principle of non-discrimination (GATT 1994);
- The principle of harmonisation (TBT, SPM);
- The principle of private property (TRIPs);
- The precautionary principle (CBD, SPS);
- The principle of informed consent (CBD);
- The principle of benefit sharing (CBD);
- The principle of labelling (Directive 90/220/EEC, Novel Foods Regulation).

A fundamental issue is the nature of the relationship between these principles. In particular can they be lexically ordered? This article concludes by making some suggestions about such a possible ordering.

No one would challenge the principle of risk assessment for GMOs. Moreover, on any view of risk assessment, it is better to have as good a database of scientific evidence and experience at one's disposal as possible. At the moment information exchange obligations appear in the Directive 90/220/EEC. There are also information exchange mechanisms to be found in the draft negotiating text of the Biosafety Protocol and the UNEP International Technical Guidelines on Biosafety in Biotechnology (1995). Information exchange is based on a paper trail that a competent authority has to follow in order to be able to release a GMO into the environment or to allow for the transboundary movement of a GMO. Procedures of information exchange need to be distinguished from information sharing as a value and normative practice. Sending risk assessment dossiers to regulatory authorities of other countries for interpretation by their experts is one thing and being in communication with experts from another country about important developments is another. The principle of information-sharing that is being suggested here relates to the idea of a continuous flow of information between experts and regulatory authorities of various countries that will increase the scientific knowledge and expertise of all regulatory authorities. In a recent report on the risk assessment for GMOs in Europe it was observed that the regulatory framework 'should continuously animate the exchange of views among experts on pertinent issues'.[54] One suspects that much more can be done in the direction of creating dialogic webs among regulatory agencies dealing with GMOs than is currently the case.[55]

A second fundamental issue concerns the relationship between the principle of risk assessment on the one hand and the principle of substantial equivalence and the precautionary principle on the other. Both the precautionary principle and the substantial equivalence principle have been the subject of criticism. The precautionary principle is usually criticised on the ground that it prescribes inaction. Critics of substantial equivalence argue that it is too vague to be of scientific use. It is, they charge, a 'pseudo-scientific concept' that has been politically purchased by commercial interests not wanting to bear the costs of a proper risk assessment of GMO products.[56] They may have a point. By definition the inference of substantial equivalence means that two entities do not share some properties. Why should we assume a principle of equivalence in preference to a principle of non-equivalence? If, for instance, we found an organism on a meteorite that was in many respects the same as some known organisms, would we happily dispense with a full risk assessment on the basis of an application of substantial equivalence and release it? Almost certainly not, one suspects. Why should we treat the organisms coming out of our laboratories courtesy of techniques and knowledge that are only comparatively recent any differently? Surely changes of context should not be allowed to have such a powerful influence on our assessments of objective risk. The precautionary principle and the substantial equivalence principle may not be good regulatory principles to build into risk assessment when it comes to the regulation of GMOs. The basic problem is that neither principle constitutes a tight rule of inference. Both allow too much scope for interpretation and therefore factional politics and regulatory compromises. Further, neither principle is really a knowledge-promoting principle. Both give too much leeway to decision-makers to dispense with further empirical investigation. All other things being equal, we should seek to institutionalise regulatory principles that are knowledge-promoting.[57] We would do better here to dispense with the two principles and concentrate instead on a principle of best practice risk assessment.

The arguments for making the principle of labelling a foundational principle are strong. Labels like trade marks lower consumer search costs. Like trade marks they also provide producers with an incentive to innovate, thereby contributing to dynamic efficiency. The labelling of GMO foods also allows consumers to satisfy preferences that are based on fundamental values. The opposition to GMO foods is sometimes based on deeply held environmental values. Why should we not provide those consumers with information about products so that they can make choices that are in

54) See Guy Van Den Eede and Marnix Housen, *Quantitative Environmental Risk Assessment for Genetically Modified Organisms* European Commission, DG Joint Research Centre, 1999, at 64.

55) On the importance of dialogic webs to global regulation see John Braithwaite and Peter Drahos, Note 27 above, chapter 23.

56) Erik Millstone, Eric Brunner and Sue Mayer, 'Beyond Substantial Equivalence', (1999) 401 *Nature*, at 525 to 526.

57) For a discussion of institutional knowledge promotion see S. Fuller, 'Recent Work in Social Epistemology', (1996) 33 *American Philosophical Quarterly*, at 149 to 165.

accordance with their values? Labelling is also consistent with allowing consumers to make their own decisions about risk management in the case of food consumption. As part of the prudential regulation of financial services and products governments require suppliers to provide information to consumers so that consumers can balance risks and make trade-offs when making investment decisions. The provision of food products should be treated no differently. The argument that consumers are not in a position to evaluate the risks is not persuasive. Hadfield and Thomson suggest that a simple biotechnology alert label for food could be used to alert consumers to the presence of a biotechnology product.[58] Firms would have an incentive to provide that information to the public in a form that allowed members of the public to make informed decisions. It also needs to be remembered that consumer organisations would, in effect, audit the information that companies were placing on the labels. The role of government would be to monitor the truth of the information being provided to consumers. The European experience with GMO foods shows what happens if consumers are not told about the qualities of the food they are eating. The suppliers to the market lose the trust of the public and the market in GMO food products begins to shrink. The slowness with which regulatory authorities have moved to embrace the principle of labelling is one of the more shameful episodes in the history of biosafety.

There is not much doubt from a reading of the GATT, the SPM and the TBT that the trade principles of non-discrimination and harmonisation are subordinate to the principle of risk assessment. The principle of risk assessment for GMOs is widely accepted.[59] The problem, however, is at the level of practice where there are different approaches, methodologies and procedures of risk assessment. Before the principle of risk assessment can begin to have a genuine harmonising influence on the creation of standards for GMO products, the science of risk assessment will itself have to undergo a rigorous assessment. This means that risk assessment for GMOs will have to be thrown open to scrutiny by experts from many disciplines with the aim of producing harmonised procedures and protocols. Here it interesting to note the recommendation of a recent report of the EC that 'a multitude of international specialists', including those from the consumer movement, should be involved in the process of risk identification and standardisation of risk assessment for the environmental release of GMOs.[60] This kind of broad-based, pluralistic approach to risk assessment is probably the only kind of approach that in the long run is capable of uniting the many interest groups that contest GMO issues.

No real argument is needed to establish that the principle of informed consent has priority over the trade principles in those cases where risk assessment shows that there is a safety problem with a GMO. In those cases where international risk assessment establishes standards that allow for the movement of GMO products, states that are part of the trade regime will be bound by the non-discrimination principle. If international standard-setting bodies using best practice risk assessment deliver standards that allow GMO products to be traded, then states that are part of the trade regime should be bound by the principle of non-discrimination. States still have the option of showing that the standard is flawed or that it is unsuitable for their environment. They should, however, bear the cost of doing this. The trade principles should also operate in conjunction with the principle of labelling. Risk assessment and trade principles can deliver GMO products to the market, but ultimately it is a matter of consumer sovereignty and personal risk management philosophy as to whether those products will be purchased. The principle of labelling has to apply with maximum force. It follows that distinctions like the product/process distinction discussed earlier should not be allowed to mute the application of the labelling principle. If the principle is compromised by too many definitional games and legal complexities then governments and regulators will have lost almost the last means they have at their disposal to create trust in GMO products.

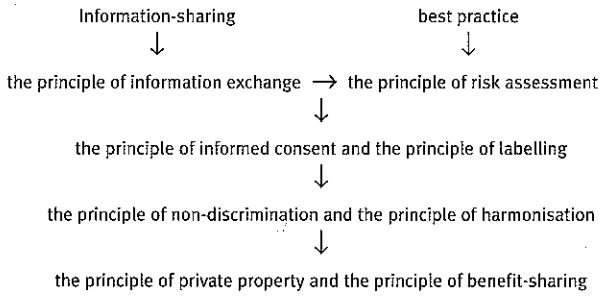
This leaves the principles of benefit-sharing and private property. Clearly the principle of private property for GMOs does not have precedence over the principle of risk assessment and the goal of protecting the environment and the health of citizens. Private property is not an absolute right that trumps all others. The regulatory implications of this ranking will have to be worked out on the basis of empirical evidence. It may be, for example, that the research exemption for patents has been narrowed too much and that the standard of inventiveness in biotech patent law has been set too low, making it too easy to acquire patents. Similarly, intellectual property rights may have to be reformed or added to in order to implement the principle of benefit-sharing. For example, it is now widely recognised that the present intellectual property rights regime does not particularly serve the economic and social interests of indigenous peoples. The World Intellectual Property Organisation through its Global Property Affairs Division is examining ways in which intellectual property standards might accommodate the collective knowledge assets of indigenous peoples.

58) See Gillian K. Hadfield and David Thomson, 'An information-based approach to labeling biotechnology consumer products', (1998) 21 *Journal of Consumer Policy*, at 551 to 578.

59) Note 52 above, at paragraph 43.

60) See Guy Van Den Eede and Marnix Housen, Note 54 above, at 63.

Our analysis suggests that the ranking for the regulatory principles that are to apply to GMOs should look something like this:



The precautionary principle and the substantial equivalence principle drop out of the picture to be replaced by a principle of risk assessment, which itself is driven by a principle of best practice. The principle of information-sharing should be adopted to help create a wider dialogue amongst regulators. The principles that we need for the regulation of GMOs are already in place. Moreover, at least some elements of the ranking are in place. There is a strong argument that the trade principles, for example, do defer to the principle of risk assessment in the context of the WTO. Other parts of the ranking are obviously not in place. Those elements of international business that have large intellectual property portfolios are pursuing an agenda that seeks to make the principle of private property a supreme principle within the emerging global knowledge economy. If this were to happen, it could have serious implications for the regulation of GMOs. For example, it is conceivable that states that enacted measures which restricted the entry of patented GMO products into their environment could find themselves on the end of a non-violation nullification and impairment complaint under the GATT (Article XXIII). The argument would be that such measures deprived the patent-owner of the benefit of the patent. In order for such a complaint to succeed, intellectual property rights would have to be characterised as positive rights.[61] This is just the sort of characterisation that business players are seeking. They would like to see intellectual property rights become positive rights of investment.

The emerging global regulatory order for GMOs will see within it a contest over the regulatory principles that are to govern the development, use and exploitation of GMOs. The key question will be whether this regulatory order will serve the health and environmental interests of citizens everywhere or whether it will be compromised by the influence that multinationals continue to exert over this developing regulatory order. A discussion of the strategies of the actors involved in this contest is beyond the scope of this article. But on the question of strategy there is, in closing, one observation worth making. Every state should as a matter of priority adopt at the national level a principle of best practice risk assessment for biosafety. Without such risk assessment at its side a state has no hope of influencing the supra-national standard-setting game for biosafety and very little chance of discharging the evidentiary burdens that are likely to arise in the context of a WTO dispute resolution proceeding involving GMOs. In adopting such risk assessment a state will also best serve the interests of its citizens.

61) See Frederick M. Abbott, 'WTO Dispute Settlement and the Agreement on Trade-Related Aspects of Intellectual Property Rights', in Ernst-Ulrich Petersmann, *International Trade Law and the GATT/WTO Dispute Settlement System*, Kluwer Law International, London, The Hague, Boston, 1997, at 415 and 434.