Genetic Engineering and the World Trade System

World Trade Forum

EDITED BY

Daniel Wüger and Thomas Cottier

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GENETIC ENGINEERING AND THE WORLD TRADE SYSTEM

While the WTO agreements do not regulate the use of biotechnology *per se*, their rules can have a profound impact on the use of the technology for both commercial and non-commercial purposes. This book seeks to identify the challenges to international trade regulation that arise from biotechnology. The contributions examine whether existing international obligations of WTO Members are appropriate to deal with the issues arising from the use of biotechnology and whether there is a need for new international legal instruments, including a potential WTO Agreement on Biotechnology. They combine various perspectives on and topics relating to genetic engineering and trade, including human rights and gender; intellectual property rights; traditional knowledge and access and benefit sharing; food security, trade and agricultural production and food safety; and medical research, cloning and international trade.

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ABBREVIATIONS

CBD	Convention on Biological Diversity
CDM	Clean Development Mechanism (of the Kyoto Protocol)
CGIAR	Consultative Group on International Agricultural Research
CI	Consumer International
DFID	(United Kingdom) Department for International Development
ECOWAS	Economic Community of West African States
EGE	European Group on Ethics in Science and New Technologies
ETH	Swiss Federal Institute of Technology
FAO	Food and Agriculture Organization (of the United Nations)
GAB	Gender Advisory Board (of UNCSTD)
GATS	General Agreement on Trade in Services (WTO)
GATT	General Agreement on Tariffs and Trade (WTO)
GEA	Genetic Engineering Act (Switzerland)
GM	genetically modified
GMO	genetically modified organism
GSP	generalised system of preferences
GTL	Gene Technology Law (Switzerland)
GWG	Gender Working Group (preceded GAB)
HIV/AIDS	human immunodeficiency virus/acquired immunodeficiency syndrome
HRC	Human Rights Commission
IBC	International Bioethics Committee (UNESCO)
ICCPR	International Covenant on Civil and Political Rights
ICESCR	International Covenant on Economic, Social and Cultural Rights

IFOAM	International Federation of Organic Agriculture Movements
IGBC	Intergovernmental Bioethics Committee (UNESCO)
IPR	intellectual property right(s)
IRRI	International Rice Research Institute
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
LMOs	living modified organisms
MEAs	multilateral environmental agreements
MFN	most favoured nation
NGOs	non-governmental organisations
OAU	Organization of African Unity (now African Union)
OPEC	Organization of Petroleum Exporting Countries
PPMs	process and production methods
SDC	Swiss Agency for Development and Cooperation
SEARICE	Southeast Asia Regional Initiatives for Community Empowerment
SPS Agreement	Agreement on the Application of Sanitary and Phytosanitary Measures (WTO)
TBT Agreement	Agreement on Technical Barriers to Trade (WTO)
TK	traditional knowledge
TRIPS Agreement	Agreement on Trade-Related Aspects of Intellectual Property Rights (WTO)
UNCED	United Nations Conference on Environment and Development
UNCSTD	UN Commission on Science and Technology for Development
UNESCO	United Nations Educational, Scientific and Cultural Organization
UPOV	International Convention for the Protection of New Varieties of Plants
WARDA	Africa Rice Center
WEF	World Economic Forum
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

PART I

Introduction and systemic issues

1

The many faces of modern biotechnology

DANIEL WÜGER

A Introduction

The current debate on the implications of modern biotechnology for humans and agriculture epitomises the philosophical dividing lines of modernity. On the one side are fears that modifying DNA endangers life as such. The term 'life' is used in an almost metaphysical way to refer to something unchangeable, perfect, whose integrity has to be preserved at any cost. Any interference with life is strictly taboo and DNA is at the core of it. These views seem to be based on a strict separation between nature and technology. With nature, perfect as it is, one may not interfere or doom is certain – as if our actions can be separated from what nature does, or as if the secret code of our well-being has been enshrined in DNA.

On the other side there is a strongly held belief in the capacity of science and technology to modify biological processes in whatever way would benefit humanity. From this viewpoint scientists do nothing that does not also occur in nature. Any unintended consequences can be controlled by technological means, i.e. there are no unknown or uncontrollable risks either to human health or to the environment – as if our actions could not have any unintended consequences that technology would not be able to deal with.

A compromise between these positions is hardly attainable. While scientists speed ahead finding new facts every day, politicians and regulators battle over fundamental positions on modern biotechnology using scientific information that is twenty or thirty years old based on philosophical concepts of technology from 200 years ago. Today, the development of modern biotechnology is essentially irreversible. A pragmatic scientific perspective on technology cannot ignore this fact.

In some ways, there is nothing new about biotechnology, as the use of 'biological systems, living organisms, or derivatives thereof, to make or

modify products or processes for specific use'[1] has occurred since the earliest human civilisations. For instance, biotechnology helps to produce beer and yoghurt, to conserve food and to treat waste water. In the 1970s, however, 'in vitro nucleic acid techniques' that allow the 'fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers'[2] – techniques referred to as 'modern biotechnology' – opened up a completely new range of possibilities for studying and making use of biological mechanisms. Since then, biotechnology has evolved rapidly, venturing into many new areas and leading to the development of a large number of applications in such diverse industrial fields as medicine, food production and computer technology. Modern biotechnology has become a key technology in our time.

The different applications require specific policy considerations. The effects on human health vary not only according to the specific uses of the technology but also according to the hazards presented by the applications. A food product that is ingested on a daily basis requires completely different policy considerations to a bio-fuel. Again, a food-protein cannot be treated in the same way as a pharmaceutical. There is also a great difference between the regulation of biotechnology at the research stage and its regulation when marketed. Similar considerations are valid for the ethical or environmental implications of modern biotechnology. There are no unique characteristics that can be used as guidelines when regulating biotechnological applications. Rather, each field of application has to be looked at separately.

This book attempts a pragmatic approach to looking at the many faces of biotechnology. Its focus is the challenges that arise from biotechnology for international trade regulation. At its core lies the central question of whether trade law is sufficiently well equipped to deal with modern biotechnology or whether there is a need for new instruments, e.g. a WTO agreement on biotechnology as suggested by Cottier (see Cottier, chapter 2, below). The contributions were initially prepared for the World Trade Forum 2005, held at the World Trade Institute in Berne, Switzerland, and subsequently revised. They provide a stimulating and thought-provoking overview of the subject matter.

[1] Art. 2 of the Convention on Biological Diversity (CBD).
[2] Art. 3(i) of the Cartagena Protocol on Biosafety to CBD (Cartagena Protocol).

B Sustainable development, modern biotechnology and international trade: conflict and coordination

Any policy framework today has to contribute to sustainable development, that is, development 'that meets the needs of the present without compromising the ability of future generations to meet their own needs', according to the Brundtland Report.[3] Although there are very few hard criteria that flow from the concept, it should still influence our current thinking as a guiding principle. Its three elements – economic, social and environmental sustainability – offer a valuable normative framework for thinking about the many conflicting views on biotechnology and international trade. The following paragraphs use this framework to synthesise the – sometimes concurring and sometimes conflicting – contributions to this collection and to point to issues that were not raised by the authors.

1 Environmental sustainability of modern biotechnology

The metaphysical critique of modern biotechnology is most prominent when it comes to the environmental effects of genetically modified (GM) plants and microorganisms. There are fears that modified plants may pass on their modified DNA to soil microorganisms that will develop into killer bacteria. Others fear that GM plants are uncontrollable and will displace entire populations of wild plants, thereby drastically reducing biodiversity or destroying entire biospheres. Or, biotech plants might kill large groups of animals due to proteins ingested from GM plants. These fears are frequently combined with opposition to economic globalisation, to the concentration of (seed) industries or to intensive farming. The proponents of modern biotechnology, on the other hand, deny that any of the risks posed by GM organisms are new or real.

As always, the truth probably lies somewhere in between. Assessing the environmental sustainability of biotechnology requires a case-by-case approach that takes into account the specificity of an application as well as the specific environment in which it will be used. It makes a difference whether a product will be introduced into the environment directly or could end up in the environment only by accident, and

[3] Report of the World Commission on Environment and Development, 'Our Common Future' (Brundtland Report), UN Doc. A/42/427 (1987).

whether it will be used on a large scale or only for test purposes. The potential advantages of the specific product, such as lower pesticide use, increased resistance to environmental stress, etc., have to be considered as well. Generally, the debate tends to ignore the advantageous effects that GM products may have on the environment, e.g. where bio-remediation could be used to clean up waste, where they lead to cleaner industrial processes or when bio-fuels could lead to reduced emissions of greenhouse gases.

In light of this, each WTO Member has to find its own policy mix to ensure environmental sustainability in its territory. The trading system should not interfere but should prevent domestic policies being adopted for illegitimate reasons. There has often been criticism that the science-centric approach of the WTO's Agreement on Sanitary and Phytosanitary Measures (SPS Agreement) adopted for this purpose fails to properly address the specific concerns with modern biotechnology. However, when a WTO Member claims the existence of environmental risks when adopting a trade-restrictive measure, who other than scientists can provide a basis for the existence of these risks? Not even the Cartagena Protocol crosses that threshold (see Perrez, chapter 11, below on the compatibility of the Cartagena Protocol and the SPS Agreement). If domestic governments adopt measures that restrict trade in biotech products for ethical reasons or because consumers simply do not want biotech food, then they should not criticise the SPS Agreement's scientific basis. Consumer protection or *ordre public* measures are not environmental measures and should not be framed in terms of environmental regulations.

Much of the dispute between the USA and the EC arises from the different perceptions of modern biotechnology and the resulting regulatory approaches. In the EC, modern biotechnology is generally viewed with suspicion. The EC has therefore enacted specific regulatory tools for the approval and monitoring of all GM products. In the USA, the focus is more on products and their potential differences from conventional products and less on the technology. Only if such differences exist and have a negative impact on consumers or the environment may such products not be marketed. Producers have to ensure the safety of their products and liability is the consequence it they fail to do so. Whether the European approach is consistent with WTO law is contentious. The legal problems with the EC measures stem not from their different approach as such but rather from the inconsistent application of that approach. Although there has been a general policy decision to allow

GMOs on the EC market, the actual regulations and their application almost entirely prevent the use of GMOs within the EC. It is no wonder that the EC faces a difficult challenge in defending its regime before the WTO. Questioning the appropriateness of WTO law misrepresents the problem.

So far, no farmers in the EC have used GMOs. The discussions of the past few years have now started to focus on whether the existing regulatory environment is adequate for agricultural production with GMOs. Some question whether GMOs should be planted at all in Europe in light of the prevalence of small farms and the greater mixture of conventional and organic farming. Others caution that there is a need for specific regulatory safeguards such as rules on coexistence and, in particular, liability (see Petitpierre-Sauvain, chapter 8, p. . . ., below). Some countries such as Switzerland have already adopted specific liability regimes. The debate is also taking place within international environmental law. Under the Cartagena Protocol, negotiations on international obligations to enact liability rules for living modified organisms are currently being conducted, as mandated by its Article 27. Whatever the outcome of the negotiations within the framework of the Cartagena Protocol, there should be no concerns that WTO law would not support it. No conflict between liability rules negotiated under the Cartagena Protocol and WTO law is evident. As Perrez emphasises (see chapter 11, below) there is no *a priori* conflict between the two legal regimes and there are ample legal tools that can be applied to support their mutual supportiveness. Boisson de Chazournes and Mbengue (see chapter 10, below) agree and call for strengthening the principle of mutual supportiveness between the two systems of law.

Some authors call for strengthening the environmental sustainability of modern biotechnology by taking environmental risks into account in patent procedures. Expecting patent officers to assess environmental implications might not be the best solution however, unless a patent claim relates to an invention that, if implemented, could obviously have disastrous effects on the environment (and hence violate *ordre public*). Patent officers do not have the expertise to assess environmental risks. Considering environmental risks at the patenting stage would require risk assessments by qualified personnel. This would increase costs both for the administration as well as the patent applicants. Moreover, at the patenting stage, researchers usually have very little concept of the potential environmental or health risks of any product that is

ultimately developed from the patented invention. Pharmaceuticals, for example, take up to ten years to progress from patenting to the marketing stage. Such a requirement would also disadvantage smaller and medium-sized companies and research institutions, as bigger companies can more easily spread development costs and financial risks over other products and profit from greater economies of scale. It would be inappropriate to perform risk assessments on all patent claims preventively.

Finally, governance aspects require giving thought to the capacity of developing countries to administer complicated regulatory safety regimes. Smaller developing countries, in particular, face problems in this respect, for example when trying to reconcile biosafety with food security due to a lack of expertise and effective governmental control. Indeed, research in modern biotechnology and the handling of GM plants and animals require a sophisticated governmental system including regulations that can guarantee that newly developed products are scrutinised and that existing applications are implemented safely. From this perspective, it is important to ensure that developing countries are ready to meet these governance challenges. The food aid controversy highlights these difficulties. A developing country allowing food aid into its territory in the form of GM-seeds (mainly GM corn) faces the challenge of ensuring that these seeds are only used as food. Should farmers plant the seeds – as is the custom in many developing countries – a country that has no control schemes in place will not be able to remove the seeds from its production cycle. This would effectively turn the country into a country producing GMOs because of the low tolerance thresholds of food-importing countries. Needless to say, neither can the environmental effects be controlled. Once milled, the corn no longer poses the same risks – corn flour cannot be planted. That was one of the main reasons why countries such as Zambia insisted on not accepting whole grains of GM corn as food aid. It is important that developing countries are supported and can obtain the technical assistance necessary to deal with these problems. Providing a regulatory framework for biotechnology in the Cartagena Protocol could help too. Any such framework would have to take into account the criteria that stem from WTO law.

In trade law, the question remains how and whether developing country aspects can be taken into account. It is unclear how the need for special and differential treatment can be factored into the WTO Agreements. Obviously, no developed country will lower its

environmental or health standards for products from developing countries. Specific support schemes for developing countries and help with installing quality management systems will probably remain the only realistic options. Developing countries' own regulatory systems do not, however, have to be scrutinised according to the same rules as the environmental regulations of developed countries. Developing countries could be allowed, for example, to restrict trade in biotech products by referring to governance problems.

2 Economic sustainability of modern biotechnology

Technological process depends to a large extent on private innovation. Private innovation can only take place in an environment that provides appropriate incentives and the degree of freedom necessary to venture into unknown territory. Intellectual property rights, especially patents, are the traditional legal instruments that guarantee exclusivity on various forms of innovations and thereby allow the inventor to profit from his ideas. Indeed, biotechnological inventions can be patented like other inventions provided they fulfil the general criteria of patentability laid down in the TRIPS Agreement. However, these criteria are not applied equally in all jurisdictions throughout the world. Many States today allow for the patenting of organisms, plants and animals developed with the help of modern biotechnology. In other countries, protection is unavailable or is granted only by means of plant variety rights, also called *sui generis* rights. Most developed countries allow patenting of biotechnological inventions. In these countries, the debate centres on the question of whether DNA sequences isolated from an organism should be patentable as well. Many developing countries tend not to welcome patents on organisms or on DNA sequences.

Intellectual property rights have become a genuine field of trade regulation since the Uruguay Round. Indeed, the question as to whether TRIPS should mandate WTO Members to allow patents on biotechnological inventions has taken centre-stage in current negotiations. Yet, in light of the diverging positions, it is not surprising that the debate on appropriate protection of biotechnological inventions in the WTO is still ongoing. So far, no agreement has been reached on the revision of Article 27.3 of TRIPS that allows WTO Members to exclude plants and animals from patentability (see van Overwalle, chapter 4, below).

Beneath this debate a bigger controversy is lurking. What is at stake is the delicate balance underlying intellectual property systems between

the granting of a private monopoly for using a certain piece of information and technological progress at large. Ultimately, such limited exclusive rights should contribute to overall welfare and not lead to a disproportionate concentration of market power. Views on how the appropriate balance should be struck again vary from country to country. India, for instance, is at the forefront of those WTO Members that are concerned about patents on biotechnological inventions because they fear traditional livelihoods being put at risk. Other countries such as the USA build their industrial policy on private property and, hence, are very much in favour of biotech patents. Very little is known about the correlation between modern biotechnology, patents and welfare. More studies are urgently needed on the effects of the contemporary practice of patenting biotech inventions on competition including such phenomena as strategic patenting and patent clusters. Can the need for large economies of scale in today's global economy be combined with an adequate scope of concentration of patents in the hands of big companies?

Related to these issues is the question of who should benefit from patents. Many agree that countries that are rich in genetic resources, mostly developing countries, should benefit from the use of such resources by industry that resides mostly in developed countries. The way in which industry can gain access to genetic resources and the sharing of the benefits that stem from these resources constitute some of the most important issues of distributive justice today. It is to be hoped that, ultimately, extending territorial sovereignty over genetic resources will also contribute to their preservation. Similarly, if knowledge that contributes to a patented invention is held by traditional communities, these communities should benefit from its exploitation (see Lenzerini, chapter 6, below).

When there are discussions on what might be the appropriate forum for international rules in this area, the WTO should play an important role. Together with many other areas such as health and environmental regulation, the protection of intellectual property rights is a genuine trade issue today. The amendment of Article 27.3 of TRIPS should not be separated from the protection of traditional knowledge and access to genetic resources.

Innovation does not depend only on intellectual property. Industries are influenced by the entire regulatory environment that relates to their activities. Excessively burdensome regulations – for example, the requirement for conducting risk assessments at the patenting

stage – can have the effect of restricting activities too much. Burdensome regulation also tends to favour larger economic actors, a factor which developing countries in particular might want to consider if they wish to foster domestic research capacity and smaller start-up companies. A regulatory environment that provides inadequate guidelines, though, could lead to market inefficiencies and be detrimental to national welfare. The challenge is to find the appropriate balance between these poles. Again, this cannot be done without looking at the strategic considerations, i.e. a general vision of what role biotechnology should have in a given society.

The appropriate role for the WTO framework cannot be to determine its Members' biotechnology policy. Its main task must be to avoid national policies being allowed to result in protectionism, i.e. illegitimately restricting international trade. It is for the WTO Members to find the appropriate balance, taking into account other international legal obligations, especially in multilateral environmental agreements (MEAs) such as the Cartagena Protocol. In academic discussions and political discourse, this relationship is often seen as precarious, thus making it difficult for WTO Members to reconcile their international legal obligations when determining their own biotechnology policy. Often, the focus is on the danger of the environmental regime being trumped by trade rules. Yet, economic opportunities may also be impaired by environmental rules. It is important to consider that, in the trading regime, some fundamental principles are enshrined that should not fall by the wayside. In this sense, the Cartagena Protocol should also be interpreted in accordance with WTO law and not only *vice versa*. In any case, in legal practice, the controversy is less intense. The Cartagena Protocol and WTO Agreements do not conflict *per se* (see Perrez, chapter 11, below). Indeed, the onus should be on the mutual supportiveness (see Boisson de Chazournes and Mbengue, chapter 10, below) of the two regimes and thus on strengthening their coherence.

3 Social sustainability of modern biotechnology

The advent of a new technology carries the potential for income redistribution. Especially within the NGO community, but also within developing country governments, there are concerns that allowing modern biotechnology products to be used in agriculture could work to the detriment of subsistence farming, rural livelihoods, indigenous

communities and women. These concerns arise mainly because most of the seed producing companies are large multinationals. The change to GM seeds could lead vulnerable groups into unsustainable debt, and require large-scale intensive forms of production that would have a profound impact on social structures in developing countries. Also, structural change in agriculture could endanger food security when it results in excessive concentration on the production of cash crops.

However, the impact of the bioindustry on socio-economic issues has not so far been sufficiently researched. The intensification of the Article 26.2 process of the Cartagena Protocol encouraging parties to cooperate on research and information exchange on the socio-economic impacts of living modified organisms could thus be one way to foster such research. The lack of knowledge on the relationship between biotechnology and social development is exemplified in the context of gender and modern biotechnology. There is evidence that women tend to lose out on the sharing of benefits of science and technology for development in general. Yet, data on the effect of introduction of biotechnological applications on women is very limited (see Wagner, chapter 3, below).

Hence, the thesis that modern biotechnology necessarily goes hand in hand with big multinational business should not be accepted too readily. Increasingly, there might be niches for smaller specialised companies offering business opportunities for developing countries, and their number may increase in the future. The structure of the industry might not stay as it is. Furthermore, increased attention to building up domestic research capacity in developing countries and supporting smaller start-up firms rather than focusing only on organic forms of production could help developing countries to reap the benefits that the technology offers while at the same time contributing to solving some of their most significant economic and social problems.

Biotechnological research on improving industrial processes or medicines, for example, could also offer new economic opportunities for developing countries. Indeed, some have started incentive programmes for developing such research capacities, even attracting scientists from abroad. Economic opportunities for developing countries might also lie in the field of bio-fuel production. Here, modern biotechnology can make a contribution to energy security and foster structural change in developing countries. Zarrilli (see chapter 7, below) emphasises that major innovation in this sector is essential for development.

When it comes to food security, authors often paint a mixed picture of the potential of modern biotechnology. Some emphasise its risks while others stress the contribution the technology could make to improving food security. A way must be found to develop food crops that address the specific needs of developing countries. More attention could be given to developing orphan food crops that can meet the needs of local subsistence farming populations. Further discussions within the framework of the Cartagena Protocol could pay more attention to this problem and aim at developing appropriate solutions. Fostering domestic research and higher education could also contribute to making the potential benefits of modern biotechnology available to developing countries. Naturally, such decisions must be embedded in an overall political strategy. For example, there must be enough arable land available when planning to grow crops exclusively used for bio-fuel production, taking into account a potential increase in agricultural productivity to safeguard food security (see Zarrilli, chapter 7, below).

The bearing of trade law on these societal aspects is limited. Obviously, any domestic measure adopted that is part of a biotechnology industrial strategy may not illegitimately restrict international trade. The potential for systemic trade conflicts is very limited though. Furthermore, the international trading system should not interfere with national industrial strategies or social legislation either.

Last but not least is the big ethical debate on what techniques should be allowed in medical research. Stem cell research holds great promise, but the enthusiasm of the early years has already given way to a more pragmatic view on how quickly such promise can be realised. There is continuing controversy on where the line of human dignity separates ethical from unethical research practices. It does not make sense to stifle these discussions by imposing an international standard, and the trading system should be the last to interfere. Rather, its role, as always, should be restricted to prevent any abuses of ethical arguments being used to disguise national trade restrictions.

Nevertheless, there are discussions taking place in the international community on adopting binding legal rules that provide an ethical framework for research with human DNA. So far, these attempts have failed and have not gone beyond declarations and other soft law instruments. They will not succeed as long as national views continue to diverge to such a large extent. There is probably a consensus that at least some forms of reproductive cloning should not be permitted (see El Zein, chapter 13, below). Beyond that, however, there seems to

be little agreement on what should be permitted. There is no reason why trade regulation should be concerned with these issues.

Ultimately, there remains the question as to whether there are currently any relevant trade issues at all. Besides patentability, an area where most commentators agree that WTO Members should be free to regulate the patentability of inventions relating to the human body according to their own needs (see van Overwalle, chapter 4, below), there is not much else. It is difficult to envisage a WTO Member that will prohibit the importation of a pharmaceutical only because one stage of product development involved research which is considered unethical by its domestic legislation. It is possible that some WTO Members might prevent certain research services from being provided or consumed across the border in the future. However, there is no indication that the existing trade law instruments will be unable to cope with such cases in the future. International trade law already allows WTO Members to impose restrictions based on the 'moral exceptions' contained in its agreements (see Brownsword, chapter 12, below).

There might be more potential for controversy in the field of animal biotechnology. How much deference should be given to national views on which forms of genetic modifications of animals should be permitted and which not? Should WTO Members be permitted to ban the importation of aquarium fish that have been modified to glow in the dark? What about dogs with the same modifications? Again, WTO Members need a lot of leeway to decide these questions in their domestic jurisdictions without the trading system interfering beyond the prevention of protectionist measures.

C Biotechnology in a multilayered regulatory environment

Thinking along the three normative dimensions of sustainability one should not forget that proposed regulatory solutions have to take account of today's complex regulatory environment consisting of multiple layers and various specialised regimes. Thinking about the appropriate regulatory forum is thus important. International trade law cannot and should not be the linchpin of contemporary international law. Its appropriate bearing on biotechnology, as on any other issue, therefore, has to be carefully evaluated.

Today's regulatory environment consists of multiple layers: national, regional and global. It comes as no surprise, that stakeholders are active on all levels and trying to stimulate regulation that would favour their

constituency. However, from a normative standpoint, it is important to regulate on the appropriate level. In the absence of minimal international support, international legal rules – if they come into existence at all – will be meaningless and become obsolete.

Especially when asking what should be regulated on the international level, the more the better is not a valid argument. Add to this the fact that there is no coherent process of law-making internationally. Law-making occurs in various specialised organisations involving different networks, and, as a consequence, the appropriate forum is not always evident, or regulation leads to coordination problems. Trade regulation is not of equal relevance in all areas. For example, although it does provide for proprietary rights in the form of intellectual property rights, limits on exploitation of such rights stem from other fields of law such as human rights law and international environmental law, among others. Adequate interfaces, especially when enforcement mechanisms are stronger in one area (e.g. the WTO dispute settlement mechanism), are of the essence in safeguarding the legitimacy of the trading regime (see Perrez, chapter 11, below; and Boisson de Chazournes and Mbengue, chapter 10, below).

One important aspect is thus the extent to which harmonisation of biotechnology regulation on the international level has to be advanced. Various arguments are expressed in the contributions to this book. Authors with strong environmental concerns, such as Anne Petitpierre-Sauvain, Federico Lenzerini and Michael Hahn, frequently argue in favour of imposing strict obligations on States to strengthen their domestic environmental laws. By contrast, authors who do not share these concerns but see the economic potential of modern biotechnology, including Geertrui van Overwalle, Roger Brownsword and Simonetta Zarrilli, stress that there are already too many obstacles that hamper the commercialisation of biotechnological inventions. They therefore argue in favour of imposing obligations on States to enact domestic legal frameworks that provide incentives to the biotech industry.

In this debate, it is frequently forgotten that multilateral trade rules have little to do with favouring one regulatory system over the other. Trade rules traditionally focus on guaranteeing a level playing field on the market. It should be remembered that the reduction and elimination of traditional trade barriers (tariffs and quotas) does make national regulatory systems more vulnerable to foreign competition. The need for international harmonisation of non-trade regulation therefore

increases as well. However, the international trade system has not proven to be the place to impose specific views on how States should protect their environment, labour markets etc. Nevertheless, the costs of unilateralism, especially for smaller economies, are rising, and the need for harmonisation increases the further economic integration progresses. Still, it is not for the international trade regulator or trade judge to impose a particular regulatory choice on individual countries especially where major disagreements occur. Rather, domestic legal systems or various specialised regimes of international law are the places for such regulation. The trade system should provide an appropriate level of deference and should be restricted to preventing extraterritorial effects as far as possible.

Ultimately, from a 'constitutional' perspective, legitimate national processes of decision-making on biotechnology should not be circumvented by international regulatory activities. This is easier said than done because the task of drawing the line in trade law between legitimate national policy interests (deference/leeway to national policies) and illegitimate blocking of foreign products is a difficult one. In a contentious area such as biotechnology, a cautious approach is required, encroaching upon the political debate as little as possible. Once one accepts that international regulation is of the essence, the trading system is not necessarily the first choice. It is not the appropriate regime for harmonising environmental, social or other non-trade standards. Such regulatory questions should be left to the appropriate specialised regime.

Naturally, views will vary as to what intensity of regulation of biotechnology in international law is appropriate. Yet, any viewpoint should include such constitutional elements. The contributions to this collection provide a variety of perspectives that will give the reader a unique starting point for thinking about these regulatory questions and many remarkable proposals on how to deal in international trade law with the many faces of biotechnology.

2

Genetic engineering, trade and human rights

THOMAS COTTIER

A The focus on trade regulation

Regulation of genetic engineering or biotechnology[1] mainly pertains to domestic law. It is here that the processes of democracy and judicial assessment of fundamental rights and principles produce regulatory frameworks, commensurate with basic attitudes in society. Inherently, regulations vary from country to country. To what extent is there a need to involve international law and treaty-making? To what extent is there a need to achieve common and shared perceptions, and to regulate the interfacing of different regulations? These questions address the proper role of international law, and answers are far from clear, as the growing literature on the subject indicates.[2]

In international trade regulation, all these questions translate into demands for market access and fair conditions of competition for competing biotechnological or genetically engineered products, on the one hand, and to demands for trade restrictions on the other hand. It is not a coincidence that trade law is the prime area where such divergences are truly felt in international law, and serious conflicts are emerging. It is submitted that a need to coordinate and integrate widely diverging attitudes and regulations primarily shows in this field of international law. Again, it is here that a necessary process of coordination and eventually of integration of different regulatory traditions and attitudes to biotechnology emerges.

[1] While the term 'biotechnology' is broader than genetic engineering, also encompassing traditional uses of bacteria (see http://en.wikipedia.org/wiki/Biotechnology), we use the two terms interchangeably here.

[2] See G. Annas, 'Protecting the Endangered Human: Toward an International Treaty Prohibiting Cloning and Inheritable Alterations' (2002) 28 *American Journal of Law and Medicine* 151; A. Ayer, 'Stem Cell Research: The Laws of Nations and a Proposal for International Guidelines' (2002) 17 *Connecticut Journal of International Law* 393; S. Pridan-Frank, 'Human-Genomics: A Challenge to the Rules of the Game of International Law' (2002) 40 *Columbia Journal Transnational Law* 619.

Trade regulation essentially deals with the interfacing of different national legal orders and the different and diverging ways products and processes are dealt with. Commonly accepted products are traded widely, and mutually used. The principle of comparative advantage relies upon the assumption of such acceptance of mutual benefit. Products ideally are traded on the basis of efficient allocation of resources and benefits. International trade, to a large extent, responds to these assumptions. Most products are widely shared and accepted, and thus accessible to open trade. New products, however, may challenge existing structures and patterns of consumption. They may be met with suspicion and diverging assessment by, and within, different jurisdictions. This is particularly true for products and processes based upon genetic engineering and DNA recombination.[3] They are met with diverging attitudes, ranging from acceptance to outright rejection. Within societies and States, this leads to difficult political debates. In international relations, the problem risks triggering trade wars. These tensions need to be addressed. How should international law deal with them? What are appropriate rules? To what extent are shared perceptions and harmonisation indispensable? And to what extent should they be left to domestic jurisdictions?

Few uniform answers can be found to the questions regarding technology since it is employed in very different contexts. Biotechnology and genetic engineering encompass a wide field of human activities and applications. Currently, the main areas of genetic engineering (DNA recombination, properly speaking) are: first, genetic engineering as applied to humans in medical research and treatment of illnesses; secondly, genetic engineering as applied to crops and animals, both essential to support human life; thirdly, additional applications emerge in the field of energy production; and fourthly, genetic engineering has been employed in the field of biological warfare and offers a dangerous and uncontrollable potential for mass destruction. While the technology shares common scientific foundations in all these areas, assessments within societies of these main areas as to their effects vary widely and cannot be dealt with uniformly in law. Genetic engineering for

[3] G. Isaac and W. Kerr, 'Genetically Modified Organisms at the World Trade Organization: A Harvest of Trouble' (2003) 37 *Journal of World Trade* 1083. For a historical account, see M. F. Cantley, 'The Regulation of Modern Biotechnology: A Historical and European Perspective', in D. Brauer (ed.), *Biotechnology*, vol. 12, *Legal, Economic and Ethical Dimensions* (Weinheim: Wiley-VCH, 1995), pp. 505–795.

improving health is largely accepted. Genetic engineering for mass destruction is widely rejected. Genetic engineering for food and agriculture is perhaps the most controversial field. This is certainly true in respect of international trade regulation.[4]

The host of areas of international trade regulation affected, and of largely unresolved problems, is impressive when we look at those issues falling under the scope of WTO law relating to the importation and exportation of genetically modified products:[5]

- Importation and exportation of stem cells, obtained either from human tissue of living persons or from human stem cells obtained from non-sustainable human embryos produced by way of artificial insemination: moral exceptions (Article XX(a) GATT).[6]
- Importation and exportation of products obtained on the basis of genetic engineering (food, seeds and plants, animals, and medicines) (Article XX(a), (b), (g) GATT).
- Importation and exportation of biological substances and services relating to warfare and mass destruction: national security (Article XI GATT, Article XIV *bis* GATS).[7]
- The identification of genetically obtained products: labelling (Articles III, XX GATT).
- The assessment of the safety of genetically obtained products (GATT, TBT[8] and SPS[9] measures relating to risk assessment and risk management, and corresponding trade restrictions).
- Marketing approval of GMOs: recognition of test results: mutual recognition agreements (MRAs).
- The impact of genetically obtained products on the environment: setting free GMOs and the risk of involuntary cross-breeding and

[4] See Isaac and Kerr, n. 3 above.

[5] See also R. Howse and P. Mavroidis, 'Europe's Evolving Strategy for GMOs – The Issue of Consistency with WTO Law: Of Kine and Brine' (2000) 24 *Fordham International Law Journal* 348.

[6] General Agreement on Tariffs and Trade (GATT), Annex 1A to the Agreement Establishing the World Trade Organization, Marrakesh, 15 April 1994.

[7] General Agreement on Trade in Services (GATS), Annex IB to the Agreement Establishing the World Trade Organization, Marrakesh, 15 April 1994.

[8] Agreement on Technical Barriers to Trade (TBT Agreement), Annex 1A to the Agreement Establishing the World Trade Organization, Marrakesh, 15 April 1994.

[9] Agreement on the Application of Sanitary and Phytosanitary Measures, Annex 1A to the Agreement Establishing the World Trade Organization, Marrakesh, 15 April 1994.

implications for natural habitats: the Cartagena Protocol[10] and the precautionary principle.[11]

- Liability for potential damages incurred and the problem of extensive insurance costs: a potential non-violation issue under Article XXIII(1)(b) GATT.
- Patenting life forms: to what extent should DNA recombination be subject to appropriation and exclusive rights under the TRIPS Agreement?[12]
- The implications on social and economic development in developing countries: the problem of special and differential (S&D) treatment, and the protection of traditional knowledge in relation to genetic engineering under the TRIPS Agreement.
- The implications for conventional production and processes. To what extent do they need protection by means of tariffs and domestic support in the light of competition by more efficient genetically engineered crops and industrial production? How could an appropriate balance be achieved between conventional crops, including organic farming, and the use of genetically modified crops, all with a view to supporting sustainable development, biological diversity and food security?
- The regulation of therapeutic services employing genetic engineering: GATS.

B Underlying issues

Trade disputes arising in these areas must be assessed on the basis of existing international law. They are unlikely to produce widely

[10] Cartagena Protocol on Biosafety to the Convention on Biological Diversity of 5 June 1992; see also the Universal Declaration on Cultural Diversity, United Nations Educational, Scientific and Cultural Organization, Paris, 2 November 2001. In doctrine, see R. Pavoni, 'Biosafety and Intellectual Property Rights: Balancing Trade and Environmental Security – The Jurisprudence of the European Patent Office as a Paradigm of an International Public Policy Issue', in F. Francioni (ed.), *Environment, Human Rights and International Trade* (Oxford: Hart Publishing, 2001).

[11] Principle 15 of the Rio Declaration on Environment and Development, Report of the United Nations Conference on Environment and Development, June 1992, UN Doc. A/CONF.151/26.

[12] Agreement on Trade Related Aspects of Intellectual Property Protection (TRIPS Agreement), Annex IC to the Agreement Establishing the World Trade Organization, Marrakesh, 15 April 1994, (1994) 33 ILM 1197.

acceptable results since trade rules, essentially based upon the principle of non-discrimination, do not address the underlying valuational issues or operate on assumptions which were created for commonly accepted, conventional products. Trade disputes, in other words, are only the tip of the iceberg of fundamental underlying problems which are beyond the scope of current international trade rules. These underlying problems include:

- The ethics of genetic engineering: is the technology good or evil? In pluralist societies, and more so in the pluralist international society, it is not possible to seek uniform answers to these basic questions. They are bound to vary in light of largely diverging rational attitudes and interests. Moreover, they vary in different fields of application.
- The utility of genetic engineering: is it useful to the large majority of the population and to society at large, even if it may impair individuals? Again, general answers are unlikely as they depend on different factual circumstances in different fields of application of the technology.
- How far can science, research and industrial applications be trusted, in the light of the economic constraints and personal agendas of researchers and science-based institutions, competing with each other?
- The safety of genetic engineering: what are the long-term implications of the technology? Answers again depend on diverging facts in different settings and fields.[13]
- The economics of genetic engineering: to what extent does genetic engineering lead to *de facto* monopolies and the exclusion of competition, in particular in the field of seeds?[14]
- The global politics of genetic engineering: what are the implications of the advanced and highly sophisticated technology in terms of relations for competing knowledge-based economies? What are the implications for power relations?[15]
- Finally, the trade angle of genetic engineering: to what extent are objections motivated by rent-seeking protectionism, in order to

[13] Cf. Parliamentary Assembly of the Council of Europe, 'Genetically Modified Organisms', Resolution 1419, 26 January 2005, §§ 6 and 7.

[14] See J. Barton and P. Berger, 'Patenting Agriculture' (2001), available at www.issues.org/17.4/p_barton.htm.

[15] See T. Bernauer, *Genes, Trade and Regulation: The Seeds of Conflict in Food Biotechnology* (Princeton, NJ: Princeton University Press, 2003).

protect conventional products and methods of production? And to what extent are they motivated by truly ethical concerns? Are there unholy alliances?

- In a pluralist society, how can we find the right answer to all these questions? Does majority ruling provide the appropriate answers? How are these processes informed and led?[16] What is the role of normative principles?

These and other questions entail fundamental problems for different legal orders and nations. The complexity of these questions is multiplied once it is transferred to the global level and thus to the realm of international law. We need to examine carefully to what extent international rules are necessary, both in terms of harmonisation and in terms of interfacing different national rules. In areas which are mainly left to domestic applications short of international exchange of goods and services, the best answers may leave matters to domestic or regional law and regulatory competition. This would seem particularly appropriate in shaping framework conditions for basic research prior to the generation of tradable products. However, as soon as tradable products are placed on the market, international regulation becomes indispensable if distortions and misallocation of resources to the detriment of humankind are to be avoided.

In the process of globalisation, it is evident that harmonisation of principles and rules offers the best answer, from the point of view of international trade and legal security.[17] Once tradable goods and services emerge, once common standards, reflecting shared perceptions, are achieved, trade problems can be solved. The problem is, of course, that regulatory harmonisation on substance cannot be readily expected. The contemporary existence of largely diverging views, essentially based upon beliefs rather than scientific evidence, cannot be easily overcome. We are faced with the question: What can we reasonably expect from international trade regulation in the field of genetic engineering? Second-best solutions would allow for rational interfacing of diverging attitudes on the basis of existing techniques addressing the interface.

[16] UN Economic and Social Council, 'Human Rights and Bioethics', Resolution 2001/71, 10 February 2003, UN Doc. E/CN.4/2003/98, para. 8.

[17] E.-U. Petersmann, 'Biotechnology, Human Rights and International Economic Law', in F. Francioni (ed.), *Biotechnologies and International Human Rights* (Oxford: Hart Publishing, 2007), pp. 229–74.

Where does the law stand today? Can it assist in bringing about common and shared perceptions in the long run?

At this point, it may be useful to ask whether international law offers the basis of common perceptions by referring to widely accepted standards in human rights. Human rights reflect the basic perceptions of justice, fairness and equity in contemporary society. Many of them, but by no means all, substitute for formerly held religious beliefs. They provide a valuational and ethical system upon the basis of which people may approach and assess underlying problems relating to genetic engineering. This, at least, is true for the Western world, but it is increasingly of global reach in the light of extensive commitments made for the protection of a wide range of human rights.

This chapter thus seeks to explore the relationship of trade regulation and human rights in the field of genetic engineering. It addresses the potential impact of trade regulation in genetic engineering on human rights, and the potential normative impact of human rights on regulating trade in this field. It is submitted that human rights values are an important ingredient to be taken into account in international trade regulation in order to achieve viable and acceptable interfaces between diverging perceptions.[18] They can offer a path towards shared understanding and common rules. We explore to what extent existing trade rules offer portals for human rights considerations. At the same time, we observe that the impact on, and of, human rights cannot be defined in the abstract. It depends on the context of a particular problem and application in the various fields open to genetic engineering. Except for specific areas, there are no uniform answers. Trade rules therefore need to be read and shaped in a manner that takes into account the context of a particular constellation. To this effect they should first provide for appropriate procedures.

C Foundations

We first seek briefly to address the potentially relevant substantive human rights in biotechnology and to provide a short survey of the relevant trade regulations in WTO law. The lack of explicit links between the two fields is subsequently addressed.

[18] See generally T. Cottier, J. Pauwelyn and E. Buergi (eds.), *Human Rights and International Trade* (Oxford: Oxford University Press, 2005).

1 Core human rights relating to genetic engineering

The following core human rights, drawn from the 1948 Universal Declaration of Human Rights,[19] are of particular importance in the present context: the protection of human dignity (Article 1) provides the overall foundation and purpose of post-World War II international human rights protection. It establishes a core value to be respected in all fields of life. It is of particular relevance in genetic engineering, given the potential of manipulation of genetic information, but likewise of beneficial applications. It is supported by the right to life and the prohibition of slavery (Article 3). The former entails both encouragement and restrictions of the technology, while the latter clearly acts as a barrier to manipulations and oppression. The right to freedom of thought, conscience and religion (Article 18) protects the right to advocate, but also to oppose, genetic engineering and thus to accept and protect diverging views on the subject. It provides the foundation of pluralism. The right to adequate standards of living, including the right to food and the right to medical care (Article 25), offers a potential foundation in support of the technology, while the right to property (Article 17, not reflected in global human rights treaties) and the right to protection for moral and material interests resulting from scientific production (Article 27(2)) raise the issue of proprietary rights in the field. The Declaration sets forth an ambitious right to a social and international order in which the rights of the Declaration can be fully realised (Article 28). The provision encourages the respect for human rights in shaping regulations, in particular international trade regulations, in line with the core standards alluded to by the Declaration. Finally, the generic right to development, often, but disputably, qualified as a human right,[20] must today be understood in the wake of the 1992 Rio Declaration and subsequent instruments as a principle of sustainable development. Legitimacy of genetic engineering therefore also depends upon its long-term impact on social and economic development and ecology, in particular biodiversity.

A detailed account and analysis of all relevant human rights instruments is not possible here. Further studies need to examine a

[19] Universal Declaration of Human Rights, UN GA Resolution 217 A (III), 10 December 1948.

[20] UN GA Declaration on the Right to Development, Resolution 41/128, 4 December 1986, A/RES/41/128, GAOR 34th Sess. Res. 66.

comprehensive list of rights affected, including procedural rights.[21] It will be argued in this chapter that they are of particular relevance. In addition, it will be important to take into account constitutional rights enshrined in many legal systems, such as the freedom to conduct scientific research.[22] At this stage, it is sufficient to note that a number of core individual rights are likely to influence the legal environment of genetic engineering. Human rights essentially require the adoption of a homocentric view while taking into account the needs of environmental protection and the preservation of nature.

2 Current WTO rules addressing genetic engineering

No agreement specifically addressing biotechnology exists in WTO law. Domestic regulations on genetic engineering therefore are subject to the rules of the GATT 1994, the SPS Agreement and/or the TBT Agreement. Other agreements on goods may also be relevant (agriculture, licensing, etc.).

Trade regulation in the WTO essentially favours free exchange of goods, subject to tariffs. It assesses whether restrictions imposed on the basis of SPS or TBT measures can be justified. Under the SPS Agreement, domestic standards are thus subject to obligations of risk assessment. Under the TBT Agreement, measures need to respond to the requirements of necessity and proportionality. None of these restrictions is explicitly based upon human rights considerations. To the extent that a measure falls within the SPS Agreement, it will be examined under this agreement, prior to the TBT Agreement and the GATT 1994. The regulatory triangle of these agreements is currently under review by a WTO dispute settlement panel in *European Communities – Measures Affecting the Approval and Marketing of Biotech Products*, and clarification as to their application is expected to emerge in the case law.

[21] In particular the International Covenant on Civil and Political Rights (ICCPR), adopted 16 December 1966, UN GA Resolution 2200, 21 GAOR, Supp. (No. 16) 52, UN Doc. A/6316 (1966); International Covenant on Economic, Social and Cultural Rights (ICESCR), adopted 19 December 1966, UN GA Resolution 2200, 21 GAOR, Supp. (No. 16) 49, UN Doc. A/6316 (1966); for a useful comprehensive analysis of these and related instruments, see e.g. T. Meron (ed), *Human Rights in International Law: Legal and Policy Issues* (Oxford: Clarendon Press, 1984).

[22] See M. Eibert, 'Human Cloning: Myths, Medical Benefits and Constitutional Rights' (2002) 53 *Hastings Law Journal* 1097.