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INTERNATIONAL LAW ON BIOTECHNOLOGY

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I. Mandate of the Committee

Biotechnology or genetic engineering touches upon many quarters of the law: human rights and property protection, trade regulation and environmental law, all these areas being closely interlinked. A great variety of policy areas are affected, from research, family planning, health care to biodiversity, from environmental degradation to energy, nutrition and agricultural policies, to name just a few. Most of these policies are primarily matters of domestic law. The regulation of biotechnology mainly takes place in domestic fora. Yet, countries share common concerns. Biotechnology has been on the agenda of different international fora and organizations. Partly, common intentions were discussed. Partly disagreement confirmed, and partly common rules adopted. The Committee was asked to examine the implications of international law as it exists, and to identify regulatory areas which would need to be addressed by future rules: The mandate adopted reads as follows:

Biotechnology regulation cuts across many areas of law, public, private, national, regional and international. The Committee seeks to focus on aspects of international law of biotechnology regulation,

and to take national regulations into account to the extent required to understand and further develop rules of international law. Consideration will need to be given to regulations on biotechnology *per se* in relation to intellectual property (including the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), patent harmonization and the European Patent Office (EPO)), to environmentally motivated regulations (Cartagena Protocol), to food standards and technical barriers to trade (TBT), to the Agreement on Sanitary and Phytosanitary Measures (SPS Agreement) and the Agreement on Technical Barriers to Trade (TBT Agreement)) and possible future instruments which have yet to be developed, for example in relation to market approval rules, labelling rules and production and process methods. The Committee will also need to address liability rules which are currently far from harmonized and range from product liability to strict liability rules in some countries, thus creating an uneven playing field for the industry. Consideration will also need to be given to the side effects of biotechnology, in particular in agricultural policies. This will require a look into the potential for enhancing the protection of traditional knowledge in order to counterbalance the potential of patenting biotechnology. This is an area of law that is currently under development (both in the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO)). The main focus of this work will be on the law of plant genetic resources for agriculture and the relationship with the International Treaty on Plant Genetic Resources for Food and Agriculture of the Food and Agriculture Organization of the United Nations (FAO). Work will need to be coordinated with other Committees, in particular the International Trade Law Committee which may deal with specific related aspects.¹

The 2008 draft report sets out by exploring the relationship of human rights protection and genetic engineering, mainly focusing on matter of health. It addresses the relationship of appropriation and public goods in the field of intellectual property as well as access and benefit sharing. It turns to issues of international trade regulation, including market access, non-tariff barriers and subsidies. The report concludes with an assessment from the point of view of international environmental law.

The 2008 report is an interim report, based upon contributions drafted by members and observers of the Committee submitted by Members and observers in a personal capacity and edited by the chair and reporters. Views expressed in these chapters should not be ascribed to the Committee at this stage; the Committee will present its agreed views and recommendations in the final report and resolution only. The report thus does not include draft recommendations, but will serve as a basis for further work of the Committee, to be concluded in 2010 with a report and a resolution containing specific recommendations for further action in the development of international law on biotechnology. The Committee will identify in its future work regulatory needs and instruments in international law and seek to make a contribution to bring about greater coherence between the different areas of application. It will examine these issues from a perspective of multilayered governance and proper vertical allocation of regulatory powers.

The Committee met for two conferences in preparing this report. The results of the World Trade Forum 2006 are published.² The Members of the Committee are particularly grateful to the staff of the World Trade Institute, University of Bern, and the NCCR Project Trade Regulation, funded by the Swiss National Science Foundation for unprecedented support in preparing this report. Non-Member contributors join the report as observers. The Committee in particular thanks Fitzgerald Temmerman for coordinating the work.

¹ The mandate is reproduced in the ILA newsletter 18, 2003.

² WUEGER, D. and COTTIER, Th., (eds.), *Genetic Engineering and the World Trade System: World Trade Forum*, (2008 Cambridge, University Press).

II. Human Rights and Bioethics

A. Human Rights Guarantees Relating to Biotechnology

The development of modern biotechnology or genetic engineering, i.e. the modification of genetic code and sequencing of DNA, has triggered formidable new challenges to legal systems and the international community at large in safeguarding the paramount values of human dignity and fundamental human rights.³ Issues are firstly addressed by morality and ethics, and then may find regulations in domestic law. It is not a prime matter for international law. A number of non-binding standards have been established in the realm of bioethics.⁴ International law, however, does not remain without remedies against these threats. The law of human rights applies to biotechnology. The lack of binding legal instruments of universal scope for regulating *specifically* the matter at issue does not prevent, *inter alia*, the main principles of soft law regulating bioethics being subsumed within the scope of certain long-established principles of international human rights law presently in force.⁵

1. THE PROTECTION OF HUMAN DIGNITY

In international relations, the discourse on *human dignity* has constantly accompanied the evolution of human rights law since the Universal Declaration on Human Rights of December 10, 1948. Today, the fundamental character of human dignity is universally recognized. It allows judicial authorities to consider unlawful a given behaviour even though it may not be prohibited by positive law⁶ or to declare illegal unconstitutional a rule which was properly approved by the competent legislative body.⁷ Likewise, human dignity was called upon by the European Court of Justice in restricting economic activities.⁸ In these constellations of constitutional

³ Sections A, B and C of Chapter I of this report are based upon a draft written by Federico Lenzerini. See LENZERINI, F., *Biotechnology, Human Dignity and the Human Genome*, in FRANCONI, F., and SCOVAZZI, T. (eds.), *Biotechnology and International Law* (2006 Oxford, Hart Publishing), 285–340. On the subject see also COTTIER Th., *Genetic engineering, trade and human rights* in WUEGER, D., and COTTIER Th., (eds), *Genetic Engineering and the World Trade System, (World Trade Forum)*, (2008 Cambridge, University Press), 17-55; BROWNSWORD, R., *Genetic engineering, free trade and human rights: global standards and local ethics* in WUEGER, D., and COTTIER Th., (eds), *Genetic Engineering and the World Trade System, (World Trade Forum)*, (2008 Cambridge, University Press), 287-314.

⁴ See *infra* II (B).

⁵ Proclaimed by relevant treaties and – mostly – crystallized into rules of customary international law. The first preambular paragraph of the 1948 *Universal Declaration of Human rights* (UDHR), U.N. G.A. Res. 217A (III), available at <http://www.unhchr.ch/udhr/lang/eng.htm> (last visited 11 June 2008), recognizes the *inherent* dignity ‘of all members of the human family [as] the foundation of freedom, justice and peace in the world’; the UDHR also proclaims, at Article 1, the basic principle according to which ‘[a]ll human beings are born free and equal in dignity and rights’; in addition, it uses the concept of dignity as the parameter for establishing the economic, social and cultural rights to which all individuals are entitled (Article 22) as well as the level of remuneration due to workers, in order to ensure them and their families ‘an existence worthy of human dignity’ (Article 23). Both the 1966 *International Covenant on Civil and Political Rights* (ICCPR), 999 UNTS 171, available at http://www.unhchr.ch/html/menu3/b/a_ccpr.htm (last visited 11 June 2008) and the 1966 *International Covenant on Economic, Social and Cultural Rights* (ICESCR), 993 UNTS 3 available at http://www.unhchr.ch/html/menu3/b/a_ceschr.htm (last visited 11 June 2008), reiterate in the Preamble the principle enshrined in the first paragraph of the UDHR Preamble, adding that ‘the equal and inalienable rights of all members of the human family’ *derive* ‘from the inherent dignity of the human person’; furthermore, Article 10 paragraph 1 ICCPR states that ‘[a]ll persons deprived of their liberty shall be treated with humanity and with respect for the inherent dignity of the human person’. To a similar extent, Article 13 paragraph 1 ICESCR affirms the commitment of State parties to ensure that ‘education shall be directed to the full development of the human personality and the *sense of its dignity*’ (emphasis added).

⁶ See e.g., French Conseil d’État, *The renowned French dwarf-throwing case* (Commune de Morsang-sur-Orge and Ville d’ Aix-en-Provence), 27 October 1995.

⁷ This happened, for example, in 1975 in Germany, with respect to the first national law on abortion; See 1975 39, BVerfGE 1, cited by LANDFRIED C., *The Impact of the German Federal Constitutional Court on Politics and Policy Output*, 1985 20, Government and Opposition 522, 533.

⁸ See ECJ C-36/02, *Omega Spielhallen- und Automatenaufstellung GmbH v Oberbürgermeisterin de Bundesstadt Bonn* (Omega Case) available at <http://europa.eu.int/eur-lex/lex/LexUriServ/LexUriServ.do?uri=CELEX:62002J0036:EN:HTML> (last visited 11 June 2008).

adjudication, the principle of human dignity assumes a creative role in addressing new challenges to human rights law, often induced by technological advances. The principle thus works as the rationale for adapting human rights law to the values perceived by society as worth safeguarding – at any time – as a result of its social, ideological and technological progress. An offence against the dignity of any person – even with his or her own free and informed consent – intolerably offends society at large, and cannot be sustained. Such characterization of human dignity is of particular significance in the context of biotechnology, especially with respect to the contemporary debate concerning the possible applications of human-DNA-related technology in medicine.⁹ Human dignity allows importing consideration of bioethics into legal and human rights protection.

Biotechnology offers new opportunities to promote and enhance human dignity in combating diseases and shortcomings in meeting human needs, both in medicine and nutrition. Yet, it equally entails substantial risks to human dignity. Probably the most prominent issue of this debate is the question whether or not the free and informed consent of the person(s) concerned makes lawful certain experimentations on the human genome – such as human cloning and eugenic practices – which are subject to strong disagreement in ideological terms. In the field of bioethics, the risk that biotechnological applications may result in violations of human dignity is further amplified in developing countries, because of the gap that exists between these countries and developed ones in terms of opportunities to have access to the benefits of biomedicine. This limited access is in itself inconsistent with respect for human rights. In addition, it may ‘persuade’ governments of developing countries to reduce the attention being given to the degree of respect for human rights standards in the context of biomedical research and experimentation, in order to attract foreign biotechnology.

2. SPECIFIC GUARANTIES OF HUMAN RIGHTS

The subject of bioethics undoubtedly represents the most interesting and controversial issue in interfacing human rights and biotechnology. A multitude of human rights and values are affected. While human dignity offers the foundation to import considerations of bioethics into the legal discourse, the field is equally pertinent for many other and more specific human rights. The prohibition of inhuman and degrading treatment amounts to the most specific landmark in the field, enjoying the status of *jus cogens* and thus of a non-derogable right. The guarantee of personal liberty substantially limits interventions short of consent by persons affected. The right to health, to food, to sustainable development, as well as protection of property and economic rights are touched upon by biotechnology. In addition, procedural rights relating to due process and to participatory decision-making as a matter of good governance are essential. These rights, in combination with human dignity, offer substantial points of reference by which domestic regulation and practices can be monitored and contained, in particular by regional courts for the protection of human rights. International law can and will support constitutional courts in making difficult choices and determinations.

The rapid evolution of genetic engineering offers enormous potentials in terms of improving the quality of human life, especially in nutrition and the medical sector. Biotechnology has triggered, on the one hand, many hopes in the field of healthcare, particularly with respect to previously incurable genetic diseases. On the other hand, it has raised profound ethical questions relating to the compatibility of certain methods and techniques applied in the field and the protection of human dignity.

Often, several rights will be affected and may compete. A complex process of balancing and weighing different interests and ethical considerations will determine priorities of rights protection in the end. While basic rights and principles relating to biotechnology based upon human dignity offer guidance, they will often – with the exception of non-derogable rights – be subject to balancing of interest which in turn depends upon a case by case analysis and offers little guidance for mainstream practices. Claims might not always lead us to clear-cut decisions, and in utilitarian branches of (trade) law such as patent law, the evaluation of human dignity as an individual concept might not lead to optimum solutions.¹⁰ Ultimately, the balance of interest inherent to an assessment of human rights will primarily depend upon the utility and the risks of the involved technology in a particular context. Currently, judgements about utility and the long-term impact of genetic engineering vary.

⁹ For an overview of medical applications of biotechnology see JANKOWSKI, D., *Human Biological Products and Inventions in Biotechnology*, NCCR International Trade, stocktaking Paper 2008, forthcoming (on file with chair).

¹⁰ See TEMMERMAN, M., *Human Rights in the Patent Procedure: The issue of Prior Informed Consent of Human Donors to the Patenting of Inventions Based upon their genetic Material*, NCCR Trade Regulation Working Paper No. 2007/36, 2007 Bern, available at www.nccr-trade.org and <http://www.ssrn.com/> (last visited 11 June 2008).

While utility is increasingly demonstrated in the field of medical research, it has not been fully established in the field of plant genetic resources. The long-term impact of genetically modified crops on food security and on social and economic development, as well as in terms of consumer benefits cannot be adequately assessed at this stage.

Human rights are an important ingredient to be taken into account in international trade regulation in order to achieve viable and acceptable interfaces between diverging perceptions.¹¹ They offer a path towards shared understanding and common rules. At the same time, we observe that the impact on, and of, human rights cannot be defined in the abstract. It strongly 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. Genetically modified products and processes are both supported and challenged by human rights claims. The right to food, for instance, is supportive of genetic engineering to the extent that it offers options to combat famine and plant disease. At the same time it is detrimental to the extent that the technology destroys the conventional food base, biodiversity and thus food security. Moreover, human rights are not directly operational in all areas of international law. It should be noted that the present law of the WTO does not contain an explicit reference to human rights.¹² Instead, the instruments are based upon the precepts of non-discrimination; (most-favoured nation (MFN) and national treatment) are emanations of the fundamental principal of equality.¹³ They primarily relate to the treatment of products (goods and services). To the extent that they also protect persons as service providers under GATS or holders of intellectual property rights, they might be conceived in terms of human rights of non-discrimination and equality as applied to a specific context.¹⁴

Human protection, in other words, cannot be found conclusive one way or the other in assessing biotechnology. It offers, on the basis of human dignity, a framework based upon which rational decision can be taken both in legislation and in adjudication. More specific rights have been emerging within specific legal instruments, giving expression to underlying fundamental rights and ethical concerns.

B. Specific Legal Instruments and Rights Addressing Bioethics

The existing international legal framework on bioethics is mainly expressed in terms of soft law instruments¹⁵, particularly the United Nations Educational, Scientific and Cultural Organization (UNESCO)'s *Universal Declaration on the Human Genome and Human Rights* (UDHGHR, 1997),¹⁶ the *International Declaration on Human Genetic Data* (IDHGD, 2003), the *Universal Declaration on Bioethics and Human Rights* (UDBHR, 2005), and the *United Nations Declaration on Human Cloning* (UNDHC),¹⁷ adopted by the General Assembly in 2005. The notable exception is the European regional level, where the Council of Europe's 1997 *Convention on*

¹¹ See generally COTTIER, Th., PAUWELYN, J. and BUERGI, E. (eds.) *Human Rights and International Trade* (2005 Oxford, University Press).

¹² Consequently, there is a call in doctrine, including the ILA Committee on International Trade, for an explicit WTO declaration, committing all WTO Members and bodies to respect universal human rights obligations. See PETERSMANN, E.-U., *Biotechnology, Human Rights and International Economic Law* in FRANCIONI, F. (ed.), *Biotechnologies and International Human Rights*, (2007 Oxford, Hart Publishing) 229. See also United Nations Commission on Human Rights, Economic, Social and Cultural Rights, *Liberalization of Trade in Services and Human Rights, Report of the High Commissioner*, June 25th 2002, E/CN.4/Sub.2/2002/9.

¹³ COTTIER, Th. and OESCH, M., *International Trade Regulation: Law and Policy in the WTO, The European Union and Switzerland*, (2005 Bern and London, Staempfli Publishers and Cameron May) 347 and 382.

¹⁴ Cf., UN Commission on Human Rights, Economic, Social and Cultural Rights, *Liberalization of Trade in Services and Human Rights, Report of the High Commissioner*, June 25th 2002, E/CN.4/Sub.2/2002/9.

¹⁵ See also EL-ZEIN, S., *The regulation of human genetics by international soft law and international trade* in WUEGER, D., and COTTIER Th., (eds.), *Genetic Engineering and the World Trade System: World Trade Forum*, (2008 Cambridge, University Press), 315-343.

¹⁶ Adopted by the UNESCO General Conference on 11 November 1997 (the full texts of all relevant UNESCO instruments are available at <http://www.unesco.org> (last visited 11 June 2008) and endorsed by the UN General Assembly on 9 December 1998 (Doc.A/RES/53/152).

¹⁷ See Doc.A/RES/59/280 of 23 March 2005.

Human Rights and Biomedicine (Oviedo Convention)¹⁸ and its three protocols (the 1998 Protocol concerning the prohibition of human cloning,¹⁹ the 2002 Protocol concerning transplantation of organs and tissues of human origin,²⁰ and the 2005 Protocol on biomedical research²¹) set up a binding and comprehensive legal regime on bioethics. These instruments are reinforced by human rights protection and thus adequate in relation to action taken by government bodies. It is less clear to what extent they also encompass in binding terms conduct and action by private operators. Human rights do not generally enjoy per se horizontal effect, and specification to this effect requires implementation and specification in domestic law, or in particular international instruments obliging Parties to legislate.

An analysis of the most important international legal instruments regulating bioethics allows identifying a series of basic principles that, if correctly and effectively applied, are suitable for minimizing the possible adverse effects of the implementation of human-related applications of biotechnology and, therefore, for giving concrete realization to the basic dogma of the primacy of human dignity. These principles clearly apply to governments and private actors alike. They inform domestic legislation and are in particular, the following:

i) *The right to prior, free and informed consent*: this principle is constantly reiterated as a mandatory requirement by all relevant legal instruments; it relates to the obligation to obtain, for any application of biomedicine, the prior, free and informed consent of the person(s) concerned.²² The principle of consent has been defined by the European Group on Ethics in Science and New Technologies as ‘the very origin of modern biomedical ethics’²³. It is an important prime safeguard and plays an essential role in preventing biomedical applications from degenerating into intolerable abuses of human dignity. We emphasize, however, that consent cannot legitimize practices which are *inherently* incompatible with the value of human dignity. This core value cannot be freely disposed of, even by the person(s) exclusively concerned in the context of a given medical or scientific practice. The breach, amounts to a violation of prime public interests.²⁴ The essential condition for consent to make a biomedical intervention lawful is that it is validly given; therefore, it must be given prior to the intervention, completely on a voluntary basis, and upon receiving adequate information in the sense that the person concerned must be fully aware of all implications and possible consequences arising from the practice to which he or she gives his or her consent.²⁵ Consent, when validly given, can only be intended to cover the specific purposes for which it has been provided.²⁶ The person giving his or her consent to an application of biomedicine concerning his or her person retains the right to withdraw his or her consent ‘at any time and for any reason without

¹⁸ *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*, CETS No. 164, available at <http://conventions.coe.int/treaty/en/treaties/html/164.htm> (last visited 11 June 2008).

¹⁹ *Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings*, CETS No. 168, available at <http://conventions.coe.int/treaty/en/treaties/html/168.htm> (last visited 11 June 2008).

²⁰ *Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin*, CETS No. 186, available at <http://conventions.coe.int/Treaty/En/Reports/Html/186.htm> (last visited 11 June 2008). As stated in Article 2, this Protocol only applies ‘to the transplantation of organs and tissues of human origin carried out for therapeutic purposes’.

²¹ *Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research*, CETS No. 195, available at <http://conventions.coe.int/Treaty/en/Treaties/Html/195.htm> (last visited 11 June 2008).

²² See Article 5(b) UDHGHR; Articles 6(d) and 8 IDHGD; Article 6 UNBHR; Articles 5 and 16 of the Oviedo Convention, Articles 13, 17 and 20 of its Second Protocol and Article 14 of the Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research, available at <http://conventions.coe.int/Treaty/en/Treaties/Html/195.htm> (last visited 11 June 2008); Article 3 of the EU Charter of Fundamental Rights; Article 7 ICCPR (qualifying as inhuman and degrading treatment any medical and scientific experimentation carried out without the free consent of the interested person).

²³ See *Citizens Rights and New Technologies: A European Challenge*, Report on the Charter on fundamental rights related to technological innovation requested by President of the Commission, Romano Prodi, 23 May 2000 at 13.

²⁴ In this respect see, e.g., the French case of dwarf-throwing, *cit.*, note 6.

²⁵ See, in this respect, Article 6(d) IDHGD. See also Article 8 IDHGD, Article 7 UNBHR Article 6 of the Oviedo Convention, regulating the sensitive issue of the protection of persons unable to give their consent.

²⁶ In this regard see, in particular, Article 16 IDHGD.

disadvantage or prejudice'.²⁷ Limitations or exceptions to the principle of consent are only acceptable for compelling reasons, when prescribed by law and if consistent with international human rights law.²⁸ They may apply to persons unable to consent under circumstances compelling to save lives, in particular due to unconsciousness or infancy. In terms of existing human rights standards, the requirement for free and informed consent is based upon the right to personal liberty and the prohibition of inhuman and degrading treatment. Violations affect the integrity of the person and may lead the individual concerned to suffer deep interferences within his/her intimate sphere of privacy and identity. Subject to exceptions mentioned, treatment and therapy carried out without his or her informed consent, turns a person into an object and thus to degrading treatment.²⁹

ii) *The right to privacy and confidentiality*: the matter of privacy of genetic information is a highly sensitive issue in bioethics. Genetic information relating to a particular person is considered private information. It involves the very intimate identity of the human being. For such reason, the principles of privacy and confidentiality assume a key role in its regulation. Any collection of such data implies a potential restriction of privacy and thus requires statutory authority to collect and use it, for example in criminal prosecution and proceedings. The right to privacy and confidentiality are emphasized by all relevant instruments (although using different formulations).³⁰ They are reiterated by the foremost international institutions dealing with this issue at various levels.³¹ A proper application of the principles of privacy and confidentiality allows preventing and remedying most violations of human rights and dignity which may occur in the context of bioethics – such as genetic discrimination and all practices related to it. In addition, compliance with these principles promotes the confidence of individuals in biomedical research. It contributes to the establishment of a conducive social environment supporting their effectiveness and improvement. The right to respect for the principles of privacy and confidentiality can be plainly subsumed within the human right to privacy, expressly provided for by a number of relevant treaty provisions.³² Also, in the field of biotechnology, breaches of the principle of privacy and confidentiality – resulting in the diffusion of information of particularly sensitive nature – are capable of making the person concerned the object of grave practices of denigration, which may amount to inhuman or degrading treatment and trigger discrimination for genetic reasons.

iii) *The right to information and to the right to be protected from disclosure of information*: the right to information amounts to yet another essential guarantee for persons involved in biomedical research. It is particularly important in the field of healthcare to enable a person to consciously take any decision concerning his or her own health. As biomedical research may disclose a person's particular predisposition to genetic diseases (although in most cases there is no certainty that the person will eventually develop the actual illness), the relevant international instruments cover, in addition to the right of *being* informed, the right of *not being* informed³³ (since knowing one has such a predisposition may greatly worsen (often needlessly) one's quality of life and psychological well-being). The instruments thus protect individuals from disclosure by governments of sensitive information to the individual concerned and, foremost, to third parties. Violations of this right amount to a breach of a number of long-established internationally recognized human rights, including the rights to physical and mental health and integrity, the freedom from inhuman and degrading treatment and to an adequate

²⁷ See, in particular, Article 9 IDHGD, Article 6 UDBHR and Article 5 of the Oviedo Convention.

²⁸ See Article 9 UDHR and Article 8(a) IDHGD. Article 6.2 UNBHR states that '[e]xceptions to this principle should be made only in accordance with ethical and legal standards adopted by States, consistent with the principles and provisions set out in this Declaration [...] and international human rights law'.

²⁹ See Article 7 ICCPR (which, after having expressed the general principle that none shall be subjected to torture or similar treatment, adds that, '*in particular*, no one shall be subjected without his free consent to medical or scientific experimentation' (emphasis added)) and Article 3 of the EU Charter on Fundamental Rights (which, in affirming the right of everyone to respect for his or her physical and mental integrity, specifies that in the field of medicine and biology 'the free and informed consent of the person concerned' must be obtained).

³⁰ See Article 7 UDHR, Article 14 IDHGD, Article 9 UDBHR, Article 10 of the Oviedo Convention, Article 23 of the Protocol to the Oviedo Convention concerning transplantation of human organs and tissues, Article 25 of the Protocol to the Oviedo Convention on biomedical research.

³¹ See LENZERINI, F., *cit.*, note 37, 328.

³² *E.g.* articles 12 UDHR, 17 ICCPR and 8 ECHR.

³³ See, in particular, Article 5(c) UDHR, Article 10 IDHGD, as well as Article 10 of the Oviedo Convention and articles 13 and 26 of its Protocol on biomedical research.

standard of living to ensure the health and well-being of the person. Disclosure by private parties is more difficult to assess. It is not sufficiently captured by human rights protection and thus requires statutory regulation in domestic law.

iv) *The prohibition of discrimination based on genetic traits.* Throughout history, most of the major discriminatory practices in society and law were founded upon characteristics which are determined by genetic differences (in particular race and skin colour). The mapping of the human genome has revealed that 99.9% of the genetic structure is common and similar to all human beings.³⁴ Genetics thus disqualify any attempt to translate genetic differences into class and the existence of ‘superior’ and ‘inferior’ races. At the same time, contemporary and future genetic testing may provide room for new and serious forms of discrimination, *e.g.* in relation to life expectancy as applied to employment and insurance.³⁵ For such reasons, genetic discrimination is explicitly forbidden by Article 6 UDHR, Article 7 IDHGD, Article 11 UDBHR, Article 11 of the Oviedo Convention and Article 21 of the EU Charter on Fundamental Rights. The provisions are expressions of the well-established principle of racial non-discrimination, which is today crystallized as one of the strongholds of international human rights law, at the level of both treaty³⁶ and customary law. They are further discussed in section C below.

v) *The prohibition of human reproductive cloning:* There is agreement within the international community on an absolute repudiation and ban of human reproductive cloning.³⁷ Such reproduction is universally considered to be incompatible with the fundamental principle and right of human dignity. The situation is different for therapeutic cloning, *i.e.* the use of reproduced genetic material for purposes of healing. The legal analysis requires an evaluation within the wider context of research on human embryos. Any conclusion reached on this issue will depend on whether or not the human embryo is to be considered, as a matter of law, as a human being. In this respect, and at this stage, it is impossible to draw up any general rule in international law. There is an absolute lack of agreement on this issue in the context of the international scientific and legal community.³⁸

vi) *The prohibition of non-therapeutic eugenic practices:* with the development of biomedical research, eugenic practices (the selection of the genetic characteristics of people) have gained new impetus. Modern genetic techniques allow the prenatal selection of both physical and mental characteristics of an individual.³⁹ The technology offers potential benefits in terms of healthcare, allowing for the modification of defect genes directly in the embryo so as to remove an individual’s predisposition to a given genetic disease before his or her birth. Eugenic techniques, however, may also be used for the modification of certain physical characteristics of a person which are not related to health, *e.g.* skin colour, eye colour or height. If such gene manipulations were commonly practised, they could eventually lead to the development of serious discrimination against individuals who do not possess the ‘right’ properties.. For this reason, eugenic practices should only be considered lawful when performed to promote health or for the purpose of scientific research linked to healthcare and provided that the principles of consent – when applicable – and of information and confidentiality are fully respected. , Eugenic practices unrelated to the promotion of health should be prohibited, as they are incompatible with the principle and right to human dignity. The conclusion is consistent with the position adopted and expressed by the

³⁴ See High Commissioner’s Expert Group on Human Rights and Biotechnology, ‘Conclusions’, Geneva, 24–25 January 2002, available at <http://www.unhchr.ch/biotech/conclusions.htm> (last visited 11 June 2008), paragraph 26.

³⁵ See, more comprehensively on these issues, LENZERINI, F., *cit.*, note 3, 330.

³⁶ See *inter alia* Article 2 ICCPR, Article 14 ECHR and Article 1 ACHR. See also Article 7 UDHR.

³⁷ See, *e.g.*, Article 11 UDHR, letter (b) of UNDHCR (which calls upon UN Member States ‘to prohibit all forms of human cloning’), Article 1 paragraph 1 of the Protocol to the Oviedo Convention specifically dealing with human cloning (also extending the prohibition to ‘[a]ny intervention seeking to create a human being genetically identical to another human being, whether living or dead’) and Article 3 of the EU Charter on Fundamental Rights. For a more comprehensive essay concerning the legal and ethical problems arising from human cloning and the relevant practice see LENZERINI, F., *cit.*, note 3, 308.

³⁸ The lack of agreement referred to in the text was recently epitomized by the Grand Chamber of the European Court of Human Rights, which, on 7 March 2006, found that, any ‘consensus on the scientific and legal definition of the beginning of life’ is lacking (see *case Vo v France*, Application, No. 53924/00, judgment of 8 July 2004, paragraph 82); although the Court referred to the European context, its conclusion exactly reflects the situation existing today throughout the world.

³⁹ See also JANKOWSKI, D., *cit.* note 9, 29.

relevant international instruments.⁴⁰ The difficulty, of course, remains that it is sometimes difficult to identify the motive of intervention and to determine whether it is made for the sake of promoting health or merely for purposes of aesthetics. The grey area in this field is wide, and best relies upon an analysis case by case.

vii) *The prohibition on using the human body for economic profit*: the principle that the human body, or any part of it, must not be used for economic profit is expressly stated by the most pertinent legal instruments at the European level,⁴¹ as well as by Article 4 UDHGHR, as well as by the 1996 *Resolution of Bioethics* of the Organisation of African Unity.⁴² It should be noted, however, that the issue is very controversial in light of the claims to exclusive commercial use of inventions relating to body parts, combining it ‘with a technical process enabling it to be isolated or produced for an industrial application’.⁴³ In other words, although an element of the human body per se may not be appropriated in itself, it may be a part of a product which is patentable⁴⁴ and meets the criteria of novelty and inventive steps which biotechnology may establish. The principle that the human body may not be used for economic gain retains its practical significance with respect to practices unrelated to inventions and patentability issues. The transplantation of organs needs to be organised in a manner which deters the pursuit of profits both on the part of donors as well as hospitals. Illegal and widespread trade in body parts amounts to inhuman and degrading treatment.

viii) *The right to reparation for harm caused by biotechnology*: particularly relevant in the context of genetic testing, the award of damages for harm caused is conceived by the relevant instruments as a right ‘to just reparation for any damage sustained as a direct and determining result of an intervention affecting [one’s] genome’ or to ‘compensation for undue damage’.⁴⁵ The right to reparation for biotechnology-related harm is based upon the corresponding right provided in general terms for human rights breaches by the most relevant international instruments.⁴⁶ Compensation must be fair (or, to use the terminology of the UDHGHR, ‘just’), in the sense that it has to be proportional to the damage suffered and adequate to compensate the person(s) concerned – to the extent possible – for such damage.

C. Non-derogable Rights

Depending on the specific circumstances of specific cases, most of the rights and rules referred to in the previous paragraph are susceptible to derogation in exceptional circumstances for reasons of *ordre public*, national security or public health, as well as when required by an urgent need to preserve the health of the person(s) involved in the operation of genetic engineering. The possibility of derogating from these rights, however, is to be interpreted restrictively. Any derogation requires a strict preventive balance between the value infringed and the interest pursued. Such comparative evaluation has to be made on the basis of the principle of proportionality, requiring that three conditions are met: 1) the objective pursued must be legitimate; 2) the derogable measure taken must be appropriate to achieve such objective; 3) there must be no alternative means to achieve the same

⁴⁰ See, in particular, Article 2(b) UDHGHR, Articles 12, 13 and 14 of the Oviedo Convention and Article 3 of the EU Charter on Fundamental Rights (which generally prohibits ‘eugenic practices, in particular those aiming at the selection of persons’).

⁴¹ See, in particular, Article 21 of the Oviedo Convention, Article 21 of its Protocol concerning transplantation of human organs and tissues and Article 3 of the EU Charter on Fundamental Rights.

⁴² *Resolution of Bioethics*, available at <http://www.africa-union.org/root/au/Documents/Decisions/hog/6HoGAssembly1996.pdf> (last visited 11 June 2008) 47, 48 paragraph 3.

⁴³ See European Court of Justice, Case C-377/98 *Kingdom of the Netherlands v European Parliament and Council of the European Union*, Judgment of 9 October 2001, paragraph 72.

⁴⁴ *Id.* paragraph 73. This conclusion was implicitly confirmed by two US cases, Supreme Court of California, *John Moore v the Regents of the University of California*, 9 July 1990 and District Court of Florida, *Greenberg v Miami Children’s Hospital Research Institute, INC.*, 264 F. Supp. 2d 1064.

⁴⁵ See, for the first quotation, Article 8 UDHGHR, and, for the second, Article 24 of the Oviedo Convention, Article 25 of its Protocol on transplantation of human organs and tissues, and Article 31 of the Protocol to the same Convention concerning biomedical research.

⁴⁶ See, e.g., Article 2(3)(c) ICCPR and Article 14 of 1984 UN *Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment*, G.A. Res. 39/46 of 10 December 1984, available at <http://untreaty.un.org/English/TreatyEvent2001/pdf/07e.pdf> (last visited 11 June 2008).

objective which is less onerous in terms of human rights infringement. Only when these requirements are met may derogation be considered lawful. Importantly, some of the above principles, especially those relating to bioethics, may form part of the realm of non-derogable rights and must not be impaired even though requirements of proportionality may be met. They are part of core values which cannot be disposed even for purposes of public policy.⁴⁷ The standards pertinent to the present enquiry, which are characterized by being non-derogable, are, in particular, the freedom from inhuman and degrading treatment and the worst form of systematic discrimination, such as apartheid banned by jus cogens. Both of which, as shown in the previous paragraph, are relevant to many of the guarantees that must be respected in order to ensure that the use of biotechnology is consistent with the basic requirements of human dignity. No considerations of emergency, public utility or *raison d'état* may allow a State authority to lawfully derogate from these guarantees when they are related to non-derogable rights, as they reflect values representing the essential and indisputable cornerstone of any civil society.

The Committee is of the view that a ban on biological weapons appertains to the realm of non-derogable rights. No justification can be found whatsoever to introduce genetic manipulation as a weapon in war under the principle of human dignity. In addition, it must be stressed that biological warfare in general cannot be controlled upon dissemination and damage done is irreversible. It cannot be sustained even if admitted to an examination of proportionality in the context of defending vital interests of national security.

D. Procedural Aspects of Human Rights Law

Given the regulatory ambiguity and vagueness of normative guidance under human rights standards, it would seem important to stress procedural requirements in regulating genetic engineering.⁴⁸ Perhaps more than in substantive rules, it is here that emphasis should be placed in the context of pluralist societies. Procedural due process, entailing the right to be informed and heard before a determination is made, an obligation to argue and justify decisions in a rational and non-arbitrary manner, a right to appeal and judicial review provide essential elements based upon which procedures involving genetic engineering should be shaped. In addition, freedom of speech, freedom of the press, freedom of association and the right to obtain information from government (sunshine acts) are of paramount importance with a view to conducting an informed political debate on the subject. It will be necessary to examine to what extent all these guarantees, and possibly additional ones, generally emanating from constitutional and administrative law, also belong to the realm of international human rights protection. Chapter II will do so for the realm of agricultural policies.

E. Selected Issues: Discrimination on the Basis of Genetic Information

Among human rights related issues, discrimination based upon genetic discrimination perhaps amounts to the most important issue.⁴⁹ The matter is mainly dealt with by domestic law, and international law has not developed more specific criteria beyond the basic principles set forth above. It partly addresses the matter. Human Rights litigation could offer substantial guidance in the field, but no case law has developed on the international level to this point in time. The Committee suggest to these matters up in non-binding instruments to the extent that these inherently domestic affairs transgress human rights protection.

Diverging definitions of genetic discrimination can be found in international legal instruments.⁵⁰ One of the first proposals defined genetic discrimination as 'discrimination against an individual or against members of that

⁴⁷ The status of non-derogability of the most important human rights standards is declared by the main relevant international instruments, including ICCPR (Article 4.2), ECHR (Article 15.2) and ACHR (Article 27.2).

⁴⁸ See also COTTIER, Th., *Procedural Aspects of Human Rights relating to Biotechnology* in FRANCIONI, F., (ed.) *Biotechnologies and International Human Rights*, (2007 Oxford, Hart Publishing), 275–315.

⁴⁹ Section E of Chapter I of this Report is based upon a draft prepared by Iulia Motoc. See also WAGNER, C. Z., *Gender dimensions of biotechnology policy and trade* in WUEGER, D., and COTTIER Th., (eds), *Genetic Engineering and the World Trade System*, (World Trade Forum), (2008 Cambridge, University Press), 56-74.

⁵⁰ See *World Medical Association Declaration of Helsinki: Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects* (Declaration of Helsinki), adopted by the 18th World Medical Assembly, Helsinki, Finland, 1964 and as revised by the World Medical Assembly in Tokio, Japan in 1975, in Venice, Italy in 1983, and

individual's family solely because of real or perceived differences from the "normal" genome of that individual⁵¹ It distinguished it from 'discrimination based on disabilities caused by altered genes'. From this viewpoint, the criterion for genetic discrimination is whether or not a disease has actually developed. If the disease has not yet occurred, the discrimination is termed genetic. If the disease is expressed, it becomes another type of discrimination, most likely discrimination based on a person's status of health. One question prevalent in the literature is whether genetic discrimination is significantly dissimilar from discrimination on the basis of general health status.⁵² In the Committee's view, it is necessary to draw a clear distinction between the two indications for two reasons. First, discrimination based upon health is supported by the right to health and efforts to improve health conditions of persons. Second, it appears necessary from a utilitarian perspective, as it could help to reduce fear and thereby facilitate scientific research that contributes not only to the progress of knowledge but helps to relieve human suffering and improve the health of individuals and humanity as a whole. The distinction, however, is difficult to sustain in practical terms, as the examples of sexual discrimination, insurance policies and criminal investigation show. International law has not been able to address these issues properly and conclusively.

1. WOMEN AND CHILDREN

Women are particularly likely to suffer from genetic discrimination. In the context of biotechnology, it is mainly relating to new techniques of reproduction, mostly in terms of pre-natal selection. Genetic discrimination clearly distinguishes between prohibition of sexual selection for 'social reasons' (gender balance or the wish of the parents) and for medical reasons. Sexual selection for 'non-medical' reasons is clearly prohibited by Article 21 of the WHO Draft Guidelines for Bioethics,⁵³ Article 14 of the European Convention on Human Rights and Biomedicine,⁵⁴ and Article 68 of the Report of the International Bioethics Committee of the UNESCO on Pre-Implantation Genetic Diagnosis and Germ-Line Intervention.⁵⁵ The world, however, is far from uniform standards. E.g. the People's Republic of China implemented its 'Law on Maternal and Infant Health Care'.⁵⁶ The bill requires couples to undergo pre-natal testing. If the child is found to be disabled, it has to be aborted. If one of the partners suffers from a sexually transmitted disease or a mental illness, the couple cannot marry unless it agrees to use long-term contraception. If one accepts the argument that the birth of a 'defective' child should be prevented, then it is but a small step to accept the premise that giving birth to certain classes of 'defective' children should be equally prevented, not just for the benefit of the parents, but also for the benefit of society as a whole through the protection of the 'public welfare'. The lines are blurred. Indeed, law suits are being brought by parents who have relied on medical information and the mother has given birth to a child that she would not

in Hong Kong 1989, available at <http://www.fda.gov/oc/health/helsinki89.html> (last visited in April 2008); *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine* (European Convention on Human Rights and Biomedicine), April 4th 1997, available at <http://conventions.coe.int/treaty/en/treaties/html/164.htm> (last visited in April 2008); *Universal Declaration on the Human Genome and Human Rights* (UDHGHR), November 11th 1997, available at http://portal.unesco.org/en/ev.php-URL_ID=13177&URL_DO=DO_TOPIC&URL_SECTION=201.html (last visited in April 2008); *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, 2002, available at http://www.cioms.ch/frame_guidelines_nov_2002.htm (last visited in April 2008) *International Declaration on Human Genetic Data* (IDHGD), October 16th 2003, available at http://portal.unesco.org/en/ev.php-URL_ID=17720&URL_DO=DO_TOPIC&URL_SECTION=201.html (last visited in April 2008); *Universal Declaration on Bioethics and Human Rights* (UDBHR), October 19th 2005, available at http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html (last visited in April 2008).

⁵¹ BILLINGS, P. et al., *Discrimination as a Consequence of Genetic Testing*, 1992 Vol. 50, AJHG 476.

⁵² For an up-to-date review of the state of research in biotechnical applications see JANKOWSKI, D., *cit.* note 9.

⁵³ Article 21 of the WHO Draft Guidelines for Bioethics states: 'Sex is not a disease. Except for severe sex-linked genetic disorders, the use of genetic services for the purpose of sex-selection is not acceptable.'

⁵⁴ 'The use of techniques of medically assisted procreation shall not be allowed for the purpose of choosing a future child's sex, except when serious hereditary sex-related disease is to be avoided.'

⁵⁵ Destruction of embryos for non-medical reasons or termination of pregnancies because of the specific gender, are not 'counterbalanced' by avoiding later suffering from severe disease.' See also JANKOWSKI, D., *cit.* note 9, 37.

⁵⁶ Law of the People's Republic of China on Maternal and Infant Health Care, available at http://www.unescap.org/esid/psis/population/database/poplaws/law_china/ch_record006.htm (last visited 11 June 2008).

otherwise have carried to term if the parents had received the correct information.⁵⁷ Once testing is agreed to for whatever reason, the use of it is bound to spill-over in societal considerations, considered unlawful under existing international agreements.

Freedom of choice and non-directive genetic counselling is the lynch-pin of the argument that genetics does not essentially lead to eugenics. Freedom from outside coercion is equally an essential principle. It is also a fact that the ease with which pre-natal screening and abortion may be obtained is seen as very positive by many women, particularly in families where there is already a child with a genetic disorder.

2. INSURANCE AND EMPLOYMENT

To the extent that insurance schemes are based upon principles of collective, mandatory and social insurance, genetic risks do not seem to play an important role as they neither contribute to an increase in insurance rates, nor determine exclusion from the insurance system. It is only in the case of private life insurance policies, or insurance against injuries or disability that genetically based health risks may tip the balance to the detriment of the individual person concerned. The law seeks to protect consumers from inappropriate use of private information.⁵⁸ It may not sufficiently do so at this stage. At the federal level in the US, the existing protection against discriminatory use of genetic information in the workplace falls short of the comprehensive law needed to protect the rights of workers. In 2002 the Equal Employment Opportunity Commission (EEOC⁵⁹) filed a petition for a preliminary injunction against Burlington Northern Santa Fe Railroad, looking for an end to the practice of genetic testing of all employees who filed claims for work-related injuries based on carpal tunnel syndrome. Within days of the EEOC action, Burlington Northern agreed to stop requiring genetic testing of employees who filed claims for carpal tunnel syndrome.⁶⁰ A similar case occurred in Hong Kong where a court ruled in favour of three persons and awarded them compensation because they were refused employment on the ground that their parents suffered from schizophrenia.⁶¹ Even if there are only a few cases where discriminatory use of genetic information on the workplace was the main charge; they have been reported to the International Labour Organization (ILO). The subject remains to be addressed in international instruments. This also entails the issue to what extent this is a matter to be addressed under domestic regulation in the GATS of the WTO.

⁵⁷ In *Taylor v Kurapati*, 1999 600, N.W.2d 670, 691 (Mich. Ct. App.), the radiologists misread two ultrasounds and did not detect severe birth defects – a missing right shoulder, a fused elbow, missing fingers, a missing femur bone on the left leg and an abnormally short femur bone on the right leg. The parents sued, arguing that they would not have had the child if they had been aware of the birth defects. The court was extremely uncomfortable with the idea of recognizing a tort for wrongful birth – and ultimately did not – because, it posited, such a claim requires the ‘the unseemly spectacle of parents disparaging the value of their children or the degree of their affection for them in open court’. In other words, the court did not want to entertain a discussion of the relative worth of different children based on the presence of disability. The court's discomfort was so great that it did not allow recovery for damages. Thus, the Taylors, who may or may not have the resources to raise an unexpectedly disabled child, were left with no recourse. The court, obviously mindful of the cost it was imposing on unwitting families, still refused to recognize this cause of action. The constant back and forth and internal rhetorical question and answer in the opinion suggests that the court was wrestling with a eugenic legacy that, under very different circumstances, also made relative calculations of worth based on disability.

⁵⁸ In this respect article 23 of the IDHGD states: ‘Human genetic data, human proteomic data and biological samples linked to an identifiable person should not be disclosed or made accessible to third parties, in particular, employers, insurance companies, educational institutions and the family, except for an important public interest reason in cases restrictively provided for by domestic law consistent with the international law of human rights or where the prior, free, informed and express consent of the person concerned has been obtained provided that such consent is in accordance with domestic law and the international law of human rights. The privacy of an individual participating in a study using human genetic data, human proteomic data or biological samples should be protected and the data should be treated as confidential.’

⁵⁹ Equal Employment Opportunity Commission, www.eeoc.gov (last visited 11 June 2008).

⁶⁰ *EEOC v. Burlington Northern Santa Fe Railway Co.*, 2002 No. 02-C-0456, E.D. Wis.

⁶¹ See ILO Report *Equality at work: Tackling the challenges. Global Report under the follow-up to the ILO Declaration on Fundamental Principles and Rights at Work*. International Labor Conference, 96th Session 2007, Report I (B), 49.

3. CRIMINAL INVESTIGATION

Recourse to generic engineering in criminal procedures amounts to one of the most important implications for human rights protection. Art. 12 of the IDHGD states: 'When human genetic data or human proteomic data are collected for the purpose of forensic medicine or in civil, criminal and other legal proceedings, including parentage testing, the collection of biological samples, in-vivo or post-mortem, should be made only in accordance with domestic law consistent with the international law of human rights. International human rights protection therefore is supposed to offer guidance in the field. The matter has been largely left to domestic law.

DNA evidence raises several questions relating to the protection of genetic privacy. Human rights organizations have recognized the important role played by DNA evidence in criminal investigations, but remain opposed to the permanent retention of all DNA samples.⁶² In the US, federal legislation on criminal DNA data-banking was first passed in the 1994 Violent Crime Control and Law Enforcement Act, which authorized the FBI to establish a software system for sharing information contained in state DNA databases (the Combined DNA Identification System, or CODIS).⁶³ Obtaining consent from their source does not violate any US federal regulations. It is, nevertheless, inconsistent with the recommendations of several commentators as well as the American College of Medical Genetics.⁶⁴ One can furthermore question whether it is truly possible to anonymize tissue samples that have been collected for the controversial purpose of maintaining identifying information.⁶⁵ Defendants have challenged the constitutionality of DNA collection as an unreasonable search and seizure under the Fourth Amendment of the US Constitution.⁶⁶ Article 1c of the IDHGD stipulates an exception for criminal investigations mentioning at the same time that such exceptions have to respect human rights.

III. Proprietary Rights and Public Goods

A. The Impact of the International Patent System

This chapter assesses the impact of patents on biotechnology, and the role of international law to this effect.⁶⁷ It examines whether additional legal efforts at harmonization are required in the field as applied to biotechnology.⁶⁸ Designed to promote innovation by granting *negative* monopoly rights to inventors while at the same time publicly disclosing their contribution to the state of the art, the patent system is in essence designed to be applied to every new invention. It should be recalled that patents neither grant the right to exploit nor to *use* a patented invention. Neither are they as such part of the regulatory system of health and safety regulations. Nor do they necessarily allow certain research projects to be conducted.⁶⁹ Patents only grant the right to *prevent third*

⁶² See JANKOWSKI, D., *cit.* note 6, 47–48

⁶³ CODIS includes a Convicted Offender Index that stores the DNA profiles of people convicted for sex offences as well as other violent crimes, giving law enforcement agencies a powerful tool to identify repeat offenders and link together crime scenes. CODIS also contains a Forensic Index, which compiles DNA profiles developed from evidence left at crime scenes. Matches made in the Forensic Index can link crime scenes together and identify the possibility of a serial offender. Another feature of CODIS is its Population File, an anonymous database of DNA profiles of the general population that determines the statistical significance of a match. CODIS also includes a National DNA Index System (NDIS), which enables participating agencies to exchange and compare DNA profiles on a national level. Currently, all fifty states, as well as Puerto Rico and the United States Army, participate in NDIS.

⁶⁴ www.acmg.net (last visited 11 June 2008).

⁶⁵ See LEWIS, L. *The Role Genetic Information Plays in the Criminal Justice System*, 2005 Vol. 47, Arizona Law Review 519.

⁶⁶ Available at <http://caselaw.lp.findlaw.com/data/constitution/amendments.html> (last visited 11 June 2008).

⁶⁷ Section A of Chapter III of this Report is based upon a draft written by Michelangelo Temmerman.

⁶⁸ For a recent overview of what could be patentable in biotechnology see JANKOWSKI, D., *cit.* note 9, 4–7 and 61–65. See also *ibid.* 10, note 14 on the question of patentability of 'expressed sequence tags' (ESTs).

⁶⁹ *Cf.* research on human embryonic stem cells, human cloning, etc.

parties – not having the owner’s consent – from using the invention, thus triggering investment in research projects.

Patent laws are fairly abstract and need this feature for the proper, smooth functioning of the system. Since technologies develop very fast, especially in the field of biotechnology, enacting new technology-specific legislation every time again would substantially hold back the functioning of the patent system. Moreover, rapidly changing technologies mean that the patent rules cannot be too technical. Otherwise they would be rapidly outdated. The patent system normally adjusts to new technologies in a process of trial and error, and eventually is stabilised in case law.⁷⁰ In technologies attracting high investments, such as biotechnology,⁷¹ the main question is whether the cost of this evolutionary process might not be too high. For the purposes of this report we examine whether legislative action is needed.⁷²

International law plays a significant role in defining patentability of biotechnological products.⁷³ Both the WTO Agreement on Trade-Related Intellectual Property Rights, as well as regional instruments, such as the European Patent Convention set forth common provisions defining at least minimal standards to be respected in assessing the patentability of biotechnological inventions. Art. 27 of the TRIPs Agreement obliges Members to grant process and product patents in all fields of technology, including biotechnology, without discrimination. In genetic engineering, the minimum standard entails patents for invention for non-biological and microbiological processes. Members, however, are entitled to exclude inventions relating to animals and plants and essentially biological processes, provided that either a *sui generis* systems for the protection of plants or protection under the UPOV Convention is secured. The two options allow Members to link the protection of plant with policies of access and benefit sharing under the Convention on Biodiversity, or to model protection parallel to patent protection. The European Patent Convention, compared to the TRIPs Agreement, is more inclusive in Art. 53, as exemptions are limited to plant varieties and not plants in general. The distinction resulted in fairly expansive protection of plants to the extent that a particular invention is not assigned to the taxonomy of a particular plant variety.

In the field of biotechnology, patents are not limited to inventions in the tradition of mechanics. The identification of a particular and existing gene, and its use in a different context than naturally occurring, amounts to innovation and does not qualify as a discovery in nature. On the one hand, these findings are crucial in protecting core areas of research and thus investment in biotechnology. On the other hand, they potentially imply expansive protection which may duly limit third party research and use of naturally occurring genes. Overall, the application of patent law, originally designed for chemical and mechanical inventions, has resulted in extensive protection and thus enhanced monopolization in the field. At the same time, patents in biotechnology are often contentious, and litigation entails high costs. This is one of the reasons why research based companies tend to acquire interesting start up companies and patent claims which come along with the transaction. International law, to this point, does not limit Members to tolerate and even encourage such developments. The TRIPs Agreement is conceived as a minimum standard. It does not prevent Members from adopting more extensive protection than called for by international law.

Although the international patent system continues to operate on the principle of territoriality, the impact of international law is likely to be stronger here than in other regulatory field relating to biotechnology. The respective minimum standards make sure that inventions can be protected one way or the other in other jurisdictions and thus market access cannot be impaired for products based upon the respective invention. It is controversial to what extent additional harmonization is required in the field of genetic engineering.

⁷⁰ In biotechnology, however, due to the rapidity of developments in this field, the state of the art is said to remain hard to catch and changing fast: GRUBB, P., *Patents for Chemicals, Pharmaceuticals and Biotechnology*, (1999 Oxford, Oxford University Press) 226.

⁷¹ For instance: ERNST & YOUNG, *Swiss Biotech Report 2006*, (2006 Urnäsch, Säntisprint AG).

⁷² MERRILL, S., LEVIN, R. and MYERS, M. (eds.), *A patent System for the 21st Century*, (2004 Washington, the National Academies Press) 3.

⁷³ For a detailed account see VAN OVERWALLE, G., *Biotechnology and patents: global standards, European approaches and national accents* in WUEGER, D., and COTTIER Th., (eds.), *Genetic Engineering and the World Trade System*, (World Trade Forum), (2008 Cambridge, University Press), 77-108; OPOKU AWAKU, E., *Intellectual Property rights, biotechnology and development: African perspectives* in *ibid.*, 109-117.

B. Harmonization in International Law

Patents are intrinsically linked to trade and investment. Therefore, firstly, international harmonization of patent rules is generally advisable – at least among developed countries – in order to further the establishment of equal conditions for trade as well as to enhance the creation of a ‘level playing field’ and thereby also to ensure the legal security and predictability necessary to encourage investment. A lack of stable and predictable conditions for patenting, particularly in the industry very sensitive to investment protection, amounts to a disincentive to investment, and hence also to innovation.

1. BIOETHICAL CONSIDERATIONS

It would seem that harmonisation may be the best response to the bioethical challenges encountered in the field. However, given the limited nature of patents, the utilitarian nature of the system and the difficulties in finding an *international* ethical standard upon which to base international legal actions, the need for such an effort seems unclear. A common basis of perception could be sought in human rights; yet the concrete assessment of human rights in patent law as in other fields discussed above reveals the issue to be problematic. Human rights arguments in relation to patent law tend to cut both ways and may not be best suited to regulating such a complex, technical area as patent law on their own.⁷⁴ Certain issues such as prior informed consent of human donors of genetic material might nonetheless be found necessary in respecting the human right to privacy or even in certain interpretations of the concept of human dignity; yet the practicalities of obtaining such a prior informed consent, and the utilitarian arguments must be balanced with these human rights arguments.⁷⁵ A human-dignity approach as well as a general need for clarification to the public might however support an explicit exclusion of the human body from financial gain and patentability; along with a clarification that patent law only applies to isolated human substances and never to the human body as such.

2. THE QUEST FOR TAILOR-MADE SOLUTIONS

Secondly, it is not simply a matter of expanding protection, but to render it tailor-made with a view to bring about positive effects on innovation and research. Members of the WTO thus enjoy the choice to use the patent system, develop sui generis systems or participate in the UPOV system in protecting biotechnology as applied to plants and plant varieties. Related to this is the issue of scope of protection and rights granted to right holders. In this respect, the “theory of the anti-commons” is relevant. Indeed, specifically in relation to biotechnology, many patents achieve scopes of protection which are larger than in other fields of technology. This is rooted in the application of established principles of the patent system by granting absolute compound protection to a technology. In the case of biotechnology, these principles result in generally broad claims covering a large number of potential applications.⁷⁶ Given the high number of patents granted in this field,⁷⁷ and their concentration in the hands of small groups of enterprises in certain areas, the way they are used/licensed, and the increasingly stronger enforcement of patents in general, legal scholars argue that research is likely to be hampered and the technologies underused. This theory however, lacks strong empirical evidence and may be

⁷⁴ See COTTIER, Th., *Genetic Engineering, Trade and Human Rights* in FRANCONI, F., *Biotechnology and International Law*, (2006 Oxford, Hart Publishing) 285.

⁷⁵ See TEMMERMAN, M., *Human Rights in the Patent Procedure: The Issue of Prior Informed Consent of Human Donors to the Patenting of Inventions Based upon their Genetic material*, 2007 Bern, NCCR Trade Regulation Working Paper, No. 2007/36, available at www.nccr-trade.org and <http://www.ssrn.com> (to be published in ‘Consent and the Law’; edited by the Institute of Chartered Financial Analysts of India).

⁷⁶ In most countries, genes are treated by patent law identically to, for example, a cogwheel or any other invention (and mostly in practice are patented like chemical substances). Using the cogwheel in a new context would not exceed the scope of the original patent claim because this will have been granted absolute protection: to every function even those not yet discovered (every device having such a cog without the patent-holder’s authorization would be infringing the patent). When applied to biotechnology, this results in a broader scope of protection since the interest in gene sequences is entirely focused on their function and since gene sequences can moreover qualify for many more than one function.

⁷⁷ On the increased number of patents per R&D Dollar in the US, see MERRILL, S., LEVIN, R., MYERS, M. (eds.), *A Patent System for the 21st Century*, (2004 Washington, National Academies Press) 28.

rooted in the way patents were granted in the past.⁷⁸ While patents are a prerequisite to secure market access, they inherently impede trade by temporarily granting exclusive monopoly rights. These effects are inherent to the patent system and peculiar to biotechnology patents. An unjustifiably broad scope of patents, however, may distort the balance between the advantages and disadvantages of the system. It may excessively hinder access to inventions and hence the access of new players to the market. The scope of patents in biotechnology therefore is an issue of relevance to international trade regulation and needs to be examined on the basis of empirical studies which are still outstanding. An assessment is required whether rules limiting the scope of protection, such as the research exemption, or a limitation to specific purposes (purpose bound protection)⁷⁹ or similar provisions should be introduced in a mandatory manner in international law. Alternatively, the matter may be taken up by domestic competition laws. Curtailing overly broad patent monopolies is not merely a matter of rearranging patent law, but also of competition law. Concentration of patents in certain specific areas of biotechnology, in the hands of only a few patent holders, raises questions of potential abuses of dominant positions. It begs the question whether these conditions should be harmonised in WTO law, either within an agreement on competition or in amending the TRIPs Agreement.⁸⁰

3. REGIONAL DEVELOPMENTS AND GRADUATION

Thirdly, the debate on harmonization needs to address the desirability of international harmonization as compared to regional harmonization. Improving the situation may be less a matter of harmonizing the rules on patenting of biotechnology, than one of harmonizing general patent law. In the EU, it is suggested to introduce a Union wide unitary patent – in particular in the field of genetic engineering.⁸¹ In relation to developing countries the theory of graduation might reveal itself to be particularly useful in order to take into account evolving levels of social and economic development in shaping the obligations in the field of biotechnology patents.⁸² Also, the question arises whether exceptions, such as the research exemption, implemented at the international level, would favour developing countries in their access to technologies and development and hence are also, or especially, needed from this perspective. Regional harmonization might be more realistic from a practical point of view: attitudes towards and needs for patenting biotechnology might vary considerably according to local sensitivities and diverging public opinions. In relation to developing countries in a broader context, attention should be given to the eventual adaptation of the TRIPS Agreement to favour international technology transfer in a more effective way than is done today. This would also involve the further scrutiny and establishment of a legal framework for public–private partnerships.⁸³

⁷⁸ Contesting the theory of anti-commons: CAULFIELD, T., COOK-DEEGAN, R., KIEFF, F. and WALSH, J.P., *Evidence and anecdotes: an analysis of human gene patenting controversies*, September 2006 Vol. 9 (24), *Nature Biotechnology* 1091; See also for further empirical research VERBEURE, B., MATHIJS, G., and VAN OVERWALLE, G., *Analysing DNA Patents in Relation with Diagnostic Testing*, 2006 Vol. 14, *European Journal of Human Genetics* 26.

⁷⁹ Implementing purpose bound protection would clarify the dependency situation; its potential effects on investments and research remain unclear however. (See BOSTIJS, S., *Patenting DNA sequences (polynucleotides) and scope of Protection in the European Union: an Evaluation*, Background Study for the European Commission, 2004 Office for Official Publication of the European Communities, 63.)

⁸⁰ The issue is also bound to the effective establishment and use of existing domestic rules. We might recall in this context the action of the European Commission in 2005, when Astra Zeneca was fined 60 million euros for misusing the patent system to delay the entry of rivals to its ulcer drug Losec. See EUROPEAN COMMISSION, *Competition: Commission fines AstraZeneca €60 million for misusing patent system to delay market entry of competing generic drugs*, 15 June 2005 Press release, IP/05/737.

⁸¹ European Commission and Council, *Development and Implications of Patent Law in the Field of Biotechnology and Genetic Engineering*, 2002 COM, 545, 7.

⁸² See COTTIER, Th., *From Progressive Liberalisation to Progressive Regulation in WTO Law*, 2006 Vol. 9 (4), *Journal of international Economic Law* 779–821.

⁸³ See KARAPINAR, B. and TEMMERMAN, M., *Benefiting from Biotechnology: Pro-poor IPRs and Public-Private Partnerships*, 2007 Bern, NCCR Trade Regulation Working Paper 2007/35, available at <http://www.ssrn.com> and www.nccr-trade.org (to be published in the 'Biotechnology Law Report').

4. PRACTICAL CONCERNATION

Finally, it should be noted that harmonizing patent law is not only a matter of creating new and additional provisions in international law, as one of cooperation between judicial authorities and harmonization of patent examiner's guidelines. In Europe, for instance, most countries have drafted research exemptions⁸⁴ in their domestic patent laws that were based upon the wording of the draft Community Patent Convention; but diverging jurisprudential interpretations led them to evolve in totally different directions.

C. Flanking Measures – Sui Generis Rights

This section looks at how a balance can be found between the system of intellectual property rights to biotechnological invention and the recognition of prior art in access to the genetic resources (GR) and related traditional knowledge (TK) in the areas of agricultural and pharmaceutical grassroots innovation and breeding.⁸⁵ In the legal order regarding genetic resources, technological changes brought about the strengthening of intellectual property rights. This development is continuing with the industrialized countries pursuing enhanced standards for patenting life forms.⁸⁶ In this context, insight into the value of GRs has increased. Questions of ownership of naturally existing resources, as well as of property rights and prior art regarding transformed resources have gained importance. From the point of view of intellectual property rights, the latter types of innovation are in the public domain and freely accessible. Yet it is argued that the relationship between industrial research and development or breeding processes and traditional informal innovation needs to be defined in such a manner that all contributions are respected and obtain adequate rewards, firstly for reasons of equity, but secondly in order to create incentives for the maintenance of the biological diversity inherent in these systems. In order to create a level playing field, the specific needs of the developing countries are to be taken into account: the rights to prior art need to be strengthened. To achieve this, the fundamental balance between private goods and public goods should be reviewed. This also concerns the impact of patents on biological material on the means of access to and exchange of materials in traditional breeding processes. In several instances these needs have been answered by proposing parallel rights intended to protect the results of traditional innovation: firstly, the farmers' rights, as an answer to the plant breeders' rights; and secondly the rights to TK, to clarify the origin of information generated in traditional ways by local and indigenous peoples. Likewise, the Convention on Biological Diversity (CBD), with its system of access and benefit sharing (ABS), endeavours to create some control over access to GR and TK, albeit only in a contractual setting. Yet these systems and rights are not really operational and/or effective, and solutions for their concretisation need further scholarly attention and deliberation.

1. ACCESS TO GENETIC RESOURCES AND BENEFIT SHARING

The system of ABS⁸⁷ of the CBD endeavours to balance the rights and duties for providers and users of genetic resources⁸⁸ and traditional knowledge.⁸⁹ Yet its implementation is proving to be complex. ABS has a contractual

⁸⁴ In general, one could say that the research exemption is allowing the use of a patented invention without the patent-holder's authorization and without financial contribution; in as far as this use is conducted for research or for experimental purposes. (See Cottier Th., DOLOTBAEVA, A., JUSOH, S., and TEMMERMAN, M., *The Research Exemption in Patent Law: Issues of Harmonization, Fostering Research and Competition*, NCCR Trade Regulation, forthcoming).

⁸⁵ Section C of Chapter III is based upon a draft written by Susette Biber-Klemm. See also LENZERINI, F., *Traditional knowledge, biogenetic resources, genetic engineering and intellectual property rights* in WUEGER, D., and COTTIER Th., (eds.), *Genetic Engineering and the World Trade System*, (*World Trade Forum*), (2008 Cambridge, University Press), 118-148.

⁸⁶ For instance in bilateral TRIPS-plus agreements, requiring adherence to UPOV 1992 and the abrogation of the farmer's privilege that exempts harvested seeds from the breeder's rights.

⁸⁷ ABS: 'the fair and equitable sharing of the benefits resulting out of the utilization of genetic resources' (Art. 1 CBD).

⁸⁸ The obligation of the providers to create conditions to facilitate access to genetic resources is matched by the obligation of the users to take measures to assure the sharing of benefits arising from the use of the genetic resources (see Article 15.7 CBD).

basis. It provides no property rights to the holders of genetic resources. This, together with the specific features of trade in genetic resources, has led to the difficulties with which the Contracting Parties to the CBD are struggling. Contentious issues in relation to the topic are: the definition of the subject matter and clarity about the scope of application; control of the use made of the genetic resources and related TK, and more efficient devices for the implementation of the system.

Firstly, regarding the *subject matter* and *scope* of the ABS system, there are open questions as to the interpretation of terms and some specific resources to be included. Many key terms of the CBD remain contentious.⁹⁰ In particular with regard to the scope of the term ‘genetic resources’ one of the controversial issues is whether access to the so-called ‘derivatives’⁹¹ is also to be integrated into the ABS system. As regards the types of resources to be included, at present two questions arise. The question of the implications of the ABS system for access to animal genetic resources, particularly to domesticated breeds, has up to now not been dealt with.⁹² Furthermore, as the access and benefit sharing regime of the CBD is not applicable to marine genetic resources in *the High Seas* beyond national jurisdiction,⁹³ the question of access to these resources is largely open and in need of scientific assessment.⁹⁴

Secondly, with regard to the *control* over use made of genetic resources and TK, two concepts are at the forefront of the debates: a) the certificate of origin;⁹⁵ and b) the disclosure in the patent procedures. The *certificate of origin* is meant to serve as a tracing mechanism to ensure transparency in the flow of such resources. Yet, various stakeholder groups fear that such a system complicates the procedures; that it is not cost-efficient, and is technically difficult for developing countries to implement. The question is whether there are parallels and possible synergies (in methodology) with the Material Transfer Agreement developed in the framework of the Multilateral System of the International Treaty for Plant Genetic Resources for Food and Agriculture (ITPGRFA).⁹⁶ The *disclosure of origin* is – within the ‘implementing issues’ of the Doha negotiations – discussed in the TRIPS Council. There is broad consensus about the necessity of such a system. Nonetheless, diverging opinions between developing countries and industrialised countries exist regarding the appropriate treaty regime, the scope of the disclosure,⁹⁷ the trigger for the disclosure, and consequences of non-compliance. We argue that the TRIPS Agreement is the appropriate forum.⁹⁸ Yet it must also be taken into

⁸⁹ The inclusion of the ‘traditional knowledge of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity’ into the ABS system has been strengthened by the ‘Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization’ (Bonn Guidelines, COP Decision VI/24, 2002). See BIBER-KLEMM, S. in BIBER-KLEMM, S. and COTTIER, Th., (eds.) *Rights to Plant Genetic Resources and Traditional Knowledge: Basic Issues and Perspectives*. (2006 CABI Wallingford UK and Cambridge USA), 290/1.

⁹⁰ Such as: ‘access’, ‘genetic resources’, ‘utilization’ and ‘traditional knowledge’.

⁹¹ The term is not clearly defined and applied with different meanings. It is considered to encompass a) material that is later bred, cultivated or otherwise generated through some multiplication process in the user country; b) meta-extracts, fractions or essences obtained from a plant, animal or other sample; and c) a product or commodity created in utilizing the genetic resource (See TVEDT, M. W. et al., *Legal Aspects of Exchange, Use and Conservation of Farm Animal Genetic Resources* FNI Report 1/2007, 74.

⁹² This is in contrast to the plant genetic resources for food and agriculture (PGRFA) where a lot of conceptual work has been done.

⁹³ An exception could be States who regulate bio prospecting by their nationals according to the CBD, LEARY (2005), quoted from GREEN, J. *Bioprospecting in the High Seas*, in FAO (2005) Report on DEEP SEA 2003, *An International Conference on Governance and Management of DEEP-SEA Fisheries Queenstown, New Zealand*, 1–5 December 2003.

⁹⁴ Questions include: Is a regulation analogous to the CBD necessary? What would be the rationale? What would be the legal status of genetic resources of the high seas? Is a clear delimitation of high-sea resources possible? In which legal regime could an ABS system be integrated, and how?

⁹⁵ Certificate of origin/source/legal provenance.

⁹⁶ Available at <http://www.planttreaty.org/> (last visited 11 June 2008).

⁹⁷ Declaration of source/origin or proof of prior informed consent, benefit sharing.

⁹⁸ There are various arguments to this end: first, the TRIPS Agreement owes a duty to developing countries. Then the TRIPS Agreement is obliged to address the relationship to the CBD under the Doha Declaration; and within the framework

account that there is a significant number of ‘traditional’ products in the life-style, wellness and food additive sector that make use of TK but which are not patented. Even if the raw material for these products does not fall under the ABS system, the associated TK clearly does. There are no data available about this market and as yet no suggestions as to options for control were made.

Thirdly, regarding the *implementation* of the ABS system, it is recommended that the issue of registration of the information and instruments to assure the sharing of benefits should be further explored. *Documentation of TK* is discussed in its defensive function to prove prior art in the patenting processes, or in the context of positive legal protection, either by existing intellectual property rights; new *sui generis* rights to TK or the use of contractual rights. There is very little evidence of documentation and databases used as instruments to further trade.⁹⁹ Such a proactive function of documentation would be facilitated if the information was protected by clearly allocated and enforceable rights. Such a system could be supported by institutional devices, such as clearing houses or societies analogous to collector’s societies.¹⁰⁰ The sharing of benefits resulting from the use of GRs and TK is based on a purely contractual relationship between the ABS parties. More stringent solutions ought to be evaluated, in particular at the interface with technology transfer, such as: voluntary licensing,¹⁰¹ the option of compulsory licensing for products resulting from the accessed information; or the pooling of patents, joint ownership of rights and creation of joint ventures. Further research on this issue, is needed.¹⁰²

Fourthly, as regards the legal protection of TK, we propose to further assess the development of specific *sui-generis* intellectual property rights (traditional intellectual property rights; TIP-Rights¹⁰³). Art. 10bis of the Paris Convention, forming part of the WTO TRIPs Agreement, offers a foundation in place on unfair competition rules. Even if that provision, in principle, is sufficient to prevent so-called bio-piracy, a specific *sui-generis* right would clarify conditions and rights, including their potential registration.¹⁰⁴ TIP-rights serve as an improved basis for access and benefit sharing. As the rights to TK are related to intellectual property protection, we suggest integrating these rights into a reform of the WTO intellectual property disciplines. They offer the opportunity to rebalance the TRIPs Agreement in light of the medium-to-long-term need to enhance patent and plant variety protection.

2.ACCESS TO PLANT VARIETIES AND ANIMAL BREEDS

The situation regarding access to plant varieties and animal breeds and the relevant property rights is rather fragmented and unclear. As to *plant varieties*, the rights of breeders to their (industrially bred) plant varieties are regulated by the UPOV Convention; in addition, or alternatively, patenting of novel varieties is possible if the relevant requirements are fulfilled. Landraces, as bred by farmers do not fall under UPOV protection, because they do not fulfil the DUS (distinctness, uniformity, stability) requirements. Consequently, they are in the public

of the WTO an integrated, coordinated approach to issues regarding conservation and sustainable use of GR and TK is possible. This is relevant for the negotiating process, where trade-offs with other than intellectual property rights and a balanced package of rights and obligations can be envisaged. Furthermore, the TRIPs Agreement offers a broad coverage of Members, and disputes arising fall under the jurisdiction of the WTO dispute settlement mechanisms.

⁹⁹ But see the Indian National Innovation Foundation, cited in BIBER-KLEMM, S. et al., *Flanking Policies in National and International Law*, in BIBER-KLEMM, S. and COTTIER, Th., (eds.) *cit.*, note 119, 260.

¹⁰⁰ See BIBER- KLEMM, S. et al., *Flanking Policies in National and International Law* in BIBER-KLEMM, S. and COTTIER, Th., (eds.) *cit.*, note 119, 239 ff.

¹⁰¹ As a moral obligation, included in criteria for ‘good governance’ of industrial companies.

¹⁰² *A priori* it is put forward that patent pooling, joint ownership of rights and joint ventures are a means to avoid negotiations on licences. All instruments, in particular patent pooling, request equal capacities of both partners (with a view to contribution of information to invention; to negotiation capacity; financial, production capacity); its appropriateness for many TK-holders must therefore, at least at present, be questioned. In theory the pooling of rights to TK and industrial patents in order to create a joint venture is possible. Further open questions concern the relationship to competition law if an exclusive licence on TK is granted.

¹⁰³ See COTTIER, Th., and PANIZZON, M., *A New Generation of IPR for the Protection of Traditional Knowledge in PGR for Food, Agricultural and Pharmaceutical Uses* in BIBER-KLEMM, S. and COTTIER, Th. (eds.), *cit.*, note 119, 203 ff.

¹⁰⁴ The examination of novelty; inventive step and the utilisation of the principles of fair competition in Article 10bis of the Paris Convention should in principle be sufficient to prevent the so-called piracy of (at least) TK.

domain. Regarding the ABS system, the issues concerning plant genetic resources for food and agriculture, and the implementation of farmers' rights were delegated to the FAO's Global System on Plant Genetic Resources, by the assembly concluding the CBD¹⁰⁵ and later laid down in the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). The ITPGRFA has established the so-called Multilateral System for Facilitated Access. This system is operational for plant varieties listed in an annex to the International Treaty and features a standardised Material Transfer Agreement thereby replacing individually negotiated contracts. The varieties not listed in the annex in principle fall under the CBD's ABS procedures. Yet, it is far from clear how this system is to be implemented, in particular as regards the *in-situ* collection of farmer's varieties. In particular, the implementation of the benefit sharing with regard to small farmers needs further thought as the farmers' rights, as regulated in Article 9 of the ITPGRFA do not include any (property) right of farmers to their varieties.¹⁰⁶ Regarding animal breeds, the question of rights as well as the relevance and implications of the ABS regime has not so far been systematically approached, although there are calls by stakeholders' groups for an International Treaty on Animal Genetic Resources, Animal Breeders' Rights and for Livestock Keepers' Rights.

Considered from the perspectives of equitable recognition of prior art, and of the creation of incentives for smallholders for conservation of genetic diversity, it is recommended to examine on the one hand options to strengthen the position of farmers and small breeders, and on the other to assess the impact of intellectual property rights for animal and plant breeding on access to genetic resources by smallholders. Firstly, in order to strengthen the rights of farmers in the framework of the ITPGRFA, mechanisms to facilitate access to the Multilateral System for smallholders ought to be created, as well as specific criteria for the allocation of funds. Secondly, with regard to the rights of farmers to their breeds, it will be necessary to examine whether the DSU criteria in the UPOV system could be partly adapted and relaxed to allow protection of improved farmer's varieties that result from controlled on-farm breeding processes. Third, the impact of biotechnology patents for innovation in the area of plant and animal breeding need to be assessed, as well as the effects of TRIPS-plus treaties on the farmer's privilege. Fourthly, regarding animal genetic resources, by analogy to the investigations on plants and plant breeding, the basic processes in animal breeding and the instruments used to protect animal breeds should be further investigated, and the interface with biotechnological methods analysed. On this basis, possible solutions for defining animal breeders' rights and livestock keepers' rights can be assessed and the ABS system of the CBD tested for its application on animal genetic resources for food and agriculture.

IV. Market Access and International Trade Regulation

A. GATT, SPS and TBT Agreements

The current international trading system, including the 1993 Uruguay Round results, was essentially designed before biotechnology took centre stage in world trade.¹⁰⁷ Yet, the general rules that govern international trade in goods apply equally to trade in biotech products. We focus here on the applicability of the GATT, SPS and TBT Agreements¹⁰⁸ on trade in biotech products. The implications of the TRIPS Agreement were already dealt with in Chapter III.

¹⁰⁵ By resolution 3 of the Final Act to the CBD.

¹⁰⁶ See also BIBER-KLEMM, S., CULLET, Ph. and KUMMER-PEIRY, K., *New Collective Policies in BIBER-KLEMM, S. and COTTIER, Th., (eds.) cit.*, note 119, 283. Within the Multilateral System, the main benefit is deemed to be the access to the multilateral system. Furthermore, a funding system is planned but seems not yet to be operational. Here the question is how small farmers' access to these benefits can be fostered, in order to create incentives for the conservation of landraces.

¹⁰⁷ Section A(1). of Chapter IV is based upon a joint draft by Der-Chin Horng and Bernard O'Connor.

¹⁰⁸ For a general description of the disciplines of these Agreements see COTTIER, Th., *The Challenge of WTO law: Collected Essays*, (2007 London, Cameron May); BYTTEBIER, K., *WTO Obligations and Opportunities: Challenges of Implementation*, (2007 London, Cameron May); MATSUSHITA, M., SCHOENBAUM, T.J. and MAVROIDIS, P., *The World Trade Organization: Law, Practice and Policy*, (2006 Oxford, Oxford University Press); COTTIER Th. and OESCH, M. *International Trade Regulation: Law and Policy in the WTO, the European Union and Switzerland*, (2005 Bern &

1. THE GATT AGREEMENT

Biotechnology and biotech trade involve ethical, legal, social, economic, political and scientific complexity.¹⁰⁹ Various scientific and regulatory debates on biotech issues at both the national and international levels have taken place over the past few years during which it has been generally recognized that biotech products pose potential threats to human health and the environment. In this context, the question arises whether biotech products may be treated as 'like' or 'equivalent' to conventional products. If biotech products are considered 'like' with respect to conventional ones, then there is no reason to adopt any different treatment regimes for them, such as mandatory authorization and identification schemes. In other words, the principle of non-discrimination, contained in related GATT/WTO provisions should be applied.¹¹⁰ For a product to be considered a 'like product', the GATT will first consider which domestic product(s) it can be compared to. In GATT/WTO practice, some criteria have been suggested for determining, on a case-by-case basis, whether a product is like or similar: (1) the product's properties, nature and quality; (2) the product's end-uses in a given market; (3) consumers' tastes and habits, which vary from country to country; and (4) the product's tariff classification.¹¹¹ In the context of trade in biotech products, the debate on 'likeness' between biotech products and conventional products concentrates on Article III (4) of the GATT¹¹² and involves the question whether process and production methods (PPMs) should be taken into account in the determination of 'like products'.

Another important issue concerning biotechnology is the possible justification of trade restrictions set out in GATT Article XX (GATT Article XX (b) on health considerations and GATT Article XX (g) on biodiversity conservation). Article XX GATT gives countries the legal means to balance their trade obligations with important non-trade objectives, such as health protection or the preservation of the environment, which form part of their overall national policies.¹¹³ In order to comply with Article XX, the measures at issue 'must not be applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade'.¹¹⁴ Given that Article XX is an exception to the general rule, panels and the Appellate Body have tended to interpret Article XX very restrictively.¹¹⁵ But at the same time, the exceptions relating to the health or biodiversity considerations have been given a relatively broad interpretation.¹¹⁶ In the *EC-Asbestos* case, the Appellate Body held that where there is a scientifically proven risk to health 'WTO Members have the right to determine the level of protection

London, Staempfli Publishers and Cameron May); JACKSON, J., *The World Trading System, Law and Policy of International Economic Relations*, (1997 Cambridge, Massachusetts, Cambridge and London, MIT Press).

¹⁰⁹ The *General Agreement on Tariffs and Trade* (GATT 1947), available at <http://www.worldtradelaw.net/uragreements/gatt.pdf> (last visited 11 June 2008).

¹¹⁰ Including articles I, III, XIII, XIX GATT; Article II, X, XVII GATS; Article 2.1 TBT and Article 2.3 SPS.

¹¹¹ GATT, *Report of the Working Party on Border Tax Adjustments*, adopted on 2 December 1970, 1972 BISD 18S/97, 102; *Japan - Customs Duties, Taxes and Labelling Practices on Imported Wines and Alcoholic Beverages*, adopted on 10 November 1987, 1988 BISD 34S/83, 115-117, as confirmed by the WTO Appellate Body report, *Japan - Taxes on Alcoholic Beverages* (Japan - Alcoholic Beverages), November 1st 1996, /DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R, p.113.

¹¹² The first sentence of Article III (4) GATT states as follows: 'The Products of the territory of any contracting party imported into the territory of any other contracting party shall be accorded treatment no less favourable than that accorded to like products of national origin in respect of all laws, regulations and requirements affecting their internal sale, offering for sale, purchase, transportation, distribution or use.'

¹¹³ See WTO Appellate Body Report, *United States-Import Prohibition of Certain Shrimp and Shrimp Products* (Shrimp - Turtle), October 12th 1998, WT/DS58/AB/R, paragraphs 156; available at <http://www.worldtradelaw.net/dsc/Searchmain/SearchReportsHP.asp> (last visited 11 June 2008).

¹¹⁴ See the chapeau of GATT Article XX.

¹¹⁵ See *Shrimp - Turtle*, *cit.*, note 113, paragraph 127.

¹¹⁶ The wider interpretation relates especially to GATT Article XX (g) since under this provision, a national measure has to be 'relating to' conservation of natural resources. Under Article XX (b), the measure has to be 'necessary' to protect human, animal or plant life or health - this condition has been given a more restrictive interpretation by the panel and Appellate Body. See WTO Appellate Body Report, *European Communities - Measures Affecting Asbestos and Asbestos - Containing Products* (EC - Asbestos), March 12th 2001, WT/DS135/AB/R, paragraph 172; available at <http://www.worldtradelaw.net/dsc/Searchmain/SearchReportsHP.asp> (last visited 11 June 2008).

of health that they consider appropriate'.¹¹⁷ Therefore, Article XX (b) GATT could be successfully invoked if there was proof of the negative impact of biotech products on human health or biodiversity.¹¹⁸

2. THE SPS AGREEMENT

The SPS Agreement¹¹⁹ aims at allowing Members to protect human, animal and plant health at whatever level is considered appropriate, while at the same time seeking to minimize the negative effects these standards may have on market access.¹²⁰ Regulations based on a scientific risk assessment of the actual or potential risk of biotech products can be compatible with the SPS Agreement.¹²¹ Where the science is uncertain, Article 5.7 SPS permits the provisional adoption of precautionary measures on the basis of available pertinent information. The relevant provisions of the SPS Agreement have been analysed by the WTO panel and Appellate Body in several disputes. In *EC – Hormones*, the Appellate Body agreed with the finding of the Panel that the precautionary principle did not override the provisions of Articles 5.1 and 5.2 of the SPS Agreement.¹²² The risk evaluated in a risk assessment must thus be an ascertainable risk; theoretical uncertainty cannot be assessed under Article 5.1.¹²³ In *Japan – Agricultural Products II*, the Appellate Body identified four requirements imposed upon a Member having recourse to Article 5.7. The Appellate Body added that these four requirements are cumulative in nature. It was established that a WTO Member may provisionally adopt an SPS measure if this measure is: (1) imposed in respect of a situation where relevant scientific evidence is insufficient; and (2) adopted on the basis of available pertinent information. Such a measure may not be maintained unless the Member that adopted it: (3) seeks to obtain the additional information necessary for a more objective assessment of risk; and (4) reviews the measure accordingly within a reasonable period of time.¹²⁴ In the recent *EC – Biotech* case it was also the SPS Agreement on which the complaining parties primarily based their charges. The Panel stated that Article 5.7 'should be characterized as a right in relation to Article 5.1, rather than as an exception from a "general obligation" under Article 5.1'.¹²⁵ This has important consequences for the allocation of the burden of proof when a complaining party presents a claim of violation under Article 5.1. Thus, the burden is on the complaining party to establish a *prima facie* case of inconsistency with both Article 5.1 and Article 5.7 of the SPS Agreement.¹²⁶ The Panel finally rejected the EC's claim that the measures of EC Member States prohibiting the use of biotech products could be justified as precautionary measures. The Panel argued that sufficient scientific evidence was available to carry out an adequate risk assessment.

¹¹⁷ See *EC – Asbestos, cit.*, previous note, paragraph 168.

¹¹⁸ The parties in *EC – Biotech* did not rely on Article XX (g) GATT; See WTO Panel Reports, *European Communities – Measures Affecting the Approval and Marketing of Biotech Products* (EC – Biotech), September 29th 2006, WT/DS291, 292, 293/R, available at <http://www.worldtradelaw.net/dsc/Searchmain/SearchReportsHP.asp> (last visited 11 June 2008).

¹¹⁹ Agreement on the Application of Sanitary and Phytosanitary Measures (SPS), available at http://www.wto.org/english/docs_e/legal_e/15-sps.pdf (last visited 11 June 2008).

¹²⁰ See Article 2 SPS.

¹²¹ See Article 5.1 SPS.

¹²² See WTO Appellate Body Report, *EC Measures Concerning Meat and Meat Products* (EC – Hormones), January 16th 1998, WT/DS26, 48/AB/R, paragraphs 123–125, available at <http://www.worldtradelaw.net/dsc/Searchmain/SearchReportsHP.asp> (last visited 11 June 2008). The case concerned a ban imposed by the EC on bovine meat and meat products from cattle treated with growth hormones.

¹²³ See *EC – Hormones, cit.* in the previous note, paragraphs 123–125.

¹²⁴ See WTO Appellate Body Report, *Japan – Measures Affecting Agricultural Products* (Japan – Agricultural Products II), 22 February 1999, WT/DS76/AB/R, paragraph 89. Available at <http://www.worldtradelaw.net/dsc/Searchmain/SearchReportsHP.asp> (last visited 11 June 2008).

¹²⁵ See *EC – Biotech, cit.*, note 118, paragraph 7.2997.

¹²⁶ *Ibid.* paragraphs 7.3000-3001.

3. THE TBT AGREEMENT

Like the GATT, the TBT Agreement¹²⁷ states that trade restrictive measures should not discriminate between imported products and like products of domestic or foreign origin. If biotech products are considered to be like products in relation to non-biotech products, there are no grounds for applying any more burdensome treatment to them. In this respect, the view generally held in the trade community is that the TBT Agreement was not intended to apply to PPMs, unless the PPM is product-related (detectable in the final product).¹²⁸ Furthermore, in relation to labelling and documentation requirements related to food, nutrition, quality and packaging, biotech regulations can be subject to the TBT Agreement. The TBT Agreement is applicable to ‘technical regulations’ ‘standards’, and ‘conformity assessment procedures’ applicable to such technical regulations and standards.¹²⁹ The Agreement seeks to achieve a fine balance between permitting Members the regulatory autonomy necessary to protect legitimate interests (through the use of technical regulations, standards and conformity assessment procedures) and ensuring that such technical regulations, standards and conformity assessment procedures do not become unnecessary obstacles to international trade.¹³⁰ While SPS measures may be imposed only to the extent necessary to protect human, animal or plant health from food-borne risks or from pests or diseases, WTO Members may enact TBT regulations when necessary to meet a number of legitimate objectives. A non-exclusive list of objectives is given by Article 2.2 of the TBT Agreement and includes the prevention of deceptive practices, the protection of human health or safety, animal or plant life or health, or the environment.

4. DEVELOPING COUNTRIES AND BIOTECHNOLOGY RISK ANALYSIS

In its 2006 Draft Report,¹³¹ the ILA Committee on Biotechnology recognized two basic positions regarding the application of special and differential treatment (S&D) to developing countries in the SPS/TBT area.¹³² The first position stresses that developed countries cannot be forced to relax their safety standards because of S&D considerations and that there should not be a trade-off between safety and development. The second position stresses that the participation of developing countries in international standard-setting institutions should be enhanced. Research pursued in the meantime now provides legal proposals to converge the two positions. The new proposals combine arguments based on the concept of graduation¹³³ which considers safety issues as special cases, with the doctrine of risk analysis.¹³⁴

¹²⁷ Agreement on the Application of Sanitary and Phytosanitary Measures (SPS), available at http://www.wto.org/english/docs_e/legal_e/15-sps.pdf (last visited 11 June 2008).

¹²⁸ However, Members have notified certain non-product-related (NPR)-PPMs to the TBT Committee. This has been the case, for example, for eco-labelling schemes based on a life-cycle analysis.

¹²⁹ These terms are each defined in Annex 1 of the Agreement.

¹³⁰ See Dispute Settlement, World Trade Organization, Module 3.10, *Technical Barriers to Trade*, 4, available at http://www.unctad.org/en/docs/edmmisc232add22_en.pdf (last visited 11 June 2008).

¹³¹ International Law Association, 2006 Toronto Conference, *International Law on Biotechnology*. Available at <http://www.ila-hq.org/pdf/Biotechnology/Draft%20Report%202006.pdf> (last visited 11 June 2008).

¹³² Section A (4) of Chapter IV is based upon a draft prepared by Mr. Michael Burkard.

¹³³ COTTIER, Th., *From Progressive Liberalisation to Progressive Regulation in WTO Law* in 2006 Vol. 4 (9), *Journal of International Economic Law* 779–821.

¹³⁴ According to the doctrine of risk analysis, risk assessment is a science-based process, whereas risk management is the process of weighing policy alternatives. According to this doctrine, there should be a functional separation between the assessment and the management of risks. In the food safety context, the risk assessment at the international level is performed by bodies of scientific experts, namely the Joint FAO/WHO Expert Committee on Food Additives (JECFA), the Joint FAO/WHO Expert Meetings on Pesticide Residues (JMPR), and the Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment (JEMRA). By contrast, risk management is performed by the Codex Alimentarius Commission (CAC) and its subsidiary bodies. Risk communication, as the third component of risk analysis, is defined as the dialogue among all stakeholders (Procedural Manual of the Codex Alimentarius Commission, 16th Edition, Section I, *Definitions for the Purpose of the Codex Alimentarius*. FAO, Rome).

a) The New Role of the SPS Agreement for Biotechnology after EC – Biotech

The Panel in the *EC – Biotech* case clarified that the SPS Agreement is not only decisive for products derived from biotechnology applications in foods but also for related environmental concerns.¹³⁵ The rapid and deep penetration of biotech applications not only in plant breeding but also increasingly in animal breeding indicates the need for a re-evaluation of the SPS Agreement in light of the panel's broad interpretation of the scope of the SPS Agreement in the *EC – Biotech* case. The focus is on the risk assessment provisions of the SPS Agreement and whether they are appropriate to address the particular food safety and biosafety issues of biotechnology applications in agricultural products. Closely related is the case of insufficient scientific evidence regarding biotechnology applications in agriculture and related environmental concerns. In this regard, the appropriateness of existing provisional measures (article 5.7 SPS) is discussed, in light of the lack of an explicit risk management provision in the SPS Agreement.

b) Biotechnology Risk Assessment

Biotechnology risk assessments are a complex task. Specific factors distinguishing biotechnology risk assessments from ordinary risk assessments¹³⁶ include scientific uncertainty, undisclosed confidential business information¹³⁷ and scarce public funding for independent research activities in the area of biotechnology applications. The distinctive feature of biotechnology risk assessment becomes most apparent when considering the situation of developing countries in general and least-developed countries (LDCs) in particular. How can we assume that developing countries and LDCs could overcome the threshold of article 5.1 SPS considering risks deriving from the application of biotechnology in agriculture when developed countries have problems with providing even ordinary risk assessments?¹³⁸ Member States of the European Communities (EC) failed to deliver risk evaluations which were considered as proper risk assessments in the sense of Article 5.1 of the SPS Agreement by the panel in the *EC – Biotech* case.¹³⁹ If even the national governments of developed countries are

¹³⁵ *EC – Biotech, cit.*, note 118, paragraphs 7.197 et seq. Under the subtitle 'Protection of the environment', the Panel subsumed environmental concerns under Annex A(1)(a) and A(1)(d) of the SPS Agreement (*EC – Biotech*, paragraphs 7.212 et seq.; paragraphs 7.363 et seq.), food safety concerns in the narrower sense under Annex A(1)(b) of the SPS Agreement (*EC – Biotech*, paragraphs 7.287 et seq.), and health concerns under Annex A(1)(c) of the SPS Agreement. Furthermore, the Panel also subsumed the EC labelling regime, aimed at identifying biotech products, under the scope of Annex A of the SPS Agreement (*EC – Biotech*, Panel Report, paragraphs 7.381 et seq.). In the same way, the Panel subsumed the EC requirements regarding consumer information, as far as dangers to consumers were concerned, under Annex A of the SPS Agreement (*EC – Biotech*, paragraphs 7.394 et seq.).

¹³⁶ The fact that ordinary risk assessments are already a very complex issue was highlighted by a workshop on the question: *Food Safety Risk Assessment at the International Level: Do Existing Mechanisms Ensure Unbiased Outcomes?*, held at the World Trade Institute in Berne, Switzerland, on 3 October 2007. See <http://www.nccr-trade.org/ip-9-past/workshop-food-safety-risk-assessment--do-existing-mechanisms-ensure-unbiased-outcomes-.html> (last visited 11 June 2008).

¹³⁷ Considering the lack of scientific data in cases where new technologies have been applied to agriculture, biotechnology applications can be compared to the application of growth hormones which was similarly inventive at that time. The Appellate Body in the *Hormones* case found with regard to the hormone melengestrol acetate (MGA) that there was 'an almost complete absence of evidence on MGA in the panel proceedings' because the United States and Canada 'declined to submit any assessment on MGA upon the ground that the material they were aware of was proprietary and confidential in nature' (*EC – Hormones, cit.*, note 155, paragraph 201). However, the Appellate Body dismissed the claim of the European Communities (EC) that the Panel had erred in law by not requesting undisclosed scientific evidence from Canada and the United States by pointing to Article 11 of the Dispute Settlement Understanding (DSU), concluding that 'we see nothing in Article 11 to suggest that there is an obligation on the Panel to gather data relating to MGA and that it was therefore required to request the submission of this data' (*EC – Hormones, cit.*, note XX, paragraph 136).

¹³⁸ In fact, the threshold of article 5.1 SPS with respect to scientific rigour and resource implications can be demonstrated by an analysis of SPS cases decided so far. The analysis reveals that in none of the SPS cases was a risk evaluation carried out at the national level accepted as a proper risk assessment in the sense of Article 5.1 SPS (*Salmon, Agricultural Products*). Only risk evaluations carried out at the regional or at the international level were accepted as proper risk assessments (*Hormones, Biotech*).

¹³⁹ The Panel in *EC – Biotech* accepted as proper risk assessments only risk evaluations which were conducted at the regional level, *i.e.*, by the leading competent authority (CA) of the EC Member State to which the product applications were originally submitted and by the EC scientific committees (EC Scientific Committee on Plants (SCP), EC Scientific Committee on Food (SCF), EC Scientific Committee for Pesticides (SCPE), and EC Scientific Committee on Animal Nutrition (SCAN)). In contrast, the Panel refused to accept the various documents produced at the national level, *i.e.*, by

unable to carry out proper risk assessments in the sense of article 5.1 SPS in general, this is all the more so for biotechnology risk assessments and the specific constraints of developing countries and LDCs with regard to scientific capacity and resources.

As an indication of the complexity of biotechnology risk assessments, the challenges the Panel faced in the *Biotech case* are of relevance. The Panel considered the volume of the materials to be considered as ‘quite simply, enormous’.¹⁴⁰ In consequence, it is postulated that developing countries and LDCs on the one hand and developed countries on the other hand should have equitable access to biotechnology risk assessment tools. But, as the analysis of SPS case law demonstrates, the requirement for equitable access to operable biotechnology risk assessments cannot be met at the national levels for the reasons outlined above. Therefore, it is proposed that risk assessments, especially for complex and new risks, *e.g.*, risks deriving from the application of biotechnology, should be administered at the international level. A risk assessment body at the international level should be created, accessible to risk managers from developed countries as well as from developing countries and LDCs. It would enable in particular the latter, to overcome the threshold of article 5.1 SPS.¹⁴¹ In conclusion, it is recommended that article 5.1 SPS shall be reformulated,¹⁴² thus shifting the burden of (biotechnology) risk assessment from developing countries and LDCs to international organizations. The concept of graduation is not considered suitable for food safety issues, except for procedural and administrative matters.¹⁴³ Nevertheless, the proposal at hand offers a tool for mitigating structural imbalances between the scientific capacities of developed countries, and those of developing countries and LDCs.

c) Biotechnology Risk Management

If it is acknowledged that relevant risk assessment procedures should be re-assigned at the international level, then article 5.7 of the SPS Agreement must also be re-considered. Initially, it must be clarified that the determination of the appropriate level of sanitary or phytosanitary protection in article 5 SPS in general and article 5.7 SPS in particular would fall under the definition of risk management, if the doctrine of risk analysis had been applied to the SPS Agreement at the time of its drafting. Considering the complexity of risk assessments in general and biotechnology risk assessments in particular, the obstacles when invoking article 5.7 SPS, in a case where relevant scientific evidence is insufficient, become obvious. Therefore, it is proposed that the reference to international organizations in article 5.7 SPS should be reinforced. It is recommended that in the second sentence of article 5.7 SPS, WTO Members and especially developing countries and LDCs can rely on additional information provided by the relevant international organizations instead of being urged to provide the additional scientific data themselves.

individual EC Member States, as proper risk assessments (*e.g.*, the Reasons Documents, the Hoppichler Study, the Hilbeck study, the BEC reports, etc.).

¹⁴⁰ *EC – Biotech, cit.*, note 118, paragraph 7.39.

¹⁴¹ Of course, a legal response by amending the SPS provision on risk assessment only covers one aspect of the problem. The legal remedy has to be accompanied by capacity-building and structural reforms to enable risk assessment bodies at the international level to respond to the demand, especially from developing countries and LDCs, for complex risk assessments in general and biotechnology risk assessments in particular. In an evaluation report on activities of Codex Alimentarius, it was noted that ‘at present poorer countries and, to a lesser extent, those with limited importance for trade, have too little involvement and influence. Many countries outside of North America, Australasia and the European Union feel that it is difficult to make their voices heard in Codex’ (TRAILL, B., et al. *Report of the Evaluation of the Codex Alimentarius and other FAO and WHO Food Standard Work*; chapter 4.4.3.8. 2002 FAO, Rome).

¹⁴² The proposed wording was discussed at the workshop on food safety risk assessment at the international level (see *supra* note 191) and is particularly inspired by the comments of Philippe Verger, MD, PhD, head of the research unit Met@risk of the National Institute for Agricultural Research (INRA), Paris.

¹⁴³ COTTIER, Th., *From Progressive Liberalisation to Progressive Regulation in WTO Law* in 2006 Vol. 9 (4), *Journal of International Economic Law* 800–801.

B. The Subsidy Agreements

With the advent of biotechnology in the field of energy, subsidies no longer are essentially limited to agricultural biotechnology, but extend to biofuels. The respective agreements of the WTO therefore are of accrued importance to the field.¹⁴⁴

1. INDUSTRIAL SUBSIDIES

The specific WTO agreement governing industrial subsidies to the industrial sector is the Agreement on Subsidies and Countervailing Measures (ASCM).¹⁴⁵ All subsidies granted to industrial goods are covered by the disciplines of this agreement, whereas for agricultural subsidies, sector-specific subsidy disciplines are contained in the Agreement on Agriculture (AoA). Since Annex I of the AoA excludes fish and fish products from its coverage,¹⁴⁶ government subsidies on the application of biotechnology in industrial as well as marine and aquatic processes are covered by the ASCM. Under the ASCM, two types of subsidies are prohibited: export subsidies or subsidies 'contingent' on export performance (Article 3.1 (a)); and import-substitution subsidies or subsidies 'contingent' upon the use of domestic over imported products (Article 3.1 (b)). Other types of subsidies are actionable under the ASCM and can be successfully challenged only if they are 'specific' within the meaning of the ASCM Article 2¹⁴⁷ and their adverse effects on trade are demonstrated according to Chapter III of the Agreement. In short, subsidies which are widely available throughout a country (general subsidies) or which do not distort trade are not banned by the WTO.

There is an expired category of 'non-actionable subsidies' in the ASCM. Article 8 of the ASCM provides some exemptions for certain environmental, research and development (R&D) as well as regional (disadvantaged regions) subsidies. From a legal viewpoint all these subsidies are currently actionable according to the ASCM if proved to be 'specific'. This is because this so called 'green-light category' was provisionally applicable for five years and was not extended by Members after its expiration according to Article 31.¹⁴⁸ Therefore if a subsidy programme of a WTO Member for biotech research has a trade-distortive effect (if for instance it has a depressive effect on prices), the subsidies could be countervailed or a request made for them to be withdrawn through the WTO dispute settlement system.

2. AGRICULTURAL SUBSIDIES

The Agreement on Agriculture (AoA) covers all biotech products classified under the Harmonized System (HS) Chapters 1 to 24 (except for fish and fish products) as defined by Annex 1 of the Agreement. Hence the AoA applies to the biotechnology for agricultural applications, including production of and trade in GM crops. The AoA disciplines consist of market access commitments and subsidy disciplines including the disciplines on domestic support. Domestic support measures are usually classified into three broad categories which are often referred to as boxes. These are: amber box support which is considered highly trade-distortive and subject to reduction commitments during the implementation period (1995–2000); blue box support which is subject to production-limiting conditions but currently exempt from reduction commitments; and green box support which is deemed not trade-distortive (or only minimally so) and thus subject to no discipline.¹⁴⁹ If the Doha Round negotiations conclude successfully, it may be expected that amber box subsidies will be subject to further cuts.

¹⁴⁴ Section A.2 of Chapter IV of this Report was written by Mr. Sadeq Z. Bigdeli.

¹⁴⁵ Also Articles VI and XVI of the 1994 *General Agreement on Tariffs and Trade* (GATT), *cit.*, note 140, contain subsidy disciplines which are cumulatively applicable.

¹⁴⁶ See BIGDELI, S, BARACOL, D., and DUGAL, M., *The WTO Law of Subsidies Relevant to Fisheries – Possible WTO DSB Challenge on 'access fees' as 'subsidies' under ASCM*, Commonwealth Secretariat, forthcoming.

¹⁴⁷ A subsidy is specific if it is granted to 'certain enterprises', *i.e.* to an enterprise or industry or group of enterprises or industries within the jurisdiction of the granting authority (See Article 2.1 ASCM).

¹⁴⁸ See BIGDELI, S., *Incentive schemes to promote renewables and the WTO law of subsidies*, Cambridge University Press, forthcoming. For more on suggestions on the way forward see KIM, H.-J., *Reflections on the Green Light Subsidy for Environmental Purposes*, 1999 Vol. 33 (3), *Journal of World Trade* 167–175.

¹⁴⁹ See DESTA, M.G., *The Law of International Trade in Agriculture, From GATT 1947 to the WTO Agreement on Agriculture* (2002 The Hague, Kluwer Law International), 394.

This would include all subsidies granted to farm production and any other subsidy which has a distortive effect on trade or production in the agriculture sector. In order for biotech subsidies not to be affected by the amber box disciplines, the exemptions in Annex 2 of the Agreement or the green box exemptions may be sought as follows.

Annex 2 of the AoA in its paragraph 1 sets two general conditions for green box subsidies: first, the support should be through a publicly-funded government programme not involving transfers from consumers. Second, the support in question shall not have the effect of providing price support to producers. In addition to these broad conditions which apply across the board to all green box measures, there are specific rules, envisaged in paragraphs 2–12, applicable to particular policies seeking green box exemptions under Annex 1. It appears that any subsidy granted to green biotech products which have a production or trade distortive effect would not fulfil the green box criteria. Only the subsidies granted for R&D (for instance relating to research on a certain GM crop) may qualify as green box measures as part of government service programmes (paragraph 1 chapeau and subparagraph (a) of Annex 2). This is subject to a precondition that they do not involve direct payments to producers and processors. Hence Annex 2 basically provides exemptions for crucial government spending for R&D in the field of biotechnology. This includes for example research projects being undertaken by some biotech firms aiming at turning cellulosic materials into transport fuels, which are expected to offer more environmental benefits than biofuels produced from food crops such as corn or sugarcane while having less impact on food prices.¹⁵⁰

Before 2004 all green box measures were immune from challenges under the general subsidy disciplines of the ASCM. According to Article 13 of the AoA, known as the ‘Peace Clause’, Members were to apply due restraint in challenging the subsidies which were consistent with the provisions of the AoA. Since the expiry of the Peace Clause in January 2004, there has been legal uncertainty as to whether this should continue to be the case. The general understanding is that since green box measures are supposed to be non-trade distortive (or only minimally so) they hardly pose any trade problem to be challenged under the ASCM.¹⁵¹ This is particularly so because the ASCM only disciplines the trade-distortive effects of subsidies and no more. Thus the measures that fully conform to the provisions of Annex 2, such as R&D support as mentioned above, are not likely to give rise to any trade dispute. But in the absence of any per se exemption for R&D support with the expiration of non-actionable subsidies, in principle they remain challengeable under general disciplines.¹⁵²

3. BIOTECHNOLOGY FOR BIOFUELS

Amidst the doubts raised as to the degree to which traditional biofuels contribute to safeguarding the environment¹⁵³ and about their impact on food security,¹⁵⁴ the so-called second generation of biofuels still seems to be a promising development in a global shift towards low carbon economies. Biofuel produced from traditional crops uses first-generation technology while the second-generation biofuels utilize crops specifically grown for fuel.¹⁵⁵ For example the cellulosic parts of crops may be converted into sugar and then fermented and

¹⁵⁰ See e.g. SCHUBERT, C., *Can biofuels finally take centre stage?*, July 2006 Vol. 24, Nature Biotechnology 7, available at <http://www.unb.br/ib/cel/microbiologia/bm/06.pdf> (last visited 11 June 2008). See also LYND, L.R. et al., *How biotech can transform biofuels*, 2008 Nature Publishing Group. For recent policy developments, see EurActiv, *Biofuels, the Second Generation*, available at <http://www.euractiv.com/en/energy/biofuels-generation/article-165951> (last visited 11 June 2008).

¹⁵¹ See CHAMBOVEY, D. *How the Expiry of Peace Clause (Article 13 of the WTO Agreement on Agriculture) Might Alter Disciplines on Agricultural Subsidies in the WTO Framework*, 2002, Journal of World Trade 305–310, 36.

¹⁵² See BIGDELI et al. *cit.*, note 146. This view is supported by STEINBERG, R. H. and JOSLING, T. E., *When the Peace Ends: The Vulnerability of US Agricultural Subsidies to WTO Legal Challenge*, 2003 Vol. 6, J. Int'l Econ. L. 369. See also HALVERSON – CROSS, K., *King Cotton, Developing Countries and the ‘Peace Clause’: The WTO's US Cotton Subsidies Decision*, 2006 Vol. 9, J. Int'l. Econ. L. 149.

¹⁵³ KOJIMA, M., MITCHELL, D. and WARD, W., *Renewable Energy; Considering Trade Politics for Liquid Biofuels*, Energy Sector Management Assistance Program (ESMAP), 2007 The World Bank Group, available at http://siteresources.worldbank.org/INTOGMC/Resources/Considering_trade_policies_for_liquid_biofuels.pdf (last visited 11 June 2008).

¹⁵⁴ See KAHN - RIBEIRO, S. et al. *Transport and its infrastructure* in METZ, B., DAVIDON, O.R., BOSCH, P.R., DAVE, R., and MEYER, L.A. (eds.), *Climate Change 2007: Mitigation; Contribution of Working Group III to the Fourth Assessment Report of the Intergovernmental Panel on Climate Change*, (2007 Cambridge, Cambridge University Press) 344.

¹⁵⁵ *Biofuels: Promises and Constraints*, IPC Discussion Paper December 2006.

processed to produce ethanol. Biotechnology is playing an important role in making this process more economically viable.¹⁵⁶ Currently a number of biotech firms are involved in different R&D activities striving to develop new technologies in the field.¹⁵⁷ In the midst of the controversy surrounding biofuels produced from foodstuff as regards the effect on food prices, biofuels produced from 'second-generation feed stock' could emerge as a tool for combating climate change. Moreover, because the land used for food crop production is not replaced for the production of biofuels feedstock, which is the case when using the cellulosic materials, second-generation technology will relax the upward pressure of biofuels on food prices.

The classification of biofuels has an important impact on determining the rules applicable to them and on import tariffs applied to them at borders. It is moreover a decisive element in determining how the WTO negotiations on market access will lead to liberalization of biofuels markets. In the HS,¹⁵⁸ bio diesel, as one of the two important biofuels, is classified under Chapter 38 and is clearly defined with specific reference, in the World Customs Organization (WCO) Explanatory Notes, to its composition, production process and end-use as a fuel for diesel engines.¹⁵⁹ Yet it is argued that this definition may not cover bio diesel produced with the second-generation technology.¹⁶⁰ The current classification of bio-ethanol is more problematic. Ethanol as a biofuel is not specifically referred to in the HS system. This leaves ethanol to be classified merely according to its chemical composition making it subject to a more general categorization as undenatured (HS 220710) or denatured alcohol (HS 220720).¹⁶¹ The classification of ethanol under Chapter 22 would make the rules of the AoA applicable to this biofuel in addition to the general rules of the ACSM.¹⁶² It is also proposed that biofuels should be classified as environmental goods and their related services as environmental services in order for them to benefit from the ongoing negotiations at the WTO on environmental goods and services liberalization.¹⁶³ This proposal was met with much criticism.

C. The Relationship of WTO law to MEAs

Biotechnology increasingly empowers humankind to redefine biological processes, offering the opportunity to use this newly acquired knowledge for the benefit and wellbeing of all.¹⁶⁴ Hence, it has to be considered that this emerging 'biotechnical revolution' is accompanied by various challenges of ethics and risk control both for human health and nature. On the international level, on the one hand, these fields are covered by Multilateral Environmental Agreements (MEAs), which build their judicial content upon a precautionary approach and which are discussed in Chapter V below. On the other hand, WTO trade law is deemed to focus on the abolition of trade barriers and the combating of protectionism and unjustified discrimination. Therefore, there is a potential

¹⁵⁶ See LYND, L.R., et al., *cit.* note 150. For recent policy developments see EurActiv, *Biofuels, the Second Generation*. Available at <http://www.euractiv.com/en/energy/biofuels-generation/article-165951> (last visited 11 June 2008).

¹⁵⁷ For instance see *Advanced Biofuels, Ethanol, Schmethanol*, *The Economist* 29 Sept. – 5 Oct. 2007, 80.

¹⁵⁸ Officially known as 'Harmonized Commodity Description and Coding System' available at http://www.wcoomd.org/home_wco_topics_hsoverviewboxes_hskonvention_hsnomenclaturetable2007.htm (last visited 11 June 2008).

¹⁵⁹ At the 35th Session of the WCO in March 2005, biodiesel was reclassified under 3824.90 described as 'a mixture of mono-alkyl esters of long chain fatty acids derived from vegetable oils or animal fats, which is a domestic renewable fuel for diesel engines and which meets the specifications of ASTM D 6751. It can also be used as a fuel additive.'

¹⁶⁰ MOTAAL, D.A., *The Biofuels Landscape: Is there is Role for the WTO?*, 2008 Vol. 42 (1), *Journal of World Trade* 77.

¹⁶¹ According to UNCTAD, both types of ethanol are used for production of biofuels, but the report states that undenatured ethanol is more suitable for use as a fuel. See ZARRILLI, S., *The Emerging Biofuels Market: Regulatory, Trade and Development Implications*, (2006 Geneva, UNCTAD). According to the US Environmental Protection Agency 'ethanol produced for use as motor vehicle fuel is denatured specifically so that it can only be used as fuel'. See Regulation of Fuels and Fuel Additives: Renewable Fuel Standard Program, Environmental Protection Agency available at <http://www.epa.gov/EPA-AIR/2006/September/Day-22/a7887a.htm> (last visited 11 June 2008).

¹⁶² BIGDELI, S., *Incentive Schemes to Promote Renewables and the WTO Law of Subsidies*, World Trade Forum 2007, (2008 NCCR Trade Regulation, forthcoming).

¹⁶³ Submission by Brazil, 2005 TN/TE/W/59.

¹⁶⁴ Section C Chapter IV of this Report is based upon a draft written by Mr. Fitzgerald Temmerman.

for conflict between trade law and MEAs, especially in the field of biotechnology. Most of the public debate centres on the compatibility of the Cartagena Protocol with the SPS Agreement.¹⁶⁵ We look here at the issue from the point of view of WTO law and jurisprudence and thus place the section prior to dealing with environmental law.

Firstly, it remains unclear which information can be used as the basis upon which environmental measures can be taken. The SPS Agreement requires that any measure must be based on scientific evidence that a risk exists. However, in the absence of full scientific proof, precautionary measures are allowed as long as they do not constitute an arbitrary or unjustifiable discrimination or protectionist trade restriction.¹⁶⁶ On the other hand, the general objective of the Cartagena Protocol, namely ‘the conservation and sustainable use of biodiversity’ is built upon the precautionary approach as stated in Article 15 of the Rio Declaration, which is far less restrictive.¹⁶⁷ In general, MEAs focus on the precautionary approach when it comes to risk assessment. National risk assessment, particularly in the field of biotechnology, could thus give rise to high levels of protection under the application of an MEA, which presupposes a potential for conflicts with international trade law. In this context, it needs to be determined how general international law rules on interpretation can be used to create a workable interface between trade law and MEAs. Also, the WTO dispute settlement system finds itself confronted with the question of the extent to which taking inspiration from the provisions of the Cartagena Protocol as such is legally possible when it comes to the settlement of disputes in the field of trade in GMOs. Furthermore, in the field of biotechnology, process and production methods (PPMs) are at the heart of the matter. However, at present, the use of different PPMs is not part of the criteria for determining ‘like products’.¹⁶⁸ Thus, a genetically modified product and the same non-genetically modified product fall under the definition of a ‘like product’ that should not be discriminated between.¹⁶⁹ When a different production method is used however, a different impact on health and the environment is possible.

First it should be recalled that WTO jurisdiction confirms that WTO trade law cannot stand ‘hostile and isolated in front of public international law’.¹⁷⁰ In line with this rule, the SPS Agreement can indeed be interpreted in a flexible way. Article 3.3 SPS states that each member has the right to install a higher level of protection than that prescribed by the international standard. In the *Hormones* case, the Appellate Body reaffirmed that the precautionary principle is reflected in Article 5.7 SPS¹⁷¹ and recognized that WTO Members do not have to provide strict equality in levels of protection adopted under different measures.¹⁷² Thus, a wide margin of appreciation is granted to the national level, allowing for the possibility of taking into account social, ethical and environmental factors in their risk assessment.¹⁷³ Also Article XX (b) of the GATT could be successfully

¹⁶⁵ See International Law Association, 2006 Toronto Conference, *International Law on Biotechnology*, 7; available at <http://www.ila-hq.org/pdf/Biotechnology/Draft%20Report%202006.pdf> (last visited 11 June 2008).

¹⁶⁶ Preamble of the SPS Agreement, *cit.*, note 151, paragraph 1; Article 5.7 SPS; See also for the criteria of application of Article 5.7 SPS Japan – Measures Affecting Agricultural Products, *cit.*, note 157, paragraph 80.

¹⁶⁷ Cf. Chapter III above. Article 1 Cartagena Protocol. Article 15 Rio Declaration on Environment and Development (Rio Declaration), available at <http://www.unep.org/Documents/Multilingual/Default.asp?DocumentID=78&ArticleID=1163> (last visited 11 June 2008) which indicates that ‘[i]n order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation’.

¹⁶⁸ See *EC – Asbestos*, *cit.*, note 116, paragraphs 99–103.

¹⁶⁹ See Section A 1. of Chapter IV, *GATT, SPS and TBT Agreements*, *supra* 25.

¹⁷⁰ See WTO Appellate Body Report, *United States – Standards for reformulated and conventional Gasoline* (US – Gasoline), 20 May 1996, WT/DS2/AB/R, 17, available at [http://www.worldtradelaw.net/reports/wtoab/us-gasoline\(ab\).pdf](http://www.worldtradelaw.net/reports/wtoab/us-gasoline(ab).pdf) (last visited 11 June 2008).

¹⁷¹ *EC – Hormones*, *cit.*, note 155, paragraph 124. See on the issue and content of precaution PERREZ, F.X., *Risk Regulation, Precaution and Trade* in COTTIER, Th., and WÜGER, D. (eds.), *Genetic Engineering and the World Trade System*, (World Trade Forum), (2008 Cambridge, University Press), 252–260 and 280–283. See UNEP 2002, *Precaution from Rio to Johannesburg: Proceedings of a Geneva Environment Network Roundtable*, 37–44, available at www.environmenthouse.ch/index.php?page=publications (last visited 11 June 2008).

¹⁷² *EC – Hormones*, *cit.*, note 155, paragraph 213.

¹⁷³ See more particularly, on the need to take into account non-scientific aspects and effects of agricultural biotechnology in risk assessment, Chapter II of this Report, *Good Governance and Agricultural biotechnology*, *supra* 12.

invoked, if there was proof of any negative impact of biotech products on human health or biodiversity.¹⁷⁴ Furthermore, the possibility should not be excluded that GMO regulations could fall under the provision of article XX (g) of the GATT.¹⁷⁵ Hence, it should be underlined that such possibilities are in line with the general objective of the international trade law regime, namely that of contributing to sustainable development and the well-being of all humans.¹⁷⁶ Similarly, MEAs are not intended to foster protectionism or unjustifiable discrimination. The preambular paragraph of the Cartagena Protocol states that ‘trade and environment should be mutually supportive with a view to achieving sustainable development’. Consequently, it is submitted that MEAs and WTO Agreements on trade law are not deemed to conflict and that there is enough room for flexibility and negotiations.¹⁷⁷ Therefore, the Committee does not make any recommendations *de lege ferenda*. *De lege lata*, the Committee recommends the application of general international rules on interpretation and, more specifically, the application of principles and criteria of coexistence and coherence, *i.e.* the ‘principle of not adding to or not diminishing the rights and obligations’ and the concept of ‘no hierarchy, mutual supportiveness and deference’. The principle of not adding to or not diminishing the rights and obligations is introduced in most MEAs and in WTO trade law.¹⁷⁸ While this principle presupposes the absence of hierarchy between MEAs and international trade law, its main purpose is to prevent the application of the ‘*lex posterior derogate legi priori rule*’ which would *in casu* require the implementation of the provisions of the Cartagena Protocol over WTO trade law provisions in case of conflicts.¹⁷⁹ Closely related to this, the concept of ‘mutual supportiveness’ requires that both MEAs WTO trade law agreements should ‘mutually support’ each other by focusing on their proper domains and avoiding exclusions on the other one’s domains.¹⁸⁰ This concept also presupposes the absence of any hierarchical relationship and requires the taking into account of the interests and concerns of the other party (deference). ‘Mutual supportiveness’ can be promoted by strengthening inter-institutional cooperation between the representing bodies of both the WTO and MEAs on their common long-term strategies and policies. Consequently, there is a need to determine what value could be given to such information exchanges. Also the criteria for a mutual observer status should be clarified.¹⁸¹ ‘Mutual supportiveness’ could also be promoted by the development of international standardization of risk assessment criteria. As to the question of the extent to which inspiration by the provisions of the Cartagena Protocol is legally possible when it comes to the settlement of disputes in the field of trade in GMOs, the Committee refers to the ‘concept of indirect applicability’.¹⁸² This

¹⁷⁴ Note: the parties in the recent *EC-Biotech* (*cit.*, note 150) did not rely on Article XX (g) GATT.

¹⁷⁵ BOISSON DE CHAZOURNES L. and MBENGUE, M.M., *Trade, Environment and Biotechnology: On Coexistence and Coherence* in COTTIER, Th., and WÜGER, D. (eds.), *Genetic Engineering and the World Trade System, (World Trade Forum)*, (2008 Cambridge, University Press), 240. See COTTIER, Th., *Implications for Trade Law and Policy: Towards convergence and integration* in BAIL, C., FALKNER, R. and MARQUARD, H. (eds.), *The Cartagena Protocol on Biosafety: Reconciling Trade in Biotechnology with Environment and Development* (2002 London, Earthscan), 474–478.

¹⁷⁶ See the preamble of the 1994 *Marrakesh Agreement Establishing the World Trade Organization*, available at http://www.wto.org/english/docs_e/legal_e/04-wto.doc (last visited 11 June 2008). See also the *Doha WTO Ministerial Declaration, Declaration on the TRIPs Agreement and Public Health* (Doha Declaration), November 14th 2001, WT/MIN(01)/DEC/2, available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf (last visited 11 June 2008), paragraphs 6 and 51.

¹⁷⁷ In international law and jurisdiction with regard to the interface of trade law and MEAs, a ‘presumption against conflicts’ prevails. See BOISSON DE CHAZOURNES L. and MBENGUE, M.M., *cit.*, note 210, 217–222; See Permanent Court of Arbitration, *Arbitration regarding the Iron Rhine (‘IJzeren Rijn’) Railway between the Kingdom of Belgium and the Kingdom of the Netherlands*, Award of the Arbitral Tribunal, 24 May 2005, paragraph 59, available at <http://www.pca-cpa.org> (last visited 11 June 2008). See also *Shrimp – Turtle*, *cit.*, note 145, paragraphs 161–176, where the Appellate Body indicated that it that it would respect the existence and content of MEAs.

¹⁷⁸ For an in-depth analysis of the ‘principle of not adding to or diminishing the rights and obligations’ see BOISSON DE CHAZOURNES L. and MBENGUE, M.M., *cit.*, note 177, 222–228.

¹⁷⁹ See also COTTIER, Th., *cit.*, note 175, 465–481.

¹⁸⁰ For an in-depth analysis of the concept of ‘no hierarchy, mutual supportiveness and deference’ see PERREZ, F.X., *cit.* note 171, 275–280.

¹⁸¹ A reference can be made to the Sutherland Report on the *Future of the WTO: Addressing Institutional Challenges in the New Millennium*, Report by the Consultative Board to the former Director-General Supachai Panitchpakdi, 2004, paragraphs 159–160 and paragraph 7 of the Principal conclusions and recommendations of the Consultative Board. Available at http://www.wto.org/english/thewto_e/10anniv_e/10anniv_e.htm#future (last visited 11 June 2008). See BOISSON DE CHAZOURNES L. and MBENGUE, M.M., *cit.*, note 210, 230–231.

¹⁸² BOISSON DE CHAZOURNES L. and MBENGUE, M.M., *cit.*, note 175, 242–244.

concept offers a possibility for the WTO dispute settlement bodies to consider MEA law, *i.e.* the Cartagena Protocol, in the interpretation of WTO trade law without the obligation of *mutatis mutandis* applicability. Additionally, the Secretariat of the Cartagena Protocol can be consulted during WTO dispute settlement on GMO issues in accordance with article 13.1 Dispute Settlement Understanding (DSU).¹⁸³ It is hereby to be emphasized that the successful implementation of individual MEAs could ultimately depend on the more effective multilateral system.¹⁸⁴

Concerning the issue of PPMs, it should firstly be recalled that WTO law as such does not prohibit differentiation based on PPMs in the assessment of like products, but in practice so far there has been a reluctance to accept it. However, jurisprudence has become increasingly responsive to non-trade concerns¹⁸⁵ and it has been specified that the interpretation of WTO rules should be carried out in a way that allows for the taking into account of the goal of sustainable development.¹⁸⁶ Therefore, the possibility should not be excluded that differentiation based on PPMs could become an acceptable criterion for the determination of 'like products' in the near future. The Committee sees two well-founded reasons why such a method of differentiation of 'like products' should become practice under WTO trade law jurisdiction. Firstly, 'consumer tastes perceptions and habits' are recognized as a criterion for the determination of 'like products'.¹⁸⁷ Accordingly, the fact that consumers are becoming increasingly concerned about PPMs, especially in the field of biotechnology, takes on a greater importance. Secondly, it is submitted that PPMs may have a greater influence on the environment than the end-product itself.¹⁸⁸ Therefore, states should also have the possibility to develop PPM-based policies.¹⁸⁹

D. Biotechnology, Consumer Protection and WTO Law

1. CONSUMERS AND THE WTO

The GATT and WTO include some provisions and agreements directly or indirectly addressing consumer protection, ranging from product standards to sanitary and phytosanitary measures.¹⁹⁰ These provisions and agreements target the protection of food safety, public health and human life, environmental preservation and biodiversity, among other concerns. While standards facilitate international transactions and improve production efficiency, they can become trade barriers if employed to serve protective ends. The major objectives of the WTO Agreements, in particular the TBT Agreement and the SPS Agreement, are to avoid such self-serving standards and measures, and to avoid creating unnecessary obstacles to international trade. To these ends, WTO case law has also developed some meaningful jurisprudence on the regulation of biotech products and consumer matters. Regarding biotech trade, the European Union and many other countries have by and large adopted the following measures for consumer protection: (1) pre-marketing approval procedures; and (2) post-marketing labelling and information requirements. These measures are deemed critical to risk assessment and the management of food safety, and are grounded in the principle that informed choice is a consumer right. Are the approval procedures for biotech products and labelling and information requirements consistent with SPS measures? This is one of the major legal issues addressed in the *EC – Biotech* case, and the Panel's ruling on that matter has had a far-reaching impact on shaping WTO jurisdiction over biotech trade. The approval of biotech products should be subject to Article 8 and Annex C (1) (a) of the SPS Agreement. Article 8 SPS states that WTO 'Members shall observe the provisions of Annex C in the operation of control, inspection and approval procedures'. Annex C (1) (a) provides that WTO Members shall ensure that 'such procedures are undertaken and

¹⁸³ *Ibid.*, 165. Article 13.1 DSU states as follows: '[e]ach panel shall have the right to seek information and technical advice from any individual or body which it deems appropriate'. See also Article 13.2 DSU.

¹⁸⁴ COTTIER, Th., *cit.*, note 175, 481.

¹⁸⁵ See for example *EC – Asbestos*, *cit.*, note 116, paragraphs 113 and 114 where the Appellate Body accepted potential health risks as a legitimate criterion in the determination of 'like products'.

¹⁸⁶ See *Shrimp – Turtle*, *cit.*, note 113, paragraphs 151–152.

¹⁸⁷ See *EC – Asbestos*, *cit.*, note 116, paragraphs 99–103.

¹⁸⁸ Perez F.X., *cit.*, note 171, 266.

¹⁸⁹ *Ibid.*

¹⁹⁰ Section D of Chapter IV of this Report is based upon a draft written by Der-Chin Horng..

completed without undue delay and in no less favourable manner for imported products than for like domestic products'. In addition, it has been established that safeguard measures for biotech products should be based on risk assessments and scientific evidence as specified in Articles 5.1 and 2.2 of the SPS Agreement.¹⁹¹ The above-mentioned requirements were supported by the WTO panel in the *EC-biotech* case. This case concerns two distinct matters: (1) the operation and application of the EC regime for approval of biotech products; and (2) certain safeguard measures adopted by six EC Member States prohibiting or restricting the marketing of biotech products which were already authorized by the EC. This case involved a general *de facto* moratorium on the approval of biotech products by the EC between October 1998 and May 2005, which restricted imports of biotech products from the US, Canada and Argentina. On 29 September 2006, the WTO Panel found that the EC's measures were inconsistent with its obligations under Annex C (1) (a) and Article 8 of the SPS Agreement because the *de facto* moratorium led to undue delays in the completion of EC approval procedures. Regarding the safeguard measures of the EC Member States, the panel also ruled that the EC had acted inconsistently with Articles 5.1 and 2.2 SPS, because these safeguard measures were not based on risk assessment and hence it was presumed that they were being maintained without sufficient scientific evidence.

The second issue relates to labelling requirements for GM products. The EU and many countries have made labelling of biotech products mandatory for: (1) products that consist of GMOs or contain GMOs; and (2) products derived from GMOs but no longer containing GMOs if DNA or proteins remain from the original genetic modification. Labelling enables consumers to receive more comprehensive information on the nature, contents and the composition of products, and allows consumers to make informed choices. Labelling is thus recognized in many countries as a necessary component of the consumer's right to information, and as a tool for making an informed choice. Explicit labelling also alerts and sensitizes operators, users and competent authorities to the presence of biotech products, and promptly and effectively informs them in case of an incident or if an unanticipated risk arises due to a biotech product. This may allow for a determination as to whether additional measures or changes in approval (amendment or termination) are necessary to protect consumers or for other purposes.¹⁹² Whether the labelling requirement is also linked to the protection of human health and the environment, and hence is a measure applied for one of the purposes identified in Annex A (1) of the SPS Agreement may be determined by reference to Annex A (1), which specifies that SPS measures include, '*inter alia*,' packaging and labelling requirements directly related to food safety. The term '*inter alia*' indicates that the requirements specifically mentioned are not necessarily intended to exclude similar requirements. Hence, labelling requirements may be imposed for purposes other than food safety, such as protecting human health or the environment from possible unanticipated effects of GMOs. In the case of environmental protection, it would fall within the scope of Annex A (1) (a), (b) or (d), depending on what the anticipated adverse effects may be. In the case of human health, it would fall within the scope of Annex A (1) (b) or (c). For these reasons, a labelling requirement designed to avoid adverse effects or risks to the consumer as a result of the presence of a biotech product may be considered an SPS measure, which is covered by Annex A (1) of the SPS Agreement.

2. ARGUMENTS AND BASIS FOR A CONSUMER MODEL

Historically, international trade law, in particular the GATT and the WTO, has been largely based on protecting industrial interests. Trade remedies such as anti-dumping, countervailing duties and safeguards, all require a demonstration of injury to domestic industry of like products in the importing country. However, in a time of global interconnectedness, there is also a need to give serious consideration to consumer interests in international biotechnology law.¹⁹³ The reasons for consumer-oriented regulation of biotech products are as follows: to promote consumer welfare; to enhance public confidence in the biotech products; and to balance the interests of the consumer and the biotech industry. To raise living standards, effective demand, and environmental protection while pursuing sustainable development are among the core objectives of the WTO as recognized in the Preamble of the Agreement Establishing the WTO. With regard to consumer welfare and public health, food

¹⁹¹ Article 5.1 states that WTO Members shall ensure that their safeguard measures are based on a risk assessment. Article 2.2 reads that WTO Members shall ensure that any safeguard measures shall be applied only to the extent necessary to protect human, animal or plant life or health, should be based on scientific principles, and shall not be maintained without sufficient scientific evidence.

¹⁹² EMIROGLU, H., *Foods produced using biotechnology: how does the law protect consumers?* September 2002 Vol. 26 (3), *International Journal of Consumer Studies* 201–205.

¹⁹³ WATSON, M., *Trade Justice and Individual Consumption Choices: Adam Smith's Spectator Theory and the Moral Constitution of the Fair Trade Consumer*, June 2007 13 (2), *European Journal of International Relations* 285.

safety is the most important aspect, and to that end biotech products in many countries are often subject to mandatory pre-marketing authorization procedures involving a scientific assessment of potential risks. The marketing approval for biotech products, therefore, should be considered acceptable by the WTO to ensure food safety.¹⁹⁴ Many different purposes are served by authorizing biotech products. The approval procedure covers human and animal health, and the environmental aspects of biotech products. For instance, a fundamental objective of the EU's Regulation 258/97, as stated in the preamble, is to protect public health and to ensure that GMOs present in foods are 'safe for human health'. Regarding consumers' concerns, the EU's marketing approval procedure states that biotech products must not: (1) present a danger to the consumer; (2) mislead the consumer; and (3) differ from food or foodstuff ingredients which they are intended to replace to such an extent that their normal consumption would be nutritionally disadvantageous for the consumer.¹⁹⁵

3. THE USE OF LABELS

Labelling is the other important means for consumer protection and is one of the most important and direct means of facilitating communication between consumers and producers/sellers. Labelling serves three major functions: (1) it provides basic product information such as: the common name, list of key ingredients, net quantity, shelf-life, grade/quality, country of origin and name/address of responsible manufacturer, dealer or importer; (2) it provides health/safety and nutrition information; and (3) it functions as a vehicle for marketing, promotion and competition – advertises and promotes sale and trade via label vignettes, promotional information and label claims.¹⁹⁶ Mandatory labelling can provide consumers with an account of a product's nature, composition and quality, enabling them to make an informed choice. For these reasons, labelling should be meaningful to the consumer. Labelling declarations are generally required for biotech products if these products contain GM ingredients above a specific threshold. In the EU, the threshold for labelling is now 0.9%, and accidental contamination of up to 0.5% is permitted without labelling.¹⁹⁷ The prescribed alternative labels are: 'This product contains genetically modified organisms' and 'produced from genetically modified [name of organism]'.¹⁹⁸ Consumers also have the right to expect that the information relating to GMOs will be comprehensive, that is, written clearly and legibly and in the officially recognized language(s) of each country. In addition, any information displayed should be clearly visible and placed in a highly visible position on the product. As a whole, the general purpose of the labelling is to ensure that accurate information is available to consumers to enable them to exercise their freedom of choice in an effective manner.

International standards on food safety developed under the Codex Alimentarius¹⁹⁹ are officially recognized international guidelines for ensuring food safety and fair trade practices. So far Codex Alimentarius has not adopted any GMO labelling standards; the Committee suggests that this gap be filled, which would considerably enhance legal certainty for the use of GMO labelling under the WTO.²⁰⁰ WTO philosophy should gradually shift its focus from the supply-side interests of industry to the demand, welfare-side of the general consumer,²⁰¹ but to

¹⁹⁴ ROTT, P., *Genetically Modified Products and Consumer Concerns under WTO Law*, July 2003 Vol. 6 (4), *Journal of World Intellectual Property* 580–584.

¹⁹⁵ Article 3(1): Regulation 258/97.

¹⁹⁶ OECD, *Analysis of Non-Tariff Measures. The Case of Labelling: Overview and Analysis of WTO Data*, TD/TC/WP(2002)40/Final, 13 November 2003 Paris, OECD, 7.

¹⁹⁷ Article 8 of Regulation 258/97 concerning novel foods and novel food ingredients, OJ 1997, L43-1; Articles 4(B), 6(2) of Regulation 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC, OJ 2003, L268/24.

¹⁹⁸ Articles 12(2), 24(2), 47(1) of Regulation 1829/2003 on genetically modified food and feed, OJ 2003, L268/1.

¹⁹⁹ Available at http://www.codexalimentarius.net/web/index_en.jsp (last visited 11 June 2008)

²⁰⁰ Article 2.4 TBT Agreement mandates the case of international standards. The Codex has a membership of over 165 countries accounting for 98% of the world population. At the heart of Codex is its mission to protect consumer health and ensure fair trade practices.

²⁰¹ KELSO, D.D., *Recreating Democracy*, in SHURMAN, R.A. and KELSO, D.D. (eds.), *Engineering Trouble: Biotechnology and its Discontents*, (2003 Berkeley, University of California Press) 249–252; BAUER, M.W. and GASKELL, G., *The biotechnology movement*, in BAUER, M.W. and GASKELL, G. (eds.), *Biotechnology: The Making of a Global Controversy* (2002 Cambridge, University Press), 400–402.

do so, a legislative change incorporating a consumer clause in the WTO Agreement will be necessary. The WTO Agreements can be amended through a decision either by all Members or by a two-thirds majority depending on the nature of the provision concerned.²⁰² Such a consumer clause could help establish consumer confidence in biotech products and allow a compromise to be reached between national public interest and the ongoing development of biotechnology. Consequently, this clause would demonstrate a creative and innovative element in the WTO capable of accommodating changes and challenges resulting from later developments in biotechnology, and increase the legitimacy of the WTO based on public health and economic democracy.²⁰³

V. International Environmental Law

Advances in biotechnology have prompted debate and development in the field of international environmental law.²⁰⁴ Recognition of potential benefits of the application of modern biotechnology has generally been coupled with acknowledgement of the need for appropriate risk assessment and management.²⁰⁵ Agreements such as the 1992 Convention on Biological Diversity (CBD) and the 2000 Cartagena Protocol on Biosafety specifically address the issue. The FAO International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGFRA) might also be mentioned here, although it is not an environmental agreement *strictu sensu*. The main area of environmental concern has been the potential effect of intentional or unintentional releases of genetically modified organisms (GMOs). Such releases are specifically addressed, albeit rather briefly, by the CBD, and the transboundary movement of GMOs is addressed in more detail by the Biosafety Protocol. These provisions are addressed in section II below. However, the agreements mentioned cover only some of the issues at stake. Despite the legal developments that have occurred at the international level, a number of issues are not fully addressed, or are not addressed at all by existing international agreements. Several important questions are left open and may be governed by general international law for the time being.

A. Controlling Environmental Risks of the Release of Genetically Modified Organisms into the Environment

Biotechnology often entails the release of the resulting GMOs into the environment. This is true for the ‘green’ branches of that technology, which mainly aim at developing improved breeds of plants and animals. However, modified organisms may also be developed for release for other ‘technical’ reasons, including, for instance, environmental clean-up. Furthermore, a release of modified organisms may occur accidentally during transport or be released unintentionally from a facility for the contained use of such organisms. The potential impact of such releases on other species and ecosystems has not yet been considered to be fully explored or understood. Moreover, once released into the environment, it is difficult to control the further spread of these organisms, their seeds or genetic traits. To date, not all States have established applicable legal frameworks or a system for the control and management of these risks. Notwithstanding the adoption of the Protocol in 2000, in 2004, the World Conservation Union (IUCN) World Conservation Congress adopted a resolution calling for a moratorium on further environmental releases of GMOs until they could be demonstrated to be safe for biodiversity and for human and animal health beyond reasonable doubt.²⁰⁶

²⁰² See WTO, *Understanding the WTO*, 3rd ed. (2003 Geneva, WTO), 102.

²⁰³ COTTIER, Th., *Implications for trade law and policy: towards convergence and integration* in BAIL, C., FALKNER, R. and MARGUARD, H., *The Cartagena Protocol on Biosafety: Reconciling Trade in Biotechnology with Environment and Development* (2002 London, Royal Institute of International Affairs), 473; LINDBLON, A.-K., *Non-Governmental Organizations in International Law* (2005 Cambridge, University Press), 6–36.

²⁰⁴ Chapter V of this Report is based upon a draft jointly written by Ruth Mackenzie and Peter-Tobias Stoll, Subchapter D is based upon an inserted draft written by Mihalis Kritikos.

²⁰⁵ See HAHN, M., *Food Security and agricultural production with genetically modified organisms: a comment* in WUEGER, D., and COTTIER Th., (eds), *Genetic Engineering and the World Trade System, (World Trade Forum)*, (2008 Cambridge, University Press), 193-202.

²⁰⁶ World Conservation Congress, held in Bangkok (Thailand), 17–25 November 2004, Resolutions and Recommendations, IUCN-World Conservation Union 2005, Resolution 3.007, *A moratorium on the further release of*

B. The Convention on Biological Diversity

Article 8 of the CBD²⁰⁷ addresses the regulation of risks associated with GMOs²⁰⁸ by calling on Parties to ‘(g) establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health.’ The provision is noteworthy, because it acknowledges the potential existence of a risk and the likelihood of ‘adverse environmental impacts’, which could even affect the conservation and use of biodiversity. According to its Article 1, such conservation and sustainable use are among the main objectives of the CBD. Preamble paragraph 3 of the Convention, even considers the conservation of biological diversity a ‘common concern of mankind’. Thus, the control of the releases of GMOs at national level as called for by Article 8(g) serves an international or common concern. Furthermore, it should be noted, that Article 8(g) also mentions human health as an additional concern. The obligation of Parties to the CBD under Article 8(g) to take national measures is complemented by Article 19(3) and (4). Paragraph 3 of Article 19 envisages a Protocol relating to the safe transfer, handling and use of any GMO resulting from biotechnology and has served as a basis for the negotiation and adoption of the Biosafety Protocol. Paragraph 4 contains a duty concerning the provision of information in the context of the introduction of a GMO from one Party to another. Other provisions of the CBD relating to in-situ conservation, which do not specifically or solely relate to GMOs, nonetheless are of relevance to the proper protection of the environment from risks associated with modern biotechnology. These include, for example, the obligation to identify and monitor processes and categories of activities which have or are likely to have significant adverse impacts on biological diversity, and to regulate or manage such activities.²⁰⁹ The CBD also requires Parties to regulate or manage biological resources important for the conservation of biological diversity whether within or outside protected areas with a view to ensuring their conservation and sustainable use.²¹⁰ It further requires Parties to promote the protection of ecosystems, natural habitats and maintenance of viable populations of species in natural surroundings.²¹¹ The CBD also contains provisions concerning exchange of information regarding activities likely to have significant adverse effects on the biodiversity of other States or areas beyond the limits of national jurisdiction and in cases of imminent or grave danger or damage.²¹²

C. The Cartagena Protocol on Biosafety

The Biosafety Protocol²¹³ supplements the provisions of the CBD on regulating risks associated with GMOs. It specifically focuses on transboundary movements of ‘living modified organisms’ and envisages a system of an advanced informed agreement (AIA) in this regard. This procedure, which parallels in some respects the prior

Genetically Modified Organisms (GMOs), 6–7; available at <http://cms.iucn.org/resources/documents/index.cfm> (last visited 11 June 2008). A number of government members of IUCN stated that they could not support the Resolution, and one stated for the record that it had refrained from engaging in deliberations on the Resolution and took no national position on it. See also General Statements on the IUCN Motions Process, *ibid.*, x–xi.

²⁰⁷ *Convention on Biological Diversity (CBD)*, *cit.*, note 82, available at <http://www.cbd.int/doc/legal/cbd-un-en.pdf> (last visited 11 June 2008).

²⁰⁸ In the CBD and the 1992 Cartagena Protocol, the term ‘living modified organisms’ is used. For the sake of consistency in this report, we have used the broader term GMOs throughout. ‘Living modified organisms’ are defined in Article 3(g) of the Biosafety Protocol as ‘any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology’. The terms ‘living organism’ and ‘modern biotechnology’ are defined in Article 3(h) and (i) of the Protocol.

²⁰⁹ CBD, Articles 7(c) and 8(l).

²¹⁰ CBD, Article 8(c).

²¹¹ CBD, Article 8(d).

²¹² CBD, Article 14(1) (c) and (d).

²¹³ *Cartagena Protocol on Biosafety (CPB)*, *cit.*, note 79, available at <http://www.cbd.int/doc/legal/cartagena-protocol-en.doc> (last visited 11 June 2008). Parts of the summary of the Biosafety Protocol in this section are drawn from MACKENZIE, R., *The Cartagena Protocol on Biosafety and the Development of International Environmental Law*, in FALKNER, R. (ed.), *The International Politics of Genetically Modified Food: Diplomacy, Trade and Law* (2007 Palgrave MacMillan), 213–228.

informed consent required under the Basel²¹⁴ and the PIC²¹⁵ Conventions, basically provides that the importing Party shall be informed and must agree before a movement of such GMOs may take place. The Protocol contains a set of rules relating to the methods, procedures and review of related decisions. It also envisages a system of the exchange of information through a clearing-house, whereby Parties may communicate decisions made at the national level on certain GMOs. The focus of the Protocol is on the transboundary movement of GMOs. The central procedural mechanism set out in the Protocol to regulate the transboundary movement of living modified organisms is the advance informed agreement (AIA). The AIA procedure essentially requires that, before the first transboundary movement of a GMO, the Party of import is notified of the proposed transboundary movement and is given an opportunity to decide whether or not the import should be allowed and upon what conditions. This decision must be based upon a risk assessment, carried out in a scientifically sound manner, taking into account recognised risk assessment techniques. Article 15 of the Protocol sets out the risk assessment requirements in more detail, and Annex III contains guidance on the objective of risk assessment, the general principles of risk assessment, and the methodology to be applied. The Protocol recognises that risk assessment must be environment-specific, that is, it must consider the risks associated with the release and use of the GMO in the environmental conditions into which it is to be introduced. Where there is a lack of scientific certainty about the extent of the potential adverse effects of a GMO, a Party may take precautionary action to avoid or minimise the potential adverse effects.²¹⁶ The Party of import may also take into account certain socio-economic considerations, pursuant to Article 26 of the Protocol, in reaching a decision on the proposed import. However, any such consideration must also be consistent with that Party's other international obligations. In addition, the Biosafety Protocol contains certain obligations regarding public awareness and participation as regards the decision-making process, although the obligation to involve the public in decision-making on GMOs is qualified by a reference to national laws and regulations.

The AIA procedure only applies to the first transboundary movement of a particular GMO into a country for *intentional introduction into the environment* (for example, seeds for open field trials or for commercial growing). Separate and less onerous provisions in Article 11 apply to the import of GMOs intended for direct use as food or feed or for processing (essentially agricultural commodities and GMOs used in industrial processes). This procedure, which basically comprises a multilateral information exchange mechanism, centres on the biosafety clearing-house (BCH), which was established under Article 20 of the Biosafety Protocol. Parties that authorise domestic use of a GMO that may be used directly as food or feed, or for processing inform other parties through the BCH; and Parties that require advance notification and approval before the import of such a GMO into their territory, alert other Parties and exporters to this fact through the BCH. In effect, the provisions of Article 11 allow Parties to subject GMOs intended for direct use as food or feed, or for processing, to similar import requirements to those under the AIA procedure. The approach taken in the Protocol differs from the prior informed consent procedures established for hazardous wastes and certain hazardous chemicals and pesticides in other multilateral environmental agreements in two significant respects. *First*, the prior informed consent regimes in respect of transboundary movement of hazardous wastes and chemicals, apply to categories of substances and materials, upon which it is internationally agreed, through the relevant multilateral environmental agreement (MEA), to be hazardous in nature. By contrast, the Protocol sets out a procedure to be applied on a GMO-by-GMO basis, in the context of specific proposed uses and receiving environments.²¹⁷ There is still significant disagreement at the international level as to the nature and extent of any special risks that GMOs in general, or any specific GMO, might pose to the environment and human health. *Secondly*, there is a significant degree of flexibility in how the Protocol's procedures, including AIA, are to be applied by Parties. The Protocol confers some discretion upon Parties as to what GMOs are subject to the AIA procedure, and as to whether to follow the AIA procedure itself or some similar domestic regulatory procedure. This flexibility is constrained by the requirement that any such alternative measures must be 'consistent with this Protocol'. The import and export provisions of the Biosafety Protocol are backed up by requirements setting out what information must be

²¹⁴ *Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal*, 22 March 1989, entered in force 24 May 1992, 1989 (28), ILM 657, available at <http://www.basel.int/text/con-e.pdf> (last visited 11 June 2008).

²¹⁵ *Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade*, 11 September 1998, entered in force 24 February 2004, 1999 (38), ILM, available at http://www.opbw.org/int_inst/env_docs/rotterdam-text.pdf (last visited 11 June 2008).

²¹⁶ CPB, Article 10(6).

²¹⁷ STOLL, P-T., *Controlling the Risks of Genetically Modified Organisms: The Cartagena Protocol on Biosafety and the SPS Agreement*, 2000 (10), Yearbook of International Environmental Law 82–119.

provided in documentation accompanying transboundary movements of GMOs.²¹⁸ This information is intended to provide a means to identify and track transboundary movements of GMOs; provide information to the Party of import at the border; and offer a contact point for further information about the consignment in question. The specific requirements vary according to the intended use of the GMOs in question. The Protocol does not prohibit trade in GMOs between Parties and non-Parties, but it requires that such transboundary movements be carried out in a manner ‘consistent with the objective’ of the Protocol.²¹⁹ Since major exporters of GMOs remain non-Parties, this provision is of enormous potential significance. The phrase ‘consistent with the objective of this Protocol’ has not been the subject of any authoritative interpretation.

The Biosafety Protocol does not contain specific provisions relating to the settlement of disputes arising under it. Instead, it relies on the relevant provisions of its parent convention, the CBD, which provides for optional judicial or arbitral settlement of disputes or compulsory (at the request of one party), but non-binding, conciliation.²²⁰ In common with numerous other recent MEAs, the Protocol also provides for the establishment of a non-compliance procedure, and such a procedure has been established.²²¹ The flexibility built in to the Protocol’s AIA provisions, and the exclusion from the AIA procedure of certain types of transboundary movement of GMOs,²²² calls into question any conclusion that the Protocol establishes a fully harmonised regulatory system for transboundary movements of GMOs. Nonetheless, the Protocol does establish basic elements of such a system. In addition, due to its focus on transboundary movement, in many respects the Biosafety Protocol hardly adds any more precise guidance to Article 8(g) of the CBD on the control of the use of GMOs *within* a country, although Article 16 of the Protocol contains some broader provisions on risk management. The Protocol does, however, provide for some rules in the case of unintentional transboundary movements of GMOs in Article 17. These mainly envisage a duty of notification and information exchange. Since the Protocol entered into force in September 2003, its governing body²²³ has met four times, adopting a number of decisions initiating further work and elaborating institutional arrangements and understandings of certain provisions of the Protocol.²²⁴ The underlying issue is one of good governance in the field. We are faced with the question to what extent the matter should be addressed and possibly harmonized in international law, and to what extent it should be left to regulatory competition in light of diverging interests and philosophies pursued in the field of biotechnology.

D. The Quest for Good Governance in Open-Field Biotechnology

Governance is an umbrella term used to denote the process of decision-making or policy-making and its implementation, which has signalled ‘a shift in regulatory arrangements where governing is not confined to a single domain such as, for example, the state.’²²⁵ It is a shift from ‘command and control’ to negotiation²²⁶ where policies are developed among a wider set of actors that also shape their implementation. A definition of good governance breaks down into three parts, defining it as ‘a process whereby societies or organizations make their

²¹⁸ CPB, Article 18.

²¹⁹ CPB, Article 24.

²²⁰ CBD, Article 27.

²²¹ CPB, Article 24 and Decision BS-I/7, adopted at the first meeting of the Conference of the Parties to the CBD acting as the meeting of the Parties to the Cartagena Protocol, available at <http://www.cbd.int>, (last visited 11 June 2008).

²²² For example, LMOs in transit (Article 6(1)); LMOs destined for contained use in the Party of import (Article 6(2)); and LMOs for direct use as food or feed, or for processing (Article 7 and Article 11).

²²³ The Conference of the Parties to the CBD serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP/MOP), CPB, Article 29.

²²⁴ The decisions of the COP/MOP are available at <http://www.cbd.int> (last visited 11 June 2008). The fourth and most recent meeting of the COP/MOP was held from 12 to 16 May 2008 in Bonn, Germany.

²²⁵ HIGGINS, V. and LAWRENCE, G., *Introduction: Globalization and agricultural governance* in HIGGINS, V. and LAWRENCE, G., (eds.) *Agricultural Governance: Globalization and the new politics of regulation* (2005 London - New York, Routledge), 2.

²²⁶ PIERRE, J. and PETERS, B.G., *Governance, Politics and the State*, (2000 New York, St. Martin’s Press).

important decisions, determine whom they involve in the process and how they render account.²²⁷ In the framework of this report, good governance is approached as a form of administering public decision-making characterized by public accessibility and participation, consensus orientation, transparency and responsiveness. Its primary focus is on the main pillar of good governance, that is the element of public participation, as this constitutes the most tangible and crucial aspect of each public regulatory control scheme in fields of risk and social regulation. The integration of these elements into the operation of public authorization frameworks is aimed at strengthening the involvement of local actors and civil society in decision-making procedures, and broadening the scope of regulatory oversight so as to include socio-economic and ethical considerations. By these means, it effectively serves to increase the social legitimacy of those regulatory frameworks that deal with issues under a high level of public scrutiny, such as biotechnology.

In the case of agricultural biotechnology, the international discussion of the need for integrating good governance principles into the relevant authorization structures has been initiated in the framework of the discussions for the amendment of Article 6 of the Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (The Aarhus Convention).²²⁸ In fact, whether or not risk assessment, and, in general, the prior authorization structure would also be based on socio-economic and ethical considerations – which would in effect provide space for a meaningful and influential participation of the public as well as of non-expert actors – has become one of the most contentious issues, especially between developed and developing countries, in the framework of both the Cartagena Protocol and the Aarhus systems of rules.

Open-field biotechnology is a unique field of scientific enquiry. In examining the major scientific features of this novel technological field, one should, first note the limited time for which open-field application of this technological sector has been taking place in a commercial context. In contrast to the existence of broad databases and of well-established theories on the hazards of physical technologies, ‘the study of the hazards of biotechnology is as yet in embryonic state’²²⁹ and there is no integrated historical biosafety database on the behaviour of different GMOs in a variety of open-field contexts.²³⁰ Up to now, there is not conclusive evidence of harm produced, but uncertainties remain which need to be properly addressed in procedural terms. The introduction of GMOs into the environment has been characterized by the existence of significant scientific uncertainties in the prediction and assessment of the relevant long-term and indirect effects and risks. Considering that individual genes are being introduced into highly complex genetic structures and the resultant organisms are being propagated in complex ecosystems, even if a GMO has been tested and found safe in the ecosystem in which it is manufactured, its use may have unintended consequences in other ecosystems. Due to the ability of a genetic modification to link together quite distinct forms of life that could not occur in nature’,²³¹ the potential environmental risks such as toxicity, unintentional gene flow, the displacement of native species, the degradation of local ecosystems or the transformation of the introduced species into pests might be unique and irreversible.

1. AGRICULTURAL BIOTECHNOLOGY AS A *SUI GENERIS* OBJECT OF REGULATORY CONTROL?

In view of the possibility that GMO-related risks will be magnified as populations of organisms multiply, colonize and adapt over time, the required regulatory net is expected to have an intense safety dimension. In the case of the regulation of plant biotechnology, it is contentious as to whether the required regulatory control is

²²⁷ Institute on Governance, *Principles for Good Governance in the 21st Century*, Policy Brief No. 15 Ottawa, Canada at 1. Available at <http://www.iog.ca/publications/policybrief15.pdf> (last visited 11 June 2008).

²²⁸ UNECE, *Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters*, 25 June 1998, Aarhus, available at www.unece.org/env/pp/documents/cep43e.pdf (last visited 11 June 2008).

²²⁹ RAVETZ, J. and BROWN, J.M., *Biotechnology; Anticipatory Risk Management* in BROWN, J.M. (ed.), *Environmental Threats* (1989 London, Belhaven) 67–68.

²³⁰ JASANOFF, S., *Product, process, or program: three cultures and the regulation of biotechnology* in BAUER, M. (ed.), *Resistance to new technology - nuclear power, information technology and biotechnology* (1995 CUP and Science Museum) 312.

²³¹ BURLING, D., *The European Community and the Legislating of the Application and Products of Genetic Modification Technology*, Autumn 1995 Vol. 4 (3), *Environmental Politics* 468.

also expected to cover the potential socio-economic effects of its development and the ethical questions that arise from the commercial application of biotechnology in the open natural and agricultural environment. A further challenge for the regulators of genetic engineering is how to balance the range of interests and perspectives and to take into consideration a mosaic of different social, ethical, and environmental and public health concerns, interests and risk perceptions. As has been acknowledged, genetic engineering, in addition to its effects on human health and biodiversity,²³² might pose considerable risks to economic and social structures. There is thus also a need to address non-environmental risks.²³³ In view of the societal character of the risks related to agricultural biotechnology, there is a need from this point of view to establish participatory regulatory structures, expanding the risk assessment to incorporate comparative evaluations and socio-economic criteria, and adopting liability clauses for potential financial harm to farmers who produce non-GM crops as well as more generally for damage to the environment and human health.²³⁴ The question is as to how this can best be achieved, and what role international law is bound to play in this process. To this effect, diverging views exist. International law will need to take into account diverging views into account and work towards commonly accepted disciplines in international economic law and international trade regulation.

a) The Philosophy of Inclusive and Comprehensive Risk Analysis

Owing to the absence of sufficient databases with information on the possible effects of GMO releases, the nascent stage of the relevant scientific research, and the structural difficulties in identifying and quantifying the various potential long-term impacts, the formulation of an ex-ante risk analysis framework seems the most appropriate model of organizing the required system of rules on licensing. This model of authorization would contain an obligation to provide detailed information on the organism in question and to seek the prior informed consent of the relevant national authority. Furthermore, because plants cannot be uniformly resistant to specific diseases, pests or other climate conditions, and natural ecosystems are dynamic in their functioning and unique in their features, each release should be evaluated individually. Moreover, the formulation of the necessary structures not only for the dissemination of technical information, but also for the provision of procedural opportunities to the various stakeholders to express their ethical and socio-economic views, is to be considered as a necessary element of a framework for the regulation of genetic engineering. The social unease in some parts of the World, in particular Western Europe, about the consequences of the planned open-field releases of GMOs and the information asymmetries due to the private control of the development of the science of genetic engineering call for an authorization framework that would encourage public involvement and the incorporation of social concerns and views of laypersons into the licensing framework. The regulatory challenges of agricultural biotechnology that have been examined indicate its special character as an object of regulatory control.

b) The Philosophy of Scientific Risk Assessment, Risk Management and Product Liability

Biotechnology is part of technology and may be approached as other technologies for which legal system developed strategies of risk analysis and rules on liability. Another point of view, mainly supported by governments supporting recourse to genetic engineering in agriculture, denies the sui generis nature of biotechnology and seeks to deal admission and approval by means of established regulatory proceedings of product admission and ex post liability in case of damages incurred. Participation in the process is defined in terms of administrative procedures, and does not entail the consideration of social and economic factors. Risk assessment is seen as a process exclusively based upon scientific evidence. Risk management, on the other hand, responds to risks scientifically assessed. It allows governments to define appropriate levels of risks to be incurred (including the option of zero risk). It is here that social and economic factors may be considered. The philosophy allows applying the precautionary principle whenever assessments are not conclusive. Finally, in case of hazards incurred, liability will be assessed on the basis of regular product liability.

²³² Secretariat of the CBD, 2000; FAO, 2004; WHO, 2003.

²³³ LA VINA, A., *Genetically Modified Organisms and the Cartagena Protocol on Biosafety: What is at Stake for Communities?* 2003 Washington DC, World Resources Institute, retrieved 15 September 2004, available at: http://pdf.wri.org/lavina_cartagena.pdf (last visited 11 June 2008).

²³⁴ See on this issue, CROMPTON, T. and WAKEFORD, T., *Socioeconomics and the protocol on biosafety*, 1998 Vol. 16, *Nature Biotechnology* 697–698.

2. GOOD GOVERNANCE AND THE CARTAGENA PROTOCOL

The Cartagena Protocol is essentially based upon the philosophy of comprehensive risk analysis. The particular public participation clause – contained in Article 23 of the Protocol – is the sole evidence of the Cartagena Protocol's approach towards good governance.²³⁵ It touches upon all the main parameters that determine what constitutes an accountable, accessible and transparent framework as it establishes an obligation of the Parties to promote and facilitate public awareness and participation. In fact, Article 23 establishes a two-level structure for public participation. At the first level, the obligation to promote public awareness and participation – wherever necessary through cooperative means with other states is addressed to States parties. At the second level, states are obliged to involve the public in accordance with their laws and regulations. Overall, the provision is minimally prescriptive although it leaves the choice of means of fulfilment to the parties involved. The first paragraph of Article 23 fails to indicate the type of information regarding GMOs that should be made available to the public. It is evident in the second sub-paragraph that the emphasis is on the promotion and facilitation of public awareness and education rather than on public participation. The second paragraph of Article 23, which refers to public consultation in the decision-making process regarding GMOs, conditions its application upon its consistency with each Party's laws and regulations and the confidential character of the information contained in the notification file. It should also be noted that there is no reference to what might constitute public participation in the process for the authorization of GMO releases. Such a minimalist approach and abstract reference to the role of the public in a legislative framework which touches upon the environmental and social pillars of 'sustainable development', might impede its harmonious implementation and undermine the establishment of a unified good governance approach towards biosafety. At the same time, the absence of any definitions (*i.e.* as to what should constitute 'confidential information') or of minimum standards for the type of information that needs to be made publicly accessible, and the level of involvement of non-expert actors seem to confer upon the Parties broad discretion in adjusting this good governance element to their own administrative models of public consultation, provided that the basic commitment of undertaking consultation with the public is secured under the Protocol.

Both the preamble and Article 8 of the Convention on Biological Diversity (CBD)²³⁶ explicitly recognize the need to foster awareness towards the role of agriculture and development in conserving and utilizing biodiversity in a sustainable manner, something which is held to require social and economic factors to be considered.²³⁷ The Protocol allows, but does not prescribe, taking social and economic factors into account. Article 26 though, seems to curtail the range of socio-economic considerations that may be taken into account.²³⁸ This occurs through the prioritization of one particular type of socio-economic consideration that Parties are expected to take into account, that is 'the value of biological diversity to indigenous and local communities' and by conditioning the invocation of socio-economic considerations upon their consistency with the Parties' 'international obligations,' which mainly stem from multilateral trade agreements. The provision may be inchoate as it is unclear as to whom the matter of socio-economic considerations is addressed, and how they might be achieved. The absence of a discussion platform or of an institutional structure that will identify and specify those socio-

²³⁵ Article 23 of the Cartagena protocol on 'public awareness and participation' reads as follows: '1. The Parties shall: (a) Promote and facilitate public awareness, education and participation concerning the sale transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking into account risks to human health. In doing so, the Parties shall cooperate, as appropriate, with other States and international bodies; (b) Endeavour to ensure that public awareness and education encompass access to information on living modified organisms identified in accordance with this Protocol that may be imported. 2. The Parties shall, in accordance with their respective laws and regulations, consult the public in the decision-making process regarding living modified organisms and shall make the results of such decisions available to the public, while respecting confidential information in accordance with Article 21.3. Each Party shall endeavor to inform its public about the means of public access to the Biosafety Clearing-House.'

²³⁶ UN, *Convention on Biological Diversity*, concluded in Rio de Janeiro on 5 June 1992, available at <http://www.cbd.int/doc/legal/cbd-un-en.pdf> (last visited 11 June 2008).

²³⁷ STREET, P., *Trading in risk: the Biosafety Protocol, genetically modified organisms and the World Trade Organization*, 2001 Vol. 3, *Environmental Law Review* 251.

²³⁸ Article 26 of the Cartagena Protocol on 'Socio-economic considerations' reads as follows: 'The Parties, in reaching a decision on import under this protocol or under its domestic measures implementing the Protocol, may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities. 2. The Parties are encouraged to cooperate on research and information exchange on any socio-economic impacts of living modified organisms, especially on indigenous and local communities.'

economic considerations that are pertinent to the commercialization of agricultural biotechnology and the use of the term *may* instead of *shall* are further indication of the Cartagena Protocol's soft-law approach towards the role of socio-economic considerations in biosafety decisions. In paragraph 2 of Article 26, the Cartagena Protocol seems to encourage Parties to the Cartagena Protocol to cooperate on research and information exchange on any socio-economic impacts of living modified organisms (GMOs), especially – but not limited to – impacts on indigenous and local communities. However, there is no clear mechanism for introducing such concerns into the central control mechanism of the risk assessment. Non-scientific issues have not been embodied in a standardized manner within this particular licensing framework either as part of its substantive content or of its set of procedural rules. Furthermore, there is no reference or example as to which sort of non-scientific considerations can be taken into account. The examination of these concerns does not constitute a procedural requirement when reviewing an application, thus these considerations seem to be marginalized in the framework of the Cartagena Protocol's context as is evident in the under-defined character of the role and the status of the interests and views of non-experts.

Public participation and the potential inclusion of socio-economic considerations constitute two of the least elaborated aspects of the Cartagena Protocol in terms of their discussion by the Meeting of the Parties and the relevant expert working groups. The relevant decisions and references seem to focus more on the various international capacity-building initiatives on public awareness and education than on further elaboration of Article 23 and/or on ways of involving the public from the early stages of the decision-making procedures relating to the release of GMOs into the environment and onto the market. In other words, the elaboration of this specific issue within the framework of the Aarhus system of rules seems to overshadow the efforts made in the framework of the UNEP institutional context. As noted above, the amended Article 6 of the Aarhus Convention is supposed to cover a substantial amount of this 'good governance' gap through the specification of minimum standards for public participation at the early stages of the process making decisions on licensing, allowing for reasonable time frames for the different stages of participation and ensuring that the public becomes involved while the options are still open. The Cartagena Protocol, as such, does not seem to reflect these developments and its persistent ambiguity regarding both the role of the public and of the socio-economic considerations in the framework of the decision-making procedures has created a wide normative gap which in effect has decreased the effectiveness and enforceability of the relevant provisions. At the same time, its implementation at the national level indicates a conceptualization of the public as a mere recipient of technical information whose participation has been curtailed as it would need to comply strictly with the technical assessment requirements and standards of the prescribed authorization procedure.

3. GOOD GOVERNANCE AND THE AARHUS CONVENTION

Various top-down initiatives have been used for the establishment of some minimum normative good governance standards and methodological standards in the field of biosafety. The most important one was the Meeting of the Parties to the Aarhus Convention. More concretely, the development and specification of the terms of operation of the Cartagena Protocol's public participation provision has been taking place within the framework of the GMO Working Group of the Aarhus Convention. The Convention recognizes that sustainable development can only be achieved through the involvement of all stakeholders and seeks to promote greater transparency and accountability in the operation of public decision-making mechanisms through safeguarding the rights of public access to information on the environment, public participation and public access to justice in matters pertaining to the environment. The GMO Working Group has drafted specific Guidelines on Access to Information, Public Participation and Access to Justice with respect to GMOs.²³⁹ These guidelines provide a non-legally binding and voluntary approach and specify, *inter alia*, the criteria that should be considered when deciding if a specific case should be subject to public participation as well as the information that should be publicly accessible. It should be noted that despite the innovative and detailed character of the guidelines adopted, neither the Decision of the Parties nor the Guidelines, as such, refer to the need for taking into account socio-economic considerations that constitute the bulk of comments submitted by the public on genetic engineering issues, thus perpetuating the technical character of the biosafety framework that effectively prevents a meaningful contribution by those actors who do not possess the required technical knowledge.

Furthermore, it should be noted that when Article 6 of the Convention ('Public Participation in decision on specific activities') was originally concluded in June 1998, decisions on GMOs were excluded from its binding

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MP.PP/2002/7.

requirements on public participation (paragraph 1(a) and Annex I of the Convention) with the parties required to apply its terms to decisions on whether to permit the deliberate release of GMOs into the environment only ‘to the extent feasible and appropriate.’²⁴⁰ This ‘wide margin of discretion as to the extent to which the remaining provisions of article 6 should be applied to decision-making on deliberate releases of GMOs’²⁴¹ and the eventual recognition of the Parties to the Aarhus Convention of the importance of applying the provisions of the Convention to deliberate releases of GMOs into the environment²⁴² eventually led to the adoption of an amendment to the Convention according to which ‘each Party shall provide for early and effective information and public participation prior to making decisions on whether to permit deliberate releases of GMOs.’²⁴³ The amended Article 6 requires Parties to inform and consult the public when decisions are made regarding the deliberate release and placing on the market of GMOs and the public should have the right to submit comments and public authorities should take these into account in the decision-making process. The authorization decision taken should be publicly available, together with the reasons and considerations upon which it is based, whereas information associated with decisions on GMOs would be made available to the public subject to the usual protection for commercially confidential information. An important development that has been marked by the adoption of this revision is the establishment of limits on the use of the confidentiality clause that cannot be extended to information on the intended uses of the release or on the assessment of environmental risk. In other words, the scope of this revision has been the safeguarding of transparency in the dissemination of all information that relates to the use and environmental impact of GMOs (article 21(6) of the Cartagena Protocol). The amendment is an important development if one considers that the introduction of these good governance clauses ensures a minimal standardized approach to how public participation and access to information should be organized at the international level, and the role of the public in making decisions on GMOs. At the same time it leaves space for national biosafety frameworks to adopt stricter measures that could enhance public participation and access to information in the field of agricultural biotechnology.

E. Relevant Regional Rules on Biotechnology

In addition to efforts on global scale, some rules and procedures of regional application have been developed or have been proposed. The most established system is that in place within the European Union, but proposals for harmonised regional approaches to risk regulation in relation to GMOs have also been put forward, for example, in the Association of Southeast Asian Nations (ASEAN) and the African Union. It remains to be seen to what extent such proposals will be reflected and made operational through national laws. The Biosafety Protocol makes provisions for such approaches in Article 14. In addition, it should be recognised that other non-biosafety-specific regional agreements may nonetheless be of relevance to aspects of the regulation of the use and release of GMOs. These include, for example, biodiversity-related treaties and regional seas agreements, as well as agreements establishing certain procedural rights, such as the Aarhus Convention.

F. General Principles and Customary Rules of International Environmental Law

As discussed above, specific treaty provisions have been adopted imposing a general obligation upon states to regulate risks relating to the use and release of GMOs, and imposing more specific duties in relation to the transboundary movement of such organisms. Nonetheless, customary rules and principles of general international law remain relevant, particularly as regards non-parties to the CBD and/or Cartagena Protocol, to aspects of the regulation of risks associated with GMOs that are not fully addressed by the Biosafety Protocol.

²⁴⁰ Paragraph 11 of Article 6 of the Convention states: ‘Each Party shall, within the framework of its national law, apply, to the extent feasible and appropriate, provisions of this article to decisions on whether to permit the deliberate release of genetically modified organisms into the environment.’

²⁴¹ UN-Economic and Social Council—Economic Commission for Europe, Draft Decision I/4 *Genetically Modified Organisms* First Meeting of the Parties to the Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters MP.PP/2002/5, 12 August 2002, fourth paragraph of the Preamble.

²⁴² ECE/CEP/43/Add.1/Rev.1.

²⁴³ UN Economic and Social Council, Economic Commission for Europe, Decision II/1 *Genetically Modified Organisms* Addendum – Report of the Second Meeting of the Parties adopted at the second meeting of the Parties held in Almaty, Kazakhstan, on 25–27 May 2005, ECE/MP.PP/2005/2/Add.2, 20 June 2005.

The Committee suggests giving further consideration to the role of Principle 21 of the Stockholm Declaration,²⁴⁴ the principle of cooperation,²⁴⁵ and the relevance of the precautionary principle to the protection of the environment from risks associated with biotechnology.

The issue of state responsibility is relevant to biotechnology since the international nature of trade in biotechnology products, such as biotechnological agricultural products, means that the risks attached to it are also of an international nature.²⁴⁶ The obligation on a state, at least in relation to transboundary environmental harm, which is also relevant to harm caused by biotechnology, has two parts: first, to take measures to prevent the occurrence of transboundary environmental harm and, secondly, to redress the damage if transboundary harm occurs. States will continue to be under the general obligation of customary law not to cause, by activities originating from their territory or under their control, injury to another state,²⁴⁷ based on the principle of good neighbourliness as enunciated in the Trail Smelter Arbitration Tribunal²⁴⁸ and the International Law Commission's Articles on State Responsibility.²⁴⁹ There are a few areas which could still result in the fragmentation of the state liability rules in biotechnology. First, it has been argued that transboundary 'injury' is a relative and vague notion,²⁵⁰ which is arguably compounded by the additional qualification of 'significant' as discussed in various cases such as *Trail Smelter*²⁵¹ and *Corfu Channel*.²⁵² This may make it 'impossible to formulate a general rule of international law fixing a level at which the damages produced by transfrontier pollution can be deemed to be substantial.'²⁵³ Second, there is a problem in choosing which standards should apply to injury caused by biotechnology. They are either to be based on fault liability, on strict liability, on absolute liability, or on a mixture of these standards. Traditionally, international law has conditioned the imposition of state responsibility on a showing of negligence.²⁵⁴ There are however arguments that the nature of biotechnology-related injuries makes 'negligence' no longer suitable, thus favouring strict liability. Third, the question whether liability under international law requires culpability remains disputed.²⁵⁵ While in the past both

²⁴⁴ *Declaration of the United Nations Conference on the Human Environment*, UN Doc. A/Conf/48/14/Rev.1 (1973), 1972 (11), ILM 1416. Available at <http://www1.umn.edu/humanrts/instreet/humanenvironment.html> (last visited 11 June 2008).

²⁴⁵ For example, the *International Law Commission Draft Articles on the Prevention of Transboundary Damage from Hazardous Activities*, UN Doc. A/CN.4/L.601 (2001), available at <http://daccessdds.un.org/doc/UNDOC/LTD/G01/615/40/PDF/G0161540.pdf?OpenElement> (last visited 11 June 2008).

²⁴⁶ HILSON, C., *Information Disclosure and the Regulation of Traded Product Risks*, 2005 17 (3), *Journal of Environmental Law* 305.

²⁴⁷ Which can be 'joined and several' in certain cases. See *Case of the Treatment in Hungary of Aircraft of the USA* (Anglo-Chinese Shipping Co Ltd v U.S. 349 US 938), 1954 ICJ Reports 99.

²⁴⁸ *Trail Smelter Arbitral Tribunal (Trail Smelter I)* 1939 33, *Am. J. Int'l L.* 182.

²⁴⁹ International Law Commission (ILC) *Draft Articles on Responsibility of States for International Wrongful Acts with commentaries*, 2001 Vol. II (2), Yearbook of the International Law Commission. Available at http://untreaty.un.org/ilc/texts/instruments/english/commentaries/9_6_2001.pdf (last visited 11 June 2008). For an overview of the ILC work on state responsibility, see ROSENSTOCK, R., *The ILC and State Responsibility*, ILC's State Responsibility Articles, 2002 Vol. 96, *The American Journal of International Law* 792.

²⁵⁰ HANDL, G., *National Uses of Transboundary Air Resources: The International Entitlement Issue Reconsidered*, 1986 Vol. 26, *Nat. Resources. J.* 405, 409–421.

²⁵¹ *Trail Smelter Arbitral Tribunal (Trail Smelter I)*, *cit.*, note 299; *Trail Smelter Arbitral Decision (Trail Smelter II)*, (U.S. v Canada), 1941 35, *Am. J. Int'l L.* 684.

²⁵² International Court of Justice (ICJ), *The Corfu Channel Case* (United Kingdom of Great-Britain and Northern-Ireland v Albania), 9 April 1949, 1949 ICJ Reports 4; available at <http://www.icj-cij.org/docket/index.php?p1=3&p2=3&code=cc&case=1&k=cd> (last visited 11 June 2008).

²⁵³ HANDL, G., *cit.*, note 250.

²⁵⁴ See OPPENHEIM, L., *International Law*, (LAUTERPACHT, H., 8th ed. 1963) 311. See also MECHAM, V., *United Mexican States* (U.S. v Mexico), 1929 Vol. 4, *R. Int'l Arb. Awards* 440, 443. See also *The Convention on International Liability for Damage Caused by Space Objects*, 20 March 1972, available at

http://www.faa.gov/about/office_org/headquarters_offices/ast/media/Conv_International_Liab_Damage.pdf (last visited 11 June 2008).

²⁵⁵ SCHWARZENBERGER, G., *International Law as applied by International Courts and Tribunals*, Volume I (1957 London, Stevens) 632 et seq.

academia and jurisprudence,²⁵⁶ based on Hugo de Groot's '*qui in culpa non est, natura ad nihil tenetur*,'²⁵⁷ required culpability, the lack of any corresponding rule of treaty law makes one wonder if this is still the case.

International civil liability can be defined as 'liability of any legal or natural person under the rules of national law adopted pursuant to international treaty obligations establishing harmonized minimum standards.'²⁵⁸ An international agreement on civil liability establishes a body of unified substantive rules on the liability of private actors, to be applied by the national courts of the states Parties to the agreement, in international civil liability litigation between private entities.²⁵⁹ Any substantive issues that are not addressed by the agreement remain subject to the national law of the court where a case has been brought. There are several areas where fragmentation in international civil liability rules exists. First, there are different international rules governing cross border litigations which could be applicable to biotechnology civil liability claims. For example, the *Brussels Convention* uses the 'domicile' criterion,²⁶⁰ whereas the United States Courts, in determining whether they have jurisdiction over a matter, use the 'minimum contacts' test²⁶¹ and the 'purposeful availment' test. Even if a court concludes that it has jurisdiction, it may decide not to exercise its discretion over the particular matter on the basis of the *forum non-conveniens* doctrine.²⁶² Secondly, there are conflicting rules on applicable law depending on the rule in an individual country where no single solution may be wholly satisfactory for all torts. One major example is the 'closest connection rule', methodology which the United States still refuses to apply.²⁶³ Thirdly, rules on the enforcement of foreign judgment vary from one jurisdiction to another. A foreign award can only be enforced if it is recognized by the legal system of the country where the enforcement will take place. In most European countries, the main rules allow for a 'free circulation of judgments.' In the United States the case of *Koster v Automark Ind. Inc.* held that under US law, a court may only assert personal jurisdiction over a defendant when that defendant has 'purposefully availed themselves' of the privileges of conducting activities in the forum State.²⁶⁴

Contemporary technological and industrial development involving biotechnology has led to the emergence of the concept of international liability focusing specifically on reparation for harm arising from acts not prohibited by international law, which carry the risk of transboundary harm.²⁶⁵ The new concept is more concerned with reparation of loss or injury that may arise from such activities, than with the wrongfulness of the conduct of the state causing the damage. This new concept of liability is considered as complementary to the classic responsibility of states for wrongful acts. International liability rules in biotechnology, in the form of state responsibility and/or civil and state liability, are fragmented and subject to the national laws, rather than being part of a comprehensive and harmonized system.

²⁵⁶ Arbitral Tribunal, *Case Portugal v Germany – Naulilaa*, 1928 2 RIAA, 1012 et seq., 1025; Arbitral Tribunal, *Case United Kingdom v Panama – Matter of the Death of James Pugh*, 1942 Vol. 36, AJIL 708 et seq., 713 et seq.

²⁵⁷ GROTIUS, H., *De iure belli ac pacis*, II, Chapter 17, § 21.

²⁵⁸ SANDS, P., *Principles of International Environmental Law* (1995 MUP) 629.

²⁵⁹ See among many others BOYLE, A. D., MURPHY, S. and CHURCHILL, R., *Facilitating (Transnational) Civil Liability Litigation for Environmental Damage by Means of Treaties: Progress, Problems and Prospects*, 2001 Vol. 12, YBIEL.

²⁶⁰ Article 20 of the *Brussels Convention on Jurisdiction and the Enforcement of judgments in Civil and Commercial Matters* (Brussels Convention), 27 September 1986, Brussels, available at <http://curia.europa.eu/common/recdoc/convention/en/c-textes/brux-textes.htm> (last visited 11 June 2008).

²⁶¹ See *case concerning International Shoe Co. v Washington* 326 US 310 (1945). One of the parties has 'certain minimum contacts with the [forum] state such that the maintenance of the suit does not offend 'traditional notions of fair play and substantial justice.'

²⁶² The doctrine was originally developed in Scotland in the *case concerning Sim v Robinow* 1892 19, R. 665 in which Lord Kinnear delivered a much quoted judgment later adopted in other common-law jurisdictions. See JUENGER F.K., *Forum Shopping, Domestic and International*, 1989 63, Tulane Law Review 553. For the rules in the United States see Supreme Court decisions of *Gulf Oil v Gilbert and Piper Aircraft cases* 1947 330, US 501.

²⁶³ DESSEMONTET, F., *Conflict of Laws for Intellectual Property in Cyberspace*, 2001 Vol. 18 (5) Journal of International Arbitration 487–510.

²⁶⁴ U.S. Court, *The Koster v Automark Industries, Inc. Case*, 640 F2d 77 (7th Cir. 1981).

²⁶⁵ 1973 ILC Yearbook Vol. 1, 211, 1243rd meeting, paragraph 37.

G. Harmonization

Harmonization can be broadly defined as the process of making different domestic laws, regulations, principles and government policies substantially or effectively the same or similar.²⁶⁶ In the field of biotechnology, the motive seems to be to set up an international standard to combat any negative effects and to handle risks from the new technology. There are several arguments in favour of harmonization such as to provide for familiarity, efficiency and a level playing fields and to reduce the race to the bottom. On the other hand, there are several arguments against harmonization such as its being costly, restricting political sovereignty over domestic regulations and it creates problems of standard setting. The role of international actors in the domestic system is becoming important in new areas such as biotechnology where Valaskaki finds that there is still a vacuum in the global governance of biotechnology and genetic engineering.²⁶⁷ He asserts that biotechnology is totally unregulated worldwide and that there are no institutions likely to change this situation in the near future. Legislation by individual states is quite meaningless since their jurisdictions can be circumvented by going elsewhere. The strongest case in favour of world regulation and harmonization seems to be the argument based on so-called international public goods.²⁶⁸ International public goods are public goods whose benefits reach across borders, generations and population groups. Public goods are said to be harmonized when all traders belonging to the same market choose to unite in a single jurisdiction.²⁶⁹ The introduction of new technologies such as biotechnology challenges the classic definition of public goods. The mixed public-private goods nature of biotechnology products can also be described by the involvement of the private sector companies in production and in the creation of regulation at the national and international levels.²⁷⁰ Furthermore, harmonization of certain rules such as standards of liability in biotechnology is being influenced by public perception, which is complex. A consideration of public perceptions of biotechnology requires an understanding of the relationship between society and technology since biotechnology is a special case of the more inclusive social dynamics.²⁷¹ A negative perception could lead to greater rigidity of the standard, leading to the acceptance of strict liability over fault liability.

The main process of harmonization of liability rules in biotechnology is taking place within the Cartagena Protocol framework and the end result could be limited to the liability arising from activities and products or materials within the scope of the Protocol. The Parties to the Cartagena Protocol established an open-ended 'Ad Hoc Working Group of Legal and Technical Experts on Liability and Redress' to carry out the process pursuant to Article 27 of the Protocol.²⁷² The latest position of this Ad Hoc Working Group is reflected in the following table, extracted from the Report of its third meeting:

<i>Possible approaches to liability and redress</i>	<i>Scope</i>	<i>Damage</i>	<i>Primary compensation scheme</i>	<i>Supplementary compensation scheme</i>	<i>Settlement of claims</i>

²⁶⁶ MAYEDA, G., *Developing Disharmony? The SPS and TBT Agreements and the Impact of Harmonization on Developing Countries*, 2004 7(4), JIEL 737–764, 740.

²⁶⁷ VALASKAKI, K., *Long-term Trends in Global Governance: From “Westphalia” to “Seattle” in Governance in 21st Century*, 2001 OECD Paris Future Studies.

²⁶⁸ SALIN, P., *World Regulations and Harmonization*, 2001 VI (1), *The Independent Review* 59–80.

²⁶⁹ CASELLA, A. and FEINSTEIN, J.S., *Public Goods in Trade: on the Formation of Markets and Jurisdictions*, May 2002 Vol. 43 (2), *International Economic Review* 437.

²⁷⁰ NEWELL, P. and GLOVER D., *Business and biotechnology: regulation and the politics of influence*, July 2003 IDS Working Paper 192, Institute of Development Studies.

²⁷¹ FLEISING, U., *Public Perceptions of Biotechnology*, in SPRINGHAM, D., (ed.), MOSES, V. and CAPE, R., (eds.) *Biotechnology, The Science and the Business*, (1991 Amsterdam, Harwood Academic Pub, 2nd edition) 89–102, 89.

²⁷² Decision BS-1/8, available at <http://www.biodiv.org/decisions/default.aspx?m=MOP-01&id=8290&lg=0> (last visited 11 June 2008).

<i>State responsibility</i>	1. Reference to existing rules and procedures
<i>State liability</i>	1. Development of international rules and procedures (legally binding and/or non-legally binding) 2. No rules and procedures
<i>Civil liability</i>	1. Development of international rules and procedures (legally binding and/or non-legally binding) 2. Development of international guidance for national rules and procedures 3. Combination 4. No rules and procedures
<i>Administrative approach</i>	1. Development of international rules and procedures (legally binding and/or non-legally binding) 2. Development of international guidance for national rules and procedures 3. Combination 4. No rules and procedures

In tandem with its work on State responsibility, the International Law Commission (ILC) has, since 1978, been considering the issue of 'International liability for injurious consequences arising from acts not prohibited by international law'. During its fifty-eighth session in 2006, the ILC adopted the text of the preamble and a set of eight draft principles on the allocation of loss in the case of transboundary harm arising from hazardous activities. The Commission concluded that the form of the instrument, *i.e.* draft principles, has the advantage of not requiring a harmonization of national laws and legal systems and that widespread acceptance is more likely if the outcome is cast as principles. The preamble to the draft principles places the principles in the context of the 1992 *Rio Declaration on Environment and Development* and the ILC's earlier *Draft Articles on the Prevention of Transboundary Harm from Hazardous Activities* from 2001. The draft adopts the strict liability approach. The commentary justifies this approach by stating that hazardous and ultra hazardous activities, involve complex operations and carry certain inherent risks of causing significant harm. In such matters, it is widely recognized that it would be unjust and inappropriate to make the claimant shoulder a heavy burden of proof of fault or negligence in respect of highly complex technological activities whose risks and operation the concerned industry closely guards as a secret. The case for strict liability is strengthened when the risk has been introduced unilaterally by the defendant.²⁷³

H. Other open questions

The Cartagena Protocol has been in force for just five years,²⁷⁴ and it remains difficult to assess its effectiveness. Many Parties are still in the process of developing and seeking to operationalise national legislation to implement the Protocol, and relatively little information is available about transboundary movements of GMOs

²⁷³ ILC, Report on the work of its fifty-eighth session, see note 300, paragraph 13, 156.

²⁷⁴ The CPB entered into force on 11 September 2003.

taking place within the Protocol's framework. It is clear that many Parties have yet to establish a working national biosafety regulatory system and/or may lack the capacity to maintain such a system. Beyond questions of implementation of existing legal rules, there remain a number of questions which may require further action of clarification. They include the following.

1. NON-PARTIES TO THE BIOSAFETY PROTOCOL

The Biosafety Protocol enjoys a wide, but not a universal membership.²⁷⁵ It does not regulate in detail transboundary movement of GMOs between Parties and non-Parties, requiring only of Parties that such movements be 'consistent with the objective' of the Protocol.²⁷⁶ It might also be noted, however, that Parties to the CBD, even if they remain non-Parties to the Protocol, remain bound by Article 19(4) of the CBD which contains a general obligation to provide pertinent information. Nonetheless, there is a need to point out that transboundary movements of GMOs may to some extent be the subject of the customary international rules on preventing transboundary environmental harm, if occurring in relation to a non-Party. In that context, the principle of precaution and other relevant principles may be applicable.

2. SENSITIVE ECOSYSTEMS AND CENTRES OF ORIGIN AND OF DIVERSITY

It is questionable whether the existing rules provide sufficient protection for sensitive ecosystems, and centres of origin or of diversity. As mentioned above, the CBD addresses the protection of ecosystems and habitats,²⁷⁷ and the Biosafety Protocol directs Parties when conducting a risk assessment regarding the first import of a GMO for release into the environment to consider the environment into which it is proposed to introduce that GMO.²⁷⁸ The Committee considers that it should be explored whether some further specific guidance on this point could be achieved by action taken under the CBD and/or the Protocol or under other relevant international environmental agreements, such as, for instance, the Ramsar Convention²⁷⁹ or other biodiversity-related treaties. The situation in regard to the marine environment and areas beyond national jurisdiction is also in need of clarification. The Cartagena Protocol does contain some provisions addressing transport and packaging of GMOs²⁸⁰ that may be relevant, *inter alia*, to maritime transport of such organisms. However, it does not specifically require advance informed agreement procedures for transit of GMOs.²⁸¹ More generally, while policy debates have for the most part focused on considerations relating to agricultural biodiversity, special consideration may need to be given to particular risks posed by GMOs in and to the marine environment.

3. SPECIFIC TYPES AND SPECIFIC TRAITS OF GMOs

The Biosafety Protocol does not specifically address specific types of GMOs (e.g. genetically manipulated fish or genetically manipulated trees) or specific traits associated with certain GMOs. However, Article 16(5) does provide that Parties are to cooperate with a view to identifying 'living modified organisms or specific traits of living modified organisms' that may have adverse effects on the conservation and sustainable use of biological diversity, and take appropriate action regarding the treatment of such organisms or traits. The Protocol's COP/MOP has not as yet taken specific action under this provision. However, it is noteworthy that the Conference of the Parties (COP) to the CBD, at its most recent meeting in May 2008, has addressed particular concerns relating to genetically manipulated trees. The COP reaffirmed the need for a precautionary approach

²⁷⁵ 147 Parties as at June 2008.

²⁷⁶ CPB, Article 24(1).

²⁷⁷ See especially, CBD Article 7(a), Article 8 and Annex I.

²⁷⁸ CPB, Article 15, and Annex III. With regard to the receiving environment, paragraph 9 (h) of Annex III directs Parties to consider '[i]nformation on the location, geographical, climatic and ecological characteristics, including relevant information on biological diversity and centres of origin (...)'.²⁷⁹

²⁷⁹ *Ramsar Convention on Wetlands of International Importance especially as Waterfowl Habitat*, 2 February 1971, entered in force 21 December 1975, 11 ILM (1972) 963; available at http://www.ramsar.org/key_conv_e.htm (last visited 11 June 2008).

²⁸⁰ CPB, Article 18.

²⁸¹ CPB, Article 6(1). See also CPB, Article 2(3).

and called on parties to authorise the release of genetically manipulated trees only after completion of studies in containment as well as science-based and transparent risk assessments.²⁸² It seems likely that further attention will need to be given to this issue in the future, and possibly to other specific types and traits of GMOs.

²⁸² *Summary of the Ninth Conference of the Parties to the Convention on Biological Diversity* (19–30 May 2008), 2 June 2008 (9) 452, Earth Negotiations Bulletin, available at: <http://www.iisd.ca/vol09/enb09452e.html> (last visited 11 June 2008). The full text of this COP decision was not available at the time of writing this report, but will be made available in due course on the Convention website at <http://www.cbd.int> (last visited 11 June 2008).