INTERNATIONAL LAW ON BIOTECHNOLOGY

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Keywords: bioethics, biotechnology, Codex Alimentarius, Convention on Biological Diversity, consumer protection, human dignity, human genetic data, human genome, human rights, public participation, risk analysis, UNEP, UNESCO, UNFAO, WHO, WTO.

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Summary

Modern biotechnology is a fast-growing technology which creating new opportunities and posing potential risks to the international community. International law on biotechnology is a typically example of how the international community creates regulatory responses to problems and challenges arising from scientific innovation and technological change. Existing international agreements on biotechnology have adopted a set of principles, rules, guidelines, code of conduct and resolutions in response to these challenges and changes. They also generally provide a system combining legislative, administrative, judicial and adaptive functions for the implementation of these agreements. As a whole, they have already established an international regime for the governance of biotechnology. Existing international biotechnology agreements have been designed and adopted to balance competing interests and to pursue sustainable development. Accordingly, they largely focus on human health, environmental protection, biodiversity and biosafety, scientific innovation, agricultural development,

human rights, development needs for all applications of biotechnology. Many objectives, doctrines, principles, rules and instruments contained in these agreements are highly consistent as they are generally drawn from similar legal regulations and practices already enacted in states or international organizations. As a whole, international biotechnology agreements have already established an appropriate framework for the regulation of biotechnology in the international community.

1. Introduction

Biotechnology has grown rapidly in the 1990s, with a revolution taking place in the field; scientific discoveries have opened up new applications in health care, agriculture, food production, and environmental protection, and the technologies hold the promise of meeting fundamental food and health needs around the world. At the same time, biotechnology also raises important policy and societal issues and has given rise to broad public debate. Great diversity exists between countries with respect to their capacity to develop, apply, and regulate the new biotech products and services. These differences have become a source of tension in international economic relations. Consequently, biotechnology presents a new challenge for international law.

At the international level, there is no single comprehensive legal instrument that covers all aspects of biotechnology or biotech products. However, a number of existing international agreements are directly relevant to biotechnology.

Many international organizations have also undertaken the task of setting standards, in particular dealing with the impacts of biotechnology on health, the environment, agriculture, trade, ethical and socio-economic aspects. These organizations include the Codex Alimentarius, the World Health Organization (WHO), United Nations Food and Agriculture Organization (FAO), the United Nations Environmental Programme (UNEP), the United Nations Educational, Scientific and Cultural Organization (UNESCO) and the United Nations Industrial Development Organization (UNIDO), etc.

The development of international agreements and standard and rule-making relating to biotechnology can be of assistance to many countries, in particular developing countries, in establishing appropriate biotech laws while, at the same time, promoting harmonization of national biotech regulations at international level. In the long run, the practices of biotech laws and agreements at both national and international levels will subsequently contribute to the formation of international biotechnology law.

2. The Background of International Law on Biotechnology

2.1. The Concept and Development of Biotechnology

The word “biotechnology” is a compound word, made up of the prefix bio-, meaning biological and technology. Karl Ereky, a Hungarian scientist, first devised the term “biotechnology” in 1919. Since its inception, the notion of biotechnology has been variously defined. The Oxford English Dictionary defines biotechnology as “*the exploitation of biological processes for industrial and other purpose, esp. genetic manipulation of micro-organisms for the production of antibiotics, hormones, etc.*”

In 1982, an expert group proposed a common definition of biotechnology for OECD member countries, in which it was taken as "*the application of scientific and engineering principles to the processing of materials by biological agents to provide good and services*." This definition is still widely referred to and remains the most informative.

In 2005, members of the OECD's *Ad hoc* Biotechnology Statistics Group developed a single, list-based definition of biotechnology. The single definition is: *the application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services*. The list-based definition of biotechnology includes the following: DNA/RNA, proteins and other molecules, cell and tissue culture and engineering, process biotechnology techniques, gene and RNA vectors, bioinformatics and nanobiotechnology, etc. The OECD definition of biotechnology is very broad as it covers all modern biotechnology and also many traditional and borderline activities.

Biotechnology has given rise to worldwide public debates about its opportunities and potential risks. The growth of the field raises some of the most fundamental issues currently facing the international community, and makes necessary a common definition at the international level to establish the legal framework and rules for biotechnology. According to Article 2 of the 1992 United Nations Convention on Biological Diversity, biotechnology is defined as: "*any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.*" Article 3 of Cartagena Protocol on Biosafety defines modern biotechnology as "*the application of: (a) In vitro nucleic and techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or (b) Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombinant barriers and that are not techniques used in traditional breeding and selection.*" In the absence of a more specific internationally-agreed upon legal definition, the Convention on Biological Diversity is an important reference.

Research on genetically modified organisms (GMOs) began in the 1970s. The technology indicated the possibility of realizing significant benefits, such as increasing agricultural output, adding nutritional value to foods, and certain environmental benefits such as reductions in the use of pesticides. The first GMO was created in 1973, but the first GMO plant was not produced until 1983. In terms of volume, the first generation GMOs remains the most common. Herbicide tolerant crops account for some 73% of commercially planted area worldwide, followed by insect resistance (18%), and stacked genes (i.e. both herbicide tolerant and insect resistant) 8%. Virus resistant and quality traits amount to less than 1% of GM crops grown worldwide.

The first significant sowing of GM crops (2.6 Mio ha) took place in 1996 and occurred almost exclusively in the US. During the period from 1996 to 2003, there was a forty-fold increase in the area growth of biotech crops worldwide. The US had the largest area of GM crops in 2003, around 63% of the total, followed by Argentina (21%), Canada (6%), Brazil (4%), China (4%) and South Africa (1%).

2.2. Issues Relating to Biotechnology

The genetic modification techniques are recognized as providing significant benefits. However, it is also recognized that this new technology also poses potential risks for human health and the environment that differ from their conventional counterparts. Possible harmful effects on human health have been identified as arising from GMOs, including toxicity, allergenicity, horizontal gene transfer, antibiotic resistance, etc. Potentially harmful effects on environment include invasiveness and development resistance, non-target effects, biodiversity risk, etc. There remains significant scientific uncertainty over the long-term effects of the GMOs on human rights and the environment.

Many biotech products are traded internationally, either as commodities or as manufactured goods. Biotech product is probably one of the biggest emerging issues affecting international trade. There is also a growing recognition that GM products and biotechnology can have significant socio-economic effects. Beyond socio-economic considerations, more and more countries are taking account of cultural, ethical and religious aspects and effects derivative of biotechnology. Modern biotechnology raises a wide variety of ethical questions, including in relation to the need to ensure food security, farmers' incomes, conservation and sustainable use of natural resources, the protection of human rights, and sharing the benefits of biotechnology in an equitable manner. Attention should also be paid to how the use of biotechnology will impact environmental integrity. Accordingly, biotechnology has become a subject of increasing public debate and regulatory concern. From the earliest days of the development of GMOs, policymakers around the world have focused on how to use and develop its potential while adequately addressing the many issues raised by the new technology. Indeed, regulation of GMOs has always been a central part of the general GMO debate. International law constitutes one of the ways in which such concerns are operationalised beyond national level.

The first GMO crop was produced in 1983. These crops were tested in field trials throughout the 1980s, and it was only in the early 1990s that the first GM crops were ready for commercialization. Evolving regulatory approaches reflect this evolution. Early regulation focused on safety standards to be respected in laboratory research and on conditions for field trials, and it was only in the 1990s that regulators began to address the question of how to deal with the marketing of GM products, and in particular the conditions under which authorizations could be granted for the commercial cultivation of GM crops and the production and marketing of genetically modified food or other products.

2.3. Regulatory Approaches to Biotechnology

There are significant differences in the kinds of regulatory approaches countries adopt on biotechnology. The United States has adopted a regulatory approach closest to a *laissez-faire* model. The Food and Drug Administration (FDA) issued a policy statement in 1992, in which it established that biotech products were generally considered to be as safe as conventional food and that pre-market approval was only necessary under certain conditions.

The great majority of countries have, so far, adopted some form of regulation on biotechnology and biotech products. The core elements for regulation on biotechnology include laboratory control, environmental release, risk analysis, and socio-economic considerations for pre-marketing authorization; also subject to regulation are labeling, traceability and other monitoring measures for post-approval surveillance. Risk analysis covers risk assessment, risk management and risk communication. Precautionary action is also provided for in the risk analysis and regulatory systems of most countries. These measures are expected to allow for a high level of protection of human health, environment and eco-system.

These measures at the national level are illustrative of a global trend, which has led to the adoption of several international instruments to address the adverse effects of GMOs. The potential of biotechnology to contribute to the alleviation of some problems associated with development and the environment was recognized by the 1992 UN Conference on Environment and Development (the "Earth Summit"), which devoted Chapter 16 of Agenda 21 to "Environmentally sound management of biotechnology." In addition to providing the basis for future negotiation of a specific protocol on biosafety, the Convention on Biological Diversity requires Contracting Parties to establish or maintain specific means to regulate risks associated with GMOs. Article 8(g) of the Convention thus required Parties, as far as possible and as appropriate, to 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.

This provision reflects a common view that "living modified organisms" are not the same as their non-GM counterparts, and that they have characteristics which inherently require the assessment of human and environmental risks.

Many international agreements relating to biotechnology are legally binding or strongly political consensus, including, *inter alia*, the UN Convention on the Law of the Sea (UNCLOS, 1982), the Convention on Biological Diversity (1992), the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement, 1994), the WTO Agreement on Technical Barriers to Trade (TBT Agreement, 1994), the International Plant Protection Convention (1997), the UNESCO Universal Declaration on Human Genome and Human Rights (1997), the Aarhus Convention (1998), the Biosafety Protocol (2000), the UNESCO International Declaration on Human Genetic Data (2003), and the UNESCO Universal Declaration on Bioethics and Human Rights (2005).

3. International Agreements and Rules on Biotechnology

3.1. The Biosafety Protocol

The Biosafety Protocol is the first international legally binding agreement on the trade of GMOs. The Protocol was opened for signature in May 2000 and entered into force on the 11 September 2003. As of 31 October 2010, 159 countries and the EU have ratified or acceded to the Protocol.

The objective of the Protocol is to contribute to ensuring — in accordance with the

precautionary approach contained in Principle 15 of the Rio Declaration — an adequate level of protection in the field for the safe transfer, handling and use of LMOs resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, while also taking into account risks to human health.

In addition, parties to the Protocol shall ensure that the development, handling, transport, use, transfer and release of any LMOs are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health. The Protocol also allows parties to take action that is more protective of biodiversity than that called for in the Protocol, provided that such action is consistent with the objective of the Protocol and is in accordance with Parties' obligations under international law. The EC legislative framework on GMOs is one example of such stricter measures.

The Protocol contains many important provisions regarding: the precautionary principle; advance informed agreement (hereinafter "AIA"); information sharing; a compliance mechanism; public participation; liability and redress; and capacity-building and financial resources for developing countries, etc.

With regard to the precautionary principle, Article 1 of the Protocol states that the objective of the Protocol is to be pursued in accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development. Article 10 further specifies the import procedure of LMOs for deliberate release. Article 10(6) states that "*lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent a party from taking a decision, as appropriate, with regard to the import of the living modified organism in question.*"

The Protocol gives the precautionary approach a significant role in the decision to regulate import of LMOs in the face of scientific uncertainty. It should be noted that the provisions on precaution are not formulated as obligations but as rights to take precautionary action.

Articles 7 and 8 contain the AIA procedure. Article 7(1) states that the AIA procedure shall apply prior to the first intentional trans-boundary movements of LMOs intended to be introduced into the environment of the importing party. Article 8 requires exporting parties to notify, or to require the exporter to notify, the competent national authority of the importing party. Notification must contain the information specified in Annex I of the Protocol, including risk assessment. According to Article 11 and 20, a Biosafety Cleaning-House is established in order to deal, *inter alia*, with the significant trade in LMOs. The Cleaning-House also serves as a multilateral information exchange mechanism.

The Protocol contains measures for explicit public participation in Article 23. Contracting parties shall: (a) promote and facilitate public awareness, education and

participation concerning safe transfer, handling and use of LMOs in relation to biodiversity conservation and sustainable use; (b) ensure public awareness and education encompass access to information on LMOs identified by the Protocol that may be imported; (c) consult the public in the decision-making process regarding LMOs and shall make decisions available to public, but respecting confidential information; and (d) each party is to endeavor to inform its public about access to information on Biosafety cleaning house.

Article 26 allows parties to take socio-economic considerations into account in reaching a decision on the import of LMOs, consistent with their international obligations, insofar as these concerns arise from the impact of LMOs on the conservation and sustainable use of biodiversity. However, decision-making may only account for the socio-economic relating to potential biodiversity loss and not more generally. It is implied that socio-economic should not be addressed in identification of hazards and assessment of risk. The parties are encouraged to cooperate on research and information exchange on any socio-economic impacts of LMOs, especially on indigenous and local communities.

The Biosafety Protocol contains most of the core elements relating to regulatory approaches on biotechnology. Prior to the Protocol, there was no global legally binding instrument to address the transfer, safe handling and use of LMOs resulting from biotechnology in the context of adverse effects on the environment that could adversely affect biodiversity. The Protocol can be seen as the most comprehensive and important international agreement on biotechnology, but by no means the only one. Other international agreements also operate in parallel with the Biosafety Protocol in the development and formation of international law on biotechnology.

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