BIOSAFETY

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Summary

Although efforts to create a regulatory framework for the safe application of biotechnology have proliferated since the 1980s, no comprehensive system exists setting out fundamental rules and principles. Existing regulation is piecemeal, and tends to focus mostly on aspects of food safety.

Viewed within this context, the Cartagena Protocol on Biosafety to the Convention of Biological Diversity, adopted in Montreal in January 2000, is a landmark in being the first international agreement to provide a comprehensive legal framework for a specific side aspect of biotechnology, (i.e., transboundary movements of living modified organisms, or LMOs). Although not regulating all aspects of modern biotechnology, it is nevertheless a crucial step towards regulation of its development and applications. As a product of sustained and prolonged negotiations, it bears the signs of compromise and is, thus, a blend of positive and negative elements. The fact that it came into being in the first place indicates the belief that LMOs are of a particular nature and should be treated differently than other goods. Its major achievement, from the perspective of sustainable development, is the prominence it gives to the precautionary approach and the advance informed agreement procedures it institutes. It also contains a specific commitment on

capacity building and technology transfer towards less developed states and states with economies in transition, as well as providing for public awareness and participation campaigns. At an institutional level, it provides for an internet-based clearinghouse mechanism to facilitate exchange of information concerning shipments of LMOs. However, it does not impose a clear obligation to segregate LMO-containing shipments from conventional ones. It is also less clear as to its relationship with the WTO agreements, although in its preamble it is stated that the two sets of rules are to be "mutually supportive."

1. Introduction

Biotechnology involves the exploitation of living organisms to carry out specific purposes. The term is not new: it was coined in 1919 by Karl Ereky, a Hungarian engineer, to refer to the science and methods that permit products to be produced from raw materials with the help of living organisms. Biotechnology practices have been known and used for centuries for the creation of food (i.e., bread, cheese, wine, or beer [fermentation]) or to breed stronger animals and crop varieties (selective breeding).

Modern (i.e., dealing with genes and DNA) biotechnology takes as its starting point 1953, when Watson and Crick elucidated the structure of DNA. Their discovery provided significant impetus to developing the knowledge base for the new technology and its practical applications. In 1973, Cohen and Boyer performed the first direct gene transfer, at Stanford. Three years later, the creation of the first biotechnology company by biochemist Boyer and venture capitalist Swanson (1976, Genentech), inaugurated the era of industrial biotechnology. Thirty years later, the accounting firm of Ernst and Young, in their Eighth Annual European Life Sciences Report 2001, noted 8 679 companies working in the "life sciences" sector in Europe, employing more than 60 000 people, generating an annual revenue of €8.6 billion with €4.9 invested in research and development. The numbers for the US were 23 750 companies, employing 162 000 people, with an annual revenue of €23.7 billion and €11.4 billion in research and development. Capitalization of the European and US markets combines reaches €451 billion. Worldwide, more than 50 million hectares are used to grow GMOs, 95% of which are located in USA, Canada, and Argentina.

Modern biotechnology moves at the intersection of several branches of science and its applications are significant in such diverse areas as agriculture, food production, medical treatment, and pharmaceutical research, environmental protection and resource-use, or ethics. Among new technologies, few have excited such widespread interest, have held more hope for solving serious problems (ranging from ending food scarcity to curing "incurable" illnesses), and have generated so many intense controversies and fear as to their possible implications both in terms of environmental protection and in terms of human health. It places complex demands on policy making, regulatory intervention, including standard setting, and implementation of existing rules both on the national and the international level, as scientific innovation and related applications move much faster than regulatory/implementation capacity. Furthermore, it would seem that policy making in the area of biotechnology is currently less related to science than to other factors, such as commercial viability (e.g., of biotech medicine too costly to be covered by national health systems). Indeed, a growing number of examples indicate a lack of

correlation between these scientific concepts used to explain the significance and consequences of biotechnology and the legal concepts used to frame public debate and regulation. Such a gap often facilitates a sense of uneasiness among the wider public, as full understanding of the issues at hand is lacking. Public perceptions of science to a large degree still correspond to a simplistic paradigm linking scientific work with creation of certainties. There is an obvious need to reconcile the public with the open-endedness of the scientific process and its interaction with society at large.

In this context, a number of international organizations have been active from early on in dealing with different aspects and applications of biotechnology. The first steps towards analyzing, and comprehending the possible implications of biotechnology had already been taken by the OECD in the 1980s. Since then, the OECD and organizations like the EU, the FAO, the WIPO, UNEP, the CGIAR, the Codex Alimentarius, the OIE, and UNESCO have directed their activities towards regulation, standard setting, regulatory and technical harmonization, dissemination of information, capacity building and protection of intellectual property rights, and the ethical challenges posed by this technology. The means that were, and still are, used to accomplish this work have mainly been Codes of Conduct, Guidelines, Committees, Task Forces, and Expert Groups, while a number of existing international agreements (like the International Plant Protection Convention (IPPC), the International Undertaking on Plant Genetic Resources (IU) or the Convention on the International Union for the Protection of New Varieties of Plants (UPOV)) have extended or are in the process of extending their scope so as to encompass some effects of biotechnology. The issue of biosafety also emerged relatively early—in fact, as soon as it was understood that use of biotechnology could engender dangers either for the environment or human health.

The relevance of biotechnology for achieving sustainable development had already been identified in 1992, by Agenda 21. In its Chapter 16, biotechnology was acknowledged as holding great potential to benefit humankind, mainly through helping to achieve food security, beneficial drugs and environmental bioremediation. However, it also stressed that biotechnology could only benefit humankind if certain conditions were met. The ability of every nation to access it and use biotechnology necessitated prudence pending the identification of potential risks. In 1995, UNEP produced its International Technical Guidelines for Safety in Biotechnology. These were greeted as part of efforts to implement Chapter 16 of Agenda 21. They were the product of a very wide consultation with other international agencies concerned with matters of biosafety. The Guidelines contain recommendations as to elements to be included in risk assessment and management, and stress the importance of information exchange, prior informed consent procedures, and particularly capacity-building as central elements in developing international strategy for regulating biotechnology and for facilitating access to the benefits it generates.

Despite their number and variety, the various instruments, programs, codes of conduct, technical guidelines that apply to biotechnology do not constitute a comprehensive *system* for its international regulation. Most of the organizations involved touch upon the issue incidentally, and only to the extent it may relate to their primary field of competence. Furthermore, most of the texts relating to biotechnology are not legally binding on states and on other actors, being essentially based on voluntary adherence

schemes and/or compliance. Hence the need for a proper legal instrument, that would impose specific obligations upon its states parties.

The Convention on Biological Diversity (CBD), signed in 1992, included an article on the handling of biotechnology and of distribution of its benefits. The article contained also mention of the Parties undertaking the elaboration of a special instrument, intended to regulate transboundary movements of LMOs. In 1995, at the second meeting of the Conference of the Parties (CoP), a decision was made to establish a working group with the purpose of preparing such a draft protocol regulating the biosafety aspects of transboundary movements of LMOs and taking advantage of all previous regulatory and standard-setting efforts in the area. It was decided that UNEP's Technical Guidelines would serve as an intermediate instrument to regulate biosafety until the Protocol to the CBD was concluded.

2. The Cartagena Protocol on Biosafety

The Cartagena Protocol on Biosafety to the Convention on Biological Diversity was adopted in Montreal, Canada, on 29 January 2000, by the Conference of the Parties to the Convention on Biological Diversity. The text of the Protocol was opened for signature at UNEP headquarters in Nairobi, Kenya, 15–26 May 2000, on the occasion of the Fifth Session of the Conference of the Parties to the Convention on Biological Diversity. Thus ended a long and difficult negotiation process that had begun four years earlier, in 1996, when the open-ended Ad Hoc Working Group on Biosafety (BSWG), established by decision II/5 of the CoP to the CBD, met for the first time to discuss adoption of a protocol "setting out appropriate procedures, including, in particular, advance informed agreement (AIA), in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity" (article 19 CBD). Although its mandate was to produce a final draft text by 1998, the BSWG failed to produce the consensus required during the five meetings it held. Finally, it was decided to convene a sixth meeting in Cartagena, Colombia, in February 1999, to enable the BSWG to come up with a draft treaty for adoption by an Extraordinary Session of the CoP (ExCOP 1) which was to follow immediately afterwards. Despite an intense negotiation period of ten days, the text that reached the ExCoP was still heavily bracketed, and real consensus was lacking on the two main issues of negotiation, namely whether there should be a special AIA procedure for commodities and what should be the relationship between the future Protocol and the WTO. Consequently, it was decided to suspend negotiations. Following a number of informal consultations in Montreal and Vienna throughout 1999, the exCoP eventually resumed its session the following year, in Montreal, Canada, and the Cartagena Protocol (named after the city where it was originally intended to be adopted) was adopted on 29 January 2000.

During the negotiations, states formed five groups on the basis of their shared interests: (1) the like-minded States, comprising most developing countries and China; (2) the Miami group, consisting of Argentina, Australia, Canada, Chile, Uruguay, and the US as an observer; (3) the EU; (4) the "compromise" group, which developed in the later stages of the negotiation and comprised Japan, Norway, Switzerland, Mexico, South Korea, Singapore, and New Zealand, and (5) the CEE group, comprising the countries

of central and Eastern Europe, including Russia. Although the US is not a party to the CBD, it was granted observer status and played a very active role during negotiations for the Biosafety Protocol. While only state parties to the CBD can become members of the Biosafety Protocol, the attendance of the US was deemed necessary as no agreement on biosafety could be expected to be effective unless it took into account the position of the US—a leading actor in that area.

Negotiations revolved around a number of particularly difficult issues: determining the scope of the protocol and the AIA procedure; the treatment of LMO-FFPs (commodities); the precautionary approach; the relationship between the protocol and other international agreements, notably those under the WTO; liability; taking into account socioeconomic factors in the risk assessment procedure; and setting up of a system for information exchange and capacity building in less developed countries and in countries with transition economies.

The like-minded group was particularly wary of the potential socioeconomic consequences of transboundary movements of LMOs. Seeing themselves as potential importers or transit countries, they advocated a strict regulatory approach, placing all types of LMOs under the Protocol's regulatory umbrella. They also pressed hard for including the precautionary principle in the main body of the Protocol, and for adopting a broader view of risk assessment incorporating socioeconomic factors.

The Miami group, on the contrary, being principally producers, and therefore exporters of LMOs, were particularly averse towards any type of regulatory structure that would slow down trade, especially in agricultural products. Consequently, they favored a narrow definition of the scope of the agreement, which would restrict the application of the protocol only to LMOs for intentional introduction in the environment (i.e., seeds) and not to those intended for direct use as food, or feed or processing (i.e., commodities).

The EU shared the like-minded states' view on setting up a strict regulatory framework. The food scares of the 1990s (BSE, dioxin) had created a growing sense of uneasiness among European consumers; they also led to increased skepticism towards use of LMOs for food production. At the time of the Cartagena negotiations, a three-year moratorium on GMO approvals was in force within the EU. In the areas of public health, environmental protection, and food safety, a system of stricter standards was created, placing the precautionary principle at the heart of the EU's policies. This approach had already been challenged within the WTO. As a result, the EU was keen to see stricter standards that reflected its own policy choices being consecrated at the international level. It favored inclusion of the precautionary principle in the text of the Protocol, arguing that (restrictive) policy measures grounded on precaution should not be considered a barrier to trade, and should, thus, be exempted from application of the WTO rules.

This particular issue had acquired a new importance, after the failure of negotiations in Cartagena and in conjunction with preparatory work for the upcoming new multilateral round of trade negotiations in Seattle. A proposition supported by Canada and Japan to create within the WTO a new working group on trade and biotechnology, and a US

suggestion for new disciplines within the WTO regulatory system concerning trade in GM products placed biotechnology immediately within the realm of the WTO agreements. With the collapse of talks at Seattle, additional pressure was put on negotiating parties in Montreal to reach an agreement. Failure to do so at this juncture would have meant having to face a resurgence of the trade and biotechnology agenda in the next round of multilateral trade negotiations.

A fourth coalition of states, the "compromise" group, was formed during the last stages of negotiations. While generally sharing the main concerns regarding LMOs, it wanted to achieve a solution that would be compatible with existing trade rules and interests. The fifth group, of CEE countries, shared mainly the views of the EU, but did point out, throughout the negotiations, their lack of capacity in dealing with problems generated by trade and transboundary movement of LMOs.

The Cartagena Protocol was finally adopted during a particularly protracted final plenary session. It comprises 40 articles and three annexes. It is a landmark in being the first international agreement to provide a comprehensive legal framework for a specific side aspect of biotechnology (i.e., transboundary movements of LMOs). Although not regulating all aspects of modern biotechnology, it is nevertheless a crucial step towards regulation of its development and applications. As a product of sustained and prolonged negotiations, it bears the signs of compromise and is, thus, a blend of positive and negative elements. The fact that it came into being in the first place indicates the belief that LMOs are of a particular nature and should be treated differently than other goods. Its major achievement, from the perspective of sustainable development, is the prominence it gives to the precautionary approach and the advance informed agreement procedures it institutes. It also contains a specific commitment on capacity building and technology transfer towards less developed states and states with economies in transition, as well as providing for public awareness and participation campaigns. At an institutional level, it provides for an internet-based clearinghouse mechanism to facilitate exchange of information concerning shipments of LMOs. However, it does not impose a clear obligation to segregate LMO-containing shipments from conventional ones. It is also less clear as to its relationship with the WTO agreements, although in its preamble it is stated that the two sets of rules are to be "mutually supportive."

2.1. Scope of the Protocol

Defining the scope of the protocol was among the most contentious issues of the negotiation. The like-minded group of states wanted to reach an all-encompassing definition for LMOs, which would include commodities, LMO-derived products, as well as pharmaceuticals for human consumption. Such a definition was justified by the still prevalent uncertainty concerning the potential adverse effects that LMOs and their derived products could have on biodiversity conservation and on human health. This uncertainty pleaded for a broader definition and for inclusion of the precautionary principle in the protocol. The like-minded group feared that a narrow definition and a weak protocol would facilitate less developed countries' dependence on the major GM seed producing companies of industrialized states.

The Miami group, on the contrary, favored a narrow definition of the scope. As major LMOs producing countries, they were particularly reluctant to consent to any type of treaty that could curtail what constituted a blooming trade. Furthermore, all Miami group States opposed inclusion of pharmaceutical products for humans in the scope of the Protocol.

Contrary to agro-biotechnology, pharmaceutical biotechnology had heretofore escaped widespread criticism: differing perceptions and acceptability of different biotechnology applications, accounted for this. While an equal amount of uncertainty existed in both cases as to their potential adverse effects, the public seemed to be weighing the derived benefits on different scales. Indeed, pharmaceutical biotechnology was perceived as directly beneficial for the consumer, hence public tolerance to risk increased. On the contrary, GM seeds and foods are seen as benefiting mainly the producers, which resulted in precipitating public hostility.

Another point of controversy that influenced the debate over the scope related to the purpose and nature of the agreement. Again, two opposite views existed. Developing countries, on the one hand, were eager to reach an agreement investing importing states with wide regulatory and control powers against the powerful agro-biotech industry; they wanted a strong protocol providing for extensive use of the AIA procedure (both for LMOs and commodities), the precautionary principle and mandatory identification (i.e., segregation of shipments containing LMOs from conventional shipments). The EU also favored the idea of a strong protocol establishing strict controls. Major LMO producers, on the other hand, were mainly preoccupied with ensuring free movement of goods and removing possible barriers to trade. In this respect, they were inclined to negotiate a treaty that would set basic biosafety standards and harmonize or facilitate approval procedures in order to boost trade in LMOs and LMO-derived commodities. Consequently, they preferred a weaker Protocol, preferably subject to the WTO's legal order, intending to cover transboundary movement of some specifically mentioned LMOs, and certainly not commodities.

The scope of the Biosafety Protocol, as agreed in Montreal, is seemingly broad, and is defined on the basis of three criteria: the type of organisms, the type of operation and the type of risk. Thus, it includes all LMOs that may have adverse effects on biodiversity (article 4), except for pharmaceuticals for humans, unless they are not "addressed by other relevant international agreements or organizations" (article 5). However, it excludes application of the AIA procedure to LMOs in transit or to those intended for contained use (article 6), and to LMO-FFPs.

2.2. Key Provisions

The protocol sets out a number of substantive and procedural requirements to govern transboundary movement of LMOs. It also sets up an institutional structure (MoP) to overview its implementation and to conduct its potential review and amendment. Its main provisions concern the AIA procedure, the setting up of an internet-based Biosafety Clearinghouse, the use of precaution and of risk assessments, and the specific provisions on capacity building and public awareness and participation.

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United Nations: www.un.org

Biographical Sketch

Catherine-Zoi Varfis is a lawyer-linguist at the Court of Justice of the European Communities, in Luxembourg. She is a member of the Thessaloniki Bar Association, a Research Associate of the Hellenic Institute of International and Foreign Law in Athens, and a Senior Research Fellow of the Center for International Sustainable Development Law, Montreal, Canada.
Dr. Varfis holds a law degree and a PhD from the Aristotle University of Thessaloniki and a *Certificat* in International Studies from the Graduate Institute of International Studies, in Geneva. Her fields of expertise include international and European environmental law, law of the Sea with emphasis on Mediterranean issues, and the international regulation of biotechnology.
She has been a program assistant with the ILO, a research and teaching assistant with the Law Faculty of the University of Geneva, and a visiting scholar at the Lauterpacht Research Center for International Law at the University of Cambridge. While in Geneva, she collaborated regularly with the International Academy of the Environment, teaching in its annual training courses on Principles and Processes of Sustainable Development. She has taught International and European Economic Law and Public International Law for the Thessaloniki branch of the Universities of Sorbonne and Strasbourg, and has also given seminars on international environmental law and marine resources in Belgium, Greece, The Netherlands, Norway, Switzerland, and the United Kingdom. She is a member of the ILA (British Branch) and a founding member of the Greek Association for International Law.