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10. Coherence in the Biotechnology Regulations: Organisation, Self-contained, Focus and Coverage

Coherent sets of international regulation tend to be overseen by a single international organisation; to require no reference to regulations outside of the set for their operation; to clearly focus on the issue that is their common purpose; and to comprehensively cover that issue. Assessment of the biotechnology regulations against the first of these four characteristics is straightforward, for the other three it is more complex.

Single International Organisation

Chapter 5 explains that in a coherent regulatory set a single international organisation will have responsibility for oversight, coordination, implementation, monitoring and development of the regulations. The existence of an international organisation was identified either through explicit mention in the regulatory text, or as the originator organisation of the text, having continued responsibility for the above roles.

Analysis

This characteristic can be easily assessed. There is no single international organisation common to all of the regulations. Some regulations (within and between issue areas) share international organisations, other regulations have no international organisation, and in total fifteen separate international organisations operate in this area. Some of the international organisations have cooperative relationships for certain issues relevant to governance of biotechnology.

The international organisations and the agreements they oversee are as follows:

- Organisation for the Prohibition of Chemical Weapons (Chemical Weapons Convention)
- World Health Organisation (International Health Regulations; Laboratory Biosafety Manual; Guidance on Regulations for the Transport of Infectious Substances; Laboratory Biosecurity Guidance)
- Office International des Epizooties (Terrestrial and Aquatic Animal Health Codes; Terrestrial and Aquatic Manuals)
- Food and Agriculture Organisation (International Plant Protection Convention; International Treaty on Plant Genetic Resources)
- Codex Alimentarius Commission (Codex Principles and Guidelines)
- Convention on Biodiversity Secretariat (Convention on Biodiversity; Cartagena Protocol; Bonn Guidelines)

- World Trade Organisation (SPS Agreement; TBT Agreement; TRIPS Agreement)
- World Intellectual Property Organisation (Patent Cooperation Treaty; Patent Law Treaty; Budapest Treaty)
- Union for the Protection of New Varieties of Plants (UPOV Convention)
- International Narcotics Control Board (UN Drugs Conventions)
- Commission on Narcotic Drugs (UN Drugs Conventions)
- United Nations Office on Drugs and Crime (UN Drugs Conventions)
- World Anti-doping Association (World Anti-doping Code)
- United Nations Educational, Scientific and Cultural Organisation (Universal Declaration on the Human Genome and Human Rights; International Declaration on Human Genetic Data; Universal Declaration on Bioethics and Human Rights; International Convention against Doping in Sport)
- United Nations General Assembly (UN Declaration on Human Cloning)

Three of these organisations cross issue areas in the regulations that they oversee: the Convention on Biodiversity Secretariat (environment and trade); the Food and Agriculture Organisation (health and trade); and the UN Educational, Scientific and Cultural Organisation (social and ethical impacts and drugs control).

There have been, and continue to be, efforts at coordination between some of these organisations. The Food and Agriculture Organisation and the World Health Organisation have jointly overseen the Codex Alimentarius Commission for more than forty years, but this institutional degree of cooperation is rare. There are now some limited efforts at coordination specifically for the area of biotechnology, for example between the World Intellectual Property Organisation and the Convention on Biodiversity Secretariat, on the issue of intellectual property rights relating to genetic resources used in modern biotechnology (CBD, April 2002, 16 January 2006; WIPO, no date) and the organisations are often invited to be present at each other's meetings. These are positive indications of cooperation but even these limited efforts have some way to go. The Convention on Biodiversity Secretariat has, for example, despite repeated applications not yet been granted observer status at the Council for Trade Related Aspects of Intellectual Property Rights, the Sanitary and Phytosanitary Committee or the Technical Barriers to Trade Committee at the World Trade Organisation, even though cooperative efforts are urgently required between these two organisations (CBD, no date).

Self-contained

This term was explained in Chapter 5 to mean that the regulations will be able to cover the particular issue that is their main focus (in this case control of biotechnology) without requiring reference to other regulations external to their set. The objectives identified in the regulatory texts for the analysis

of primary purpose have been used again here, in order to judge whether the provisions relevant to biotechnology operate independently of other international agreements. Here the analysis was difficult because of the way in which the regulations have been selected, that is because they have been selected for analysis specifically due to their relevance to the applications and impacts of biotechnology.

Analysis

Given that the regulations do not share a common purpose it is hard to make a comparable analysis of this element to the analysis of the Geneva Conventions made in Chapter 5. The question would be: do the regulations, by themselves, control biotechnology? However, since the regulations have been selected and examined precisely because they are the international regulations that cover biotechnology, this results in a circular argument. This issue is too ambiguous to allow a conclusive assessment. It is very difficult to make a comparative assessment between the international biotechnology regulations and the model of coherent regulatory sets in regard to this factor.

While all the regulations apply to the control of biotechnology, they mainly do so as part of agreements with a wider scope, on which the relevant clauses rely for their operation and in that sense they are not self-contained. This may become a problem, because if it is decided that, to meet a particular control need for biotechnology, a regulation needs to change, this may not be possible because the regulation, as it exists, is required for other purposes too. If new regulations were created that overlapped existing regulations this could also create interpretation problems and confusion.

However, the regulations do cover many of the important aspects of biotechnology that require international governance and while there are weaknesses, for example in the coverage of some social, ethical and developmental impacts, this is not because of reliance on other regulations to complete the coverage – it is because no regulations currently exist for these matters.

Clear Issue Focus

It should be clear from the text of each regulation that they focus on the particular issue that forms their common objective and this issue should be their primary focus. In order to assess this, first the regulatory texts were searched for specific indications of applicability to biotechnology (either referring to biotechnology in general or to one of its applications e.g. genetically modified organisms or genome studies). Then, if such were not found in the regulatory text, officially adopted documents on the regulations were examined for indications that such a focus existed or has developed. Given the different purposes of the regulations, it would perhaps be expected that a clear issue focus would be difficult to identify and indeed this function is not always explicit in the regulations, but in some it is, and documents of meetings of the states parties also indicate that this is the case.

Analysis

Because most of the regulations were not specifically designed to control biotechnology they generally do not have a clear focus on this issue. Often their scope is much broader and their relevance to biotechnology a side-issue to another purpose. This said there is, generally at least, recognition of their applicability to this area, shown in documents produced by their meetings of the parties and their associated international organisations. For example, the final documents produced by the five-yearly Review Conferences of the Biological Weapons Convention have repeatedly emphasised that the Convention's prohibitions on misuse of science extend to genetics, genomics and related technologies.

The following regulations contain no clear indication in their text or officially adopted documents of their relevance to biotechnology:

- The 1925 Geneva Protocol
- International Plant Protection Convention
- International Health Regulations
- Technical Barriers to Trade Agreement
- Sanitary and Phytosanitary Agreement
- Patent Law Treaty
- International Convention for the Protection of New Varieties of Plant
- Single Convention on Narcotic Drugs
- Convention on Psychotropic Substances
- Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances

All the other regulations have in their text or officially adopted documents some indication of relevance to modern biotechnology. Examples include:

- The Laboratory Biosafety Manual has a subsection focusing on risk assessment and genetically modified organisms and a section on biosafety and recombinant-DNA technology.
- The Manual of Diagnostic Tests and Vaccines for Terrestrial Animals has a chapter on Biotechnology in the Diagnosis of Infectious Diseases and Vaccine Development.
- The Convention on Biodiversity has a specific article (Article 19) on Handling of Biotechnology and Distribution on Its Benefits; biotechnology is mentioned in several other articles and biotechnology is specifically mentioned as being included in more general references to technology in the Convention.
- The Cartagena Protocol is specifically designed to ensure 'an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology' (Article 1).
- The preamble to the International Treaty on Plant Genetic Resources states: '*Acknowledging* further that plant genetic resources for food and agriculture are the raw material indispensable for crop genetic

improvement, whether by means of farmers' selection, classical plant breeding or modern biotechnologies'.

- Article 24(c) of the International Convention against Doping in Sport asks states to support research on 'the use of all emerging substances and methods resulting from scientific developments' and the prohibited list of the Convention and the World Anti-doping Code contains a prohibition on gene doping – 'The non-therapeutic use of cells, genes, genetic elements, or of the modulation of gene expression, having the capacity to enhance athletic performance is prohibited' (Prohibited List, M3).
- The Universal Declaration on the Human Genome and Human Rights, International Declaration on Human Genetic Data, Universal Declaration on Bioethics and Human Rights and UN Declaration on Human Cloning make many references to applications and impacts of biotechnology. For example: 'This Declaration addresses ethical issues related to medicine, life sciences and associated technologies as applied to human beings' (UDBEHR, Article 1.1) and 'Aware of the ethical concerns that certain applications of rapidly developing life sciences may raise with regard to human dignity, human rights and the fundamental freedoms of individuals, *Reaffirming* that the application of life sciences should seek to offer relief from suffering and improve the health of individuals and humankind as a whole' (UNDHC, Preamble).

Comprehensive Coverage of the Issue

Coherent sets of regulations ought to provide comprehensive coverage of the issue on which they are focused and there should be no major gaps in this coverage, or imbalances that leave one area poorly covered. Coverage of the regulation of biotechnology is fairly comprehensive even though it is not coherent. However, this can be difficult to assess given the fragmentation of the regulations, contradictions and imbalances.

Analysis

The issue in this case is control of the applications and impacts of biotechnology. Although few of the regulations were designed specifically to control biotechnology, it would be beneficial for them to achieve comprehensive coverage of the issues that require international control. This coverage would have to be broad, and perhaps the demand is unrealistic in terms of what states will be willing to agree to.

In one sense the regulations do provide fairly comprehensive coverage. They cover the seven identified issue areas (although to varying degrees). However, significant gaps and weaknesses can be identified. In some areas, for example human cloning and development issues, there does at least seem to be awareness of this and faltering attempts to fill some of the gaps (e.g. the intended legal prohibition on reproductive human cloning that ended up as a political declaration), but other needs are still barely recognised.

The most prominent gaps are in the area of human genetics, which is weakly regulated internationally, there only being declarations of principles agreed so far. There are important social and ethical issues in this area that will need to be addressed partly at the international level. At present if national controls are placed on the use of these technologies, groups simply move to another country to conduct the work or people go to countries in which they can get the treatment they desire. For example, when the United Kingdom's Human Fertilisation and Embryology Authority (HFEA – the regulatory authority for reproductive technologies) declined a request for use of pre-implantation genetic diagnosis to create a sibling with a genetic match on the basis that the procedure would be of no benefit to the new child, the parents involved travelled to the United States for the procedure (Boseley, 20 June 2003). Obviously these are extremely complex and controversial issues, but some international direction is needed before the technologies race even further ahead of the social debates and democratic control.

Conclusion

Fifteen international organisations are associated with the biotechnology regulations, so they clearly fail to match the characteristic of having a single international organisation. In regard to the other characteristics covered in this chapter, the assessment is not as clear cut. The selection method makes analysis of self-containment problematic and also means that the regulations provide comprehensive coverage in relation to the issue areas of interest. The issue focus of the set will not be clear because they lack a common purpose, but the emerging awareness of connections outlined in Chapter 7 under 'common identity' and in Chapter 8 under 'self-referencing' should also contribute to increased understanding of the regulations as focusing (in part) on control of biotechnology.