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8. Coherence in the Biotechnology Regulations: Referencing, Definitions and Provisions

Coherent sets of regulation were shown in Chapter 5 to refer to each other where necessary, to share definitions of key terms, to contain some unifying provisions that strengthen their common identity and for their remaining provisions to be complementary to each other. The biotechnology regulations are assessed against these four characteristics in this chapter, with the method of analysis outlined before the results are discussed.

Self-referencing

Self-referencing is an indicator of internal awareness of connections among a regulatory set. A regulation may refer to others for example to avoid duplication or to make it clear that a particular issue is covered elsewhere in the set. Primarily the assessment here involved examining the texts of the regulations to identify any references to the other regulations (a summary of this is provided in Table 8.1 at the end of this chapter). A secondary examination of documents of the international organisations and meetings of the parties (MOPs) was also made to identify any indications of emerging awareness of connections.

There is self-referencing among some of the regulations both within and between issue areas, but not across the whole set, and there are significant omissions for example between trade and environmental rules. The self-referencing that does exist is not generally done in reference to biotechnology and is therefore not a reliable indicator of internal awareness of connections in relation to the regulations' relevance to the governance of biotechnology. Extending beyond the regulatory texts to interpretive statements of MOPs or their oversight bodies, there are some further indications of awareness of the connections. This awareness may come to be incorporated into future amendments, but it may not. Unless the statements of MOPs and oversight bodies have been formally adopted the regulations are not considered to be self-referencing. The analysis does not go further than this (into e.g. NGO or academic work) because this would indicate external rather than internal awareness of the connections.

Analysis

Examples of self-referencing within issue areas include the following:

- Reference in Article XIII of the Chemical Weapons Convention to the Biological Weapons Convention and the Geneva Protocol

Nothing in this Convention shall be interpreted as in any way limiting or detracting from the obligations assumed by any state under the Protocol

for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare, signed at Geneva on 17 June 1925, and under the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) Weapons and on Their Destruction, signed at London, Moscow and Washington on 10 April 1972.

- Reference in the preamble to the Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances to the two earlier UN Drugs Conventions – ‘Recognizing the need to reinforce and supplement the measures provided in the Single Convention on Narcotic Drugs, 1961 ... and the 1971 Convention on Psychotropic Substances.’

There is, however, no consistency in self-reference patterns within issue areas.

Examples of self-referencing across issue areas include:

- Specific references in the Sanitary and Phytosanitary Agreement to the rules/standards adopted by the Codex Alimentarius Commission, the International Plant Protection Convention Secretariat and the Office International des Epizooties (OIE), as an appropriate basis for national trade measures for the protection of human, animal and plant health.

International standards, guidelines and recommendations

- (a) for food safety, the standards, guidelines and recommendations established by the Codex Alimentarius Commission relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice;
- (b) for animal health and zoonoses, the standards, guidelines and recommendations developed under the auspices of the International Office of Epizootics;
- (c) for plant health, the international standards, guidelines and recommendations developed under the auspices of the Secretariat of the International Plant Protection Convention in cooperation with regional organizations operating within the framework of the International Plant Protection Convention;

(SPS Agreement, Annex A.3)

Looking beyond the regulatory texts themselves and into interpretive documents produced by the relevant international organisations and meetings of the contracting parties, there are indications that awareness of the connections between the regulations in controlling some of the applications and impacts of biotechnology is growing, and may be incorporated into regulatory texts at a later stage. Examples include:

- Recognition of the World Health Organisation's role in disease surveillance as an important tool in the detection and identification of deliberate outbreaks of disease that may be caused by biological agents or toxins. In particular, this was recognised in two documents of the Fifty-fifth World Health Assembly – Resolution WHA55.16 (WHO, 2002a) and Report WHA55.20 (WHO, 2002b) – and in the 2004 update of the Organisation's guidance on *Public Health Responses to Biological and Chemical Weapons*.
- A document on the Cartagena Protocol (CBD Secretariat, June 2003) which states:

Although the Cartagena Protocol on Biosafety is the only international instrument that deals exclusively with GMOs, it does not exist in a vacuum. The Convention on Biological Diversity, the 'parent' of the Protocol, itself requires governments to take measures to regulate, manage or control the risks associated with the use and release of GMOs. There are also a number of separate international instruments and standard setting processes that address various aspects of biosafety.

It then lists these as including the International Plant Protection Convention, the Codex Alimentarius Commission, the World Animal Health Organisation (OIE) and the Sanitary and Phytosanitary and Technical Barriers to Trade Agreements.

- The International Portal on Food Safety, Animal and Plant Health (IPFSAPH) which has been established by seven of the international organisations involved in the regulation of biotechnology, partly in recognition of the new challenges created by the use of biotechnologies in those areas (its database contains almost a thousand documents related to genetically modified organisms). It serves as a repository for all national, regional and international documents, guidelines and rules on food safety, animal and plant health, including those of the Codex Alimentarius. The seven organisations involved are: the Food and Agriculture Organisation; the Codex Alimentarius Commission; the International Plant Protection Convention Secretariat; the Office International des Epizooties; the World Trade Organisation; the Convention on Biodiversity Secretariat; and the World Health Organisation.
- A webpage produced by the Food and Agriculture Organisation on regulatory aspects of biotechnology in food and agriculture (FAO, no date b), which outlines rules in the areas of biosafety, food safety and intellectual property rights, specifically referring to the Cartagena Protocol, the International Plant Protection Convention, the work of the Codex Alimentarius Commission, the World Intellectual Property Organisation and the International Union for the Protection of New Varieties of Plants.

Shared Definitions

To assess this characteristic the regulatory texts were examined to identify any shared definitions, particularly of key terms, with either the same or very similar wording. The previously indicated divide between regulations within issue areas and regulations in different issue areas also exists here. Since the regulations do not have a common primary purpose the terms seen as important enough to be defined within the regulations are likely to vary accordingly. Therefore, it is not surprising that there are few shared definitions and none that extend across the full regulatory set.

Analysis

The following definitions are shared or very similar:

Sanitary measure (shared by the Terrestrial Animal Health Code and Sanitary and Phytosanitary Agreement):

Sanitary measure

Means a measure ... designed to protect animal or human health or life within the territory of the OIE Member from risks arising from the entry, establishment and/or spread of a hazard.

(Terrestrial Animal Health Code, Glossary)

Sanitary or phytosanitary measure – Any measure applied:

- (a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;
- (b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or foodstuffs;
- (c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry establishment or spread of pests; or
- (d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.

(SPS Agreement, Annex A.1)

Modern biotechnology (shared by the Cartagena Protocol and the Codex Principles):

The same wording is used in both the Cartagena Protocol (Article 3, Use of Terms) and the Codex Principles (Section 2 – Scope and Definitions): ‘(i) “Modern biotechnology” means the application of: a. *In vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organisms, or b. Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive

or recombination barriers and that are not techniques used in traditional breeding and selection.’

Conventional counterpart (shared by the Codex Principles and Guidelines):

The Codex Principles and Guidelines use similar definitions of ‘conventional counterpart’, for example: “Conventional Counterpart” means a related organism/variety, its components and/or products for which there is experience of establishing safety based on common use as food’ (Codex Principles, Section 2); and “Conventional Counterpart” means a related plant variety, its components and/or products for which there is experience of establishing safety based on common use as food’ (Codex Guideline RDNA Plants, Section 2).

Ex-situ conservation and *in-situ conservation* (shared by the Convention on Biodiversity and the International Treaty on Plant Genetic Resources):

These are found in Article 2 of the Convention on Biodiversity – “*Ex-situ* conservation” means the conservation of components of biological diversity outside their natural habitats’; “*In-situ* conservation” means the conservation of ecosystems and natural habitats and the maintenance and recovery of viable populations of species in their natural surrounding and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties.’ And in Article 2 of the International Treaty on Plant Genetic Resources – “*Ex-situ* conservation” means the conservation of plant genetic resources for food and agriculture outside their natural habitat.’ “*In-situ* conservation” means the conservation of ecosystems and natural habitats and the maintenance and recovery of viable populations of species in their natural surroundings and, in the case of domesticated or cultivated plant species, in the surroundings where they have developed their distinctive properties.’

These definitions are also shared with the Bonn Guidelines, which state that ‘the terms as defined in Article 2 of the Convention shall apply to these Guidelines’ (Bonn Guidelines, Part I, B).

Article 1 of the UN Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances uses the definitions of narcotic drugs and psychotropic substances from the earlier Conventions: “Narcotic drug” means any of the substances, natural or synthetic, in Schedules I and II of the Single Convention on Narcotic Drugs, 1961 ... “Psychotropic substance” means any substance, natural or synthetic, or any natural material in Schedules I, II, III and IV of the Convention on Psychotropic Substances, 1971’.

The Laboratory Biosafety Manual and Laboratory Biosecurity Guidance share definitions of biosafety and biosecurity as they relate to laboratory facilities. The Terrestrial Animal Health Code defines biosecurity slightly

differently, with the term containment being closer to the World Health Organisation definition. The term biosafety in the Cartagena Protocol does not relate to laboratories.

Unifying Provisions

Coherent sets of regulation will have some provisions that are the same in each regulatory text. In order to assess this, the regulatory texts were examined to find such provisions. This did not require the same wording to be used and would also encompass provisions requiring the same action for the same objectives. It appears that regulations which share principles and self-reference are more likely to have provisions that can be viewed as unifying, but rarely to the extent of the identical wording found in the Geneva Conventions. There are no unifying provisions for the whole regulatory set; those which do occur are predominantly within issue areas.

Analysis

The most extensive unifying provisions (although the precise wording varies) are those on technical and financial assistance, scientific and technological cooperation, and capacity-building,¹ with a particular focus on assisting developing countries. Such provisions can be found in seventeen of the regulations: the International Health Regulations; the International Plant Protection Convention; the Codex Principles; the Convention on Biodiversity; the Cartagena Protocol; the Sanitary and Phytosanitary Agreement; the Technical Barriers to Trade Agreement; the Trade Related Aspects of Intellectual Property Rights Agreement; the Patent Cooperation Treaty; the International Treaty on Plant Genetic Resources; the Bonn Guidelines on Access to Genetic Resources; the Single Convention on Narcotic Drugs; the Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances; the Universal Declaration on the Human Genome and Human Rights; the International Declaration on Human Genetic Data; the Universal Declaration on Bioethics and Human Rights; and the UN Declaration on Human Cloning. There are also clauses in the Biological Weapons Convention and the Chemical Weapons Convention on not allowing their provisions to hamper development of states parties.

Examples include:

The contracting parties agree to promote the provision of technical assistance to contracting parties, especially those that are developing contracting parties, either bilaterally or through appropriate international organisations, with the objective of facilitating implementation of this Convention.

(IPPC, Article XX)

Efforts should be made to improve the capability of regulatory authorities, particularly those of developing countries, to assess, manage and communicate risks, including enforcement, associated with foods derived from modern biotechnology or to interpret assessments undertaken by other authorities or recognised expert bodies, including access to analytical technology. In addition capacity building for developing countries either through bilateral arrangements or with assistance of international organisations should be directed toward effective application of these principles.

(Codex Principles, point 27)

Each Contracting Party shall promote technical and scientific cooperation with other Contracting Parties, in particular developing countries, in implementing this Convention.

(CBD, Article 18.2)

Members agree to facilitate the provision of technical assistance to other Members, especially developing country Members, either bilaterally or through the support of appropriate international organizations.

(SPS Agreement, Article 9.1)

In order to facilitate the implementation of this Agreement, developed country Members shall provide, on request ... technical and financial cooperation in favour of developing and least developed country Members.

(TRIPS Agreement, Article 67)

The Contracting Parties agree to promote the provision of technical assistance to Contracting Parties, especially those that are developing countries or countries with economies in transition, either bilaterally or through the appropriate international organisations, with the objective of facilitating the implementation of this Treaty.

(ITPGR, Article 8)

States should ... continue fostering the international dissemination of scientific knowledge concerning the human genome, human diversity and genetic research and, in that regard, to foster scientific and cultural cooperation, particularly between industrialized and developing countries.

(UDHGHR, Article 18)

Complementary Provisions

Provisions of the different regulations are considered to be complementary if they work towards the same overall objectives and do not contradict

each other. To assess this, the texts were examined for provisions that complement each other in their application to biotechnology. They were also examined for any contradictory provisions, as clear examples of non-complementarity.

Despite having different purposes and principles many of the regulations' provisions can be viewed as complementary when applying the definition provided in Chapter 5 that they should extend protection over the different areas covered (in this case the different aspects of biotechnology that require regulation). However, the regulations also contain some contradictory provisions. There are also areas in which coverage is duplicated by separate regulations (e.g. coverage of access and benefit-sharing by the International Treaty on Plant Genetic Resources and the Bonn Guidelines).

Analysis

The regulations in the health area have provisions minimising their negative effects on trade that support the Sanitary and Phytosanitary Agreement which allows such restrictions where they are justified on health grounds and are not more trade restrictive than necessary. For example:

In order to minimize interference with international trade, each contracting party ... undertakes to act in conformity with the following:

- (a) Contracting parties shall not, under their phytosanitary legislation, take any of the measures specified in paragraph 1 of this Article, unless such measures are made necessary by phytosanitary considerations and are technically justified.

(International Plant Protection Convention, Article VII.2)

The purpose and scope of these Regulations are to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade.

(International Health Regulations, Article 2)

There are some agreements in the trade area that have provisions that are complementary to provisions in agreements in the areas of arms control, health and disease control, and environmental protection. For example:

Technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create. Such legitimate objectives are, *inter alia*: national security

requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment.

(TBT Agreement, Article 2.2)

Nothing in this Agreement shall be construed:

- (a) to require a Member to furnish any information the disclosure of which it considers contrary to its essential security interests; or
- (b) to prevent a Member from taking any action which it considers necessary for the protection of its essential security interests;

(TRIPS Agreement, Article 73)

Each Contracting State recognizes that it is highly desirable that, if and to the extent which the export from or import into its territory of certain kinds of microorganisms is restricted, such restriction should apply to microorganisms deposited; or destined for deposit, under this Treaty only where the restriction is necessary in view of national security or the dangers for health or the environment.

(Budapest Treaty, Article 5)

There are also complementary provisions between the Convention on Biodiversity, the Bonn Guidelines and the International Treaty for Plant Genetic Resources. These relate to their shared objectives:

The objectives of this Convention ... are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies

(CBD, Article 1)

The objectives of this Treaty are the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their use, in harmony with the Convention on Biological Diversity

(ITPGR, Article 1.1)

E. Objectives

11. The objectives of the Guidelines are the following:

- a. To contribute to the conservation and sustainable use of biological diversity;
- b. To provide Parties and stakeholders with a transparent framework to facilitate access to genetic resources and ensure fair and equitable sharing of benefits;

(Bonn Guidelines, Part I)

And to states' sovereign rights:

States have ... the sovereign right to exploit their own resources.
(CBD, Article 3)

The Contracting Parties recognize the sovereign rights of States over their own plant genetic resources for food and agriculture
(ITPGR, Article 10.1)

Nothing in these Guidelines should be interpreted to affect the sovereign rights of States over their natural resources;
(Bonn Guidelines, Part I.A)

And between the Universal Declaration on the Human Genome and Human Rights, Universal Declaration on Bioethics and Human Rights and the arms control agreements in relation to the promotion of peaceful uses and prevention of non-peaceful uses of science:

They [states] should seek to ensure that research results are not used for non-peaceful purposes.
(UDBEHR, Article 15)

States should take appropriate measures, both at the national and international levels, to combat bioterrorism and illicit traffic in organs, tissues, samples, genetic resources and genetic-related materials.
(UDBEHR, Article 21.5)

The States Parties to this Convention undertake to facilitate, and have the right to participate in, the fullest possible exchange of equipment, materials and scientific and technological information for the use of bacteriological (biological) agents and toxins for peaceful purposes.
(BWC, Article X.1)

The States Parties to this Convention undertake to facilitate, and have the right to participate in, the fullest possible exchange of scientific and technological information on the use of environmental modification techniques for peaceful purposes.
(EnMod Convention, Article III)

However, just as the principles underlying some of the agreements appear contradictory, so too are some of their provisions, as shown in the previous chapter under the sub-heading *Divergent Principles*; these include provisions of the environmental and trade agreements and of the agreements on genetic resources and on intellectual property.

Conclusion

The biotechnology regulations fail to match the four characteristics of the coherent regulatory model covered in this chapter. There is some self-referencing among the regulations within and between issue areas, but not for the set as a whole and not always with relevance to the control of biotechnology. There are also some definitions shared among regulations within and across issue areas, but none for the full set. Seventeen of the regulations have similar provisions on assistance to developing states, which are the closest to the concept of unifying provisions – but again these do not extend across the full regulatory set. Finally, although some complementary provisions can be identified within and between issue areas, there are also contradictory provisions which should not exist within coherent regulatory sets.

Table 8.1 Self-referencing among the Biotechnology Regulations

Regulation	Refers to (regulation)	Refers to (organisation)
1925 Geneva Protocol		
Biological Weapons Convention	1925 Geneva Protocol	
Chemical Weapons Convention	1925 Geneva Protocol, Biological Weapons Convention	
EnMod Convention		
International Plant Protection Convention	Sanitary and Phytosanitary Agreement	
International Health Regulations		Food and Agriculture Organisation, Office International des Epizooties
Terrestrial Animal Health Code	Sanitary and Phytosanitary Agreement	World Trade Organisation
Aquatic Animal Health Code	Sanitary and Phytosanitary Agreement	World Trade Organisation
Laboratory Biosafety Manual		
Laboratory Biosecurity Guidance	Laboratory Biosafety Manual, Biological Weapons Convention, Universal Declaration on Bioethics and Human Rights, Convention on Biodiversity, Cartagena Protocol, International Health Regulations	Office International des Epizooties, World Health Organisation, Food and Agriculture Organisation

Regulation	Refers to (regulation)	Refers to (organisation)
Guidance on Regulations for the Transport of Infectious Substances		
Manual of Diagnostic Tests and Vaccines for Terrestrial Animals	Terrestrial Animal Health Code	Food and Agriculture Organisation, Codex Alimentarius Commission, World Health Organisation
Manual of Diagnostic Tests for Aquatic Animals		
Codex Principles for Risk Analysis of Foods Derived from Modern Biotechnology	Cartagena Protocol	
Codex Guideline on Food Safety Assessment – Recombinant-DNA Microorganisms	Codex Principles	
Codex Guideline on Food Safety Assessment – Recombinant-DNA Plants	Codex Principles	
Codex Guideline on Food Safety Assessment – Recombinant-DNA Animals	Codex Principles	
Convention on Biodiversity		
Cartagena Protocol	Convention on Biodiversity	
Sanitary and Phytosanitary Agreement	Technical Barriers to Trade Agreement, and standards of the Codex Alimentarius Commission, the Office International des Epizooties and the International Plant Protection Convention Secretariat	
Technical Barriers to Trade Agreement	Sanitary and Phytosanitary Agreement	
Trade Related Aspects of Intellectual Property Rights Agreement		World Intellectual Property Organisation
Patent Cooperation Treaty		
Patent Law Treaty	Patent Cooperation Treaty	
Budapest Treaty		

(Continued)

Table 8.1 (Continued)

Regulation	Refers to (regulation)	Refers to (organisation)
International Treaty for the Protection of New Varieties of Plants		
International Treaty on Plant Genetic Resources	Convention on Biodiversity	
Bonn Guidelines on Access to Genetic Resources	Convention on Biodiversity, International Treaty on Plant Genetic Resources	World Intellectual Property Organisation
Single Convention on Narcotic Drugs		
Convention on Psychotropic Substances	Single Convention on Narcotic Drugs	
Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances	Single Convention on Narcotic Drugs, Convention on Psychotropic Substances	
World Anti-doping Code	International Convention against Doping in Sport	
International Convention against Doping in Sport	World Anti-doping Code	World Anti-doping Association
Universal Declaration on the Human Genome and Human Rights	Biological Weapons Convention, Budapest Treaty, Trade Related Aspects of Intellectual Property Rights Agreement	
International Declaration on Human Genetic Data	Universal Declaration on the Human Genome and Human Rights, Trade Related Aspects of Intellectual Property Rights Agreement	
Universal Declaration on Bioethics and Human Rights	Universal Declaration on the Human Genome and Human Rights, International Declaration on Human Genetic Data, Convention on Biodiversity, International Treaty on Plant Genetic Resources, Trade Related Aspects of Intellectual Property Rights Agreement	Food and Agriculture Organisation, World Health Organisation
UN Declaration on Human Cloning	Universal Declaration on the Human Genome and Human Rights	