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9. Coherence in the Biotechnology Regulations: Structure, Procedures, Mechanisms and Strength

This chapter assesses the biotechnology regulations on the characteristics of common structure, common administrative and review procedures, common enforcement and dispute settlement mechanisms and same strength of force. Coherent sets of international regulation are expected to clearly display these characteristics.

Common Structure

Common structure is found where related provisions are contained in the same articles in the different regulatory texts and/or where related provisions appear in the same order in each regulatory text. In order to assess this, the main structural elements of each regulatory text were identified, and listed so that the structures could be compared. The structural elements used for this analysis are: preamble/introductory text/foreword; basic provisions; substantive provisions; institutional provisions; and administrative provisions.¹

Most of the regulations that take the form of treaties have a similar structure, generally consisting of a preamble, basic provisions, specific provisions, institutional provisions, administrative provisions and any annexes. The same structure can be found in most international treaties. Regulations that take the form of voluntary guidance or declarations are generally structurally different from the treaties, and often from each other. (Table 9.1, at the end of this chapter, indicates which of the regulations are legally binding and which are voluntary.) A common structure does not exist to the same extent that it does within the coherent regulatory sets identified in Chapter 5.

Analysis

There are certain commonalities of structure to the legally binding treaties that operate in this area. However, this is the case across most realms of international law. Treaties generally start with a non-binding preamble, followed by basic, then substantive provisions, institutional provisions and finally administrative provisions. This structure does not extend across the full range of regulations.

The following illustrates the structure of the regulations:

Legally binding treaties:

1925 Geneva Protocol

- Preamble
- Substantive Provisions

Biological Weapons Convention

- Preamble
- Basic Provisions (Article I)
- Substantive Provisions (Articles II–X)
- Administrative Provisions (Articles XI–XV)

EnMod Convention

- Preamble
- Basic Provisions (Articles I–III)
- Substantive Provisions (Articles IV–V)
- Administrative Provisions (Articles VI–X)
- One Annex

Chemical Weapons Convention

- Preamble
- Basic Provisions (Articles I–II)
- Substantive Provisions (Articles III–VII, IX–XII)
- Institutional Provisions (Article VIII)
- Administrative Provisions (Articles XIII–XXIV)
- Two Annexes

International Health Regulations

- Basic Provisions (Articles 1–4)
- Substantive Provisions (Articles 5–46)
- Administrative/Institutional Provisions (Articles 47–53)
- Administrative Provisions (Articles 54–66)
- Nine Annexes

International Plant Protection Convention

- Preamble
- Basic Provisions (Articles I–IV)
- Substantive Provisions (Articles V–X)
- Administrative/Institutional Provisions (Articles XI–XIII)
- Administrative Provisions (Articles XIV–XXIII)
- Annex – Model Phytosanitary Certificate

Convention on Biodiversity

- Preamble
- Basic Provisions (Articles 1–6)
- Substantive Provisions (Articles 7–19, 22)
- Institutional Provisions (Articles 20, 21, 23–25)
- Administrative Provisions (Articles 26–42)
- Two Annexes

Cartagena Protocol

- Preamble
- Basic Provisions (Articles 1–4)
- Substantive Provisions (Articles 5–18, 21–27)
- Institutional Provisions (Articles 19–20, 28–31)
- Administrative Provisions (Articles 32–40)
- Three Annexes

Sanitary and Phytosanitary Agreement

- Basic Provisions (Articles 1–4)
- Substantive Provisions (Articles 5–10)
- Administrative Provisions (Articles 11–14)
- Three Annexes

Technical Barriers to Trade Agreement

- Basic Provisions (Article 1)
- Substantive Provisions (Articles 2–12)
- Administrative/Institutional Provisions (Articles 13–15)
- Three Annexes

Trade Related Aspects of Intellectual Property Rights Agreement

- Preamble
- Basic Provisions (Articles 1–8)
- Substantive Provisions relating to different types of intellectual property rights (Articles 9–61)
- Substantive Provisions relating to all intellectual property rights (Article 62)
- Transitional Arrangements (Articles 65–67)
- Administrative and Institutional provisions (Articles 63, 64, 68–73)

Patent Cooperation Treaty

- Preamble
- Basic Provisions (Articles 1–2)
- Substantive Provisions (Articles 3–52)
- Administrative/Institutional Provisions (Articles 53–59)
- Administrative Provisions (Articles 60–69)

Patent Law Treaty

- Basic Provisions (Articles 1–2)
- Substantive Provisions (Articles 3–14)
- Administrative Provisions (Articles 15–27)

Budapest Treaty

- Basic Provisions (Articles 1–2)

- Substantive Provisions (Articles 3–9)
- Administrative/Institutional Provisions (Articles 10–12)
- Administrative Provisions (Articles 13–20)

International Convention for the Protection of New Varieties of Plants

- Basic Provisions (Articles 1–4)
- Substantive Provisions (Articles 5–22, 30–32)
- Institutional Provisions (Articles 23–27, 29)
- Administrative Provisions (Articles 28, 33–42)

International Treaty on Plant Genetic Resources

- Preamble
- Introductory Provisions (Articles 1–3)
- Basic Provisions (Articles 4–8)
- Substantive Provisions (Articles 9–17)
- Administrative and Institutional Provisions (Articles 18–35)
- Two Annexes

Single Convention on Narcotic Drugs

- Preamble
- Basic Provisions (Article 1)
- Substantive Provisions (Articles 2–4, 18–39)
- Institutional Provisions (Articles 5–17)
- Administrative Provisions (Articles 40–51)

Convention on Psychotropic Substances

- Preamble
- Basic Provisions (Articles 1–2)
- Substantive Provisions (Articles 3–16, 20–23)
- Institutional Provisions (Articles 17–19, 24)
- Administrative Provisions (Articles 25–33)

Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances

- Preamble
- Basic Provisions (Articles 1–2)
- Substantive Provisions (Articles 3–20)
- Institutional Provisions (Articles 21–23)
- Administrative Provisions (Articles 24–34)

World Anti-doping Code

- Introduction
- Basic Provisions (Article 1)
- Substantive Provisions (Articles 2–22 and 24)

- Administrative Provisions (Article 23)
- Appendix

International Convention against Doping In Sport

- Preamble
- Basic provisions (Articles 1–2)
- Substantive provisions (Articles 3–16, 19–27)
- Institutional provisions (Articles 17, 18, 28–32)
- Administrative provisions (Articles 33–43)

Non-binding agreements:

Terrestrial Animal Health Code

- Foreword and Users Guide
- Substantive Provisions

Aquatic Animal Health Code

- Foreword and Users Guide
- Substantive Provisions

Laboratory Biosafety Manual

- Foreword
- Basic Principles (Article 1)
- Substantive Provisions (Articles 2–21)
- Two Annexes

Laboratory Biosecurity Guidance

- Basic Provisions (pp. 1–6)
- Substantive Provisions (pp. 7–25)

Guidance on Regulations for the Safe Transport of Infectious Substances

- Basic Provisions
- Substantive Provisions

Manual of Diagnostic Tests and Vaccines for Terrestrial Animals

- Basic Provisions
- Substantive Provisions

Manual of Diagnostic Tests for Aquatic Animals

- Basic Provisions
- Substantive Provisions

Codex Principles

- Basic Provisions
- Substantive Provisions

Codex Guidelines R-DNA Microorganisms

- Basic Provisions
- Substantive Provisions
- One Annex

Codex Guidelines R-DNA Plants

- Basic Provisions
- Substantive Provisions
- Three Annexes

Codex Guidelines R-DNA Animals

- Basic Provisions
- Substantive Provisions
- One Annex

Bonn Guidelines

- Preamble (within the decision that the guidelines are annexed to)
- Basic Provisions (I.A–E)
- Substantive Provisions (II.A–C; III, IV.A–D, V.A–F)
- Two Appendices

Universal Declaration on the Human Genome and Human Rights

- Preamble
- Declaration of principles

International Declaration on Human Genetic Data

- Preamble
- Declaration of principles

UN Declaration on Human Cloning

- Preamble
- Declaration of principles

Universal Declaration on Bioethics and Human Rights

- Preamble
- Declaration of principles

Common Administrative and Review Procedures

In order to assess this characteristic, the administration and review procedures of each regulatory text were examined (where such existed) and then compared to see if any commonalities could be identified. Again there is some commonality between regulations in particular issue areas, but this does not extend across the set. The legally binding treaties usually have administration and review procedures that involve the formal input and consent of member states; review of the non-legally binding regulations

is generally more autonomous to the oversight body. This is one of the reasons that the voluntary regulations tend to be more frequently updated, since the amendment/revision procedures are less burdensome and time-consuming.

Analysis

While the majority of the regulations contain review procedures (the exceptions being: the Geneva Protocol; the Laboratory Biosafety Manual; the three Codex Guidelines; the International Declaration on Human Genetic Data; the UN Declaration on Human Cloning; and the Universal Declaration on Bioethics and Human Rights), none of these review procedures are shared, not even within issue areas. The regulations that come closest to having shared review procedures are the Convention on Biodiversity and the Cartagena Protocol as the Conference of the Parties to the Convention serves as the Meeting of the Parties to the Protocol (which are the bodies responsible for review). The regulations do not have common administrative procedures either; however, some of the regulations have similar provisions where they are overseen by the same international organisation (but this is not always the case).

Broadly speaking, the legally binding regulations share a degree of formality in their administrative and review procedures, involving the formal consent of member states for amendments for example. The same degree of formality is not found in the voluntary agreements. The legally binding regulations also often require member states to meet at set intervals for the purpose of review.

Examples of legally binding regulations requiring formal consent for amendment:

Any State Party may propose amendments to this Convention. Amendments shall enter into force for each State Party accepting the amendments upon their acceptance by a majority of the States Parties to the Convention and thereafter for each remaining State Party on the date of acceptance by it.

(Biological Weapons Convention, Article XI)

2. Amendments to this Convention shall be adopted at a meeting of the Conference of the Parties ... The text of any proposed amendment to this Convention ... shall be communicated to the Parties ... by the Secretariat at least six months before the meeting at which it is proposed for adoption.
3. The Parties shall make every effort to reach agreement on any proposed amendment to this Convention ... If all attempts at consensus have been exhausted, and no agreement reached, the amendment shall as a last resort be adopted by a two-third majority vote of the Parties ... and shall be submitted by the Depositary to all Parties for ratification, acceptance or approval.

(Convention on Biodiversity, Article 29)

3. All amendments to this Treaty shall only be made by consensus of the Contracting Parties present at the session of the Governing Body.
4. Any amendment adopted by the Governing Body shall come into force among Contracting Parties having ratified, accepted or approved it on the ninetieth day after the deposit of instruments of ratification, acceptance or approval by two-thirds of the Contracting Parties. Thereafter the amendment shall enter into force for any other Contracting Party on the ninetieth day that Contracting Party deposits its instrument of ratification, acceptance, or approval of the amendments.

(International Treaty on Plant Genetic Resources, Article 23)

Common Enforcement and Dispute Settlement Mechanisms

This characteristic was assessed in a similar way to administrative and review procedures. The enforcement and dispute settlement procedures of each regulatory text were examined (where such existed) and compared in order to identify any commonalities. There are no common enforcement and dispute settlement mechanisms for the regulations, but there are some similarities between some of the regulations in this regard. Significantly, in some cases there are large disparities in the mechanisms available.

Analysis

The regulations vary widely in regard to the enforcement and dispute settlement mechanisms that are available. Again there is a general difference between the legally binding regulations and the voluntary regulations, in that the latter do not contain enforcement mechanisms to the same degree, since states are not legally obliged to be bound by their provisions. Where regulations are overseen by the same international organisation some do have similar enforcement and dispute settlement procedures, for example the World Trade Organisation (WTO) agreements, which all make use of its Dispute Settlement Understanding, but this is not always the case.

The following regulations have no identifiable dispute settlement mechanism or enforcement procedure: the Laboratory Biosafety Manual; Guidance on Regulations for the Safe Transport of Infectious Substances; Laboratory Biosecurity Guidance; Manual of Diagnostic Tests and Vaccines for Terrestrial Animals; Manual of Diagnostic Tests for Aquatic Animals; the Codex Principles and Guidelines (though disputes may be resolved through the SPS Agreement); Patent Law Treaty; Budapest Treaty; International Convention for the Protection of New Varieties of Plants; International Convention against Doping in Sport; 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.

While the regulations that have dispute settlement mechanisms vary in their specific wording most provide a variety of options including negotiation, conciliation, arbitration, mediation and in many cases the option of submitting the dispute to the International Court of Justice. These options are specifically outlined in: the Convention on Biodiversity; the International Treaty on Plant Genetic Resources; the three UN Drugs Conventions; and the International Health Regulations.

Same Strength of Force

A variety of factors can be found that work against the regulations having the same strength of force, even for regulations within a specific issue area. Significant factors include: whether the regulation is legally binding or not (although note discussions in Chapter 4 on ‘hard’ and ‘soft’ laws); number of states parties; and enforcement and verification mechanisms available to promote compliance. These have been compared across the set. Summary information on some of these factors can be found in Table 9.1 at the end of this chapter.

Analysis

There are large discrepancies among the regulations in relation to the factors that contribute to strength of force. These include: the status of the regulation as legally binding, as voluntary guidance or as a declaration of principles; the number of parties to a treaty (this varies between 24 and 193); enforcement mechanisms; verification mechanisms; and support of key international states (e.g. the United States).

An illustration of this point can be found in the disparity between the enforcement capability of the WTO agreements and the environmental agreements. The WTO agreements carry the backing of potential imposition of trade sanctions for persistent non-compliance which provides a significant motivation for states to comply with these rules. There are no such sanctions incorporated into the environmental agreements.

A further example can be found in the different verification capacities of the Biological Weapons Convention (BWC) and the Chemical Weapons Convention (CWC). The CWC contains very strong and detailed provisions in this regard including the possibility of challenge inspections against states suspected of non-compliance. The BWC does not contain such provisions – although an attempt was made to supplement it with a verification protocol – resulting in a comparative weakness.

Conclusion

The biotechnology regulations fail to display the characteristics of common structure, common administrative and review procedures, common enforcement and dispute settlement mechanisms and same strength of force. There is a basic commonality of structure in the regulations that are legally

binding treaties, but it does not go deeper than this. Not all of the regulations incorporate administrative and review procedures and those that do vary in their requirements, although generally the legally binding treaties require formal input and approval from their member states for any amendments. Enforcement and dispute settlement mechanisms are not found in all of the regulations and they vary in strength – one of the factors which contribute to the regulations not having the same strength of force. They also vary on other relevant factors, including legal status and membership levels.

Table 9.1 The Regulations, Number of Parties and Type (information up-to-date March 2010)

Regulation	Number of parties	Type
1925 Geneva Protocol	132	Legally binding
Biological Weapons Convention	163	Legally binding
EnMod Convention	73	Legally binding
Chemical Weapons Convention	188	Legally binding
International Health Regulations	193	Legally binding
Laboratory Biosafety Manual	n/a	Voluntary guidance
Laboratory Biosecurity Guidance	n/a	Voluntary guidance
Guidance on Regulations for the Transport of Infectious Substances	n/a	Voluntary guidance
Terrestrial Animal Health Code	(The OIE has 174 member states)	Voluntary guidance
Aquatic Animal Health Code	(The OIE has 174 member states)	Voluntary guidance
Manual of Diagnostic Tests and Vaccines for Terrestrial animals	(The OIE has 174 member states)	Voluntary guidance
Manual of Diagnostic Tests for Aquatic Animals	(The OIE has 174 member states)	Voluntary guidance
International Plant Protection Convention	173	Legally binding
Principles for the Risk Analysis of Foods Derived from Modern Biotechnology	(The CAC has 182 member states)	Voluntary guidance
Guideline for Food Safety Assessment – Recombinant-DNA Microorganisms	(The CAC has 182 member states)	Voluntary guidance
Guideline for Food Safety Assessment – Recombinant-DNA Plants	(The CAC has 182 member states)	Voluntary guidance

Regulation	Number of parties	Type
Guideline for Food Safety Assessment – Recombinant-DNA Animals	(The CAC has 182 member states)	Voluntary guidance
Convention on Biodiversity	193	Legally binding
Cartagena Protocol on Biosafety	157	Legally binding
Sanitary and Phytosanitary Agreement	153	Legally binding
Technical Barriers to Trade Agreement	153	Legally binding
Trade Related Aspects of Intellectual Property Rights Agreement	153	Legally binding
Patent Cooperation Treaty	142	Legally binding
Patent Law Treaty	24	Legally binding
Budapest Treaty on the Deposit of Microorganisms for the Purpose of Patent Procedure	72	Legally binding
International Convention for the Protection of New Varieties of Plants	67	Legally binding
International Treaty on Plant Genetic Resources	123	Legally binding
Bonn Guidelines on Access to Genetic Resources	n/a	Voluntary guidance
Single Convention on Narcotic Drugs	184	Legally binding
Convention on Psychotropic Substances	183	Legally binding
Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances	184	Legally binding
World Anti-doping Code	634 sports organisations	Binding for sports organisations, not states
International Convention against Doping in Sport	124	Legally binding
Universal Declaration on the Human Genome and Human Rights	n/a	Non-binding
International Declaration on Human Genetic Data	n/a	Non-binding
Universal Declaration on Bioethics and Human Rights	n/a	Non-binding
United Nations Declaration on Human Cloning	n/a	Non-binding