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7. Coherence in the Biotechnology Regulations: Purpose, Principles, Development and Identity

The analysis of the degree to which the international biotechnology regulations display the characteristics of coherent regulatory sets begins in this chapter with assessment on the characteristics of having a common primary purpose, sharing common principles and a common historical development, and having a common identity that indicates external awareness of their connectedness. The method of analysis for the characteristic is outlined, before the findings are discussed. Table 7.1, at the end of this chapter, provides a summary list of the regulations, their associated oversight bodies, and dates of adoption and entry into force.

Common Purpose

In order to identify the main purpose of the regulation the texts were searched for explicit statements of purpose, firstly in the main clauses, and if not identified within these, then in the preamble or introductory text. If nothing was stated explicitly in the regulatory text, then the purpose was identified either by deduction and/or from information provided by the appropriate international organisation. The purposes were then compared to see whether any similarities existed. The primary purposes are summarised in Table 7.2 at the end of this chapter. From the analysis that follows it is clear that the biotechnology regulations do not have a common primary purpose; however, there is commonality among some of the regulations within issue areas.

Analysis

Most of the regulations introduced in Chapter 6 were not primarily designed to deal with the applications and impacts of biotechnology. In fact, as noted earlier, some of the regulations were in force prior to the scientific revolution taking place. Their treatment of biotechnology is often as a sub-issue and in some cases incidental to the main purpose of the regulation. The primary purposes of the regulations (as listed in Table 7.2) vary widely and it is clear that there is no common purpose to the regulations in regard to governing biotechnology. Of the thirty-seven regulations, only nine are primarily aimed at controlling its applications and impacts; it is not surprising to find that these have all been adopted within the past thirteen years. They are the:

- Universal Declaration on the Human Genome and Human Rights (1997)
- Cartagena Protocol on Biosafety (2000)
- Codex Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (2003)

- Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (2003)
- Codex Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms (2003)
- International Declaration on Human Genetic Data (2003)
- Universal Declaration on Bioethics and Human Rights (2005)
- United Nations Declaration on Human Cloning (2005)
- Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals (2008)

Common Principles

In order to identify the principles on which the regulations are based, their texts were searched for principles stated explicitly in either the main text or preamble, in the form of normative statements rather than substantive action points (which come under unifying and complementary provisions covered in Chapter 8).

The picture here is a little more complex than for common purpose. As well as some of the regulations within issue areas sharing common principles, there are some common principles shared by regulations in different issue areas. A particular synthesis exists between some of the trade regulations and the health regulations. But there are also significant divergences of principles between and within some of the issue areas and there are no principles common to all of the regulations. Some summary examples of common principles and divergent principles are given below.

Analysis

Common Principles within Issue Areas

For arms control:

- Certain means and methods of warfare should be prohibited due to the grave risks they pose to humankind; and
- Means and methods of warfare must not be indiscriminate or cause unnecessary suffering.

These principles can be found in all four of the arms control agreements that are relevant to biotechnology. For example:

Determined, for the sake of all mankind, to exclude completely the possibility of bacteriological (biological) agents and toxins being used as weapons,

Convinced that such use would be repugnant to the conscience of mankind;

(Biological Weapons Convention, Preamble)

Desiring to prohibit effectively military or any other hostile use of environmental modification techniques in order to eliminate the dangers to mankind from such use;

(EnMod Convention, Preamble)

Determined for the sake of all mankind, to exclude completely the possibility of the use of chemical weapons;

(Chemical Weapons Convention, Preamble)

For health, in the area of disease control:

- Reasonable measures should be taken to prevent the spread of disease, but restrictions on travel and trade should be minimised because these can cause severe economic damage.

This principle can be found in the International Health Regulations (IHR), the Terrestrial Animal Health Code and the International Plant Protection Convention:

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.

(IHR, Article 2)

International trade in animals and animal products depends on a combination of factors which should be taken into account to ensure unimpeded trade without incurring unacceptable risks to human and animal health.

(TAHC, Article 5.1.1)

Recognizing that phytosanitary measures should be technically justified, transparent and should not be applied in such a way as to constitute either a means of arbitrary or unjustified discrimination or a disguised restriction, particularly on international trade;

(IPPC, Preamble)

For environmental protection:

- Biodiversity should be protected through the identification and management of risks and the promotion of beneficial technologies, including modern biotechnologies; and
- It is also necessary to protect the environment and human health from potential adverse effects of modern biotechnology.

These principles can be identified throughout the Convention on Biodiversity (CBD) and the Cartagena Protocol on Biosafety, for example:

Each Contracting Party, recognizing that technology includes biotechnology, and that both access to and transfer of technology among Contracting Parties are essential elements for the attainment of the objectives of this Convention, undertakes subject to the provisions of this Article to provide and/or facilitate access for and transfer to other Contracting Parties of technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment.

(CBD, Article 16.1)

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 that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question as referred to in paragraph 3 above, in order to avoid or minimize such potential adverse effects.

(Cartagena Protocol, Article 10.6)

For trade, in the area of free trade:

- Barriers to trade which are not scientifically justified unnecessarily restrict trade and should be removed;
- There must be scientific evidence of harm for action taken against that harm to be justified; and
- Trade restrictions on health protection grounds are permissible but must not be more trade restrictive than necessary (i.e. scientifically justified).

These principles can be found in the Sanitary and Phytosanitary (SPS) Agreement and Technical Barriers to Trade Agreement:

Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence.

(SPS Agreement, Article 2.1)

Members should, when determining the appropriate level of sanitary and phytosanitary protection, take into account the objective of minimising negative trade effects.

(SPS Agreement, Article 5.4)

Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create ... In assessing such risks, relevant elements of consideration are, *inter alia*: available scientific and technical information, related processing technology or intended end-uses of products.

(TBT Agreement, Article 2)

For trade, in the area of intellectual property protection:

- People should be able to protect their intellectual property and to benefit commercially from its exploitation. This will facilitate technology transfer and promote economic growth.

These principles are incorporated in the Agreement on Trade Related Aspects of Intellectual Property Rights and the Patent Cooperation Treaty:

A patent shall confer on its owner the following exclusive rights:

- (a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product;
- (b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.

(TRIPS Agreement, Article 28.1)

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge, and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

(TRIPS Agreement, Article 7)

Desiring to make a contribution to the progress of science and technology,
Desiring to perfect the legal protection of inventions,

Desiring to simplify and render more economical the obtaining of protection for inventions where protection is sought in several countries,

Desiring to facilitate and accelerate access by the public to the technological information contained in documents describing new inventions,

Desiring to foster and accelerate the economic development of developing countries through the adoption of measures designed to increase the efficiency of their legal systems,

(PCT, Preamble)

For trade, in the area of access to genetic resources:

- The conservation and sustainable use of plant genetic resources are vital for food security, and conditions should be placed on access to ensure it meets these aims;
- Farmers, indigenous and local groups who have contributed to the development of plant genetic resources and countries of origin have the right to set conditions on (but not prohibit) access to those resources, and to benefit from any subsequent commercial use.

These principles can be found in the International Treaty on Plant Genetic Resources and in the Bonn Guidelines on Access to Genetic Resources, for example:

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, and are essential in adapting to unpredictable environmental changes and future human needs;

Affirming that the past, present and future contributions of farmers in all regions of the world, particularly those in centres of origin and diversity, in conserving, improving and making available these resources, is the basis of Farmers' Rights;

(ITPGR, Preamble)

Providers should:

Only supply genetic resources and/or traditional knowledge when they are entitled to do so;

Strive to avoid imposition of arbitrary restrictions on access to genetic resources.

(Bonn Guidelines, Part II.C)

For drugs control:

- Human health and welfare should be protected from the negative effects of drug abuse and the drugs trade;
- Sufficient availability of drugs should be maintained for legitimate scientific and medical purposes.

These principles are incorporated into the United Nations Drugs Conventions and the International Convention against Doping in Sport. For example:

Concerned with the health and welfare of mankind,

Recognizing that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure the availability of narcotic drugs for such purposes,

Recognizing that addiction to narcotic drugs constitutes a serious evil for the individual and is fraught with social and economic danger to mankind,

(Single Convention on Narcotic Drugs, Preamble)

No measures taken pursuant to this Convention will impede the availability for legitimate purposes of substances and methods otherwise prohibited or controlled in sport.

(ICADS, Article 8.3)

For social and ethical impacts:

- All research and development in and applications of the life sciences which involve humans should not contravene the rules/principles of human dignity, fundamental freedoms and human rights.

These principles can be found in 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 United Nations Declaration on Human Cloning:

Recognizing that research on the human genome and resulting applications open up vast prospects for progress in improving the health of individuals and of humankind as a whole, but *emphasizing* that such research should fully respect human dignity, freedom and human rights, as well as the prohibition of all forms of discrimination based on genetic characteristics,

(UDHGHR, Preamble)

Reaffirming the principles established in the Universal Declaration on the Human Genome and Human Rights and the principles of equality, justice, solidarity and responsibility as well as respect for human dignity, human rights and fundamental freedoms, particularly freedom of thought and expression, including freedom of research, and privacy and security of the person, which must underlie the collection, processing, use and storage of human genetic data,

(IDHGD, Preamble)

Human dignity, human rights and fundamental freedoms are to be fully respected.

(UDBEHR, Article 3.1)

Emphasizing that the promotion of scientific and technical progress in life sciences should be sought in a manner that safeguards respect for human rights and the benefit of all.

(UNDHC, Preamble)

Areas of Commonality of Principles across Issue Areas

Arms control and drugs control:

Both of these areas deal with the control of dual-use materials, and they contain some common principles in this regard, for example:

- Dual-use materials should only be developed and used for legitimate purposes;
- Rules on dual-use materials and equipment should not be used as an excuse for unjustified restrictions on trade or development;
- Dual-use materials can have benefits when used for legitimate purposes.

Examples include, from the Biological Weapons Convention (BWC): ‘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’ (Article X.1).

And from the preamble to the Convention on Psychotropic Substances: ‘Recognizing that the use of psychotropic substances for medical and scientific purposes is indispensable and that their availability for such purposes should not be unduly restricted.’

Disease control and rules on free trade:

The key agreements on disease control for human, animal and plant health (the International Health Regulations, the Terrestrial and Aquatic Animal Health Codes and the International Plant Protection Convention) all share the principle of not allowing controls to unjustifiably restrict international trade. This is supported by the principle in the Sanitary and Phytosanitary and Technical Barriers to Trade Agreements that while some health protective measures may be justifiable, these should only be used where necessary and should be designed to have minimal impacts on trade.

Examples from the trade agreements include:

Recognizing that no country should be prevented from taking measures necessary to ensure the quality of its exports, or for the protection of human, animal or plant life or health ... subject to the requirement that

they are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between Members where the same conditions prevail or a disguised restriction on international trade.
(TBT Agreement, Preamble)

Reaffirming that no Member should be prevented from adopting or enforcing measures necessary to protect human, animal or plant life or health, subject to the requirement that these measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between Members where the same conditions prevail or a disguised restriction on international trade.
(SPS Agreement, Preamble)

Examples from the disease control agreements include:

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.
(IHR, Article 2)

International trade in animals and animal products depends on a combination of factors which should be taken into account to ensure unimpeded trade without incurring unacceptable risks to human and animal health.
(TAHC, Article 5.1.1)

Another common principle is shared by the Sanitary and Phytosanitary Agreement, the Technical Barriers to Trade Agreement and the Terrestrial Animal Health Code – different measures that achieve the same level of protection should be treated as equivalent.

For example:

Members shall give positive consideration to accepting as equivalent technical regulations of other Members, even if these regulations differ from their own, provided that they are satisfied that these regulations adequately fulfil the objectives of their own regulations.
(TBT Agreement, Article 2.7)

Members shall accept the sanitary or phytosanitary measures of other Members as equivalent, even if these measures differ from their own or from those used by other Members trading in the same product, if the

exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member's appropriate level of sanitary or phytosanitary protection.

(SPS Agreement, Article 4.1)

It is now recognised that significantly different animal health and production systems can provide equivalent animal and human health protection for the purpose of international trade, with benefit to both the importing country and the exporting country.

(TAHC, Chapter 5.3.2)

Broader Commonalities

- Human health and welfare should be protected.

This principle can be found in the International Health Regulations, Terrestrial Animal Health Code, Codex Alimentarius Principles and Guidelines, Laboratory Biosafety Manual, Laboratory Biosecurity Guidance, Sanitary and Phytosanitary Agreement, UN Drugs Conventions and the World Anti-doping Code. For example:

In essence the outcome of the safety assessment process is to define the product under consideration in such a way as to enable risk managers to determine whether any measures are needed to protect the health of consumers and if so to make well-informed and appropriate decisions in this regard.

(Codex Guideline Recombinant-DNA Microorganisms, point 25)

International trade in animals and animal products depends on a combination of factors which should be taken into account to ensure unimpeded trade, without incurring unacceptable risks to human and animal health.

(TAHC, Article 5.1.1)

- Risk analysis, assessment and management are important for effective control.

This principle can be found in the: International Health Regulations; Terrestrial Animal Health Code; International Plant Protection Convention; Codex Alimentarius Principles and Guidelines; Laboratory Biosafety Manual; Laboratory Biosecurity Guidance; Guidance on Regulations for the Safe Transport of Infectious Substances; Manual of Diagnostic Tests and Vaccines for Terrestrial Animals and Cartagena Protocol. For example:

The backbone of the practice of biosafety is risk assessment.

(Laboratory Biosafety Manual, p. 7)

10. If a new or altered hazard, nutritional or other safety concern is identified by the safety assessment, the risk associated with it should be characterized to determine its relevance to human health.
13. Risk assessment should apply to all relevant aspects of foods derived from modern biotechnology.
16. Risk management measures for foods derived from modern biotechnology should be proportional to the risk.

(Codex Principles)

Divergent Principles

As well as these areas of commonality, areas of tension can be identified among some of the principles embodied in the regulations. This is shown in the following two examples.

Intellectual property rights and access to genetic resources:

While the agreements on access to and benefit-sharing from the use of genetic resources include the right of farmers, local and indigenous groups to benefit from the commercial exploitation of resources that they have helped to develop, or knowledge they have about those resources, these rights are not incorporated into the rules on intellectual property protection. In those rules it is only the person/institution that took the 'innovative step' that is guaranteed reward from an invention's commercial exploitation. Some discoveries/organisms are excluded from patentability, but not all, nor their products. Some controversial cases have already occurred including disputes over the patenting of basmati rice and neem products (BBC News Online, 9 March 2005; Browne, 25 June 2000; Vidal, 8 September 2003).

This is a complex area in terms of which rules should apply or be used internationally. There have been some attempts to address these issues, including within the World Trade Organisation, World Intellectual Property Organisation, Commission on Genetic Resources for Food and Agriculture and the CBD Secretariat. One promising collaboration is that between the CBD conferences of the parties and the World Intellectual Property Organisation, which in the long term may help to resolve some of these issues (see for example CBD, April 2002, 16 January 2006; WIPO, no date; WTO, 8 August 2002). However, the content of the regulations themselves is unlikely to change in the near future.

To illustrate, these provisions from the Agreement on Trade Related Aspects of Intellectual Property Rights:

1. ... Patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.
2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is

necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment ...

3. Members may also exclude from patentability: ... (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof.

(TRIPS, Article 27)

A patent shall confer on its owner the following exclusive rights:

- a. where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling or importing for these purposes that product;
- b. where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.

(TRIPS, Article 28.1)

can be compared to the following provisions from the International Treaty on Plant Genetic Resources for Food and Agriculture:

1. The Contracting Parties recognize the enormous contribution that the local and indigenous communities and farmers of all regions of the world, particularly those in the centres of origin and crop diversity, have made and will continue to make for the conservation and development of plant genetic resources which constitute the basis of food and agriculture production throughout the world.
2. The Contracting Parties agree that the responsibility for realizing Farmers' Rights as they relate to plant genetic resources for food and agriculture, rests with national governments. In accordance with their needs and priorities, each Contracting Party, should, as appropriate, and subject to its national legislation, take measures to protect and promote Farmers' Rights including:
 - (a) protection of traditional knowledge relevant to plant genetic resources for food and agriculture;
 - (b) the right to equitably participate in sharing benefits arising from the utilization of plant genetic resources for food and agriculture; and
 - (c) the right to participate in making decisions, at the national level, on matters relating to the conservation and sustainable use of plant genetic resources for food and agriculture.

3. Nothing in this Article shall be interpreted to limit any rights that farmers have to save, use, exchange and sell farm-saved seed/propagating material, subject to national law and as appropriate.

(ITPGR, Article 9)

3. (b) Access shall be accorded expeditiously, without the need to track individual accessions and free of charge, or, when a fee is charged, it shall not exceed the minimal cost involved ...

- (d) Recipients shall not claim any intellectual property or other rights that limit the facilitated access to the plant genetic resources for food and agriculture, or their genetic parts or components, in the form received from the multilateral system ...

- (f) Access to plant genetic resources for food and agriculture protected by intellectual and other property rights shall be consistent with relevant international agreements

(ITPGR, Article 12)

Protection of biodiversity and rules on free trade:

A second example of tensions between principles is found between the Cartagena Protocol and the Sanitary and Phytosanitary Agreement and Technical Barriers to Trade Agreement. The Cartagena Protocol incorporates the precautionary principle allowing action to be taken to prevent harm occurring even if, as yet, there is insufficient scientific evidence that the harm may occur. The Protocol applies this principle specifically to decisions on the import of genetically modified organisms (GMOs) and thus it is, under the Protocol, legitimate for a state to implement trade restrictions on a precautionary basis. The Technical Barriers to Trade Agreement, on the other hand, demands evidence of harm for a trade restriction to be justified. Some flexibility is provided in Clause 5.7 of the SPS Agreement (see below) but there is great uncertainty over precisely what the standards are for applying this clause, and for whether it applies to GMO import decisions at all.

The precautionary principle incorporated in the Cartagena Protocol is derived from Principle 15 of the Rio Declaration, which states: 'Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation' (UN General Assembly, 12 August 1992).

If measures to conserve biodiversity are considered to be protecting plant health, then they may come under the SPS Agreement – however, this Agreement does not refer to the CBD or Cartagena Protocol as acceptable sources of international standards. Import restrictions on living modified organisms to conserve biodiversity may therefore come under the Technical Barriers to Trade Agreement.

The relevant provisions of the SPS Agreement are:

1. Members have the right to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health, provided that such measures are not inconsistent with the provisions of this Agreement.
2. Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence.

(SPS Agreement, Article 2)

2. In the assessment of risks, Members shall take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment.
7. In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information ... In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.

(SPS Agreement, Article 5)

The relevant provision of the TBT Agreement is:

Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade restrictive than necessary to fulfil a legitimate objective ... 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. In assessing such risks, relevant elements of consideration are, *inter alia*: available scientific and technical information, related processing technology or intended end uses of products.

(TBT Agreement, Article 2.2)

The Appellate Body of the World Trade Organisation when considering the EC-Hormones case under its Dispute Settlement Understanding looked at the precautionary principle and how it relates to the SPS Agreement (particularly to Article 5.7). Firstly, the Appellate Body refused to take a position on the

status of the principle in international law. In regard to its relationship with the SPS Agreement it made four additional points:

- That the principle has not been written into the Agreement as a basis for allowing measures that would otherwise contravene the Agreement
- That some reflection of the principle can be found in the Agreement, particularly where it allows states to apply more stringent measures than exist in the international standards
- That if a panel were to examine if ‘sufficient scientific evidence’ existed for a particular measure, it could take into account that ‘governments commonly act from perspectives of prudence and precaution where risks of irreversible, e.g. life-terminating, damage to human health are concerned’
- That ‘the precautionary principle does not, by itself, and without a clear textual directive to that effect, relieve a panel from the duty of applying the normal (i.e. customary international law) principles of treaty interpretation in reading the provisions of the SPS Agreement’ (WTO, no date).

This does not resolve confusion over whether the precautionary principle may be applied to imports of GMOs, particularly since the third point seems to apply to threats only to human health, not to the environment.

Common Historical Development

As mentioned in Chapter 5, common historical development does not require the regulations to have been adopted at the same time, but that their principles and provisions have a common developmental history. To assess whether common development exists, documents on the regulations’ history were examined. The main sources of these documents were international organisations, NGOs, academic groups and individual authors. The documents consulted were mainly fact sheets, journal articles and books.

Within some of the issue areas a common path of historical development can be identified. For example a common history can be identified for three of the arms control regulations and for the CBD and the Cartagena Protocol. This is not the case across the whole regulatory set, nor is it always the case within issue areas. Some key points in the historical development of the regulations are outlined below.

Analysis

Arms Control

A common historical development can be identified for the Geneva Protocol, the BWC and the Chemical Weapons Convention (CWC). The BWC and CWC were developed to reinforce and supplement the prohibitions of the Geneva Protocol. This is shown in the Conventions’ preambles:

Recognizing the important significance of the Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare

Recognizing that an agreement on the prohibition of bacteriological (biological) and toxin weapons represents a first possible step towards the achievement of agreement on effective measures also for the prohibition of the development, production and stockpiling of chemical weapons, and determined to continue negotiations to that end,

(BWC, Preamble)

Recognizing that this Convention reaffirms principles and objectives of and obligations assumed under the Geneva Protocol of 1925, and the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction,

(CWC, Preamble)

The Environmental Modification (EnMod) Convention does not have a strong connection to this historical development (although it is also grounded in the principles of international humanitarian law). It prohibits specific *uses* of weapons/methods of warfare, whereas the other three agreements prohibit the use of specific *types* of weapons.

Health

The disease control regulations developed separately in the areas of human, animal and plant health. They were, however, originally adopted within eleven years of each other (the Terrestrial Animal Health Code in 1968; the International Health Regulations in 1969; and the International Plant Protection Convention in 1979) and for the same basic motivation of protecting health while minimising trade disruptions. The World Health Organisation (WHO), which oversees the IHR, and the Office International des Epizooties (OIE), which oversees the Terrestrial Animal Health Code, both developed manuals to promote biosafety in laboratories as a further mechanism for preventing disease spread. The WHO developed a separate document dealing with guidelines for transport of infectious substances and diagnostic specimens – again to prevent disease spread. The OIE included sections on this subject in both its Terrestrial Code and Terrestrial Manual. The international organisations responsible for the IHR and International Plant Protection Convention (the WHO and Food and Agriculture Organisation) combined their efforts at promoting food safety through the creation of the Codex Alimentarius Commission in 1963. The Commission developed the principles and guidelines on assessing the safety of foods produced using modern biotechnology, which were adopted in 2003.

Environmental Protection

The two environmental agreements also have a closely shared history – the Cartagena Protocol was a direct development of and addition to the CBD. The potential need for such a protocol was outlined in Article 19 of the Convention – Handling of Biotechnology and Distribution of Its Benefits: ‘The Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have an adverse effect on the conservation and sustainable use of biological diversity.’

Trade

The SPS Agreement and the Technical Barriers to Trade Agreement have a common history in the development of free trade rules, outlined in Chapter 8. The other World Trade Organisation agreement of relevance to the control of biotechnology, the Trade Related Aspects of Intellectual Property Rights Agreement, does not share the same history. In fact, it has a closer historical connection to the Patent Cooperation Treaty and Patent Law Treaty of the World Intellectual Property Organisation, as they all relate to the international protection of intellectual property rights. Regulation of intellectual property did not extend into the free trade area until 1995. The International Convention for the Protection of New Varieties of Plants developed separately from the other rules on intellectual property and the rules governing access to genetic resources developed separately from the other trade rules.

Drugs Control

In the area of drugs control the two distinct sets of regulations have separate developmental histories. The United Nations Drugs Conventions were developed from 1961 to 1988 (built on agreements developed since the early twentieth century) and they focus on the control of illicit drugs in the international trade system. The international rules on anti-doping took longer to codify, only being formally approved by states in 2005; they focus on illicit use of performance-enhancing substances in sport, and are primarily directed at sports organisations.

Social and Ethical Impacts

The four international declarations in this area have a common history in the development of international human rights principles and rules. The Universal Declaration on the Human Genome and Human Rights, the International Declaration on Human Genetic Data and the Universal Declaration on Bioethics and Human Rights were all developed by the International Bioethics Committee and Intergovernmental Bioethics

Committee within the United Nations Educational, Scientific and Cultural Organisation (UNESCO). The United Nations Declaration on Human Cloning was developed within the UN General Assembly's Sixth Committee, using the principles of the Universal Declaration on the Human Genome and Human Rights as its basis. Article 11 of the Universal Declaration on the Human Genome and Human Rights specifically invited states to consider developing such an instrument: 'Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted. States and competent international organizations are invited to cooperate in identifying such practices and in taking, at national or international level, the measures necessary to ensure that the principles set out in this Declaration are respected.'

Summary

As a set the regulations applicable to the international control of biotechnology do not share a common developmental history, although within issue areas there are often many connections. The regulations largely developed separately from one another (or at least within different issue areas). They developed at different times, and thus in different historical contexts. The dates of adoption range across more than eighty years (from 1925 to 2008). Table 7.1 at the end of this chapter provides a full listing of adoption dates. Some of the regulations were adopted prior to even the scientific side of the biotechnology revolution occurring (mid-1970s) and several more before its full socio-economic implications began to be widely discussed.

Common Identity

Common identity was defined in Chapter 5 as external awareness of connections between the regulations. This identity would be established in the regulations themselves, or by the international organisation that oversees them, and would be evidenced in how the regulations are referred to by the public, media, governments and other groups and organisations – i.e. whether they are frequently referred to as a complete regulatory set. In order to assess this, evidence of external awareness was searched for in documents on the regulations, and on regional and national biotechnology regulations.

The biotechnology regulations lack such a common identity; however, there are indications that external awareness of the connections is gradually increasing. This awareness is still often limited to less than the full range of regulations. A common identity for the regulations has not yet gained general acceptance, but may be emerging.

Analysis

Some of the regulations share a common identity within an issue area. The clearest examples of this are the Single Convention on Narcotic Drugs, the

Convention on Psychotropic Substances and the Convention against Illicit Trade in Narcotic Drugs and Psychotropic Substances, which are commonly known as the 'UN Drugs Conventions'; and the Sanitary and Phytosanitary Agreement, Technical Barriers to Trade Agreement and Agreement on Trade Related Aspects of Intellectual Property Rights, which are all part of what are known as the 'World Trade Organisation agreements'.

The following studies have identified some of the regulations as biotechnology regulations:

- MacKenzie, R. (no date) *Globalisation and the International Governance of Modern Biotechnology – The International Regulation of Modern Biotechnology*.

This mentions: the International Plant Protection Convention; the Cartagena Protocol; the Codex Alimentarius (it was published prior to adoption of the principles and guidelines); the Sanitary and Phytosanitary Agreement; the Technical Barriers to Trade Agreement; the Trade Related Aspects of Intellectual Property Rights Agreement; those international standards referred to in the Sanitary and Phytosanitary Agreement (i.e. those of the Codex Alimentarius Commission, the International Plant Protection Convention and the Office International des Epizooties); and the World Trade Organisation's Dispute Settlement Understanding.

- United Nations Conference on Trade and Development (UNCTAD) (26 April 2001), *Panel on Legal and Regulatory Issues in Biotechnology: Summary Report*.

This mentions: the Trade Related Aspects of Intellectual Property Rights Agreement; the Convention for the Protection of New Varieties of Plants; the Convention on Biodiversity; the Cartagena Protocol; the Sanitary and Phytosanitary Agreement; the Technical Barriers to Trade Agreement; and the Codex Alimentarius Commission.

- Glowka, L. (2003) *Law and Modern Biotechnology: Selected Issues of Relevance to Food and Agriculture*, Rome: FAO Legal Office.

This mentions in its list of 'International Instruments Related to Modern Biotechnology': the Codex Principles and Guidelines (at this stage they were drafts); the International Treaty on Plant Genetic Resources; the International Plant Protection Convention; the Convention on Biodiversity; the Cartagena Protocol; the Sanitary and Phytosanitary Agreement; and the Technical Barriers to Trade Agreement.

- Blay, S. (2005) 'International Regulation of Biotechnology: Problems and Prospects', *Journal of International Biotechnology Law*, 02: 245–51.

This refers to: the Universal Declaration on the Human Genome and Human Rights; the International Declaration on Human Genetic Data; the United Nations Declaration on Human Cloning; the Convention on Biodiversity; the Cartagena Protocol; the International Plant Protection Convention; the International Treaty on Plant Genetic Resources; and the Trade Related Aspects of Intellectual Property Rights Agreement.

- Murphy, S. D. (Winter 2001) 'Biotechnology and International Law', *Harvard International Law Journal*, 42(1): 47–139.

This mentions: the World Intellectual Property Organisation; the Trade Related Aspects of Intellectual Property Rights Agreement; the Convention on Biodiversity; the Cartagena Protocol; the Sanitary and Phytosanitary Agreement; the Technical Barriers to Trade Agreement; the International Plant Protection Convention; and the World Trade Organisation.

Two further examples of awareness of the connections between the different areas of regulation in their relevance to control of biotechnology can be found in a guide to the UK's national biotechnology regulation – the *ibioUK Biotechnology Regulatory Atlas* (DTI/LGC Ltd, 2003) – which covers regulations in the areas of: strategy and society; intellectual property; safety and welfare; contained use of GMOs; deliberate release of GMOs; medical products; human genetics and therapy; environmental and chemical; and food and agriculture. And in a *Users Guide to European Regulation in Biotechnology* (LGC Ltd, 2005) which contains sections on: access to information; contained use of GMOs; release and commercialisation of GMOs; the genetically modified food and feed chain; transportation and international (transboundary) movement of GMOs; medicinal products and health care; and intellectual property.

Regulations at different levels (local, national, regional or international) will attach different importance to different issues, but both of these examples show awareness of the connections between the health, environmental, social and trade issues in the regulation of biotechnology.

Conclusion

The biotechnology regulations clearly fail to match the first four characteristics of coherent international regulation. They do not have a common purpose, and while some principles are shared by more than one regulation, there are none that extend across the full regulatory set. Shared historical development can be identified within some issue areas, but again it is not present for the set as a whole. There are positive signs of awareness of the connections between some of the regulations in their relevance to biotechnology, but they do not yet have a common identity.

Table 7.1 The Regulations, Their Oversight Bodies and Dates of Adoption and Entry into Force

Regulation	Oversight body	Date of adoption/ latest edition	Date of entry into force
1925 Geneva Protocol	n/a	1925	1928
Biological Weapons Convention	n/a	1972	1975
EnMod Convention	n/a	1976	1978
Chemical Weapons Convention	Organisation for the Prohibition of Chemical Weapons	1993	1997
International Health Regulations	World Health Organisation	2005	2007
Laboratory Biosafety Manual	World Health Organisation	2004	n/a
Laboratory Biosecurity Guidance	World Health Organisation	2006	n/a
Guidance on Regulations for the Transport of Infectious Substances	World Health Organisation	2009	n/a
Terrestrial Animal Health Code	Office International des Epizooties	18th edition, 2009	n/a
Aquatic Animal Health Code	Office International des Epizooties	12th edition, 2009	n/a
Manual of Diagnostic Tests and Vaccines for Terrestrial Animals	Office International des Epizooties	6th edition, 2008	n/a
Manual of Diagnostic Tests for Aquatic Animals	Office International des Epizooties	5th edition, 2006	n/a
International Plant Protection Convention	Food and Agriculture Organisation	1997	2005
Principles for the Risk Analysis of Foods Derived from Modern Biotechnology	Codex Alimentarius Commission	2003	As implemented by each member state
Guideline for Food Safety Assessment – Recombinant-DNA Microorganisms	Codex Alimentarius Commission	2003	As implemented by each member state
Guideline for Food Safety Assessment – Recombinant-DNA Plants	Codex Alimentarius Commission	2003	As implemented by each member state

Regulation	Oversight body	Date of adoption/ latest edition	Date of entry into force
Guideline for Food Safety Assessment – Recombinant-DNA Animals	Codex Alimentarius Commission	2008	As implemented by each member state
Convention on Biodiversity	Convention on Biodiversity Secretariat	1992	1993
Cartagena Protocol on Biosafety	Convention on Biodiversity Secretariat	2000	2003
Sanitary and Phytosanitary Agreement	World Trade Organisation	1995	1995
Technical Barriers to Trade Agreement	World Trade Organisation	1995	1995
Trade Related Aspects of Intellectual Property Rights Agreement	World Trade Organisation	1995	1995
Patent Cooperation Treaty	World Intellectual Property Organisation	1970	1978
Patent Law Treaty	World Intellectual Property Organisation	2000	2005
Budapest Treaty on the Deposit of Microorganisms for the Purpose of Patent Procedure	World Intellectual Property Organisation	1977	1980
International Convention for the Protection of New Varieties of Plants	Union for the Protection of New Varieties of Plant	1961/1991	1968
Bonn Guidelines on Access to Genetic Resources	Convention on Biodiversity Secretariat	2002	n/a
International Treaty on Plant Genetic Resources	Food and Agriculture Organisation	2001	2004
Single Convention on Narcotic Drugs	International Narcotics Control Board, Commission on Narcotic Drugs and UN Office on Drugs and Crime	1961	

(Continued)

Table 7.1 (Continued)

Regulation	Oversight body	Date of adoption/ latest edition	Date of entry into force
Convention on Psychotropic Substances	International Narcotics Control Board, Commission on Narcotic Drugs and UN Office on Drugs and Crime	1971	
Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances	International Narcotics Control Board, Commission on Narcotic Drugs and UN Office on Drugs and Crime	1988	
World Anti-doping Code	World Anti-doping Association	2009 edition	2009
International Convention against Doping in Sport	United Nations Educational, Scientific and Cultural Organisation	2005	2007
Universal Declaration on the Human Genome and Human Rights	United Nations Educational, Scientific and Cultural Organisation	1997	n/a
International Declaration on Human Genetic Data	United Nations Educational, Scientific and Cultural Organisation	2003	n/a
Universal Declaration on Bioethics and Human Rights	United Nations Educational, Scientific and Cultural Organisation	2005	n/a
United Nations Declaration on Human Cloning	United Nations General Assembly	2005	n/a

Table 7.2 The Main Purposes of the Regulations

Regulation	Summary of main purpose
1925 Geneva Protocol	Prevention of the use of biological or chemical weapons in war
Biological Weapons Convention	Prevention of the development, production, stockpiling and use of biological or toxin weapons at all times
EnMod Convention	Prevention of the use of certain techniques, at certain degrees, to modify the environment for warfare or other hostile use

Regulation	Summary of main purpose
Chemical Weapons Convention	Prevention of the development, production, stockpiling and use of chemical weapons, and destruction of existing weapons and production facilities
International Health Regulations	Prevention of the spread of serious human diseases through trade and travel routes, surveillance and response
Laboratory Biosafety Manual	Minimising the risk of disease transmission for people working in laboratories with dangerous pathogens and preventing transmission of disease to the public/release of pathogens into the environment
Laboratory Biosecurity Guidance	Minimising the risk of loss, theft or diversion of valuable biological materials including pathogenic agents
Guidance on Regulations for the Transport of Infectious Substances	Minimising the risk of disease transmission for people working in the transport of potentially dangerous pathogens and preventing transmission of disease to the public/release of pathogens into the environment
Terrestrial Animal Health Code	Prevention of the spread of serious animal diseases through trade and travel routes, surveillance and response
Aquatic Animal Health Code	Prevention of the spread of serious aquatic diseases through trade and travel routes, surveillance and response
Manual of Diagnostic Tests and Vaccines for Terrestrial Animals	Minimising the risk of disease transmission for people working in laboratories with or in the transport of potentially dangerous animal pathogens, preventing transmission of disease to the public or animals and the release of pathogens into the environment
Manual of Diagnostic Tests for Aquatic Animals	Minimising the risk of disease transmission during trade in aquatic animals and related products
International Plant Protection Convention	Prevention of the spread of serious plant diseases through trade and travel routes, surveillance and response
Principles for the Risk Analysis of Foods Derived from Modern Biotechnology	Ensuring effective and accurate risk analysis of the implications for human health and nutrition of genetically modified foods
Guideline for Food Safety Assessment – Recombinant-DNA Microorganisms	Ensuring effective and accurate safety assessment of foods produced using genetically modified microorganisms, including risk analysis and suggestion of risk management approaches
Guideline for Food Safety Assessment – Recombinant-DNA Plants	Ensuring effective and accurate safety assessment of foods derived from genetically modified plants, including risk analysis and suggestion of risk management approaches
Guideline for Food Safety Assessment – Recombinant-DNA Animals	Ensuring effective and accurate safety assessment of foods derived from genetically modified animals, including risk analysis and suggestion of risk management approaches

(Continued)

Table 7.2 (Continued)

Regulation	Summary of main purpose
Convention on Biodiversity	Protection and conservation of biodiversity, ensuring its sustainable use and the fair and equitable sharing of the benefits arising out of its utilisation
Cartagena Protocol on Biosafety	Protection of biodiversity from the potential risks posed by genetically modified organisms through a system of advanced informed agreement to imports
Sanitary and Phytosanitary Agreement	To limit to what is scientifically justifiable any human, animal or plant health-based restriction on trade and to harmonise such restrictions internationally
Technical Barriers to Trade Agreement	To limit to what is scientifically justifiable any technical barriers to trade and to harmonise such barriers internationally
Trade Related Aspects of Intellectual Property Rights Agreement	To internationalise standards of intellectual property protection
Patent Cooperation Treaty	To provide an optional system allowing a single international application for patent protection rather than requiring individual applications for each state
Patent Law Treaty	To enhance the international patent application scheme that was introduced in the Patent Cooperation Treaty
Budapest Treaty on the Deposit of Microorganisms for the Purpose of Patent Procedure	To allow single international deposits of microorganisms which support patent applications, rather than requiring individual deposits in each state
International Convention for the Protection of New Varieties of Plants	To provide intellectual property protection to new plant varieties
International Treaty on Plant Genetic Resources	To facilitate access to plant genetic resources of importance to food security
Bonn Guidelines on Access to Genetic Resources	To facilitate access to genetic resources under conditions that promote their sustainable use and ensure any benefits from their utilisation are shared equitably
Single Convention on Narcotic Drugs	To bring an end to the illicit international trade in narcotic drugs, while ensuring an adequate supply is maintained for medical and scientific purposes
Convention on Psychotropic Substances	To bring an end to the illicit international trade in psychotropic substances, while ensuring an adequate supply is maintained for medical and scientific purposes
Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances	To introduce further measures in support of the Single Convention on Narcotic Drugs and Convention on Psychotropic Substances

Regulation	Summary of main purpose
World Anti-doping Code	To prevent and penalise the misuse of drugs to confer unfair advantage in competitive sporting events
International Convention against Doping in Sport	To provide governmental support for the principles and objectives of the World Anti-doping Code
Universal Declaration on the Human Genome and Human Rights	To highlight particular human genetic techniques that pose risks to key principles, values and human rights and to declare certain uses of human genetics as unacceptable
International Declaration on Human Genetic Data	To declare that the collection and use of human genetic data should respect human dignity, human rights and fundamental freedoms
United Nations Declaration on Human Cloning	To acknowledge that human reproductive cloning is contrary to human dignity and human life and to declare its use as unacceptable
Universal Declaration on Bioethics and Human Rights	To outline international principles of bioethics