Rhodes, Catherine. "Findings and Implications for the Effective Governance of Biotechnology." *International Governance of Biotechnology: Needs, Problems and Potential*. London: Bloomsbury Academic, 2010. 164–172. Science Ethics and Society. *Bloomsbury Collections*. Web. 26 Apr. 2023. <<http://dx.doi.org/10.5040/9781849661812.ch-011>>.

Downloaded from Bloomsbury Collections, www.bloomsburycollections.com, 26 April 2023, 04:16 UTC.

Copyright © Catherine Rhodes 2010. You may share this work for non-commercial purposes only, provided you give attribution to the copyright holder and the publisher, and provide a link to the Creative Commons licence.

11. Findings and Implications for the Effective Governance of Biotechnology

The international regulations of relevance to the governance of modern biotechnology do not form a coherent regulatory set and are currently fragmented. The analysis in the previous four chapters suggests that several factors lie behind this. These include that: the regulations were generally not designed with the specific intention of governing the applications and impacts of biotechnology; the regulations were developed at different times and in different historical contexts; the regulations largely developed separately from one another, or at least within distinct issue areas; and the regulations differ widely in their membership. Following a summary of the assessment of the degree of coherence among the biotechnology regulations, this chapter will outline the implications of this, particularly in regard to the effective functioning of the regulations, and will discuss policy options for increasing coherence.

Lack of Coherence among the International Regulations Relevant to the Control of Biotechnology

Assessed against the model of coherent international regulatory sets, which was outlined in Chapter 5, the biotechnology regulations fail to match twelve of the sixteen characteristics, and the assessment is ambiguous on the other four (see Table 11.1). There are signs that a common identity may be starting to emerge and internal awareness of connections between the regulations also seems to be improving.

Table 11.1 International Biotechnology Regulations and the Model of Coherent International Regulatory Sets

Characteristic	Displayed in the biotechnology regulations?
Common primary purpose	No
Common principles	No
Common historical development	No
Common identity	No, but signs it may be emerging
Self-referencing	No, but improving
Shared definitions	No
Unifying provisions	No
Complementary provisions	Yes, but also contradictory provisions

Characteristic	Displayed in the biotechnology regulations?
Common structure	No
Common administration and review procedures	No
Common enforcement and dispute settlement mechanisms	No
Same strength of force	No
Single international organisation	No
Self-contained	Not comparable
Clear issue focus	No
Comprehensive coverage of issue	Ambiguous

Problems in Fulfilling the Functions of International Regulation

Fifteen key functions of international regulation were identified in Chapter 4:

- Defining the rights and obligations of states
- Regulating conduct
- Coordinating behaviour
- Providing predictability and reducing uncertainty
- Reducing costs of individual action and increasing efficiency
- Authorising or prohibiting certain actions
- Facilitating cooperation
- Imposing constraints
- Realising values
- Establishing and shaping expectations
- Channelling conflict and providing mechanisms for its resolution
- Simplifying and facilitating transactions
- Assisting policy-making
- Dealing with common threats/problems
- Promoting peace

While the international biotechnology regulations assessed individually fulfil many of these functions, as a set they face several problems in doing so because of their lack of coherence. Several illustrative examples of these problems follow.

Example 1 – Lack of Clarity about Which Rules are Applicable

Lack of coherence among the regulations can leave it unclear which rules should be applied in particular cases. To illustrate this problem, when

deciding to allow the export of a genetically engineered bacterium, states may be unclear whether they should be applying rules on trade, on disease control, on arms control, on transport of dangerous goods or on conservation of biodiversity, or a combination of some or all of these regulations.

This is particularly problematic where there is no referencing between the regulations. It is, for example, made clear in the Cartagena Protocol that it does not cover 'living modified organisms which are pharmaceuticals for humans that are addressed by other relevant agreements and organisations' (Article 5), but it does not say what these agreements are, or whether any environmental impacts need to be taken into account when applying the other agreements. Referring back to Table 8.1 in Chapter 8, in relation to this example, it can be seen that there are no references from the arms control regulations to the other regulations; no references between the trade and the environmental regulations; and only limited references between the health regulations and trade regulations.

The implications of this are that states may be unaware of the full range of rules that apply, unclear which rules they should apply and unsure which rules other states will choose to apply to a particular case. This creates difficulties for defining rights and obligations, for coordinating behaviour and for providing predictability. Uncertainty is likely to increase in such situations as states cannot predict the behaviour of others. Joyner (2005, p. 7) explains the key role of certainty about behaviour in achieving predictability through international law:

A lack of order often stems from uncertainty about the future conduct of others ... decision makers need knowledge about the current state of affairs to make informed decisions. A government's decisions are intended to preclude unwanted future effects and to facilitate desired future ends and objectives. International law, framed by legal rules for state conduct, remains the principal channel for furnishing these expectations about future state behaviour.

Example 2 – Existence of Different Dispute Settlement Mechanisms

Where different dispute settlement mechanisms exist within a set of regulations – as they do in the international biotechnology regulations – then states could choose to move disputes to the forum which they believe best suits their side of the case. This could make the resolution of conflicts difficult. It may also be difficult for the dispute settlement body associated with one regulation to resolve conflicts between states on issues where another regulation contradicts or overlaps. There is the potential scenario of one body making a ruling that effectively goes against the provisions or principles of another regulation.

In the biotechnology area a problematic case might be a dispute on intellectual property rights and genetically engineered plants (this has already proved to be a controversial area). Such a dispute might, potentially, be dealt with by the World Trade Organisation's (WTO) dispute settlement body under the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement (Part V, Article 64); the dispute settlement procedures of the International Treaty on Plant Genetic Resources (Article 22); or the dispute settlement procedure suggested by the Bonn Guidelines (Section V, point E); or indeed of those incorporated into the future international regime on access and benefit-sharing, currently under negotiation under the Convention on Biodiversity's Conference of the Parties.

Example 3 – Competition over Values

Fragmentation of the regulations could encourage (particularly powerful) states or regional blocs to compete over values by forum-shifting (explained in Chapter 4). This creates uncertainty for other states and, where the principles that underlie the regulations are put in contention, fragmentation may increase. An illustration here is the different approaches to genetically modified foods taken by the United States and the European Union (EU) (which can be summarised as producer protection versus consumer protection). The US approach appears to be better reflected by the rules of the WTO; the EU's by the Codex Alimentarius (Ching, 2005).

Example 4 – Contradictory Provisions

Provisions in the regulations which are, or can be interpreted as, being contradictory will also leave states unclear as to which rules to apply, and will affect coordination and predictability of behaviour. This is also a problem in terms of shaping expectations. As Joyner explains 'rules provide expectations. If all governments follow the same rules in their relations, they would then know what to expect from one another' (2005, p. 15). Unfortunately this will often not be the case in the governance of biotechnology. A prominent example here is the treatment of living modified organisms (LMOs) – does a state have the right to block imports of LMOs on socio-economic grounds as implied by the Cartagena Protocol, or is this right precluded by the WTO agreements? Murphy (2001, p. 90), when discussing the role of the WTO agreements in addressing concerns about biotechnology, concluded that: 'The potential for conflict with other treaty regimes is significant.'

Example 5 – Overlap of Provisions

Partly as a result of the regulations developing separately from one another there are some areas of overlap, for example in provisions on scientific and technical assistance to developing countries. Such overlaps may result in duplication of efforts. For example, one state might provide scientific

knowledge under the technical assistance or benefit-sharing provisions of the International Treaty on Plant Genetic Resources (Articles 8 and 13) and another state might provide the same knowledge under the benefit-sharing provisions of the Bonn Guidelines (Appendix II) or under the technical assistance provisions of the International Plant Protection Convention (Article XX). Such duplication will undermine the functions of reducing costs and increasing efficiency.

Example 6 – Lack of Clarity on Prohibitions

Where one regulation can be interpreted as allowing an action that is prohibited by another regulation then activities may not be effectively constrained and again this will not reduce uncertainty or enhance predictability of state behaviour. For example, therapeutic human cloning appears to be permitted (subject to certain constraints) under Article 11 of the Universal Declaration on the Human Genome and Human Rights – ‘Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted.’ However, the prohibition on human cloning contained in the UN Declaration on Human Cloning is interpreted by many states as including therapeutic cloning as well as reproductive cloning – ‘Member States are called on to prohibit all forms of human cloning inasmuch as they are incompatible with human dignity and the protection of human life’ (point b).

It is clear that the lack of coherence among the international biotechnology regulations challenges their ability to effectively fulfil several key functions of international regulation. In regard to those listed above, Table 11.2 provides a summary of likely areas of difficulty.

Table 11.2 Difficulty in Fulfilling the Functions of International Regulation

Function	Lack of coherence problematic?
Defining the rights and obligations of states	Yes
Regulating conduct	Yes
Coordinating behaviour	Yes
Providing predictability and reducing uncertainty	Yes
Reducing costs of individual action and increasing efficiency	Yes
Authorising or prohibiting certain actions	Yes
Facilitating cooperation	Yes
Imposing constraints	Yes

Function	Lack of coherence problematic?
Realising values	Not necessarily ^a
Establishing and shaping expectations	Yes
Channelling conflict and providing mechanisms for its resolution	Yes
Simplifying and facilitating transactions	Yes
Assisting policy-making	Yes
Dealing with common threats/problems	Yes
Promoting peace	Not necessarily ^b

^a Fragmentation of regulations may provide states with more opportunities to realise their values, by expanding the number of fora in which they can promote them.

^b While the existence of separate dispute settlement mechanisms may make the resolution of disputes more difficult, peaceful methods of resolution are generally available for the issues involved.

Problems in Fulfilling the Roles Required of International Biotechnology Regulations

Alongside the general functions of international regulation, four specific roles for biotechnology regulation were identified in Chapter 4:

- Promotion of benefits
- Identification, assessment and management of risks
- Prevention or minimisation of negative impacts
- Promotion of capacity-building

Again, the regulations examined individually will often fulfil these four roles, but the regulations as a set face difficulties in fulfilling the roles because of the problems faced in coordinating behaviour.

Promotion of Benefits

Just as there are contradictions in the provisions of the regulations, there are different perspectives on what ought to be prioritised as a benefit – and some of these may at times conflict. For example, should free trade (as outlined in the Sanitary and Phytosanitary and Technical Barriers to Trade Agreements) be prioritised over the protection of biodiversity (the focus of the Convention on Biodiversity and Cartagena Protocol)? Should providing rewards for innovation (as implied in the TRIPS Agreement) be prioritised over maintaining certain resources as the common heritage of mankind (as suggested in the International Treaty on Plant Genetic Resources)? When should freedom of scientific research be prioritised over the ethical, moral and cultural values of societies? These examples are all representative of ongoing wider debates between and within states and societies and it is perhaps unrealistic to expect regulation to have

resolved them – but some certainty needs to be provided if benefits are to be appropriately prioritised and promoted. It is also important that actions are coordinated. For example how should the potential benefit of increased food security through provision of genetically modified food aid be coordinated with environmental and health concerns?

Prevention or Minimisation of Negative Impacts

There are similar differences of perspective reflected in the regulations about what should be prioritised as negative impacts to be avoided. For example under the TRIPS Agreement innovators not being properly rewarded for the development of a novel (genetically engineered) crop would be a negative impact. However, under another agreement, the International Treaty on Plant Genetic Resources, the restriction of access to a plant genetic resource within its multilateral system that might result from a patent is viewed as a negative impact (Article 12.3(d)). There is no guidance as yet, as to how such issues ought to be balanced.

Identification, Assessment and Management of Risks

In trying to reach an optimal promotion of benefits and avoidance of negative impacts, effective risk identification, assessment and management are very important. Lack of coherence among the regulations could also pose problems here. It may be unclear to states what standards they should apply; how they should make their assessments; what types of assessments will be viewed as legitimate; whether they are allowed to use the precautionary principle; and whether they can include assessment of risks to social values or to economic development.

Promotion of Capacity-building

In order to be able to effectively identify, assess and manage risks, promote benefits and avoid negative impacts, states need to have the institutions, mechanisms, knowledge and funds to do so. This makes capacity-building very important for the effective governance of biotechnology. Many of the regulations have provisions that support capacity-building, particularly through financial and technical assistance, technology transfer and information exchange. However, there are still problems caused by the regulations' lack of coherence. If states are unclear about what their obligations are under the regulations, about what they should be promoting and avoiding, about what they are permitted and/or obliged to do in terms of risk assessment and management – then they are also likely to be unclear about what sort of mechanisms and institutions they need and what national legal measures they should put in place to implement the international regulations – particularly if they are worried that the legislation they put in place to implement one international regulation will be challenged under another international regulation.

Policy Proposals for Increasing the Coherence of the International Biotechnology Regulations

Any attempt to increase the coherence of the existing regulations will be difficult. It is clearer which routes cannot be taken successfully, than which might succeed.

Removing existing regulations and starting again with regulations specifically and primarily aimed at governing biotechnology will not be helpful. There are two major reasons for this: firstly, the existing regulations often have a much broader focus, and should not be withdrawn because of the other useful functions they fulfil; and secondly, this would take a long time to negotiate and without the existing regulations in place there would probably be an absence of control lasting for at least several years.

Similarly, creating one single treaty to combine all elements of biotechnology governance would be extremely problematic because there are so many issues to be covered. States may not agree to issues being taken out of existing treaty regimes – resulting in further duplications and overlaps. Negotiation of such an instrument would also take a long time.

Amendment of the existing regulations is a long-term possibility for the resolution of contradictions and imbalances, but will still be problematic because many amendment processes will be involved under the different review procedures. These would need to be closely coordinated if current problems are not to be perpetuated and again it is likely to be a very lengthy process, particularly in regard to the amendment of the legally binding treaties. Creating new agreements to fill in the gaps and strengthen weak areas is another possibility, but negotiators would need to be careful to avoid creating any more overlaps or contradictions – and this will not resolve the issue of coherence by itself.

Since the analysis shows that conflicting principles are associated with conflicting provisions (although no causal effect has been established), another proposal is establishment of an international framework of principles for international governance of biotechnology that would guide the development and implementation of the regulations. This has several advantages: prioritisation of principles is possible, although problematic – and importantly these principles would be ones that already exist and have been accepted by the international community; the framework need not be legally binding; and it may be easier to resolve contradictions by working at the level of principles, the moving up to the level of rules rather than the other way round. The international community would need to decide which principles it wishes to use as the basis of biotechnology regulation and then work from this basis towards amending or supplementing the regulations as necessary (the framework should indicate where this work needs to be done). This task too would be very difficult – for example, even within sets of internationally agreed principles there can be significant conflicts – but it is essential to find a way of enhancing coherence of the regulations. The

framework would also help raise awareness of the full range of the regulations, their connections and of the issues that need to be covered and the roles that need to be played by regulation.

More immediately, coherence at the stage of implementation of the regulations can be enhanced through increased cooperation between the international organisations responsible for the regulations. Several such initiatives are underway, but the extent and success of these depend fundamentally on the support of member states – where state support is lacking, even if the need for coordination is clearly recognised, it will be severely restrained. Positive examples can be seen, for example, where the World Intellectual Property Organisation has, on request, provided information to the World Health Organisation on patents relating to the avian influenza virus (WIPO, 2007), which informed a 2008 report by the World Health Organisation's Secretariat on Pandemic Influenza Preparedness (WHO, 2008c). An example of the limiting effects of member states' attitudes towards cooperative activities can be seen in the area of biofuels, where despite clear international recognition of the problems caused for food security and the environment from the recent massive increase in biofuel production and consumption, states have been unwilling to give necessary support to international cooperative initiatives – for example at the 2008 High Level Conference on World Food Security: The Challenges of Climate Change and Bioenergy hosted by the Food and Agriculture Organisation, states failed to produce more than a brief statement on possible future responses (FAO, 5 June 2008) despite the urgency of the problems, particularly those of food price rises, they were facing.

Conclusion

The key implication of the lack of coherence among the international regulations applicable to the applications and impacts of biotechnology is that at a time when such regulation is essential, it is presented with great difficulties in achieving coordination of state action. Separate action by individual states will be insufficient to address issues of common concern in the governance of biotechnology and the international dimensions of the revolution are unlikely to be effectively addressed by regulation as it currently stands, because it can neither fulfil the general functions of international regulation, nor the specific roles required of regulation of biotechnology. Moves towards greater coherence of the regulations will be problematic, but should not be viewed as impossible – and it is a task that the international community needs to act upon urgently, if it is to effectively manage the challenges and opportunities posed by modern biotechnology.