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4. Regulatory Needs

Regulation of the applications and impacts of modern biotechnology at the international level is a vital addition to regulation at other levels. Four key roles for biotechnology regulation are identified here and the global context of the revolution is explored – it is this context which necessitates international governance efforts. International regulation serves the key role of coordinating state action in areas of high international interdependence, where separate action by individual states will often be insufficient to address common concerns. Following a brief outline of the development and use of international regulation by states, seven issue areas are identified in which there is a recognised need for coordinated state action and in which the biotechnology revolution has significant applications and impacts – these are the areas in which international regulation of biotechnology is required. The chapter ends with an outline of the functions of international regulation. Sets of international regulation that relate to a particular matter (in this case governance of biotechnology) require coherence in order to effectively fulfil these functions.

Necessary Roles for Biotechnology Regulation

The previous chapter drew conclusions about the potential consequences of the biotechnology revolution, which are helpful in identifying what needs to be achieved by regulation. Across the range of sectors affected by the revolution, the consequences will be both positive and negative and the impacts will be unevenly distributed. In some areas there are also risks of deliberate misuse associated with the new knowledge and technologies. The negative consequences may be severe and it will be desirable to minimise or avoid them. The positive consequences (benefits), on the other hand, should be encouraged and maximised. Moves towards a more equitable distribution of consequences are also desirable, particularly in terms of enhancing countries' capacities to deal with risks and negative impacts.

In consideration of the above, there are four main roles that the regulation of biotechnology needs to play:

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

The following illustration provides an example of how these four roles apply to the regulation of one particular biotechnology application. In relation to a genetically modified food, regulation should:

- Promote the benefit of enhanced nutritional value.
- Identify and assess any risks to human health resulting from the changes made to the food and manage these risks, for example by setting a recommended daily intake.
- Prevent types of changes that produce too high a risk to human health, for example by banning insertion of genetic material from known allergenic sources.
- Promote capacity-building in the conduct of effective risk assessment.

The need for regulation to fulfil these roles extends across the full range of areas that the biotechnology revolution impacts upon.

Another important point drawn out in the previous chapter was that uncertainty exists about what the precise outcomes of the biotechnology revolution will be, particularly in the long term. This uncertainty should not be viewed as an obstacle to regulation. Once decisions are made on which outcomes are desirable or acceptable and which are not, regulatory action can be taken – it does not matter whether or not a particular outcome will occur. If, for example, it is decided that it would be undesirable for a genetically enhanced biological warfare agent to be produced, then measures can be taken to prevent this occurring, without evidence being needed that such an agent will actually be developed. In fact, a lot of regulation deals with uncertainty in this way – rather than prescribing action once outcomes have occurred, it focuses on the optimum way of achieving desired outcomes and avoiding undesirable ones.

The Context in which the Revolution is Occurring

Regulation of the biotechnology revolution is important as a mechanism through which to ensure that its outcomes are effectively managed. There are a number of levels at which such regulation can be set – local, national, regional and international. Regulation at each of these levels is valuable, but because of the global nature of the revolution, and the particular global context in which it is occurring, international regulation is an essential supplement to regulation at these other levels.

Joyner (2005, p. 292) gives a general explanation about why current globalisation trends increase the need for international regulation, particularly in regard to new technologies:

With certain technologies, globalization creates an apparent need for a high degree of international cooperation. More so than ever, technologies and information can easily move across borders. Thus if the regulatory goals are to contain or ensure the safe applications of a given technology, some level of agreement between governments will be needed to control the development and flow of such technologies. In fact, globalization increases the need for an international approach to policymaking.

The broad reason that international level regulation is essential for effective control of the biotechnology revolution is the nature of the global context in which the revolution is taking place. This context is a highly interdependent international system that has massive and persistent inequalities both between and within states. In this interdependent world neither the applications nor the impacts of modern biotechnology can be limited by national boundaries. People, knowledge, technology and material resources are highly mobile and can disseminate rapidly around the globe. The independent actions of individual states will often be insufficient in terms of control. If, for example, a particular application is stringently controlled in one state or region it can simply be moved to an area with less stringent regulation, a point which has been emphasised by The Royal Society (the UK's national science academy): 'Global cooperation on measures to prevent the misuse of scientific research is needed to ensure that misguided scientists cannot simply move to another country to carry out unsafe work' (6 September 2005).

Murphy (Winter 2001, p. 60) uses a specific example – xenotransplantation – to illustrate the dangers of inconsistent national regulation: 'national regulations may be developed in some states to prevent animal viruses from spreading to humans. However, if comparable regulations do not exist in other states, leading to the risk of such viruses originating elsewhere and then travelling to the highly regulated states, then the national regulations will be undermined'.

Because of the inequalities in the global context the impacts of the revolution will not be evenly distributed, and without intervention to achieve a more equitable distribution of benefits and burdens, the revolution may in fact exacerbate existing inequalities and create new ones. International regulation has greater potential than regulation at other levels to contribute to a more even distribution of benefits and to establish measures to ameliorate negative impacts. It can play a role in introducing accountability and responsibility for management of transnational risks; help to balance the varying needs and interests of different countries; and promote transfer of technology, financial assistance, information and skills for capacity-building.

International Regulation/International Law

The term international regulation is used in this book to mean regulation (i.e. official rules) agreed by and made for states to govern their relations and actions and which is open to all states to subscribe to, with no geographical limitations. The term covers a range of rules from voluntary standards, guidelines and codes to legally binding treaties. International regulation is closely related to international law. A distinction between the two terms is made here, however, because some theorists would dispute the inclusion of the voluntary standards, guidelines and codes in a definition of international law because they are not legally binding or of customary⁷ force, as the following definitions show: 'A rule is part of International Law if: (1) It is based upon

custom, i.e. is observed by states generally; or (2) It is embodied in a Law-making treaty' (Winfield, 1941, p. 21); 'international law consists of rules that are generally recognized as binding the members of the international community in their relations with one another' (Joyner, 2005, p. 4).

Other theorists refer to these non-binding rules as 'soft law' – and there are debates about whether such rules are as effective as 'hard law' (treaties and customary rules). Non-binding rules, it is stated, 'while not resting on very secure foundations, are nevertheless important considerations in many decision-making situations' and 'Despite their informalities, they may have as much importance in policy-making as more formal instruments and, in some cases, even more. The important point is that they do guide behaviour, and for much the same reason as treaties: The costs of breaking or repudiating agreements are often very high' (Holsti, 1994, p. 300). Since both legally binding treaties and non-binding agreements are used by states to govern their relations, both are covered in this book.

Legally binding treaties are established following negotiation (usually over several years) between states and their subsequent signature and ratification (or other instrument of acceptance such as accession) of the agreed text. Negotiations may occur within an established international organisation, or a forum specifically set up for that purpose. Soft law instruments are usually developed and drafted by an international organisation itself, although they may still require formal approval by member states of the organisation to be officially adopted.

When a treaty is not developed within an international organisation, it usually establishes one to oversee its administration and future development. Other bodies are frequently established or an existing body nominated to take responsibility for a particular role by the treaty too. These include a governing body – responsible for such matters as decision-making, review, amendment and negotiation of additional rules – that is made up of the states parties to the treaty; and a secretariat responsible for the day-to-day administration of the treaty. Additional bodies may be set up by the treaty for technical support, advice and for negotiation of further rules on either a permanent or *ad hoc* basis.

Negotiations to develop, for example, the Convention on Biodiversity (CBD) – one of the regulations covered within this book – took place under the auspices of the United Nations (UN) Environment Programme. The Convention text established the CBD Secretariat to administer the Convention (Article 24); the Conference of the Parties as its governing body (Article 23); a Subsidiary Body on Scientific, Technical and Technological Advice to assist effective implementation (Article 25); and enabled its Conference of the Parties to establish subsidiary bodies as required (Article 23).

While a variety of other actors – for example multinational corporations, international organisations and non-governmental organisations – are

playing increasingly significant roles in international relations, states remain the most significant actors and the main focus of international law/regulation. States are not only the main subjects of international law, but also its creators. There is no authority above the state in the international system, and this is a major reason why international law is different from national legal systems. There is no legislative body to create laws, and no executive body to enforce them. There is an international judicial body – the International Court of Justice – but its role is very limited: it can only rule on legal cases that are voluntarily submitted to it by the states involved or give advisory opinions on legal questions referred by the UN Security Council, General Assembly or other UN organs/specialised agencies (see Articles 36 and 65, *Statute of the International Court of Justice*, 1945, and Article 96 of the *Charter of the United Nations*, 1945).

There has been some criticism that these factors render international law weak, ineffective and unlikely to be obeyed. This is not the case. While international law suffers from some major flaws (e.g. its bias towards the interests of powerful states), it serves a variety of functions that make it extremely useful to states, who will obey it in the majority of cases. Sometimes states do choose not to obey international law, but despite the fact that there is no supranational enforcement body, there are still consequences to such action. A reputation for law-breaking dents prestige and damages relations with other states, who may be reluctant to enter into further agreements with the transgressing state. Disobedience may also provoke reprisals. Also, there are many advantages to states of obeying international law. It serves a number of important functions in international relations from which all states benefit (discussed later in this chapter).

Development of and Approaches to International Law

The development of international legal rules has been based on the need to facilitate international transactions – as the volume of transactions has expanded, so too has the need for international rules to govern them. States have long found it useful to have rules governing relations between them, but it was not until a sense of the existence of an international system or community of states began to emerge that these rules became ‘international’.

The development of the concept of the nation state as a sovereign independent unit in the seventeenth century motivated the development of generally acceptable rules to govern transactions between these units (Shaw, 1997, p. 18). The origins of international law are generally dated to the mid-seventeenth century alongside the origins of the European nation state in the 1648 Treaty of Westphalia, but some of the principles on which it is based have a much longer history.

There are two main theories that have dominated thinking on international law. These theories are mainly concerned with the sources of or basis for

international law (and also, therefore, what counts as international law). The earlier of the two theories, which can be traced back to Greek and Roman thinking, is the theory of natural law. This holds that laws can be rationally deduced from a pre-existing universal basis – be it a divine or human-reasoned ‘natural’ order (Peters, 2001, p. 27). The concept of universality is intrinsic to modern international law. In natural law theory, the law has a moral basis and provides a guide to what ought to be – in international law, what states ought to do. The other major theory – legal positivism – instead claims that law is based on what actually is, that is that law is determined by (law-making) practice, and international law by the practices of states, and particularly what they have expressly agreed to in treaties (Peters, 2001, p. 27; Shaw, 1997, p. 22).

Both the natural law and legal positivist approaches can be seen to be reflected in current international law: there are rules based on the actions of states and what they have agreed to (custom and treaties); and there is also a well-established, and widely accepted, concept of universal principles, rights and obligations (e.g. in the area of human rights).

In addition to these two dominant approaches, there are other theories of international law which provide further useful insights – three of which will be discussed briefly here. First is ‘policy-oriented jurisprudence’ or legal realism. This was developed in the United States in the early stages of the Cold War. It places law firmly within its political context. In this theory law-making is a form of policy, and it reflects the political concerns of the powerful. This is viewed as a legitimate bias. International law is indeed not separate from international politics – it is created by and for states and can be used (not always successfully) as a policy tool. As Joyner (2005, p. 9) explains: ‘Implementing political solutions for international problems can become transformed into legal rules through treaties, customs, practices, and principles. Put tersely, making international legal rules is an inherently political process.’

Second is the ‘international law and economics’ approach. This views international law as a method for states to realise their goals with limited resources – a form of ‘market participation’ (Peters, 2001, p. 32). It emphasises the bargaining process in the creation of international law. This approach also provides useful insights. In many areas of international law states seek to achieve certain (common) goals by pooling their resources – one of the key functions of international law (discussed later in this chapter) is to reduce the costs of individual state action and increase efficiency. The bargaining process is also important. The creation of new laws and the amendment of existing laws generally take many years of negotiation.

The third approach, or set of approaches, is referred to as the ‘new’ or ‘critical’ approach to international law. Like legal realism these theories

emphasise the political context of international law – particularly in terms of international power relations. Unlike legal realism they critique the existing power relations and international law as being based on maintaining those relations (generally in a disguised form). As Peters (2001, p. 33) states, in this perspective ‘the law is merely an ideology for the purpose of gaining, cementing and justifying the exercise of power’.

Again useful insights are provided by these approaches. Power is important in international politics and international law. Powerful states can, based on their superior resources, dominate the processes of international law-making. They have the resources to be able to enforce the laws that they support and to bear the costs of attempted enforcement actions by others. This said, even powerful states cannot ignore international law entirely, and can attract strong criticism for breaking it – for example, there was widespread international condemnation of the United States for its treatment of prisoners in Guantanamo Bay, and its policy of ‘extraordinary renditions’ (e.g. in the UN Economic and Social Council’s 2006 report *Situation of Detainees at Guantanamo Bay*; and the Council of Europe’s 2006 report on secret detentions).

International law expanded greatly in scope in the twentieth century driven by the increasing volume of international interactions and also the experience of two devastating World Wars. International law was initially predominantly directed towards establishing a more peaceful world order, with particular progress being made after the Second World War with the establishment of limited circumstances in which the use of force in international relations is considered to be legitimate (in the United Nations Charter, 1945) and attempts to limit the effects of any conflicts which did occur (in international humanitarian law).

Technological developments, particularly in travel, trade and communications, rapidly increased international transactions across a wide range of areas throughout the twentieth century, and so international rules were developed in these areas as well (e.g. in trade, health and environmental protection). The need for international law remains based on the need for states to facilitate transactions or coordinate action in areas in which there is a high degree of international interdependence, and where individual state action will be insufficient to address matters of common concern.

Areas Requiring International Control of the Biotechnology Revolution

Many of the applications and impacts of biotechnology affect issue areas² in which high interdependence between states exists, and for which individual state action is insufficient for effective control. Particularly, it can be seen that applications and impacts of biotechnology require international regulation in the following issue areas:

1. *Arms control*

In the area of arms control most action needs to be coordinated at the international level because for states to feel secure in limiting their own capabilities they need to be reassured that other states are taking the same action. Relevant to biotechnology is arms control in the area of biological and toxin weapons (the latter also being covered by rules on chemical weapons). International regulation needs to prevent misuse of biotechnology and reassure states that it is being prevented, while allowing beneficial research, for example in the medical field, to continue.

2. *Health and disease control*

Certain aspects of health, particularly the prevention of disease and limitation of its spread, need to be regulated internationally – this applies equally to human, animal and plant health. Measures taken to prevent disease spread can severely disrupt travel and trade and cause major economic damage, but are necessary to prevent the spread of serious diseases, which can move rapidly around the globe through transport connections. Other health-related areas subject to international control are the transport, handling and use of infectious substances – again as a measure to prevent disease spread – and also food safety, as food is traded internationally. There are many benefits to be promoted in the area of health, but also areas of risk, and harms that need to be avoided and it is an area of great global disparity.

3. *Environmental protection*

Since the early twentieth century there has been increasing recognition of the interconnectedness of the environment at the global level and the need for action at the international level towards the solution of many environmental problems. Among the areas in which international action is deemed necessary are three outlined in the CBD: ‘the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources’. Biotechnology has the potential both to protect and to damage biodiversity.

4. *Trade*

Trade is obviously an international issue and there are a variety of trade-related regulations that operate at the international level. The main motivation for trade regulation following the Second World War has been to bring an end to protectionist trade policies that can prove economically disastrous through reductions in tariffs and other barriers to trade. Rules on reducing barriers to trade, on intellectual property rights and on access to genetic resources are relevant to the end products of biotechnology, to the basic resources used in research and development and to innovative processes.

5. *Drugs control*

There is a massive international trade in illicit drugs and attempts have been made to control it internationally since the early twentieth century. There is also a large market for the use of performance-enhancing substances in sport that requires international control. Biotechnology can be misused in the production of illicit drugs and drugs designed to be undetectable in doping tests. The knowledge and techniques used in this way may also be used for licit purposes, for example the adaptation of medical drugs to avoid adverse reactions. Again there are harms to be avoided and benefits to be promoted and the supply of drugs for legitimate medical and scientific uses needs to be improved and maintained.

6. *Development*

The interconnectedness of the global economy and trading systems means that many development issues cannot be dealt with solely at the national or regional level. While biotechnology has the potential to make significant contributions to development, this will require supportive actions such as technology transfer, technical and financial assistance, information exchange and capacity-building efforts, which can be encouraged by international regulation.

7. *Social and ethical impacts*

Some of the potential social and ethical impacts of modern biotechnology can be regulated at a lower level, but there is an additional need for international coordination and direction, as these impacts affect all societies. Some of the biggest challenges are arising in the area of human genetics, although they are not exclusive to this area. The new knowledge about human genetics and its applications could have huge benefits, but again there are many risks, and decisions need to be made about how the knowledge should be controlled and who should have access to it, and whether certain applications, for example reproductive human cloning, pose too great a risk and should be prohibited.

Functions of International Regulation

International regulation has specific roles to fulfil in control of the applications and impacts of biotechnology (outlined at the beginning of this chapter). It also needs to fulfil general functions of international regulation for this area. Within the broad purpose of coordinating state action, a wide range of important functions can be identified from the literature on international law. The following list identifies key functions that it serves:³

- Defining the rights and obligations of states
- Regulating conduct
- 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

This list of functions gives an indication of what international regulation should generally be achieving. Where a set of regulations exists with applicability to a particular matter, coherence⁴ among the regulations will be important for the fulfilment of these functions. Uncertainty will not be reduced if states are unclear which rules to apply in particular cases. Improving predictability and creating expectations will be problematic too – some states may be unaware of the full range of rules that operate in a particular area and it will, therefore, be difficult for one state to know which rules others will choose to apply.

A lack of coherence can also present problems for the resolution of conflicts where more than one method/mechanism of dispute settlement is available, because states may be tempted to move around the different mechanisms to find the one that suits their case best. It is likely to be unclear exactly what the rights and obligations of states are, particularly if the regulations contain provisions that contradict (or can be interpreted as contradicting) each other. Where states are uncertain about which rules to apply and what their rights and obligations are, they are unlikely to act in a coordinated manner.

Where regulations lack coherence their provisions may overlap and duplication of certain actions could result, which will not increase efficiency. Fragmented regulation will allow states to compete over values by what is known as ‘forum-shifting’⁵ and if the principles that underlie the regulations are put in contention, uncertainty and incoherence will increase. Activities may not be effectively constrained if one regulation can be interpreted as allowing an action that is prohibited by another.

Fragmented, contradictory and overlapping regulation will not assist in simplifying transactions. States will face uncertainties in policy-making too if they are unclear which rules to apply. For all these reasons sets of regulation that do not display coherence are unlikely to adequately coordinate state action to effectively govern challenges.

Conclusion

It is clear that a number of applications and impacts of biotechnology need to be regulated at the international level, because they involve issues where

there is high international interdependence and coordinated state action is needed for effective control. The important functions of international regulations are unlikely to be adequately fulfilled by a set of regulations that lack coherence. The question, therefore, that the rest of this book seeks to answer is whether the international regulations applicable to the control of biotechnology are coherent. The following chapter establishes criteria for identifying coherent sets of international regulation. Later, the various international regulations that are applicable to the control of the biotechnology revolution are outlined and subsequent chapters will examine the degree to which the identified regulations match the criteria for coherent regulatory sets, before discussing the implications of this for the effective governance of modern biotechnology.