

# 1. Introduction

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The crucial role of genetic resources in supporting human society is frequently overlooked and greatly undervalued. They are of tremendous practical and historical significance for human life. They underpin both our daily survival and are responsible for generating a large part of the wealth of nations. (National Research Council, 1993, p. ix)

Genetic resources form a vital shared global resource with key importance to agriculture, food security and the maintenance of biodiversity, and to scientific and medical research. They are defined in Article 2 of the Convention on Biological Diversity (CBD) as ‘genetic material of actual or potential value’ (with genetic material defined as ‘any material of plant, animal, microbial or other origin containing functional units of heredity’). Scientific advances mean that the range of genetic material considered to have actual or potential value has expanded rapidly in recent years.

States have long relied on exchange of seed to maintain and renew their agricultural resources and, therefore, it is unsurprising that genetic resources have a long history as a matter of international concern. An array of rules, processes and other governance initiatives have arisen around them, creating a diverse, complex and dynamic governance environment.

## STARTING POINTS

### **Genetic Resources**

The term refers to the genetic material of any biological organism. This material is collected, stored, used and consumed for scientific and medical purposes, in agriculture and across a range of industries. Genetic resources form a hugely valuable global resource, valuable not just in the economic sense, but also in terms of playing an essential role in supporting human life and well-being, both directly, for example, through our food supplies and some medicines, and indirectly, through their role in various ecosystems. Historically plants and seeds (particularly those

widely used in agriculture) have been the main focus of international interest in genetic resources. Livestock genetic resources have a similar (and growing) importance to our food supply and are also exchanged internationally. Additionally there is now extensive interest in human and pathogenic genetic resources, particularly as we seek to understand and combat disease threats. There is also growing interest in other types/sub-types of genetic resources, for example, forestry, aquatic, marine, microbial and synthetic genetic resources, and in the interactions between genetic resources and their environments in research fields such as community genetics and metagenomics.

International interest in genetic resources stems from several areas, including:

- their role in agricultural production and food security;
- their role in developing understanding, diagnosis, prevention, treatment, and tracking of human, animal and plant disease and pest threats and their host interactions;
- their role in industrial products and processes, for example, in the production of dyes, mining, waste-processing, environmental remediation, cosmetics, food and feed additives;
- their potential contributions to climate change adaptation and mitigation;
- the importance of conserving genetic diversity (note: this does not apply to all genetic resources – in the case of pathogenic genetic resources, eradication rather than conservation may be the goal of governance efforts, for example, with smallpox, polio and rinderpest);
- protection of human rights, particularly in research on and uses of human genetic resources;
- controversies over ownership and rights over genetic resources, including the application of farmers' rights, the rights of indigenous and local communities, breeders' rights, intellectual property rights (IPRs) and state sovereign rights;
- demands for fairness in access to genetic resources and equity in benefit-sharing from subsequent research, development and use.

Both the resources themselves and the issues outlined have a strong international character. States are fundamentally interdependent with regard to genetic resources (although this may not apply to synthetic genetic resources). This is particularly true in agriculture, where no state could sustain its agricultural production in the long term based solely on the genetic resources of its own territory. Viral genetic resources move

rapidly around the globe through travel and trade links and require concerted international action to contain and manage outbreaks, and collaboration to develop and distribute treatments and vaccines. If marine genetic resources are overexploited in the coastal waters of one state, this will impact availability in other areas. There are also many genetic resources that fall into areas beyond the national jurisdiction of any state, areas that tend to be managed through international regimes (combinations of rules, organizations, guidelines and principles covering a particular matter), for example, Antarctica and many marine areas.

Matters such as food security, protection of human, animal and plant health, climate change, conservation of biodiversity, and trade in goods are widely accepted as being of international concern – areas in which states have common interests that are unlikely to be achieved through separate action by individual states, producing a need for coordinated international action.

### **Coordinated International Action**

While there are some gaps and weaknesses and many areas in which power relations play a dominant role, a great deal of state activity in the international system is coordinated by various rules, mechanisms, organizations, structures and norms. Much of this effort is taken for granted, but life would operate very differently without it – consider, for example, the operation of the postal service, telecommunications networks, travel across borders and financial transactions.

There are various ways in which such activities can be organized. The primary ones used in the area of genetic resources governance include:

- fundamental ordering principles of the international system;
- public international law in both its ‘soft’ (codes, standards, guidelines) and ‘hard’ (legally binding treaties) forms;
- activities of international organizations and their member states;
- other mechanisms and processes which support the operation and implementation of the international rules and the activities of organizations, for example, information exchange, funding mechanisms, reporting mechanisms, meetings and negotiations;
- activities of other actors such as non-governmental organizations, the scientific community and charitable foundations with a particular interest in the area.

States – while not the only international actors of significance – have a key role in the creation and functioning of international law and

international organizations, and ultimately determine the approach chosen for the management of genetic resources. While nominally equal in this regard, states vary hugely in terms of their influence; most frequently, those with the most economic and military power are the ones with the most influence in international governance processes.

### **Fundamental principles of the international system**

Here, I refer to the overarching framework for organizing the international system as developed by states over the past century or so. Core ordering principles can be found within, for example, the UN Charter and a range of other statutes and conventions, such as the Vienna Convention on the Law of Treaties and the Statutes of the International Court of Justice. A few of these principles are mentioned here to provide some basic insights useful to understanding the governance of genetic resources.

*State sovereignty* There is no authority above the state in the international system and therefore states are regarded as having sovereign authority. This includes sovereign rights over their own territory, which no other state may infringe without their consent, sovereign rights over many resources of that territory, and the determination of their own domestic and foreign policy. As described by Weiss and Hubert (2001, p. 6):

State sovereignty denotes the competence, independence, and legal equality of states. The concept is normally used to encompass all matters in which each state is permitted by international law to decide and act without intrusions from other states. These matters include the choice of political, economic, social and cultural systems and the formulation of foreign policy.

*Sovereign equality* Each state is nominally equal in international affairs, although of course actual power and influence vary enormously. Sovereign equality means that generally all states have the same rights and status within international forums and under international law. It is usual practice, for example, for each member state of an international organization to have one vote. There are some notable exceptions, such as in the Security Council of the UN (15 members, 5 of them permanent with veto powers) and the World Bank, where voting is weighted according to contributions made by the state to the International Monetary Fund (for details see World Bank, updated 12.11.12).

*Legitimate expectation and pacta sunt servanda* These are two principles relevant to the operation of international law. The first – legitimate expectation – means that states are only bound by treaties to which they have consented; the second – *pacta sunt servanda* – means that states should keep to agreements that they have made. Thus states have the right to freely choose whether or not to subscribe to any international treaty, selecting which rules will apply to them. Some treaties allow states to ratify with reservations, although this is quite rare.

### **Customary international law**

Treaties are one source of international law; another major source is known as customary international law, which the International Committee of the Red Cross (no date) explains as requiring the: ‘presence of two elements, namely State practice ... and a belief that such practice is required, prohibited or allowed, depending on the nature of the rule, as a matter of law’. The concept of customary international law means that some elements of treaty law may, through general acceptance and practice over many years, become binding on all states, regardless of whether or not they have subscribed to the treaty. A prominent example of this is related to some rules contained in the Geneva Conventions and Protocols (outlined in the International Committee of the Red Cross’s Customary International Law Database – ICRC, updated 2007).

### **International law**

Some international rules – guidelines, codes, standards and declarations – are described as ‘soft law’, as they are voluntary in nature. Others – treaties, conventions and protocols – are referred to as ‘hard law’ and are legally binding on those states that subscribe<sup>1</sup> to them. Some writers choose to restrict the scope of international law to the latter, but I include both. The reason for this is that both hard and soft law agreements can have significant influence on state behaviour and serve useful coordinating functions. Soft law can sometimes have advantages over hard law – it can be more rapidly developed and more readily adapted to scientific advances and thus retain relevance. A good comparison here is the regular process of review and updating of the World Animal Health

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<sup>1</sup> There are two stages to this: on adoption of a final negotiated text of the treaty, it will be opened for signature for a set period of time. States that sign the treaty within this period (signatory states) later need to deposit an ‘instrument of ratification’; states that join later indicate their consent through instruments of ‘accession’ or ‘acceptance’. States that have signed and ratified or acceded or accepted the treaty are referred to as its ‘states parties’ or ‘contracting parties’.

Organization's Terrestrial and Aquatic Animal Health Codes (often done on an annual basis), in comparison to the lengthy process of revising and adopting the World Health Organization's International Health Regulations, which took 10 years (from 1995), despite broad recognition of the urgency of updating them to extend their application beyond cholera, plague and yellow fever and make them suitable for the current context.

*Hard law* This refers to legally binding treaties/conventions and protocols to them, and also to customary international law. These rules are generally negotiated by states in international forums (for example, the meetings of member states within a particular international organization), often over several years or more. Once a final text is agreed it is adopted and opened for signature and ratification. Most states require approval by their domestic legislative body before ratifying a treaty. States parties to a treaty generally have decision-making powers relating to its implementation, review and, if necessary, amendment. They will often take on certain responsibilities, for example, providing a set level of finance for the treaty's operation or submitting periodic reports on their progress in implementation.

*Soft law* This refers to a variety of standards, guidelines, codes and declarations, which are also generally developed under the auspices of international organizations. They are voluntary rather than legally binding, and do not require a formal process of states' approval – although there will sometimes be, for example, a general vote or resolution passed expressing support for the document. Soft law may be developed as a precursor to negotiation of a binding agreement, or take the place of such an agreement if negotiations fail, but often it is deliberately designed to have a permanent voluntary nature and may or may not be related to an existing treaty. Some of these agreements are not primarily directed towards the highest level of government but at, for example, veterinary or public health authorities, or other actors within states, such as scientists.

Soft law agreements may contain substantive provisions giving recommendations and guidance on, for example, safe conduct of an activity (such as the World Health Organization's Laboratory Biosafety Manual) or simply contain principles of a declaratory nature with limited direction on their application to particular situations (for example, the United Nations Educational, Scientific and Cultural Organization's Universal Declaration on the Human Genome and Human Rights). Occasionally soft law agreements can take on legally binding status owing to the scope and operation of other rules – for example, the World Trade Organization's Agreement on the Application of Sanitary and Phytosanitary

Measures (binding upon its member states) refers to the standards of the World Animal Health Organization, International Plant Protection Convention and Codex Alimentarius Commission as acceptable international standards to be applied under its provisions.

### **International organizations (and their member states)**

For the purposes of this book, the term ‘international organization’ is restricted to intergovernmental organizations of potentially universal membership, that is, open to all states to become members without restriction on, for example, geographic or economic grounds. It does not, therefore, include, for example, regional inter-state organizations such as the European Union or organizations such as the Organization for Economic Co-operation and Development.

A few international organizations were created prior to World War II. Some, such as the League of Nations, are now defunct, but others – such as the Office International des Epizooties (now the World Animal Health Organization) – continue to operate, and still others – such as the International Sanitary Organization – have been subsumed into later organizations (in this case the World Health Organization, WHO). Many more organizations were founded in the couple of decades following the end of World War II, including the United Nations and also several mentioned later in this book (for example, the Food and Agriculture Organization, the Union for the Protection of New Varieties of Plants, and the World Bank). Other organizations have been established more recently, for example the World Trade Organization in 1995 and the CBD Secretariat in 1992.

International organizations are generally established by the agreement of states, with matters such as their scope, structure, funding, governance and responsibilities set out in constitutional documents. States retain most decision-making powers, which tend to be exercised through regular meetings (for example, once a year or every two years) of a governing body. Day-to-day operation of the organization takes place through an administrative staff (often referred to as the secretariat), with leadership provided by a Director- or Secretary-General. For example:

- The World Health Organization’s Constitution determines its scope as ‘the attainment by all peoples of the highest possible level of health’ (WHO, 2006b, Article 1). It is governed by the World Health Assembly (WHA, its main policy-making body), made up of representatives of all member states, with regular annual meetings, and a 34 member Executive Board elected by the Health Assembly and made up of technical experts. The Executive Board’s role is to

‘give effect to decisions and policies of the WHA’ (WHO, 2006b, Article 24) and more generally to advise the Assembly. The WHO is administered by a Secretariat, headed by its Director-General, who also serves as a figure-head for the organization.

- The mandate of the Food and Agriculture Organization (FAO) ‘is to raise levels of nutrition, improve agricultural productivity, better the lives of rural populations and contribute to the growth of the world economy’ (FAO, no date(a)). Its governing body is the FAO Conference, which has regular biennial meetings and determines its policy. The Conference elects a 49-member Council that provides ‘executive oversight of programme and budgetary activities’ (FAO, no date(a)). It is assisted by several committees that report to it on programme, budget, policy and regulatory matters (FAO, 1945, Article V). It is also led by a Director-General, who is responsible for appointing the staff necessary for carrying out the organization’s programmes.

International organizations vary in size in several ways – the number of member states, size of staff, size of budget, number of departments/divisions and sub-bodies, number of treaties overseen. In most cases they are funded by subscription from their member states, with the rate sometimes varying according to level of economic development. They may be responsible for the oversight of a single treaty or several treaties, standards, guidelines and codes. Such rules often assign additional responsibilities to the organization and may require new bodies (such as an additional secretariat specific to a treaty) to be established. The governing body of the international organization will not necessarily be the governing body of its treaties. In some cases all member states are, by virtue of being such, parties to some or all of the organization’s treaties. In other cases, they are only party to those that they separately subscribe to.

It is increasingly common for international organizations to deal with issues that fall within the scope of both their own mission and that of other organizations. For such issues there is thus potential for cooperation between international organizations, which can take various forms and is often mandated by the organization’s constitution. There are a number of examples of inter-organizational cooperative initiatives in genetic resources governance, which will be covered later. The fact that there are opportunities for and value in cooperation does not mean that it will take place – this can be due to various barriers, including lack of awareness of overlaps; concerns over jurisdiction, financing and expertise; and lack of support from member states (Rhodes, 2010).

### Other mechanisms and processes

Various other international mechanisms and processes are involved in the governance of genetic resources. These can be internal to a particular international organization or they may involve collaboration between international organizations and other bodies. They include:

- information exchange and dissemination, for example, the Clearing House Mechanism of the CBD;
- provision of forums for discussion, for example, the e-conferences of FAO-Biotech, and the CBD, and the World Intellectual Property Organization's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC), and its Intellectual Property and the Life Sciences programme;
- funding mechanisms, for example, the Global Environment Facility and the Standards and Trade Development Facility;
- the convening of high-level meetings, for example, World Health Organization–World Intellectual Property Organization–World Trade Organization joint public conferences, and FAO-led meetings on biofuels and on the global food crisis;
- collation of examples of best practice or model regulations, for example, in the World Intellectual Property Organization's Database of Legislative Texts on the Protection of Traditional Cultural Expressions, Traditional Knowledge and Genetic Resources;
- reporting for fact-finding and assessment purposes, for example, the FAO's *State of the World's Plant Genetic Resources reports*;
- provision of training, for example, through the Standards and Trade Development Facility;
- establishment of subsidiary bodies to explore topics of interest for example, the World Intellectual Property Organization's IGC;
- establishment of expert groups or registers of experts, for example, the Roster of Biosafety Experts developed to support states' implementation of the Cartagena Protocol (CBD Secretariat, 2011);
- surveillance, traceability and early warning mechanisms, such as the FAO's World Information and Early-Warning System on Plant Genetic Resources for Food and Agriculture and the World Health Organization's Global Outbreak Alert and Response Network.

There are also some mechanisms that are integral to treaties – for example, the Multilateral System on Access and Benefit Sharing of the International Treaty on Plant Genetic Resources, the Biosafety Clearing house under the Cartagena Protocol and the Roster of Experts associated

with the International Health Regulations – as well as routine meetings for reviewing operation and implementation of treaties and rules.

## OUTLINE OF THE BOOK

The book aims to provide a comprehensive overview of the landscape of international genetic resources governance, highlighting the issues, resources, rules and actors involved. This broad scope – valuable because it picks up on interactions and connections between them, and can contribute to understanding of the operation of genetic resources governance as a whole – necessarily means that some depth is sacrificed. However, there is a substantial and growing literature that can be consulted by the interested reader.

The book starts by outlining which genetic resources are of international interest and why. Early international governance efforts began with a narrow focus on facilitation of exchange of plant germplasm, but they now cover many issues, resources and actors. This expansion is partly in response to scientific developments, which have altered/added to the resources of interest and potential value and continue to shape the demand for and uses of genetic resources. The first chapter of the book examines the different types of genetic resource that are (or should be) covered by international governance. The next chapter outlines the international issue areas in which governance of genetic resources has relevance (such as food security, climate change and conservation of biodiversity).

The second part of the book outlines the current governance situation, identifying the key rules, actors and processes governing genetic resources, and their scope in terms of issues and resources covered. Some emerging governance initiatives, such as those that involve cooperative action between different international organizations, are also outlined. The final chapter in this part of the book draws attention to some problems with current governance efforts and the implications these have for effective governance of genetic resources. The third part of the book covers the ways in which governance of genetic resources might be improved, in terms of both practical initiatives and changes to content and approach.

## THE SIGNIFICANCE OF GENETIC RESOURCES GOVERNANCE

Global genetic resources are not static. They constitute a living, changing, diverse system that can best benefit humankind when thoughtfully managed. Without proper management of these resources, many of their riches – the keystones to our ability to produce food – will be lost. (National Research Council, 1993, p. 4)

A variety of political, economic and social factors and dynamics in operation internationally obstruct science from meeting its potential in contributing to addressing major global challenges. International governance efforts have implications for, *inter alia*, the science that is done, the purposes to which it is directed, who influences these choices, who participates in its progress and who shares in its benefits or is excluded from them.

Genetic resources are key to most life sciences research and its applications. They are also central to efforts to address global challenges of food security, sustainable agricultural production, climate change adaptation and mitigation, and threats to human, animal and plant health. They also have potential to make various industries and energy production less resource-intensive and less reliant on non-renewable resources and/or environmentally damaging processes.

Thus, understanding the full context and content of genetic resources governance efforts at the international level can point to ways forward and provide impetus and ideas for improvements so that it more effectively promotes access to and use of genetic resources in addressing common challenges in a way that does not exclude or marginalize large sectors of the world's population.

The book provides information of use to a variety of groups and can be read for various purposes, for example it will be of use to:

- academics and practitioners in the fields of international relations, international law, global governance, environmental studies, development studies and the life sciences;
- those with an interest in governance of genetic resources and its connection to issues such as IPRs, biodiversity conservation and food security;
- those working with genetic resources who are affected by international rules and their national implementing legislation; and
- policy-makers and practitioners involved in the governance of

genetic resources, for example, in international organizations and corresponding national government departments.

It will:

- promote awareness of the full range of processes, rules, issues and actors involved in genetic resources governance and provide information on the interactions between them;
- provide a case study of management of an issue that cuts across the remit of several international organizations and of regulatory adaptation in response to scientific developments; and
- provide a case study of complex governance and responses through the development of newer forms of governance, including inter-organizational cooperation and enhanced stakeholder involvement.