MANAGING GENETIC RESOURCES: INTERNATIONAL REGIMES, PROBLEM STRUCTURES, NATIONAL IMPLEMENTATION

Florian Rabitz

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Author's Contact: Florian Rabitz, Institute for Public Policy and Administration, Kaunas University of Technology. *florian.rabitz@ktu.lt*

WORKING PAPER SERIES EDITOR

Ayşem Mert
Department of Political Sciences
Stockholm University
(*workingpapers@earthsystemgovernance.org*)

ABSTRACT

Numerous regimes regulating access to genetic resources and the sharing of the benefits arising out of their utilization have sprung up over the last years, are under negotiation or subject to initial discussions. This text evaluates the effectiveness of three operational regimes: the Multilateral System under the International Treaty on Plant Genetic Resources for Food and Agriculture, the Nagoya Protocol to the Convention on Biological Diversity and the Pandemic Influenza Preparedness Framework under the World Health Organization. I assess effectiveness in terms of the regime-induced incentives and capacities of providers and users of genetic resources, as well as the available data on accessed resources and shared benefits. I explain effectiveness in terms of institutional design, conditioned by issue area-specific problem structures and national implementation. Major conclusions are: a) regime coverage and the configuration of sources from which materials of interest can be obtained determine whether shareable benefits will be generated or whether access will be diverted to unregulated sources; b) the viability of different approaches to the monitoring of user compliance hinges on the transfer volumes of genetic resources from sources over intermediaries to end users; c) subscription models obviate the need for monitoring and may be preferable as a means of benefit-sharing due to their greater attractiveness for prospective users; and d) inadequate national implementation, particularly in developing countries, is a major barrier to access and thus to benefit-sharing.

Keywords: genetic resources; access and benefit-sharing; biological diversity; institutional design; regime effectiveness.

SERIES FOREWORD

This working paper was written as part of the Earth System Governance Project — a global research alliance, is the largest social science research network in the area of governance and global environmental change.

Earth system governance is defined in this Project as the system of formal and informal rules, rule-making mechanisms and actor-networks at all levels of human society (from local to global) that are set up to prevent, mitigate and adapt to environmental change and earth system transformation. The science plan of the Project focusses on five analytical problems: the problems of the overall *architecture* of earth system governance, of *agency* of and beyond the state, of the *adaptiveness* of governance mechanisms and processes, of their *accountability* and legitimacy, and of modes of *allocation and access* in earth system governance. In addition, the Project emphasizes four crosscutting research themes that are crucial for the study of each analytical problem: the role of power, of knowledge, of norms, and of scale. Finally, the Earth System Governance Project advances the integrated analysis of case study domains in which researchers combine analysis of the analytical problems and crosscutting themes. The main case study domains are at present the global water system, global food systems, the global climate system, and the global economic system.

The Earth System Governance Project is designed as the nodal point within the global change research programmes to guide, organize and evaluate research on these questions. The Project is implemented through a Global Alliance of Earth System Governance Research Centres, a network of lead faculty members and research fellows, a global conference series, and various research projects undertaken at multiple levels (see www.earthsystemgovernance.org).

Earth System Governance Working Papers are peer-reviewed online publications that broadly address questions raised by the Project's Science and Implementation Plan. The series is open to all colleagues who seek to contribute to this research agenda, and submissions are welcome at any time at workingpapers@earthsystemgovernance.org. While most members of our network publish their research in the English language, we accept also submissions in other major languages. The Earth System Governance Project does not assume the copyright for working papers, and we expect that most working papers will eventually find their way into scientific journals or become chapters in edited volumes compiled by the Project and its members.

Comments on this working paper, as well as on the other activities of the Earth System Governance Project, are highly welcome. We believe that understanding earth system governance is only feasible through joint effort of colleagues from various backgrounds and from all regions of the world. We look forward to your response.

Frank Biermann

Chair, Earth System Governance Project

Ruben Zondervan

Executive Director, Earth System Governance Project

1. INTRODUCTION

Since the biotechnology revolution of the 1980s, the genetic materials of microbes, plants and animals are increasingly being used for research and development in fields ranging from pharmaceuticals and cosmetics over agriculture and bioenergy up to the production of paper, pulp, plastics or fibre (Cragg et al. 2001; Laird and Wynberg 2005; NAS 2017). Over the same time period, controversies surrounding the ownership of such materials arose (Kloppenburg 2004). The concept of fair and equitable benefit-sharing links access to and utilization of genetic resources to the partial redistribution of resulting material and immaterial assets to entitled groups, such as the original providers of the material. Three operational regimes for Access and Benefit-sharing (ABS) presently cover Plant Genetic Resources for Food and Agriculture (PGRFA), biological materials for pandemic influenza preparedness (PIP biological materials) and other genetic resources under the jurisdiction of nation states. Formal negotiations are ongoing for ABS regimes covering marine genetic resources in areas beyond national jurisdiction and genetic resources associated with Traditional Knowledge. ABS regimes for aquaculture, forest genetic resources, animal genetic resources and "orphan" genetic resources of unclear legal provenience are under initial discussion in international forums (Oberthür and Pozarowska 2013; Rabitz 2017a).

ABS involves transboundary interactions among diverse private and public entities subject to multiple sets of rules at different scales, from private contract law over national laws and regulations up to international rights and obligations as well as "soft" guidelines and codes of conduct. As a distributive conflict between users of genetic resources and entities entitled to receive benefit-sharing streams, ABS is a hard case for effective cooperation: the latter require the cooperation of the former, but the former have no intrinsic motivation to transfer parts of the monetary- and non-monetary benefits which they generate to third parties, creating a collective action problem. Other challenges result from genetic resources being available from sources under different regulatory regimes, difficulties in tracing their transboundary utilization and transfers across multiple intermediaries and users, the technical requirements of storage in ex situ collections as well as administrative and bureaucratic barriers in provider countries. The broader context of ABS, with linkages to issues such as North-South equity, sustainable development, global public health and the role of intellectual property rights in a developmental context, further complicate the effective management of provider-user transactions. All those aspects broadly relate to Access and Allocation, as well as Architecture, as analytical problems of the Earth System Governance research framework. The challenge for ABS governance is to translate the underpinning norms of fairness and equity into effective arrangements for the management of distributional conflicts between multiple types of actors operating across different scales.

Considering the remarkable institutional proliferation in ABS governance, how effectively are existing regimes in enhancing the provision and utilization of genetic resources as well as the sharing of resulting benefits? How do extra-institutional

factors shape the behavior of users and providers? What lessons can be drawn to inform the design of future ABS regimes? Those questions have only rarely been addressed in the voluminous literature on ABS. Where they have, scholars have focused on individual regimes rather than looking at the whole range of operational ABS regimes in a comprehensive manner. The present text assesses those regimes individually. While a broad literature looks into interactions and overlaps in ABS governance (Oberthür and Pozarowska 2013; Morin and Orsini 2014; Rabitz 2017a), I focus on their operations within their respective jurisdictional domains that form part of a broader institutional division of labor, where different regimes exert authority over different types and uses of genetic resources (Oberthür and Pozarowska 2013).

Section 2 develops an analytical framework for assessing the effects of institutional design, mediated by issue area-specific problem structures and national implementation. Section 3 applies this framework to the 2001 International Treaty on Plant Genetic Resources for Food and Agriculture ("Seed Treaty"), a regime that conditions access to a transnational network of seed banks on the multilateral sharing of benefits, particularly towards farmers in developing countries. Section 4 looks into the 2010 Nagoya Protocol to the Convention on Biological Diversity (CBD), a regime of broad scope geared towards bilateral ABS contracts between provider countries and users. Section 5 turns to the 2011 Pandemic Influenza Preparedness (PIP) Framework that attempts to balance access to viral materials for pandemic influenza preparedness with the multilateral sharing of benefits, such as vaccines, with developing countries. Section 6 concludes.

2. ANALYTICAL FRAMEWORK

The CBD was the first agreement that, in 1992, codified the linkage between "access" and "benefit-sharing" as a response to the perceived illegitimacy of corporations based in the Global North privatizing the world's genetic heritage through intellectual property rights. Benefit-sharing is an attempt to correct this imbalance. ABS regimes require providers of genetic resources to grant or facilitate access for specific purposes, and users to share monetary and other benefits arising from utilization. "Providers" are public or private entities that make genetic resources under their control available in the expectation of receiving benefit-sharing streams. [1] "Users" are public or private entities that utilize genetic resources in the expectation of generating benefits for themselves. "Benefits" may be commercial or non-commercial. Plant breeders that access seeds from the Multilateral System of the International Treaty on Plant Genetic Resources for Food and Agriculture are obliged, under specific conditions, to channel parts of their commercial profits to farmers in developing countries. Vaccine manufacturers that obtain biological materials from the World Health Organization's (WHO) Global Influenza Surveillance and Response System must pre-commit to two of several benefit-sharing options, with sharing obligations only kicking in during a

[1] The term "provider" is somewhat inaccurate for multilateral benefit-sharing regimes where the immediate "provider" is not the direct and only recipient of benefit-sharing streams. However, I use the term "provider" throughout the text to simplify the already quite unwieldy terminology.

global influenza pandemic. Under the Nagoya Protocol to the Convention on Biological Diversity (CBD), providers (i.e. governments or indigenous communities) and users (i.e. commercial entities or scientific institutions) are free to negotiate the terms under which genetic resources are accessed and how benefits are shared. Besides those specific benefits, all ABS regimes acknowledge the importance of global public goods, for instance the creation of scientific knowledge, as a form of benefit-sharing.

In addition to the distinction between users and providers, I also follow the common (yet somewhat imprecise) distinction between provider- and user countries. Provider countries have jurisdiction over large amounts of *in situ* or *ex situ* genetic resources of scientific or commercial interest. User countries have jurisdiction over entities capable of generating large benefit-sharing streams from the utilization of genetic resources. Some countries are both important providers and users whereas others are neither. While all countries provide and use genetic resources in one way or the other, this terminology reflects the practical differences in their respective abilities to ensure access to, and benefit-sharing from, genetic resources. Very broadly, and at the risk of oversimplification, international ABS governance is split between advanced economies with strong industrial sectors (in biotechnology, pharmaceuticals, agriculture and so forth) and large capacities for innovation on one hand, developing countries with jurisdiction over valuable genetic resources yet with fewer capacities for commercial exploitation on the other (Rabitz 2017a: 28-47).

ABS governance is transboundary and interscalar. Users incur sharing obligations towards entities in other jurisdictions. International ABS regimes create rights and obligations for states yet transactions of genetic resources and benefits take place between subnational or nonstate actors that are not direct subjects of international law. For international regimes to regulate transboundary exchanges, governments must implement policies, regulations or laws for shaping the behavior of users and providers within their respective jurisdictions. Providers and users are respectively subject to such domestic policies, regulations or laws; enter into private commercial contracts with each other setting out the terms and conditions of access, utilization and benefit-sharing; and receive facilitating support measures from international regimes through databases, guidelines or model contractual clauses. Figure 1 summarizes.

International ABS regimes are "effective" to the extent that they lead to larger amounts of benefits being shared, and higher volumes of genetic resources accessed, than would have happened in their absence. The methodological challenges of relying on such a counterfactual baseline are well-known (Hovi et al. 2003). Estimating the difference which a given ABS regime makes relative to the no-regime counterfactual requires axiomatic assumptions on what drives the behavior of users and providers of genetic resources. At a basic level, benefit-sharing is the redistribution of material or immaterial assets from users to providers. Users lack intrinsic motivations for transferring assets to third parties; and user *countries* are not interested in overregulating domestic industries to ensure the effective transfer of assets abroad, thus jeopardizing welfare gains from taxation, innovation or employment. Similarly, providers and provider countries have few incentives to grant access to genetic

resources without the expectation of future benefit-sharing streams. While we should expect altruistic or philanthropic motivations to play some role in decisions on whether to grant access or to share benefits, such outcomes are not aligned with the fundamental economic incentives. Thus, under a counterfactual no-regime scenario, the collective action problem in ABS creates disincentives for providers to grant access (since they do not expect subsequent benefit-sharing streams) as well as for users to share benefits (since international mechanisms for monitoring and compliance do not exist).

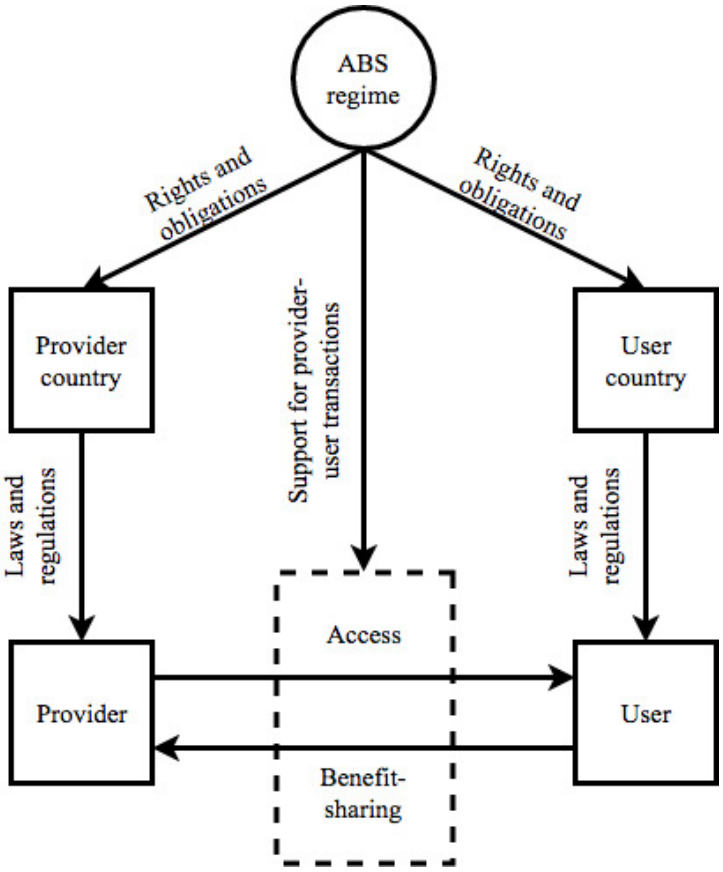

Fig.1: International, national and transnational dimensions of ABS governance. Source: author.

The effects of international regimes proceed from outputs (rules, norms, principles and decisions) over outcomes (regime-induced behavioral changes) to impacts (the consequences of behavioral changes) (Young 2001: 114). In practice, both outcomes and impacts may be difficult to determine (Underdal 2002: 5-6). Below, I draw on impact-level data (shared benefits and accessed genetic resources) to the extent that it is available. The Multilateral System of the Seed Treaty provides limited access statistics yet does not differentiate between types of users. While no monetary benefits have been shared under the Treaty so far, a potential explanation is the time lag in plant breeding from access to commercialization, making it difficult to attribute the lack of benefit-sharing to regime characteristics. Access to PIP biological materials is monitored in real time through the Influenza Virus Traceability Mechanism yet the PIP Framework's primary sharing obligations are only triggered during an influenza pandemic, which has not taken place since the agreement came into effect. The

Nagoya Protocol provides some information through its ABS Clearing House yet excludes confidential information and, as the most-recent of the three ABS regime, has not yet been fully implemented in all of its contracting parties. Due to the limited availability of impact-level data, I also focus on the output level: the ways in which the rules of the international regimes shape the incentives and capacities of users and providers.

The "effectiveness" of ABS regimes is the extent to which they enhance the provision and utilization of, as well as benefit sharing from, genetic resources by inducing behavioral changes in users and providers.

I consider two conditioning factors on regime influence. First, domestic measures condition the effect of international ABS regimes rather than independently affecting the behavior of providers and users. Due to the transnational nature of ABS, such measures are largely ineffectual in the absence of international regimes due to the core collective action problem. Second, problem structure conditions regime influence (Mitchell 2006). The concept of problem structure is being used in a variety of ways (Underdal 2002) yet here refers to the transaction patterns between providers and users of genetic resources, and the ways in which those shape the effectiveness of international ABS regimes in furthering access, utilization and benefit-sharing.

2.1 INSTITUTIONAL DESIGN

The provision of genetic resources presupposes that providers expect access and utilization to result in benefit-sharing streams. Access and utilization presuppose that an ABS regime covers materials of interest and does not impose sharing obligations, transaction- and compliance costs on users that exceed their expected gains. Users share the resulting benefits if monitoring- and enforcement mechanisms deter non-compliance. To be effective, ABS regimes must create *incentives* that are conducive to those three conditions. In addition, they must also *facilitate* types of behavior that are incentive compatible yet for which providers and users lack the capacities. Provision, utilization and benefit-sharing require appropriate technological and administrative infrastructures at the international and national levels so that users know which materials are available from where and under which conditions. The empirical analysis focuses on four design components:

a) *The link from access to benefit-sharing.* A stable link creates the expectation of benefit-sharing flows and increases the willingness of providers to make their genetic resources available. When the trigger point for sharing obligations is distanced from the point of access, a regime will have to rely on monitoring mechanisms, as user incentives to share benefits decline the more the "moment of access recedes into the past" (Tvedt and Jørem 2013: 154). Monitoring can focus on flows (when a genetic resource is tracked throughout an entire value chain) or points (i.e. placing on the market of a product or the application for intellectual property rights).

b) *User costs*. The expected costs from regulatory compliance, benefit-sharing and, in some cases, the negotiation of bilateral ABS agreements, influence the willingness and abilities of users to access genetic resources within the scope of an ABS regime. High costs lead to access diversion or limitation (see below), both of which preclude benefits from being shared. Access is enhanced through shallow sharing obligations and low transaction- and compliance costs, including from the submission of documentary evidence of lawful utilization under a regime's monitoring component. The Nagoya Protocol is presently the only ABS regime that requires providers and user to negotiate ABS contracts, presenting hurdles particularly for actors with few administrative and legal resources.

c) *Regime scope*. Regimes of broader scope offer larger numbers of genetic resources of interest. To the extent that they monopolize their supply, user costs can be ratcheted up without diverting access to unregulated sources. Narrow regime scope implies less access and thus reduces the extent to which sharable benefits arise. Gaps in regime scope, where not all sources of a genetic resource are covered, leads users to obtain materials of interests from wherever the associated costs are lowest.

d) *Facilitation of provider-user transactions*. To the extent that the above design elements make provision, utilization and sharing incentive compatible, facilitative elements lead to higher regime effectiveness by reducing transaction- and compliance costs. This includes mandating the removal of bureaucratic "red tape" at the national level; international databases specifying which genetic resources are available from where, and under which conditions; and streamlined procedures for demonstrating compliance.

2.2 PROBLEM STRUCTURES

Institutional consequences are partially determined by the characteristics of their respective issue areas (Mitchell 2006). I use the term "problem structure" to refer to the economic and technological configurations in which genetic resources are accessed, transferred and utilized. All problem structures in ABS governance can be broken down into four components that condition the institutional influence on the incentives and capacities of users and providers.

a) *Sources* are the entities from which genetic resources can be obtained. PIP biological materials can be sourced from National Influenza Centers. PGRFA are in principle available from a range of seed banks, yet large collections of materials with high commercial value are few and far between. Microbial materials of interest are held both in specific culture collections as well as in less formal settings such as public research institutions. Marine genetic resources can only be procured from those few entities that have the financial and technical capacities for deep sea bioprospecting (Leary 2007: 165-166).

b) *End users* are entities that generate commercial- or non-commercial benefits, including public goods through basic and applied science. Some end users, such as multinational seed companies or pharmaceuticals manufacturers, are capable of generating large financial flows through benefit-sharing arrangements due to the extent of their commercial operations. Others, such as scientific institutes or national agricultural research centers, create important public goods yet little in the way of tangible, monetary value.

c) *Intermediaries* are entities standing between sources and end users. Some intermediaries merely store genetic resources in ex situ collections before transferring them onward, as is the case with most seed banks. Others improve them in order to pass them further down the value chain, for instance when biotechnology companies identify lead compounds for subsequent drug development by Big Pharma. Some intermediaries act as bottlenecks, such as the US Center for Disease Control and the UK Francis Crick Institute in international transfers of PIP biological materials.

d) *Transfer volumes* refer to the amount of genetic resources passed from sources over intermediaries to end users in a given time frame. Transfer volumes depend both on the overall availability of genetic resources as well as demand. For instance, the WHO's Influenza Virus Traceability Mechanism records just over a thousand shipments of PIP biological materials since 2008 whereas over four million PGRFA have been transferred under the Seed Treaty's Multilateral System since 2006. [2]

The above is a relatively schematic conceptualization. In some instance, the boundaries between sources, intermediaries and end users blur. Biological research institutes may simultaneously fall into all three categories in the exchange of microbial genetic resources (Dijkshoorn et al. 2010). Seed banks can simultaneously be sources and intermediaries. Broadly, though, the differences in configurations across issue areas contribute to differential degrees of regime effectiveness through their mediating effects on the incentives and capacities of users and providers of genetic resources:

a) Large numbers of diverse sources make it difficult for ABS regimes to obtain comprehensive coverage. This potentially leads to genetic resources being available from both regulated- and unregulated sources. Users engage in arbitrage when they can obtain materials from sources with lower associated costs. Sharing obligations and compliance costs under an ABS regime thus divert access to outside sources. Low source diversity facilitates the formation of monopolistic ABS regimes that preclude arbitrage but may stymie access volumes if users expected costs in excess of their gains.

b) High source diversity also conditions the capacity to access genetic resources. Where few sources exist, they provide a focal point for potential

[2] See https://extranet.who.int/ivtm/ and https://mls.planttreaty.org/itt/index.php?r=stats/pubStats

users, increasing the likelihood that access takes place and that benefits will be shared. Where the number of sources is large, users may be unable to learn about the existence or location of materials of interest, requiring facilitating mechanisms such as centralized databases.

c) High end user diversity hampers provision, utilization and benefit-sharing if ABS regimes do not allow for differential treatment. Commercial users have larger capacities to fulfill compliance obligations than public research institutions yet fewer incentives to share benefits such as research results. Benefit-sharing from non-commercial users is more important in terms of knowledge and other public goods than in terms of cash flow. However, differential treatment requires ABS regimes to delineate different categories of users and control for changes in intent as well as for genetic resources being transferred between different user categories (Nijar et al. 2016).

d) Configurations of sources, channels, end users and transfer volumes condition the effect of monitoring mechanisms. High transfer volumes and multiple intermediaries complicate the monitoring of flows and reduce the likelihood that shirking of sharing obligations is detected. Low numbers of sources and end users facilitate monitoring at the points of access, utilization or commercialization.

2.3 NATIONAL IMPLEMENTATION

ABS regimes vary in the extent to which they mandate implementing legislation or regulations, or even require them to function effectively. National implementation influences the impact of international rules on the incentives and capacities of users and providers. Access requires facilitation by the provider country, for instance through clear and transparent regulations or databases that characterize the genetic resources held in public collections. Users may refrain from access when domestic regulations are burdensome and unwieldy. They will also not share benefits unless mechanisms for monitoring and enforcement exist within the jurisdiction in which they operate.

National implementation is influenced by the interests of the respective governments. This influence is direct where public agencies engage in provision, utilization and benefit-sharing; it is indirect where governments act on behalf of sectoral interest groups. Governments that hold valuable genetic resources in national collections will be keen to implement international ABS agreements in a way that maximizes their cash flow. The propensity for adequate implementation is also an issue of multilateral- versus bilateral benefit-sharing: bilateral agreements allow provider countries to appropriate more value than multilateral schemes, where implementation costs are specific and benefit-sharing flows diffuse. Conversely, governments that gain from domestic users of genetic resources in terms of taxes, innovation and jobs will hesitate to implement ABS agreements in a way that imposes excessive costs on industry.

Figure 2 summarizes the overall analytical framework.

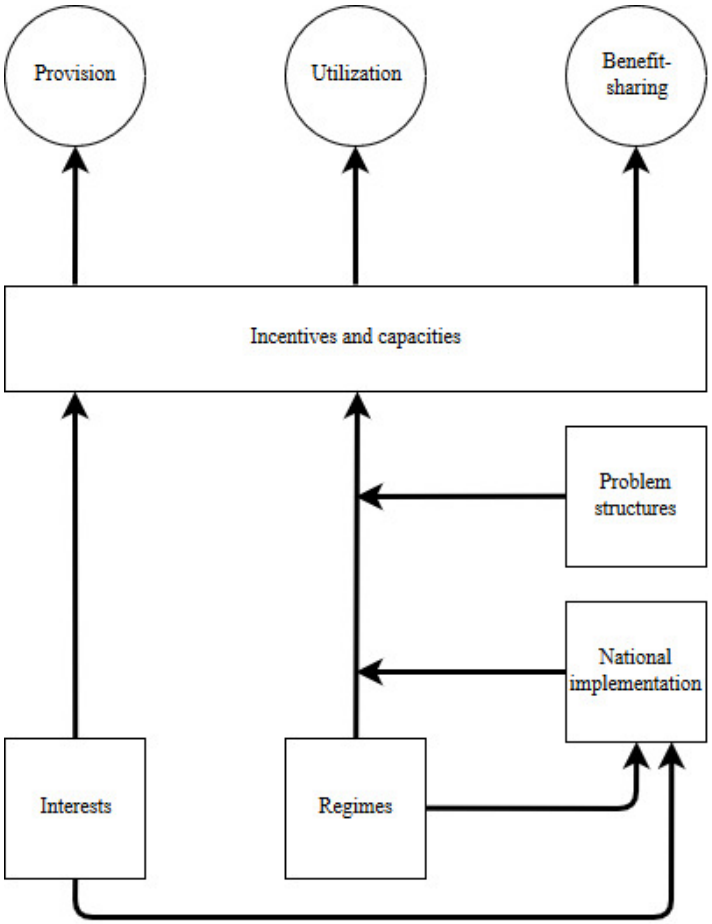

Fig. 2: The analytical framework. Source: author.

3. THE SEED TREATY

The 2001 Seed Treaty carves out a specific governance niche for ABS from PGRFA. In the 1980s, a broad coalition of developing countries, civil society organizations, activists and scientists began to contest the ways in which intellectual property rights on PGRFA allegedly undermine plant breeding based on free exchange and open access to crops, as well as privatize the benefits that arise from the collaborative activities of generations of breeders, including in developing countries (Kloppenburg 2004). Conversely, the conclusion of the CBD in 1992 threatened free exchange and open access by placing PGRFA under the sovereignty of nation states that have stronger incentives for extracting monetary value for themselves through access regulation than they have for providing their PGRFA as a global public good. The Seed Treaty is a hybrid regime that attempts to salvage the status of PGRFA as the common heritage of mankind while at the same time incorporating the principle of national sovereignty over genetic resources and allowing for intellectual property claims which, in turn, are linked to sharing obligations (Falcon and Fowler 2002; Andersen 2008).

3.1 INSTITUTIONAL DESIGN

The Seed Treaty's ABS component, the Multilateral System, covers a) PGRFA listed in its Annex I that are under the "management and control" of contracting parties and "in the public domain" (Article 11.2) and b) Annex I PGRFA held by the CGIAR centers as well as their non-Annex I PGRFA acquired before the Treaty's entry into force in 2004. Contracting parties are to "encourage" other holders within their respective jurisdictions to voluntarily include their Annex I PGRFA in the Multilateral System and, if voluntary inclusion is deemed unsatisfactory, the Treaty's Governing Body may decide to withhold access to the System for such users (articles 11.3 and 11.4). Access to PGRFA is subject to a Standard Material Transfer Agreement (SMTA) that also covers onward transfers of PGRFA to third parties. The commercialization of products (i.e. plant varieties) incorporating materials received from the Multilateral System triggers mandatory benefit-sharing where such products are protected by patents. [3] The SMTA's "evergreen clause" (article 9.2) sustains this obligation indefinitely for any new plants that incorporate ancestor PGRFA from the System. Where products are "available without restriction to others for further research and breeding", benefit-sharing is voluntary (article 13.2.d.ii). This includes protection through plant variety rights, which allow for certain unauthorized uses of protected varieties by third parties under the Breeders' Exemption. In addition, in what is arguably the most-contentious provision of the Treaty, users are prohibited from claiming patents on PGRFA, "or their genetic parts or components, in the form received from the Multilateral System" (article 12.3.d).

The Seed Treaty recognizes that access to PGRFA for the breeding of new plant varieties constitutes a benefit in itself to the extent that breeders can use those new varieties in their own breeding programs, without restrictions. However, the Treaty's link from access to monetary benefit-sharing is weak. Few countries in the world allow the patenting of plant varieties in the first place – when patents are unavailable, the mandatory sharing obligation cannot be triggered. An exception are plants that are not plant varieties, such as hybrids. Those are generally patentable subject matter, including in the member states of the European Patent Convention. The commercialization of patented hybrids created from inbred parent lines derived from PGRFA within the scope of the Multilateral System would trigger mandatory benefit-sharing. Beyond that, Japan and the US are the only contracting parties to the Seed Treaty that allow patents on plant varieties. To the extent that their domestic users have already built up private collections and have thus become independent from access to the Multilateral System (Moeller and Stannard 2013: 87), mandatory benefit-sharing becomes practically irrelevant. This directly relates to the question of regime scope: whether or not to include private collections in the scope of the Multilateral System. This issue had already been contentious in the negotiations on the Seed Treaty and its Governing Body has repeatedly postponed a decision on whether to prod private users into sharing their collections by otherwise excluding them from access to the System (Chiarolla and Shand 2013: 14-15). The system also suffers from

[3] Technical access restrictions, such as Genetic Use Restriction Technology, would also trigger the mandatory sharing obligation.

the limited number of commercially relevant PGRFA listed in Annex I, as governments preferred to leave their most-valuable materials within the scope of the CBD where bilateral, rather than multilateral, benefit-sharing promised them larger individual gains (Coupe and Lewins 2007). PGRFA of large commercial interest and relevance for food security, such as cocoa, coffee, grapes, groundnuts, melons, oil palms, onions, rubber, soybeans, sugarcane, tomatoes and tropical forages, remain outside of the Treaty's scope (Falcon and Fowler 2002: 211).

The weak linkage from access to benefit-sharing and the insufficient coverage reduce the incentives to provide, utilize and share benefits from PGRFA. Yet despite stakeholder complaints, the actual costs that the Multilateral System imposes on users are marginal. Stakeholders from the seed industry point out that the SMTA requires them to "track and trace" their utilization of PGRFA in order to avoid being found in non-compliance (OWG 2014: 6). However, internal protocols for tracking and tracing are usually already in place in order to avoid the inadvertent use of PGRFA protected with intellectual property rights and the associated risk of costly litigation (Smolders 2005: 5-6). In addition, the sharing obligation amounts to no more than 1.1% of sales of a product incorporating a PGRFA from the Multilateral System, minus 30%.[4]

3.2 PROBLEM STRUCTURE

Global exchanges of PGRFA originate from a complex array of private and public seed banks, breeding programmes and other entities. While diverse sources exist, ex situ holdings concentrate in a small number of large national and international seed banks. The International Agricultural Research Centers of the Consultative Group on International Agricultural Research (CGIAR) are the largest public holders worldwide. Their collections have formally been integrated into the Seed Treaty's Multilateral System. Brazil's National Agricultural Research System holds significant PGRFA accessions, particularly in soybeans. Germany's Leibniz Institute of Plant Genetics and Crop Plant Research holds over 151000 accessions of PGRFA from 776 different genera. The Chinese National Collaborative Network encompasses more than 40 institutions, including one seed bank for long-term storage and one for safety duplicates, holding over 350.000 accessions, particularly rice, wheat and soybeans. Similar volumes of cereals, grain and other PGRFA are held in the over 200 institutions of India's National Bureau of Plant Genetic Resources, which also oversees installations for long-term storage and cryopreservation. Besides those and a handful of other cases, many countries are unable to meet the technical and administrative requirements for conservation degradation (FAO 2010: 71) and the privatization of public breeding programs from the 1980s onward has left national research centers in disarray (Murphy 2007: 126-136). In the private sector, finally, successive waves of corporate takeovers led to a handful of multinationals acquiring the seed collections of smaller seed companies and biotechnology firms (Kloppenburg 2004: 216-217). Little is known about those private collections although their scope could be substantial (Chiarolla and Shand 2013). The private acquisition of PGRFA before the Seed

[4] Article 6.11 SMTA allows for an alternative payment scheme of 0.5% of the total sales of *all* products belonging to the same crop category as the PGRFA received from the Multilateral System.

Treaty's entry into force may even have created pools of sufficient size to provide "alternative sources of access", with "significant implications for the potential flow of payments" from benefit-sharing under the Treaty (Moeller and Stannard 2013: 87).

PGRFA sources are thus highly concentrated. Transactions normally involve multiple intermediaries, such as breeders that develop materials for end users further down the value chain. Overall transfer volumes are high, as the breeding of new plant varieties typically requires dozens of existing PGRFA as inputs. The World Intellectual Property Organization's PLUTO Plant Variety Database registers 21174 protection titles granted for new plant varieties from 2012 to 2016,[5] giving some idea of the magnitude of PGRFA flows. Under the Seed Treaty's Multilateral System, more than 4 million accessions have been transferred since 2006.[6] End users of PGRFA, finally, include a broad set of entities from private persons over smallholders and agricultural research centers up to the seed industry. The broader trend towards increasing market concentration in the seed sector implies that the number of end users that are able to generate notable monetary benefit-sharing flows is decreasing over time.

The problem structure of PGRFA thus consists of large volumes of PGRFA being transferred across multiple intermediaries from a narrow set of sources to a narrow set of commercially-important end users. Three implications arise for the Seed Treaty's institutional influence: First, as each and every transfer of PGRFA (including for PGRFA containing ancestor material) must be accompanied by an SMTA, large transaction volumes across several intermediaries raises total compliance costs in the breeding sector. Simultaneously, the Treaty neither provides for the monitoring of whether or not PGRFA-related products that are placed on the market originate from the Multilateral System, nor whether sharing obligations under the SMTA are attached to such products. An effective link from access to benefit-sharing would either require an early trigger point or the monitoring of end users.[7] The introduction of a subscription model is presently under discussion. Second, the exclusion of private collections from the Multilateral System may lead to access diversion due to compliance and benefit sharing-related costs. The forcible inclusion of private collections in the scope of the Seed Treaty is politically infeasible and would raise serious legal questions about the integrity of private property rights. Increasing the Treaty's effectiveness thus requires positive incentives for private holders to voluntarily include their collections in the System. Third, end users of PGRFA include a broad array of non-commercial entities that are incapable of generating significant cash flow but that contribute to the improvement of PGRFA as a public good. The Treaty implicitly differentiates between those entities and commercial users by setting commercialization under patent protection as the trigger point and by basing the depth of the sharing obligation on overall seed sales. While this particular method of differentiation accommodates end user diversity, it weakens the link from access to

[5] See http://www.upov.int/pluto/en/, 6 August 2017.

[6] See https://mls.planttreaty.org/itt/index.php?r=stats/pubStats , 6 August 2017.

[7] Depending on national implementation, the Nagoya Protocol can indirectly lead to end user monitoring even for genetic resources falling under the Seed Treaty if users are obliged to produce the SMTA to demonstrate the *non*-applicability of Nagoya implementing legislation and regulations.

benefit-sharing for commercial users that are capable but unwilling to make payments to the Multilateral System, as noted above.

3.3 NATIONAL IMPLEMENTATION

The Seed Treaty requires contracting parties to make their Annex I PGRFA available for utilization, but implementation is "constrained by a lack of effective access […] and by inadequate characterization and evaluation information on the accessible resources" (Moeller and Stannard 2013: xxiii). Especially the identification of Annex I PGRFA that are "under the management and control" of contracting parties and "in the public domain" (Art. 11.2) and their subsequent notification to the Multilateral System is deficient. Notification is not mandatory but "the actual functioning of the system depends […] on the information available to PGRFA users about which materials are actually included" (Noriega et al. 2013: 207). Data from 2013 shows the discrepancy between materials known to be held by contracting parties and materials notified: 2.46% of Rice accessions, 8.78% of Maize, 26.89% of Wheat and 24.55% of all other Annex I PGRFA (GB 2013: 8).

Implementation in industrialized (i.e. OECD-) countries is generally better than in developing ones. 15 out of the 25 OECD countries that are contracting parties and hold Annex I PGRFA have notified their collections, with 8 of them voluntarily granting access to their non-Annex I PGRFA. By contrast, of the 76 members of the G77/China that are contracting parties to the Seed Treaty, only 9 that are known to hold Annex I PGRFA notify *any* of them (see figure 3). Inadequate notification is not limited to developing countries that may suffer from insufficient domestic capacities but includes emerging economies such as Brazil or India. The implementation deficit is thus only partially of a technical nature and harks back to the discrepancy between the diffuse distribution of multilateral benefit-sharing flows that developing countries expect and the concrete costs of bringing national seed banks into shape in order to facilitate access in line with treaty commitments.

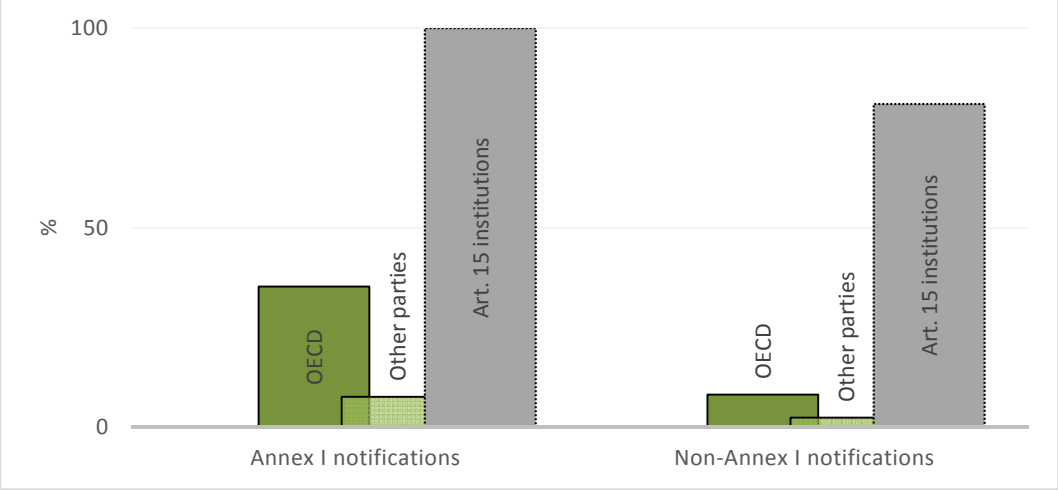

Fig.3: Notification rates of Annex I and non-Annex I PGRFA; Article 15 institutions are CGIAR centers and similar entities. Based on GB (2013).

3.4 DISCUSSION

Three implications arise from the Treaty's performance so far. First, significant amounts of contracting parties do not grant access to their PGRFA due to insufficient capacities at best, a lack of interest at worst. To the extent that disinterest results from a lack of confidence in the ability of the Multilateral System to deliver benefit-sharing flows, the problem is self-reinforcing: no benefit-sharing without prior access (Rabitz 2017b). Second, zero monetary benefits have so far been shared through the SMTA, yet commercial breeders are necessarily sourcing their PGRFA from somewhere. The Multilateral System covers some of the world's most-important crops: Rice, Maize and Wheat. Some large national holders of PGRFA are not members to the Treaty, including China, Mexico and Ukraine.[8] Non-members, and potentially private collections as well, enable institutional arbitrage as users can easily avoid compliance costs and sharing obligations by sourcing PGRFA from outside the Multilateral System. Those unregulated sources may constitute regulatory gaps that prevent the Treaty from functioning the way it is supposed to. Third, the mandatory sharing obligation is only triggered for commercialization under patent protection, which excludes large regions of the world as potential sources of (mandatory) benefit-sharing flows from the outset. Simultaneously, the unwillingness of users to share benefits *voluntarily* is unsurprising, given that they suffer no costs from doing so and are able to procure materials from the Multilateral System in the future nevertheless.

4. THE NAGOYA PROTOCOL

The 2010 Nagoya Protocol implements the ABS provisions of the CBD, pursuant to which provider countries must give their Prior Informed Consent for access subsequently negotiate contractual rights and obligations with users (Mutually Agreed Terms). Unlike the Seed Treaty and the PIP Framework, benefit-sharing is bilateral; the Prior Informed Consent requirement is explicit; Mutually Agreed Terms are established freely and without a mandatory SMTA. Both the CBD and the Protocol strike a balance between the sharing obligation and the obligation for parties to facilitate access (see Rosendal 2000). Due to the Protocol's extremely broad scope, the analysis below restricts itself to *ex situ* genetic resources in the pharmaceuticals sector, in non-commercial research and in the breeding sector for resources that are not within the scope of the Seed Treaty's Multilateral System.

4.1 INSTITUTIONAL DESIGN

The Protocol covers all genetic resources within the scope of the CBD's article 15 that are not covered by specialized ABS regimes, as long as those are "consistent with" and do not "run counter to" the objectives of either the CBD or the Protocol itself (article 4.4). This includes: PGRFA other than those included in the Seed Treaty's Multilateral System; included plant genetic resources utilized for non-agricultural purposes; other

[8] The US joined the Seed Treaty in 2017.

plant genetic resources; microbes; genetic resources associate with traditional knowledge; and animal genetic resources, including livestock and marine organisms originating from the internal waters, territorial seas and Exclusive Economic Zones of contracting parties to the CBD and the Protocol. In addition, the Protocol's *temporal* scope is a matter of extended discussion. Some argue that genetic resources *utilized* after the Protocol's entry into force in 2014 do not fall within its scope if they have been *acquired* prior to that date (i.e. Buck and Hamilton 2011: 57). Others hold that post-Nagoya utilization is subject to benefit-sharing even if the relevant genetic resources have been acquired *prior* to Nagoya yet *after* the entry into force of the CBD (i.e. 1993 to 2014; see Greiber et al. 2012: 72-73). This is not an issue of legal semantics but directly affects the status of *ex situ* collections of genetic resources transferred abroad prior to the Protocol's entry into force.

Both the CBD and the Protocol strike a balance between the sharing obligation and the obligation for parties to facilitate access. The CBD provides that "the authority to determine access to genetic resources rests with the national governments" while parties "shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses" (article 15). The Nagoya Protocol requires parties to implement domestic compliance measures to ensure that the utilization of genetic resources within their jurisdictions accords with Mutually Agreed Terms and the applicable laws and regulations of the provider country, while also providing international standards for parties to streamline their domestic access frameworks. As bilateral ABS contracts under the Nagoya Protocol are negotiated freely, the trigger point at which the sharing obligation kicks in can be determined on mutually agreed terms. Providers and users can agree to directly couple access to benefit-sharing, for instance through up-front payments. Later trigger points for the sharing obligation to kick in may be desirable where the ultimate value of inventions that incorporate genetic resources cannot be predicted from the outset or where users hesitate to commit to sharing obligations for projects of uncertain commercial success. The Protocol links access and benefit-sharing by requiring parties to "take appropriate, effective and proportionate legislative, administrative or policy measures" for ensuring that genetic resources utilized within their jurisdictions "have been accessed in accordance with prior informed consent and that mutually agree terms have been established" (article 15.1). For doing so, parties are to designate checkpoints that "collect or receive" the relevant information and transmit *communiqués* to the national authorities of the provider country (article 17; see Buck and Hamilton 2011; Greiber et al. 2012). The ambiguous phraseology in those and related articles gives wide latitude to contracting parties for implementing those obligations in a manner that minimizes their economic impact on domestic users. For instance, whether domestic checkpoints actively "collect" or merely passively "receive" compliance-related information affects the likelihood of non-compliance being detected. Despite this, cross-referencing compliance between checkpoints and provider countries allows for the combined monitoring of sources and end users while skipping everything in between. This requires both provider- and user countries to have adequate administrative capacities in place. In addition to its compliance provisions, the Protocol thus requires parties to provide users with permits "as evidence of the

decision to grant prior informed consent and of the establishment of mutually agreed terms" (article 6.3.e). In theory, this allows for the effective linking of access to benefit-sharing with minimal compliance costs for users. In practice, the efficacy of this approach is highly contingent on national implementation (see below).

The Protocol facilitates provision and utilization by requiring contracting parties to streamline their domestic access frameworks so that the rules applicable to users as well as the procedures for obtaining prior informed consent and establishing mutually agreed terms, are clear and transparent (Article 6). The transaction costs of negotiating bilateral ABS agreements affect non-commercial users more strongly than commercial ones, potentially hampering access for scientific institutions. Article 8 accordingly requires contracting parties to create "simplified measures on access for non-commercial research purposes". Similarly, to prevent the Protocol's bilateral approach from interfering with breeding practices, article 8 asks parties to "consider the importance" of PGRFA without requiring them to take specific actions. Together with the article 6 international access standards, the article 8 obligations may improve the utilization of genetic resources in non-commercial research if domestic laws and regulations are streamlined and non-commercial users receive due differential treatment. This is not necessarily the case for plant breeding where contracting parties must "consider", but not necessarily implement, differential treatment. Provider countries thus have strong incentives to appropriate the concrete benefits from the utilization of PGRFA that are within the scope of the Protocol through bilateral ABS agreements while disregarding diffuse benefit-sharing from PGRFA being made available as a global public good.

Finally, the Protocol contains several facilitating design components. The ABS Clearing House is an international mechanism for sharing ABS-related information, including on domestic access frameworks, the national focal points and competent national authorities which parties are required to designate, access permits, model clauses for ABS contracts, codes of conduct and best practices, among others (article 14). Parties shall also designate ABS National Focal Points that actively provide information on the required procedures and liaise with the CBD secretariat, as well as Competent National Authorities that grant access and provide the relevant permits (Article 13). As with other provisions, the effect of those components hinges on national implementation.

4.2 PROBLEM STRUCTURE

The problem structure of PGRFA, discussed above, is similar to that of microbial genetic resources. About 500 entities worldwide are organized in the World Federation for Culture Collections, the majority of which are public institutions (Dijkshoorn et al. 2010). Microbes are frequently sourced from abroad and their transboundary exchanges thus potentially fall within the scope of the Nagoya Protocol (McCluskey et al. 2017). Transfer volumes are difficult to estimate. A survey of 119 culture collections showed that they delivered roughly 120.000 strains to other (public and private) institutions in 2005 (Dedeurwaerdere 2010: 419). Assuming

representativeness and growing demand, this places the transfer volumes for microbial genetic resources in a similar category as global PGRFA flows.

In pharmaceuticals, a wide range of drugs have been developed from plant genetic resources, although their relevance is declining as the high-throughput screening of synthetic compound libraries offers faster results for an industry under financial pressure from expiring patents, costly litigation and the drying up of product pipelines (Li and Vederas 2009). Microbial genetic resources hold higher innovative potential. Utilization involves small- and medium-size entities acting as intermediaries that identify and supply lead compounds for large downstream manufacturers. The Protocol has a larger effect on such intermediaries (that "utilize" a large range of genetic resources in the sense of screening them for useful properties) than on manufacturers (that utilize a small number for product development). The flexibility that providers and users enjoy in negotiating Mutually Agreed Terms in principle allows for intermediaries to be exempted from the sharing obligation in order to prevent bottlenecking the transfer of genetic resources down the value chain. For contracting parties, Article 17 grants wide leeway in designing national checkpoints. Verifying compliance towards the end of the value chain ensures that compliance- and transaction costs accrue to end users, not intermediaries. To the extent that users, providers and contracting parties avail themselves of those flexibilities, they prevent the Protocol from interfering with access and utilization. However, the exemption of intermediaries from verification at checkpoints reduces the incentives to acquire genetic resources legally, which potentially undermines the sharing of benefits by end users.

Non-commercial utilization of microbial- and plant genetic resources (including PGRFA) for basic- and applied research involves a larger numbers of end users. Informal, unregulated exchanges among research centers and within scientific communities imply that users frequently act as sources and intermediaries as well (Dedeurwaerdere 2010). Parties to the Nagoya Protocol recognize that the benefits from non-commercial research are diffuse public goods rather than concrete material assets (Article 8.a). In practice, the fuzzy boundaries between the public- and private spheres in biotechnological innovation make a legal distinction between commercial and non-commercial utilization hard to sustain (Nijar 2016). As noted above, Article 8 of the Protocol is unequivocal in requiring simplified access procedures for such entities. Given proper implementation, the Protocol will not impede access for non-commercial research and might contribute to the dissemination of knowledge and other public goods as a form of benefit-sharing.

For plant breeding, the specific approach of the Nagoya Protocol leads to different effects on provision, utilization and benefit-sharing than under the Seed Treaty. The large transfer volumes that are now subject to negotiated, rather than standardized, ABS agreements decrease user capacities for utilizing breeding materials within the scope of the Protocol. Unlike for pharmaceuticals, there is a strongly negative effect on end users due to the large amount of genetic resources they require as inputs for product development. This issue is further exacerbated by the interest of provider

countries in the monetarization of PGRFA through bilateral ABS agreements and the weak Article 8 obligation to merely "consider" the special nature of PGRFA.

4.3 NATIONAL IMPLEMENTATION

At the time of writing, the Nagoya Protocol has been in force for three years yet national implementation is slow. Data from the ABS Clearing House shows that large shares of contracting parties, primarily developing countries, have not designated Competent National Authorities (CNAs), adopted implementing measures, designated checkpoints or created national databases. Of the 69 members of the G77/China that are contracting parties to the Protocol, 48 have so far failed to notify the adoption of any of those (see figure 4).[9] In some cases, the implementation deficit crosses the border to non-compliance with international obligations.[10] In the case of OECD members that are parties to the Nagoya Protocol, implementation is better.

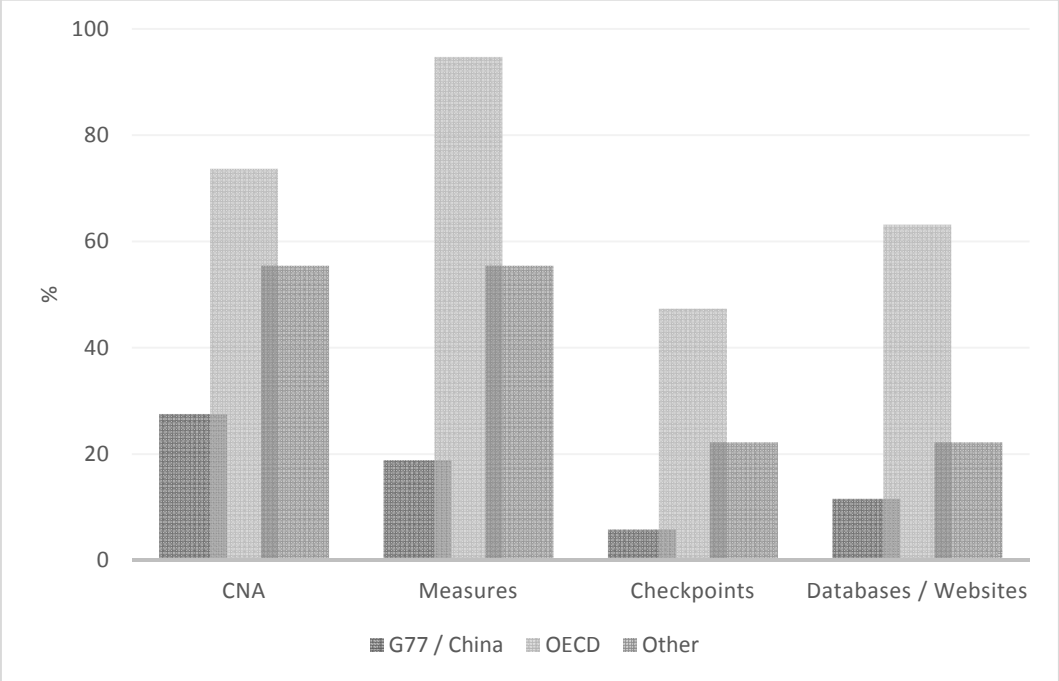

Fig. 4: Implementation of central Nagoya Protocol commitments in contracting parties (designation of Competent National Authorities; legal, administrative or policy measures; checkpoints; national websites or databases with ABS-relevance). Excludes European Union. Source: ABS Clearing House (August 2017).

Ambiguity in regards to temporal scope allows contracting parties to adopt their respectively preferred interpretation in their implementing measures. The European Union implementing regulation and the Japanese implementing guidelines apply exclusively to post-Nagoya acquisition and utilization, effectively excluding ex situ collections build up between 1993 and 2014 yet utilized thereafter. However, the cases of the EU and Japan also show how national implementation can successfully avoid

[9] See https://absch.cbd.int/ , accessed 18 July 2017

[10] Pursuant to Nagoya Protocol Article 13.4, parties "shall" notify their designated Competent National Authorities to the Secretariat of the CBD "no later than the date of entry into force of [the] Protocol" for that party.

negative impacts on the breeding sector. The EU directive allows users to fulfill their due diligence obligation in regards to non-Annex I PGRFA voluntarily included in the Seed Treaty's Multilateral System by using its SMTA (EU 2014, Article 4.4). The Japanese guidelines do not apply to the utilization of genetic resources within the scope of the Seed Treaty as such, meaning any and all PGRFA, not only those listed in Annex I (Japan 2017, No.3.2).

Implementing measures generally do not distinguish between commercial and non-commercial research (Medaglia et al. 2014: 118), thus depressing the capacities for utilization in the latter sector. For the largest part, though, the matter of "legal space" of international ABS regimes in national implementation remains an ongoing process. Insufficient differentiation between sectors poses the risk of hampering utilization, and thus benefit-sharing, through the imposition of a one-size-fits-all approach to genetic resources.

4.4 DISCUSSION

Given adequate implementation, communication between checkpoints, national focal points and the ABS Clearing House enables effective monitoring at minimal costs for users. The crux of the matter, however, is the "one-size-fits-all" approach that does not (yet) sufficiently differentiate between sectors. While sector-specific needs and challenges can be addressed in bilateral negotiations between providers and users, the Nagoya Protocol does little to pre-structure the outcomes of those negotiations. Thus, the Protocol potentially causes an access chill in regards to PGRFA. Its "special considerations" under article 8.c require parties to "consider" their "importance" yet do not *mandate the development* of dedicated rules. This will depress access to PGRFA that do not fall under the article 4.4 exemption (i.e. those that are not listed in Annex I to the Seed Treaty or have voluntarily been included in the Multilateral System). A possible solution to this impasse, an expansion of the Seed Treaty's coverage to all PGRFA, is under negotiation under the Treaty's Governing Body, with presently unclear prospects (Rabitz 2017b). Plant breeders that utilize multiple PGRFA within the scope of the Nagoya Protocol are now potentially in a situation in which they have to approach multiple provider countries in order to obtain prior informed consent and establish mutually agreed terms. The potential access chill is less serious for pharmaceuticals, where drug discovery and development revolves around single genetic resources providing lead compounds.

Finally, the "simplified access measures" for non-commercial research that parties are obliged to create pursuant to article 8.a do not necessarily absolve researchers from the need to obtain prior informed consent and to negotiate mutually agreed terms. If provider countries do not create such measures or define "simplified" in ways that are incompatible with scientific practice, user countries are still under the obligation to enforce their domestic access frameworks pursuant to article 15. Presently, "not all countries differentiate between commercial and non-commercial research and when they do, determining whether an application is for basic research or for commercial purposes has proven difficult" (Medaglia et al. 2014: 118). Unless provider countries

step up their game, the impacts on non-commercial research will be negative, hampering the supply of public goods as a form of benefit-sharing. A way out of this impasse would be the negotiation of a sectoral ABS instrument for non-commercial research, possibly in the shape of a scientific commons (Dedeurwaerdere 2010), to be subsequently recognized under Nagoya Protocol Article 4.4.

5. THE PIP FRAMEWORK

A regime for the multilateral sharing of influenza viruses for rapid vaccine development in case of a pandemic emergency has been in place under the WHO since 1952 (Kamradt-Scott 2015: 126-130). During the 2006 H5N1 epidemic in South-East Asia, the Indonesian government challenged this regime by ceasing the sharing of viral samples, claiming that patents and the Advance Purchase Agreements which many industrialized countries have in place with manufacturers restrict access to vaccines for its domestic population (Hameiri 2014). Instead, Indonesia argued that PIP biological materials constitute "genetic resources" within the scope of the CBD. Their utilization in vaccine development would thus be subject to Prior Informed Consent and would have to take place on Mutually Agreed Terms, including arrangements for benefit-sharing. The Indonesian decision threatened to upend rapid virus-sharing and vaccine development by requiring bilateral negotiations prior to access to PIP biological materials. As pandemic influenza response depends on the timely production of large quantities of vaccines, the decision raised a challenge to global health security. Simultaneously, the Indonesian controversy resonated with broader concerns over the insufficient access of developing countries to essential medicines (Muzaka 2011). The World Health Assembly adopted the PIP Framework in 2011, creating an ABS regime for PIP biological materials with an as-of-yet unclear relationship to both the CBD and its Nagoya Protocol (Rabitz 2017a: 123-125).

5.1 INSTITUTIONAL DESIGN

The PIP Framework covers "H5N1 and other influenza viruses with human pandemic potential" (Article 2.i). It uses two SMTAs that cover all transfers of human clinical specimens as well as isolates of, and candidate vaccine viruses developed from, influenza viruses with human pandemic potential (Article 4.1). The regime thus applies only to a narrow set of genetic resources, excluding both seasonal influenza viruses as well as non-influenza pathogens with human pandemic potential. Critically, its SMTAs are limited to transfers of physical materials, excluding genetic sequence data from the scope of its benefit-sharing provisions.

SMTA 1 covers transfers among the entities within the WHO's Global Influenza Surveillance and Response System (GISRS): Essential Regulatory Laboratories, National Influenza Centers, WHO Collaborating Centers, and WHO H5 Reference Laboratories. Providers and recipients are to comply with biosafety standards and relevant WHO guidelines and terms of reference. All transfers within GISRS must be covered by SMTA1. All transfers from the WHO network to non-GISRS entities,

including pharmaceuticals- and vaccine manufacturers, fall under SMTA2. The Influenza Virus Traceability Mechanism allows for the real-time monitoring of material flows into, within and out of GISRS, making non-compliance with the SMTA2 obligations easily detectable.

The SMTA2 requires users to select among several benefit-sharing options. Vaccine producers can, for instance, commit to donating a minimum percentage of real-time production to WHO, to offering the WHO preferential prices for a minimum percentage of production or to transfer technology to either WHO or developing countries through licensing agreements (SMTA2, Article 4). The trigger for those commitments is an influenza pandemic. 11 vaccine and antiviral manufacturers have concluded SMTA2s with WHO as of 2017. So far, almost all commitments on vaccine donation and reservation are below the 10% of real-time production that the SMTA2 aspires to, in some cases significantly so. At present, the aggregate commitments are estimated at roughly 350 million doses of vaccines (WHO 2016: 16). Notably, no manufacturer has thus far committed to technology transfer through licensing agreements.[11]

Additionally, all non-GISRS users participating in the WHO network are to make an annual Partnership Contribution covering 50% of the system's operating costs (PIP Framework, Article 6.14.3), essentially a subscription model. The collection target for financing half of the annual costs associated with pandemic preparedness and response has been estimated at US$ 28 million. This target is generally being achieved (WHO 2015:9). The Partnership Contribution thus solves the challenge of linking access to benefit-sharing by having both coincide, thus eliminating the possibility of shirking the sharing obligation.

Arguably, some of the benefit-sharing options under the SMTA2 impose larger costs on users than the Seed Treaty's SMTA does. This includes the option of donating a minimum of 10% of real-time vaccine production (as an "aspirational" rather than "hard" target) as well as the granting of royalty-free manufacturing licenses. Other options allow users to keep their costs in check, including reservation at "affordable" prices and the granting of licenses in exchange for "affordable" royalties. However, even where user costs are large, the PIP Framework does not induce access diversion due to its underpinning problem structure.

5.2 PROBLEM STRUCTURE

Effective influenza response requires the rapid development and production of vaccines. Influenza pandemics result from antigenic shifts: different strains of influenza virus A that transmit between animals or from animals to humans combine to allow human-to-human infections. While circulating in the field, influenza viruses undergo antigenic drift, that is, constant changes in their genetic makeup. They can thus bypass the human immune system and require the development of custom-

[11] See http://www.who.int/influenza/pip/benefit_sharing/smta2_signed/en/ , accessed 18 July 2017

tailored vaccines based on a comprehensive survey of the circulating strains. The nature of an influenza pandemic then requires the rapid production and distribution of large quantities of vaccines.

Unlike for other genetic resources, the geographical origin or PIP biological materials is variable. Pandemic threats can originate from anywhere in the world. Historically, Southeast Asia has been a center of origin for several influenza pandemics due its combination of high population density with intensive livestock cultivation. The collection and shipping of viral samples requires action by national health agencies which are the only sources of PIP biological materials. After National Influenza Centers, WHO Collaborating Centers, H5 Reference Laboratories and Essential Regulatory Laboratories have shared samples among themselves, they passed them on to vaccine manufacturers and other non-GISRS entities. In practice, a small set of Collaborating Centers and Essential Regulatory Laboratories accounts for a majority of transfers.[12] The US Center for Disease Control in Atlanta accounts for roughly half of all outbound shipments and the UK's Essential Regulatory Laboratory for a quarter. Those entities act as bottlenecks in the flow of PIP biological materials from the national level through GISRS to commercial manufacturers of vaccines, antivirals and diagnostic equipment. Less than 300 such end users are recorded as having received materials, with multinational companies like Baxter, Novartis, Sanofi Pasteur and GlaxoSmithKline being the primary commercial recipients. Non-commercial users are limited to a handful of public research institutions, most of which have received less than three shipments over the last nine years. Biosafety requirements are a hard constraint on the type of facilities that are eligible to receive shipments. The amount of recorded annual shipments peaked at 305 in 2013 yet is usually in the order of several dozen. Transfer volumes are thus substantially lower than for other types of genetic resources. Figure 5 visualizes the shipments recorded in the Influenza Virus Traceability Mechanism, depicting how a small number of entities dominates overall transfer patterns.

The problem structure for PIP biological materials is unique and limits the extent to which the PIP Framework and the Seed Treaty, despite similarities in institutional design, can be compared in a meaningful manner. First, the exclusive control that national governments enjoy over sources, as well as the low amount of intermediaries, precludes arbitrage: users wishing to obtain PIP biological materials have no alternative to GISRS. Second, low transfer volumes flow through bottlenecks to a handful of large commercial end users, allowing for extraordinarily effective monitoring. Third, little diversity exists in the types of end users. However, the PIP Framework allows for differential treatment by exempting non-commercial recipients from benefit-sharing under the SMTA2, with the exception that such users shall acknowledge the providing laboratories in relevant publications and presentations (SMTA2, Article 4.3). Overall, the problem structure of PIP biological materials tremendously simplifies the challenges involved in ABS governance.

[12] This paragraph as well as figure 5 draws on data from the WHO's Influenza Virus Traceability Mechanism, see https://extranet.who.int/ivtm/

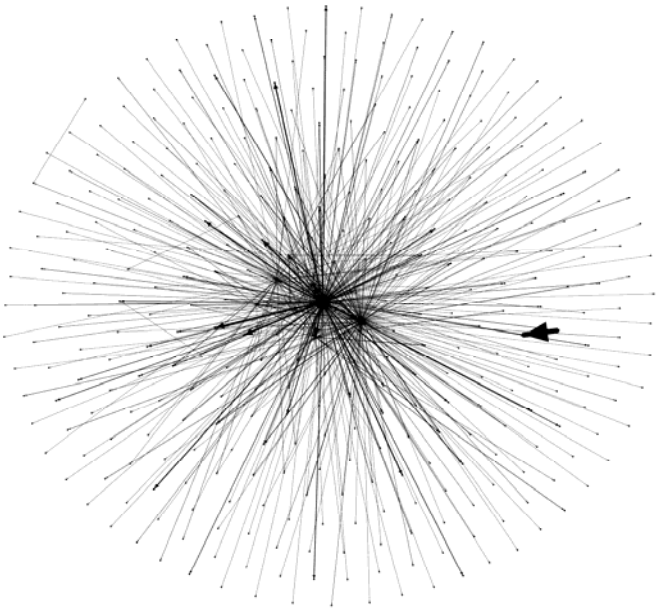

Fig. 5: Shipments of PIP biological materials since 2008. Nodes are GISRS- and non-GISRS entities, edges are transfers. Edge width denotes number of transfers between entities. Based on IVTM (extranet.who.int/ivtm ; September 2017).

5.3 NATIONAL IMPLEMENTATION

The PIP Framework requires little in the way of national implementation that goes beyond what WHO member states have been doing for the last six decades. The PIP Framework provides revised Terms of Reference for GISRS institutions, for instance requiring them to exclusively transfer PIP biological materials under the SMTA1 and to record shipments in the Influenza Virus Traceability Mechanism. However, the PIP Framework's Advisory Group notes a decrease in the amount of shared influenza viruses with pandemic potential, relative to the amount of human confirmed cases, since 2011. The decrease is partially attributed to "non-technical" causes, including political decision-making processes (WHO 2017: 3). In absolute terms, annual shipments peaked at 305 in the context of the 2013 H7N9 avian influenza infections in China, yet declined markedly in subsequent years, dropping to 43 in 2015 and 39 in 2016. In 2016, a comprehensive review of the Framework's performance concluded that the "decrease in virus sharing […] poses a potentially serious challenge to the PIP Framework's objective of improving pandemic influenza preparedness and response" (WHO 2016: 45). In addition, the Influenza Virus Traceability Mechanism "is not consistently used by all laboratories" (ibid.: 14). A final challenge is the integration of SMTA2 commitments into national pandemic response plans. Countries with domestic manufacturers need to account for rapid vaccine exports during a pandemic crisis, including through the adoption of appropriate regulation.

5.4 DISCUSSION

From the regimes under discussion here, the PIP Framework is arguably the most-effective one due to both its institutional design and the favorable problem structure underpinning it. Its subscription model as part of its benefit-sharing component solves the compliance problem by making access conditional on regular payments. Material flows into and out of GISRS are easily monitored, thus ensuring compliance with sharing obligations during a pandemic alert. However, the distributional conflict underlying the PIP Framework is more severe than in either the case of the Seed Treaty or the Nagoya Protocol. Influenza pandemics are a critical threat to vital national interests. It is doubtful whether the Framework exerts sufficient normative pull to have governments dealing with a severe domestic health emergency consent to the export of pandemic influenza vaccines so that manufacturers can comply with the SMTA2. Such a case would rekindle the debate over the legal status of PIP biological materials under the CBD and the Nagoya Protocol, which has so far been papered over (Rabitz 2017a: 123-125). However, sustained benefit-sharing through the Partnership Contribution, including for improving the capacities for pandemic preparedness and response in developing countries, will build trust among stakeholders and increase the likelihood of successful cooperation during a pandemic alert by lengthening the shadow of the future.

6. CONCLUSIONS

The discussion above highlights several broader points regarding the design and effectiveness of international ABS regimes. First, only a comprehensive regime scope can avoid the problem of access diversion to sources that do not impose sharing obligations and compliance costs. Second, having sharing obligations coincide with the point of access, for instance under a subscription model, obviates the need for compliance measures. The larger the temporal distance between access and the trigger point for sharing obligations, the more intrusive such measures will have to be. Distancing access from the benefit-sharing trigger may be necessary, however, in fields where innovation pipelines are long and benefits require substantial time to materialize. This includes plant breeding and pharmaceutical drug development. However, this increases user costs and thus exacerbates the problem of access diversion in cases where alternative sources are available. Third, inadequate implementation is pervasive. Developing countries appear to be more interested in negotiating ABS regimes than making them work. For instance, while India accounts for 74 out of the 85 Internationally Recognized Certificates of Compliance presently registered with the Nagoya Protocol's ABS Clearing House it does not notify its Annex I PGRFA to the Multilateral System of the Seed Treaty. For all the talk of global justice and North-South equity in international ABS negotiations, the motive of cash-flow maximization appears to dominate other considerations. Fourth, negotiation outcomes tend to paper over distributive conflicts with ambiguous phrasing, in all likelihood to prevent reputational damage from negotiation failure. The inconclusive debate on the precise scope of the Seed Treaty's Article 12.3.d prohibition of

intellectual property claims is emblematic of the uncertainties that subsequently arise from such political compromises, as is the indeterminacy of the PIP Framework regarding whether or not PIP biological materials constitute genetic resources under the CBD. Fifth, the consequences of institutional choices partially depend on extra-institutional factors, the implication being that not every design option may be appropriate to every issue area.

Differences in problem structure also limit the extent to which the experiences gained with one regime can be transferred to others. The PIP Framework is often likened to the Seed Treaty yet differences in problem structure arguably account for variation in outcomes. Considering the ongoing negotiations on ABS regimes for marine genetic resources as well as genetic resources associated with traditional knowledge, as well as initial discussions on potential regimes for forest-, animal- and orphan genetic resources, policy-makers and scholars alike may wish to take greater notice of the differences in issue-area characteristics to avoid institutional choices that may be effective in some cases yet not in others.

Yet the most-important future developments in ABS governance may not come from international regimes but from technological change. In the rapidly evolving field of biotechnology, two trends stand out.

The first is the growing use of genetic sequence data (GSD) rather than physical specimens. Users are less and less dependent on access to the actual material and increasingly able to innovate based on GSD alone, for instance through laboratory synthesis of desired DNA segments. For microbial genetic resources, including PIP biological materials, users can often acquire GSD from open-access databases. While there are sound reasons to welcome this trend, the turn towards GSD undermines the benefit-sharing objective. Discussions on GSD are underway both under the Nagoya Protocol and the PIP Framework. Ultimately, the CBD allows for a flexible interpretation of the term "genetic resources" (Tvedt and Schei 2014). Given the political will, there are no legal barriers to explicitly including GSD within the scope of international ABS regimes. The bigger challenge may well be at the implementation level, where GSD complicates monitoring and thus exacerbates the compliance problem (Bagley et al. 2017).

Gene editing poses a more fundamental challenge to ABS governance. Novel tools such as the CRISPR/Cas9 system have the potential to obviate the need for genetic resources as input materials for biotechnological innovation, as users can manipulate materials that do not have sharing obligations attached. Once the insertion of transgenes becomes unnecessary, there is no need for access to genetic resources and no obligation to share benefits. National sovereignty over genetic resources will become irrelevant. The world we are about to enter might thus be similar to the early 1980s, where the primary conflict line in the politics of biotechnology ran between the proponents of private property rights and those arguing for genetic resources as the common heritage of humanity. As such, this may not necessarily be a negative development. However, it raises the question of whether international ABS

governance can adapt, or rather: whether governments and commercial users alike are willing to concede that diffuse benefit-sharing flows from global public goods may be more important than the cash flows that result from the appropriation and monetarization of genetic resources.

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