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Governance of Digital Sequence Information and Impacts for Access and Benefit Sharing

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EXECUTIVE SUMMARY

The decoupling of biological information from its material source has changed the global debate about access and benefit sharing (ABS) of genetic resources. What does the digitization of biological information mean for genetic resources of proven and potential value? What implications does DSI have for individuals and groups who have invested time and effort in augmenting and refining valuable characteristics in genetic resources? These are the types of questions that have emerged with the advent of digital sequence information (DSI). This paper explores the options for governments to continue advancing the goals of access and benefit sharing, when physical access to genetic resources is no longer needed because DSI is readily accessible. To do so, implications of DSI are explored through the lens of access to genetic resources for crop/plant breeding.

Given the pressures climate change and population growth are placing on food production systems, more and better use of genetic resources is required. Emerging technologies and disciplines such as DSI, are making the already complicated international debate on genetic resource governance more complex. This complexity is explored and detailed. Interestingly, although the term 'genetic resource' is at the basis of the ABS debate, legally defining the term is difficult. With clearly divergent political and economic interests, and without a universally accepted definition for genetic resource, a wide array of entities are engaged in trying to govern ABS. The ongoing discussions and debates of the more prominent entities are detailed before the four options we anticipate for moving forward are laid out.

The four options that we believe could begin to address the governance challenge are:

1. Given the lack of governance capacity, an existing international institution could occupy this space and claim governance. This would require considerable investments, both in terms of time and resources.
2. The governance gap could be viewed as a 'greenfield' space, allowing an entirely new organization, institution or convention to claim governance. This would be a time consuming and lengthy process.
3. Collaboration through existing governance mechanisms could be engaged to reach consensus. This would coalesce existing governance into a new framework that bridges the current gap.
4. Let the current status quo continue. Possibly the simplest and most realistic option.

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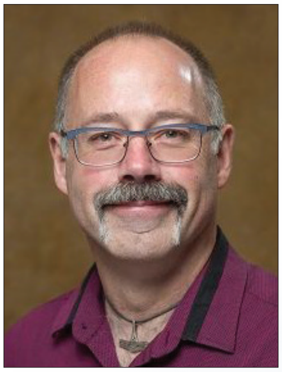

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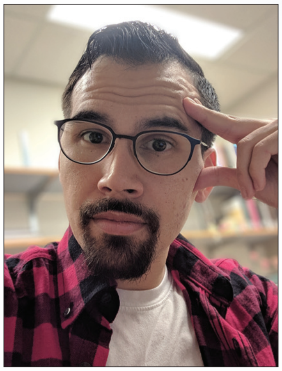

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ACRONYMS

ABS	Access and Benefit Sharing to genetic resources
CBD	Convention on Biological Diversity
DSI	Digital Sequence Information
GRAATK	Genetic Resources and Associated Traditional Knowledge
IP	Intellectual Property
IRPs	Intellectual Property Rights
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
NP	Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity
MAT	Mutually Agreed Terms
PIC	Prior Informed Consent
SB	Synthetic Biology
TK	Traditional Knowledge
WIPO	World Intellectual Property Organization

1.0 INTRODUCTION

The decoupling of biological information from its material source has changed the global debate about access and benefit sharing (ABS) of genetic resources. With the recent sequencing of many plant genomes, wheat being the latest in August 2018, physical access to a plant or plant samples is no longer required to undertake research. This paper explores the options for governments to continue advancing the goals of access and benefit sharing, when physical access to genetic resources is no longer needed because digital sequence information (DSI) is readily accessible. What makes this development most urgent is that the increasing digitization of biological information has coincided with the development of novel genome editing technologies, big data and synthetic biology. Though slightly different in their scope and depth of application, these technologies and scientific disciplines considerably loosen (or contribute to loosening) the constraints to animal, plant and microbe engineering.

What does the digitization of biological information mean for genetic resources of proven and potential value? What implications does DSI have for individuals and groups who have invested time and effort in augmenting and refining valuable characteristics in genetic resources? These are the types of questions that have emerged with the advent of DSI; as of yet, no concrete answers exist. Moreover, the products of these technologies have vast potential to contribute novel solutions to problems in agriculture, energy and health. However, part of realizing the benefits of these technologies rests on the access to (and use of) DSI from a diversity of sources.

While the digitization of biological information is likely to have an array of socio-economic implications for societies across the world, our knowledge synthesis starts with impacts in agriculture. Specifically, implications of DSI are explored through the lens of access to genetic resources for crop/plant breeding, a topic of interest that is currently being discussed in various international fora. The nuances of this activity obligate its discussion in the international arena. Commercial and public plant breeding requires access to a wide pool of genetic resources to create novel plant varieties, which themselves are genetic resources. As countries have become interdependent for their food production, international cooperation against the backdrop of emerging technologies is imperative. Many transnational, non-state actors are also directly involved in plant breeding and require access to genetic resources for basic research (for example, DivSeek http://www.divseek.org/). How we govern digital information that, at the extreme, becomes completely disembodied and independent of the underlying genetic resources will have profound direct and indirect effects on stakeholders, who at times, have complimentary and competing political, economic and social interests. Currently all of our policies, programs and practices are built on the embodied nature of genetic resources; breaking this bond challenges our existing models.

As countries have become interdependent for their food production, international cooperation against the backdrop of emerging technologies is imperative.

We explore the potential implications and issues of DSI on ABS, first by a review of how biology-based disciplines have adopted the practice. We then review the Convention on Biological Diversity's (CBD) role in international ABS governance and efforts under the CBD's Nagoya Protocol (NP) to better frame and structure an effective and equitable ABS system. We then explore the ecosystem of competing and supporting institutions, agencies, policies and programs that inform or support the work of the CBD and NP. This analysis helps to identify whether DSI can or should be incorporated into the work of the CBD and NP, or whether other venues may be more appropriate for these discussions and negotiations. To advance discussion, we compare and contrast ABS in the material realm with possibilities for ABS in the digital realm. While, currently, a clear way forward does not exist on ABS in respect of DSI, we will discuss the nature and scope of the discussions to date across the developing ecosystem.

2.0 DIGITAL SEQUENCE INFORMATION

The gradual coalescing of biology and cyberspace has created a host of novel opportunities as well as challenges (Marden 2018; Peccoud et al. 2018). The economics of genomics has accentuated this process. The cost of sequencing a genome decreased from $100 million in 2001, to approximately $1,000 in 2017. The cost per raw megabase of deoxyribonucleic acid (DNA) sequence (a million bases) declined from $10,000 in 2001 to less than one cent in 2017 (see https://www.genome.gov/sequencingcostsdata/). The digitization of biological information, i.e. DSI, can be understood in a strict semantic sense. The genome of an organism contains its genetic information (or code), which is responsible for the development and homeostasis of organelles, cells, tissues, organs and organ systems. This information can now be uncovered and subsequently stored, edited and transferred digitally. Perhaps most importantly, it can be converted into tangible biological constituents (Boles et al. 2017). Currently, scientists are able to sequence all or part of hundreds or thousands of plant samples originating from various sources. This process can yield vast amounts of data; it would be operationally very difficult to track the depth and scope of information utilized from any individual source in a final product (Marden 2018). Furthermore, although production costs of biological information might be relatively high (but falling each year), digital technologies permit storing, distributing and analyzing the disembodied data with low or zero marginal costs (Dedeurwaerdere et al. 2016). Various organizations are actively taking part in the DSI revolution. As examples, the BioBricks Foundation and DivSeek, operate a host of programs designed inter alia to streamline access to, and sharing of, DNA sequences to researchers across the globe. To do so, they make use of some or all of the technologies, techniques and standards detailed below.

2.1BIOBRICK ASSEMBLY STANDARD

A goal of biological engineering is to design genetic systems from standardized biological parts that would allow the rapid assembly of engineered organisms. Shetty et al. (2008: 2) define a biological part to be "a natural nucleic acid sequence that encodes a definable biological function, and a standard biological part to be a biological part that has been refined in order to conform to one or more defined technical standards." The BioBrick standard permits the assembly (combination) of any two BioBrick parts, and the resulting product is itself a BioBrick that can be further assembled. The standard also enables the decentralized production of compatible biological parts and is amenable with optimization and automation (iGEM 2018). BioBricks can be used to create novel characteristics or enhance existing ones in plants.

2.2 GENOME EDITING TECHNOLOGIES: CRISPR SYSTEMS AND GENE DRIVES

Mutagenetic technologies advanced rapidly in the 2000s into what are now known as genome editing. Technologies such as transcription activator-like effector nuclease (TALEN) and zinc-finger nucleases (ZFN) enable researchers to induce targeted ad controlled site-specific genome changes via the development of site-directed nucleases (SDNs). These plant breeding tools evolved rapidly, allowing for the discovery of clustered regularly interspaced short palindromic repeats (CRISPR) (Doudna and Charpentier 2014). Applications of the CRISPR system have expanded quickly, through the development of such specific tools as CRISPR/Cas 9, CRISPR/Cas12a or CRISPR/Cas13 (Chen et al. 2018; Gootenberg et al. 2018). Each Cas variation manipulates the nucleotide sequence of the guide RNA enabling the protein to be programmed to target any DNA sequence for cleavage.

Genome editing has numerous advantages over earlier technologies. Most significantly, it allows for targeted single gene mutation across an entire plant genome. The CRISPR suite of breeding tools are an easier, more versatile and accurate form of mutagenesis, capable of transferring a desired trait into a parent and then reproduced in its progeny without losing any efficacy (Georges and Ray 2017). This technology is able to substantially increase the rate of mutation within a targeted genome, making the effects on the plants more significant (Song et al. 2016), as it can be programmed to target specific segments of genetic code or edit DNA with great accuracy (Barrangou 2015). This has applications beyond crop breeding; animal and human health scientists are also excited by its potential for treating diseases.

Importantly for this discussion, genome editing holds global potential for plant breeding in both developed and developing countries, as it allows for more targeted local and regional solutions to improve food security (Scheben and Edwards 2017). For instance, Miao et al. (2018) made use of CRISPR/Cas9 technology to create a rice variety that yields 25 to 31% more than plants bred without employing the technology. This has profound implications for the potential mitigation of the effects of climate change, as well as contributing to food security. Moreover, some states have already begun delineating their regulatory approach towards this technology. Waltz (2016) reports that the first CRISPR-edited product approved in the US was the common white button mushroom; though the developer has declared that it will not be commercialized. What was unique about this approval was that the US Department of Agriculture (USDA) determined that genome editing technologies do not require regulation.

Nonetheless, for all the benefits CRISPR/Cas9 seems capable of providing, Smyth (2017) accurately predicted that not all governments will embrace this technology. In 2016, in response to a lawsuit launched by non-governmental organization, a French court referred to the Court of Justice of the European Union (CJEU) a request to interpret European Law pertaining to new plant breeding techniques, especially CRISPR/Cas9. On 25 July 2018, the CJEU ruled that genome edited crops are subject to the European Union's regulatory restrictions in the same way transgenic, genetically modified (GM) organisms are regulated(CJEU 2018). Genome edited crops developed by site-specific, targeted genetic engineering techniques will now face rigorous regulatory review before they can be introduced into the market. Most large-area GM crops, like herbicide tolerant soybeans, canola and insect-resistant maize have failed to secure full food and feed approvals, in part because the costs, time and uncertainty of regulatory compliance make the process prohibitive (Smyth et al. 2014). Smaller area, niche crops derived through genome editing would probably face the same economic calculus.

Furthermore, genome editing technologies are only part of the new generation of tools available to breeders and researchers. Gene drives are a complementary mechanism through which genetic inheritance can be 'biased'. Though they remain understudied, there are many types of engineered gene drives that provide a wide range of potential applications (Champer et al. 2016). Gene drives have been used to re-engineer mosquitoes to be sterile, helping in the fight against problematic human diseases of malaria, yellow fever and Zika (Ledford and Callaway 2015; Macias et al. 2017; Regalado 2016). Understandably, the technology has generated both great hope and apprehension because of the potential for benefit, or harm, should these technologies be used with ill-intent (Gurwitz 2014). Oye et al. (2014) call for the concepts and applications of emerging technologies capable of affecting the global commons to be proactively disclosed, so as to enable public discussion regarding their inherent uncertainties. The governance environment in which they develop will contribute to whether or not emerging genome editing technologies develop transparently. Of course, governance of these will also, to some degree, be determined by the intellectual property landscape (IPStudies 2018), which will be explored below. In what follows, the two nascent scientific disciplines that will eventually make full use of DSI are discussed.

2.3 BIG DATA IN AGRICULTURE

'Big data' is the term used to refer to large information sets and the digital tools used to collect, compile and analyze them. Scientists have always dealt with data sets to undertake research but big data is novel because of the volume of information and its accompanying constraints and opportunities. De Mauro et al. (2016: 131) identify the main themes within big data and propose a formal definition for the otherwise nebulous concept: "Big Data is the Information asset characterized by such a High Volume, Velocity and Variety to require specific Technology and Analytical Methods for its transformation into value."

Big data can be used to identify the underlying dynamics of problems in complex systems that are not readily obvious or accessible except through the mining of vast amounts of data (Symons and Boschetti 2013). Machine learning, a subfield of artificial intelligence, can make use of these vast data sets so as to allow computers to 'learn' without being explicitly programmed to do so.

Beyond the technical specifications of big data, its applications in agriculture has already generated a host of issues, especially legal and social ones about access, governance and ownership. Bronson and Knezevic (2016) reviewed current applications of big data in the agri-food sector and found that several tools used to collect and analyze it may have implications for power relationships in the North American food system. However, they posit that issues around big data are more complex than data ownership that exacerbates inequity between food system players. A series of companies, ranging from John Deere to a host of small entrepreneurial firms, are offering a range of sensors, mechanical innovations, algorithms and services whereby data on weather, soil, crops and agronomic decisions can be collected and then used by farmers to make other agronomic decisions (Phillips et al 2017). But who owns what remains contested. de Beer (2017) examines how ownership of data, which is generally not directly owned, could be governed. Open data in theory can be accessed and used or shared by anyone. In contrast, closed data is not available to anyone outside the system or organization that controls it. But data can also be shared amongst specific groups for specific purposes, with limited access otherwise. Some assert that open data will lead to positive outcomes for everyone. Quite often however, that simply leads to suboptimal use. Access and usage is influenced by resource availability, such as know-how, infrastructure and fiscal constraints. Data ownership per se depends to a great degree on social and cultural norms. In many communities, such as indigenous communities (and in some research communities), the key rules governing data are those set and enforced endogenously (Crookshanks and Phillips, 2013). Given the current governance landscape (or lack thereof), big data in plant research is likely to face the same conundrums already being seen in the agri-food sector.

2.4 SYNTHETIC BIOLOGY

Sustained research in biotechnology has led to a field now known as Synthetic Biology (SB). Depending on whom is consulted, it is regarded as either a new branch of biotechnology or a logical extension thereof (Kuzma et al. 2016). Though it may be enticing to think of SB as a neologistic product of contemporary scientific progress, this term was in fact first explicitly used in the book La Biologie Synthétique published in 1912 (Campos 2009). Thus, the theoretical underpinnings of SB were proposed just over a century ago, it is only now that technological progress has permitted the realization of its practical applications. But exactly what is SB? Due to the field being in its developing stage, and the fact that the two main fields it encompasses (biology and engineering) are vying to impose their corresponding terminology, it cannot be simply defined (Calvert 2012). In our analysis, SB is understood as the UK Royal Society (2018) explains: "the design and construction of novel artificial biological pathways, organisms and devices or the redesign of existing natural biological systems." DSI will be of significant aid to SB in any of the nascent discipline's facets.

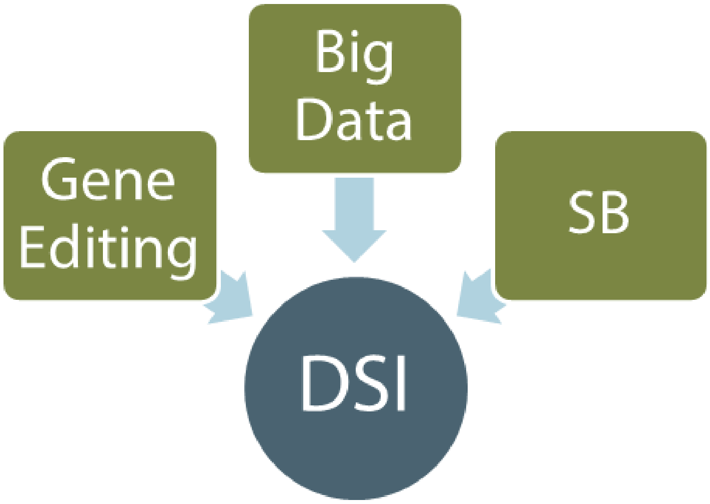
However, SB is sometimes defined differently by scientists and relevant stakeholders. A few of the more prominent definitions contained on the Synthetic Biology Project website (http://www.synbioproject.org/) are provided below:

- SyntheticBiology.org asserts synthetic biology is: a) the design and construction of new biological parts, devices and systems; and b) the re-design of existing natural biological systems for useful purposes.
- SynBERC suggests synthetic biology is a maturing scientific discipline that combines science and engineering in order to design and build novel biological functions and systems. This includes the design and construction of new biological parts, devices, and systems (e.g., tumor-seeking microbes for cancer treatment), as well as the re-design of existing, natural biological systems for useful purposes (e.g., photosynthetic systems to produce energy). As envisioned by SynBERC, synthetic biology is perhaps best defined by some of its hallmark characteristics: predictable, off-the-shelf parts and devices with standard connections; robust biological chassis (such as yeast and e. coli) that readily accept those parts and devices; standards for assembling components into increasingly sophisticated and functional systems; and open-source availability and development of parts, devices, and chassis.
- The High-level Expert Group European Commission asserts synthetic biology is the 'engineering' of biology, that is the synthesis of complex, biologically-based (or inspired) systems which display functions that do not exist in nature. This engineering perspective may be applied at all levels of the hierarchy of biological structures, from individual molecules to whole cells, tissues and organisms. In essence, synthetic biology will enable the design of 'biological systems' in a rational and systematic way.

2.5 SUMMARY

Novel genome editing techniques, big data and synthetic biology have all to varying degrees begun making use of DSI (Figure 1). Individually, because of their transformative capacities, these fields hold great potential to address a host of issues in crop breeding, energy production and human health. Though each developing field possesses its own unique controversial attributes, in combination these fields are poised to provide much needed novel tools for breeding new crops. The rest of this paper explores what the increasing use of biological information entails for ABS.

Figure 1: Fields that have begun makin use of biological information



3.0 ACCESS AND BENEFIT SHARING OF GENETIC RESOURCES

Biological resources can be understood as a form of capital that are governed by individual countries but are of importance to the entire world. As recently as 1993, food, fibre and raw materials of biological origin constituted almost half of the global economy (UNEP 1993). Given the pressures climate change and population growth are placing on food production systems, more and better use of genetic resources is needed. Emerging technologies are simply making the already complicated international debate on genetic resource governance more complex.

For Oberthür and Rosendal (2014), the international governance of genetic resources is an attempt to redistribute the benefits of biological resource utilization in order to create incentives for biodiversity conservation. They point out that many developing tropical countries are rich in genetic resources and associated traditional knowledge (GRAATK), but the technological capacity to exploit these resides mostly in developed countries. Naturally, this mismatch in ownership and technological capacity gave rise to a dichotomy in actor interest. Those rich in GRAATK wish to conserve them and benefit from their use, whereas those with the technological capacity to do so wish to exploit them. Countries rich in GRAATK had some of their interests embodied in the Convention on Biological Diversity (CBD) signed in 1992. Article 15 of the CBD recognizes the sovereignty of countries over their natural resources, thus acknowledging every country's right to legislate access to them. Article 15 also details how access to genetic resources is to occur on mutually agreed terms (MAT), and with prior informed consent (PIC).

Interestingly, although the term 'genetic resource' is at the basis of the ABS debate, legally defining the term is difficult. Tvedt and Schei (2014) note that a legal definition of the term needs to meet two contradictory virtues: (1) it must retain a protean quality, so the term maintains relevance with emerging technologies; and (2) it must be precise enough so that there is sufficient legal certainty to know whether one is operating inside or outside the ABS system. The authors think that the definition set forth in CBD (albeit a product of 1992 knowledge) is versatile enough to be relevant to emerging biotechnologies. In contrast, Deplazes-Zemp (2018) argues that genetic resources are an informational rather than tangible type of natural resource, due to their biological function and how they are currently valued and used. In her view, the CBD's definition of genetic resources (pertaining to the material), is not adequate to their actual use. Defining the term 'genetic resource' has not escaped the attention of negotiators. In the past, members of the CBD have contemplated establishing a clearer understanding of the term 'genetic resource'. However, a lack of political consensus has prevented a formal definition from being attained (CBD 2008).

With clearly divergent political and economic interests, and without a universally accepted definition for genetic resource, a wide array of entities are engaged in trying to govern ABS. The discussions and debates of the more prominent entities are detailed below.

3.1 THE CONVENTION ON BIOLOGICAL DIVERSITY

The CBD was an international response to the recognition that while biological diversity is a global asset of value to present and future generations, the threat to its loss has never been greater. The CBD's three main objectives are:

1. The conservation of biological diversity;
2. The sustainable use of the components of biological diversity; and
3. The fair and equitable sharing of the benefits arising out of the utilization of genetic resources.

Two Articles within the CBD text are useful in determining the effect of the decoupling of biological information from its material source. Article 15 recognizes the sovereign right of states over their genetic resources, as well as their right to legislate access to them. Article 8(j) calls for the respect, preservation and maintenance of knowledge, innovations and practices of indigenous and local communities. Members of the CBD recognize that most genetic resources have associated traditional knowledge. Thus, internationally governing ABS is not simply a matter PIC and MAT over genetic exchanges between states and organizations; it also involves the stewards of traditional knowledge (TK).

Conflicts and issues have emerged as interest in the use of TK has grown (Phillips 2014). There are examples of TK being transcribed into works of art, pharmaceuticals and various other products, not by its generators and without proper compensation (Posey and Dutfield 1996). Understandably, this practice has been criticized and mechanisms to safeguard TK have been sought (Mgbeoji 2007). But experts to date have been unable to fully elucidate the appropriate relationship between genetic resources and associated traditional knowledge. Nonetheless, they do agree that any ABS instrument should embrace this concept (CBD 2009). These same experts have taken notice of the World Intellectual Property Organization's (WIPO) working definition of traditional knowledge associated with genetic resources. A number of experts agree that a working definition of what is meant by traditional knowledge associated with genetic resources, no matter how deficient, is preferable to none. Some think that adapting the WIPO working definition is the most sensible way forward.

Furthermore, as the CBD does not detail how to establish adequate infrastructure or institutions to accommodate ABS or TK use, a supplementary agreement was developed to address this gap. The NP is tasked with accomplishing just that. While some genetic resource provider countries might assert that intangible genetic information falls within the scope of their national CBD or NP implementing legislation, neither legal instrument explicitly addresses the new technological reality (Bagley 2015). There are a range of significant challenges to NP. In the first instance, the NP has not been ratified by all signatories to the CBD and a few key countries, such as the US, are simply not parties to this entire scheme. Bagley points out a number of challenges of the NP itself. Frist, the temporal scope and breadth of coverage of the NP are left undetailed; it is not clear if the NP pertains to GRAATK prior to the NP coming into force or not. Moreover, once the genetic information of interest has been uncovered and used for its first purpose, can that information be stored and subsequently shared or commercialized? The NP does not address these issues. Concretely, the NP does not contemplate 'digital biopiracy' (Yilmaz 2017). Some assert the NP is a 'masterpiece in creative ambiguity' (Oliva 2011), as issues the signatory countries could not agree on were left unresolved. However, de Beer (2009) suggests that it is logical for parties to accept ambiguity when negotiating difficult subjects because ambiguity can later be negotiated to the convenience of the parties involved.

What do the CBD and NP mean for international efforts in crop breeding in a world of DSI? This is a difficult question to answer. First, it is important to remember that a unique characteristic of crop breeding is how genetic resources used in the process of creating new varieties are sourced. Most sourcing is done from ex situ collections and mainly through intermediaries (CBD 2009). This is troublesome because Davis et al. (2015) conducted a world-wide survey of botanical gardens and their awareness of ABS, the CBD and the NP. They found that many botanic gardens are not yet ready to implement the monitoring provisions of the NP, nor are their staff very familiar with the CBD, ABS or the NP itself. Furthermore, Deplazes-Zemp et al. (2018) point out that applying the same regulations to both commercial and non-commercial research of genetic resources may actually end up harming the Global South. What is abundantly clear is the lack of clarity for crop breeding in a world of DSI.

3.2 WORLD TRADE ORGANIZATION: TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS

To that point, a potential dispute between the NP and the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) has not been fully explored. Therefore, it is legitimate to question what set of rules or instruments would take precedence in the event of a dispute. The answer is of paramount importance because TRIPS is the principal legal system on which most national legislations pertaining to intellectual property rights (IPRs) are now built (Maskus 2014). Furthermore, for those countries not party to the NP, particularly influential countries such as the United States and Canada, the only recourse they would have is the WTO and TRIPs.

The exploration of a potential dispute between CBD derived instruments and WTO agreements is not without precedent. Kerr et al. (2014) explore the potential conflict between the Cartagena Protocol on Biosafety (CPB) and WTO related agreements. In analyzing these two divergent regulatory regimes, they note that when two treaties in the same subject area conflict, the latter treaty prevails in the event of a dispute between two states that are party to both instruments. They assert that the International Law Commission responded to the potential conflict between successive treaties with Article 30 of the Vienna Convention on the Law of Treaties (UN 1969). Kerr et al. (2014) conclude that because the WTO is the latter treaty, it must play a role in clarifying conflicting rules because it has the legal responsibility, as well as the institutional competence to do so.

3.3 WORLD INTELLECTUAL PROPERTY ORGANIZATION

For 17 years, the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) has had a mandate to negotiate a text-based instrument(s) for the effective protection of genetic resources, traditional knowledge and folklore. Negotiations have been ongoing on a parallel basis on three instruments, namely on a text for genetic resources, a text for TK and a text for Traditional Cultural Expressions (TCEs).

Oguamanam (2017) notes that the genetic resource text is the most advanced of the instruments. The first consolidated text on genetic resources was produced in the 20th IGC in 2012. It continued to evolve in subsequent IGC meetings: 22, 23, 29 and 30. The most recent attempt to refine the genetic resource text was at the 36th IGC in June 2018, in which member states were unable to reach a consensus on 'Consolidated Document on Intellectual Property and Genetic Resources Rev2' (IGC 2018a). The disputed draft offers a set of alternatives to Articles 2 to 7 (in Rev1), to accommodate the wish of some member states for there to be no mandatory disclosure requirement. Furthermore, an alternative to Article 4.3 (which contemplates ABS and PIC), stating that no obligation shall be placed on compliance with ABS and PIC was reinstated (Saez 2018). The group tasked with drafting the text indicated that the issues of ABS and PIC require a lot more work and deliberation. Saez (2018) noted that the particular concerns with Rev2 related to the disclosure proposals. Some countries perceive disclosure proposals as a means with which to weaken the patent system (not strengthen it) because it would allow patents to be challenged. The result might be a transfer of wealth from developed to developing countries. All draft Provisions/Articles for the Protection of TK and TCEs, and Intellectual Property (IP) and genetic resources can be found at: http://www.wipo.int/tk/en/igc/draft_provisions.html.

3.4 FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS: INTERNATIONAL TREATY FOR PLANT GENETIC RESOURCES FOR FOOD AND AGRICULTURE

The Food and Agriculture Organization (FAO), a specialized agency of the United Nations tasked with achieving food security, extensively discusses ABS and genetic resources. The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) was negotiated under the auspices of the FAO. The main goal of the ITPGRFA is to support the sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of benefits arising from their use. At its core, the ITPGRFA is a multilateral system that allows members to access a gene pool made up of 64 major crops (among them, all of the diet staples). It is important to point out that under this system, PIC is not required to access crop breeding material.

In 2018, an initial proposal for a masterplan and a description of the conceptual framework for the Global Information System (GLIS) called for in Article 17 of the ITPGRFA was undertaken (Secretariat 2018). The relative ease with which the ITPGRFA has developed and been adopted is due in part to the consistency in member objectives. That is, all members are trying to access plant genetic resources for their corresponding public or private crop breeding efforts. This may help explain why other efforts on ABS have stalled or not proceeded as rapidly.

3.5 DIGITAL SEQUENCE INFORMATION: THE CONTEMPORARY DEBATE OF EMERGING NUCLEAR AND SCIENCE TECHNOLOGY INNOVATION FIELDS

DSI has not gone unnoticed by actors deliberating in the fora explored above. In the 13th meeting of the Conference of the Parties (COP) to the CBD, an Ad Hoc Technical Expert Group on Digital Sequence Information on Genetic Resources was established (CBD 2016). In November 2018, at the 14th COP meeting, the potential implications of the use of DSI for the three objectives of the CBD will be considered. In turn, in its 35th Session the IGC discussed the non-physical access to genetic resources and how in practice this modality was overtaking physical access as a way to create inventions based on genetic resources (IGC 2018b). Perhaps the most exhaustive look into the implications of DSI to date has been undertaken by the ITPGRFA. In late 2017, a scoping report was produced to consider the implications of synthetic biology and genomics research on the ITPGRFA (Welch et al. 2017). At least three key principles of ABS could be potentially affected by DSI: identification; monitoring; and value generation. In addition, three structural components of the ITPGRFA's ABS framework could also be affected: pooling; decoupling of benefits from individual providers; and diversity of benefits.

Table 1 summarizes the relationship, key instrument and its relevant component that each institution described above has to ABS, and how they might deal (or are dealing) with DSI.

Table 1: Institutions and legal instruments relevant to ABS

Authority	**UN**	**UN**	**UN**	**WTO**
Institution	UNDRIP	CBD	FAO	
Primary objective or mandate	Indigenous rights	Environment	Food security	Trade & economy
Institution/Legal Instrument		NP	ITPGRFA	TRIPs

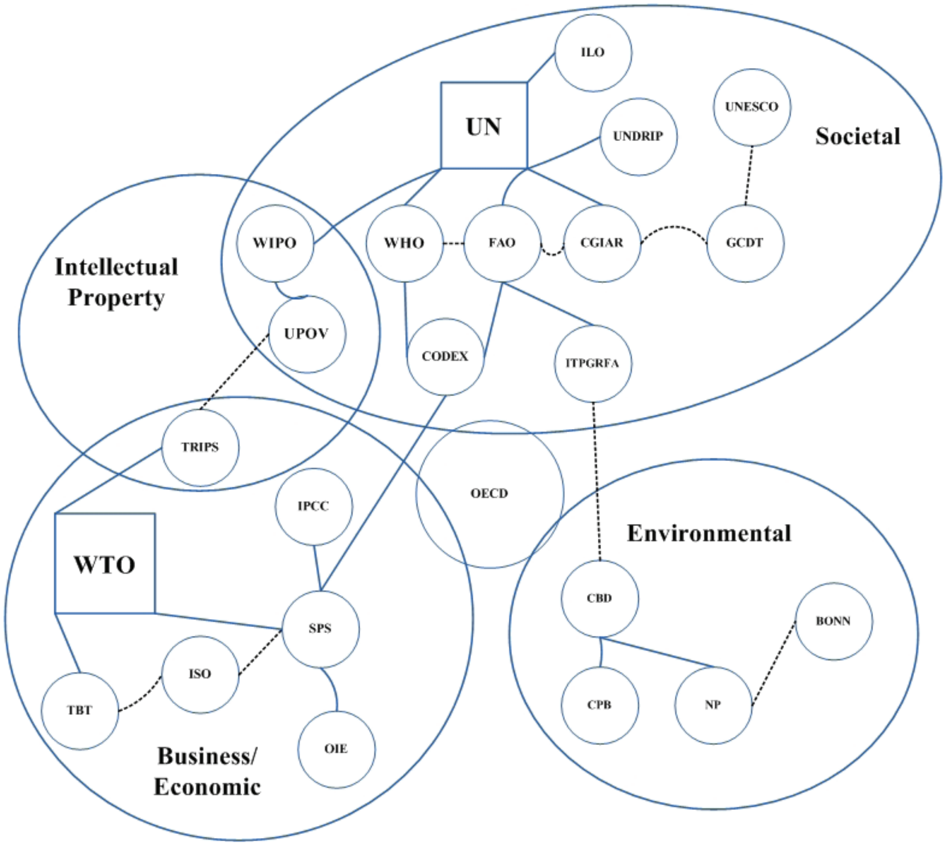
Table 2: International IP and Resource Landscape

Issue	Relevant provisions - Articles			
Indigenous intellectual property	Art.11.2, Art. 13 Art. 31	Art. 8(j)		
Ownership of resources on owned or otherwise occupied lands	Art. 25, Art. 26		Art. 12*	
Prior informed consent to genetic resources or knowledge	Art. 19, Art.32.2	Art. 19.2		
Access and benefit sharing of genetic resources	Art.28	Art. 1, Art. 15 Art. 19.3		
Patents				s. 5
Access to traditional knowledge		Art. 17.2		

* This article explicitly seeks to dissuade adoptees from claiming intellectual property rights as the overall aim of the treaty is to facilitate access to genetic resources (a list of important crops) for food and agriculture.

Related and support institutions with capacity to contribute the ABS and DSI debate are depicted below (Figure 2). Here, the four most prevalent spheres, Business/Economic, Environmental, Intellectual Property and Societal are proposed and populated with international institutions in accordance to their main objective. Solid blue lines depict direct dependencies, whereas the black dotted lines depict a common objective or lesser relation. 'Floating' intuitions that have almost no relation with other institutions but have interest and capacity to contribute to the DSI-ABS governance debate, have been situated as well. Overall, one can visibly see the potential for governance congestion.

Figure 2: Institutions with relevance in the ABS and DSI debate



3.6 MULTI-LEVEL/NETWORK GOVERNANCE

Political complexity poses further challenges to any proposed international DSI governance mechanism. In Western democracies, diffused decision-making and policy implementation is the modern political reality in respect to most important issues. Hooghe and Marks (2003) note that scholars in different disciplines have described this phenomenon as 'multi-level,' 'networked,' 'multilateral,' 'global' or 'polycentric' governance. Moreover, design of these multi-level governance systems is seldom deliberate and most often, accidental or even uncontrollable. Internationally, "multi-level governance has come to be seen as a much broader trend, one which includes the upward diffusion of power to regional and international organizations as well as the downward diffusion of power to various sub-national governments" (Harmes 2006: 725-726). This process of diffusion is not just vertical or jurisdictional. Negotiations are becoming non-hierarchical between institutions (Peters and Pierre 2001), as non-governmental actors have taken up crucial roles in new systems of governance (Rosenau and Czempiel 1992).

The challenges of multi-level governance have been discussed in the context of plant genetic resources generally (Raustiala and Victor 2004), and more recently in the context of specific agricultural products like biofuels (de Beer 2011). But the phenomenon of multi-level governance has not yet been discussed thoroughly in respect of DSI; work to this point has mainly addressed international institutions separately. However, the rising density of international institutions makes it increasingly difficult to isolate the implications of decisions reached in any one forum. In the international arena, decisions reached in one forum, for example, do not automatically extend to, or clearly undermine, agreements developed in other forums (Raustiala and Victor 2004).

As novel biological technologies diminish their reliance on genetic material and move towards the intangible (information), already limited policy analysis tools are likely to have difficulty in explaining this developing field's implications. Any proposed way forward will have to be accommodated into an already complex and overlapping ensemble of established legal norms, frameworks, directives and policies (both domestic and international). Note: The complete name for each of the institutions above can be found in Appendix 1.

4.0 DIGITAL SEQUENCE INFORMATION GOVERNANCE: NOTES ON MOVING FORWARD

Key aspects of international DSI governance need to be agreed upon by governments. Each aspect is the embodied interest of a distinct mix of private and public sectors, who in turn are comprised of groups with distinct values and divergent political and economic interests. Moreover, governments and actors have divergent institutional and human capital capacities, and thus are unlikely to perceive DSI in the same fashion. Therefore, we should not expect decisions on DSI governance in the international arena to be a function of globally averaged values and divergent political and economic interests. History of first generation biotechnology shows that countries are likely to undertake their own analyses and arrive at their own conclusions regarding novel biological technologies (Falck-Zepeda et al. 2016). The results of these analyses are likely to be ranked and 'fitted' to current biotechnological regulatory regimes and become a component (subset) of a bigger decision process. Thus, contemplating the vast array of distinct values and divergent political and economic interests is important when proposing a way forward on this issue, but it is highly unlikely that any operational international governance framework will be capable of addressing all of them.

Nevertheless, 'analysis-paralysis' is not a recommended course of action. Though the simplest option is to promulgate the status quo, this may be increasingly detrimental to some (such as owners of GRAATK) and could lead to the overall underutilization of genetic resources. That is because in the absence of a clear and transparent way forward, firms may be reluctant to invest in DSI-dependent technologies leading to a sub-optimal outcome regarding this issue. As DSI is already eroding existing ABS mechanisms and norms (Welch et al. 2017), at the very least, an exploration of potential options on how to tackle this issue is warranted.

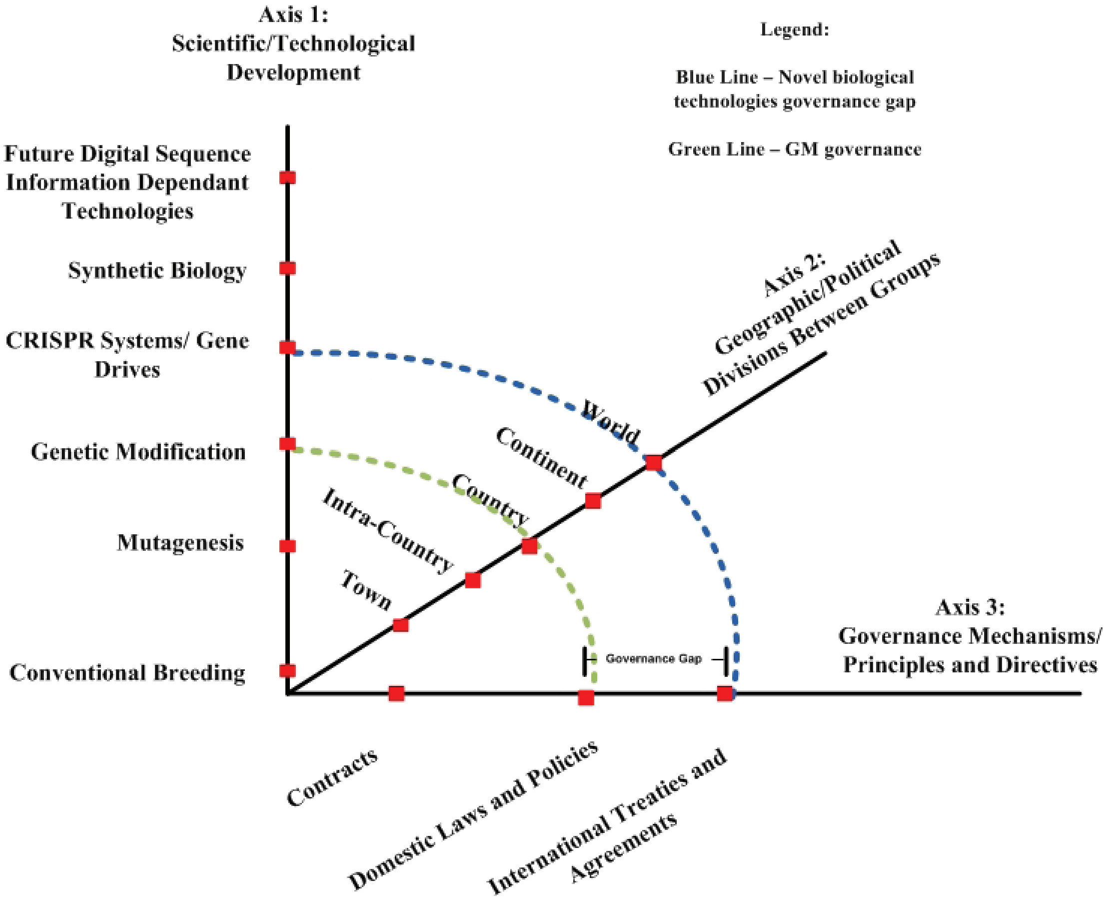
An initial approach to international DSI governance is to situate this technological development within axes whose dependent variables are relevant to first-generation biotechnology, as this would allow us to build off of what is already known (Figure 3). Conceptually, DSI can be situated within the ambit of existing legal norms and instruments whose limitations and domains have, to the extent possible, already been articulated. This will enable all relevant stakeholders to identify which aspects of DSI are governable given existing legal norms and which aspects require new, innovative policy solutions.

Thus far, governance mechanisms have been appropriately refined to accommodate novel biological technologies up to and including, genetic modification. These technologies can be situated within three collectively dependent axes: (1) Scientific/Technological Development Relevant to Biology; (2) Geographical/Political Divisions Between Groups; and (3) Governance Mechanisms, Principles and Directives. The variables (domains) that constitute these axes are known and serve as the legal, technical and economic underpinnings used to govern biologically-based technologies.

Axis 1 in Fig 2 depicts current plant breeding technologies and disciplines that sustained life science research has yielded. For most if not all of these technologies and disciplines, governance instruments have been adequately refined both to protect IP and foster ABS, using a mix of contracts, domestic laws and policies and international treaties and agreements (Axis 3). Depending on the balance of IP and ABS, these instruments have worked at the local to global level (Axis 2). When combined, the axes of the conceptual model produce a three-dimensional space in which the governance mechanisms of biologically-based technologies reside. The closer to the origin of this three-dimensional space a technology is situated (conventional breeding, using commercial contracts and located in individual communities, such as towns), the more effective existing governance mechanisms are in both protecting IP and fostering ABS. Conceptually, this is depicted with dotted lines. Individually, the salience of each axis is evident. By combining these axes, we hope to show where, and what, innovative governance mechanisms are needed.

The governance of genetic modification began in the late 1980s and over the proceeding 30 years, a governance capacity was developed for these technologies. While regulation of GM technologies exists at the domestic level there is scant governance capacity beyond this jurisdiction (green dotted line). The potential to govern DSI exists beyond the frontier of GM governance. The distance between these two governance frontiers at all three axes, identifies the governance gap that exists along each of the three axis. From a technological perspective, genome editing and gene drives are a significant advance as identified along Axis 1. On Axis 2, the gap illustrates that these technologies are being regulated at domestic levels, but there is a gap due to the lack of continental or international governance agreements (blue dotted line). Similarly, along Axis 3, there are no international agreements in place that provide any governance capacity, capability or guidance for DSI.

Figure 3: Three-dimensional International Digital Sequence Information Governance Framework



The convergence of the life sciences with engineering and computer science will continue yielding novel technologies with great transformative capacities. Existing governance mechanisms will need to be revised sooner, rather than later. However, it is far from clear what international institution will lead the way, or be the first to set precedent. Regarding DSI and crop/plant breeding concretely, though the topic is beginning to be discussed in relevant international forums, and various agreements and institutions have relevance and the ability to contribute to its governance, at this point it is an educated guess to speculate what will happen. In the following section, the authors present the result of such an exercise.

> The convergence of the life sciences with engineering and computer science will continue yielding novel technologies with great transformative capacities. Existing governance mechanisms will need to be revised sooner, rather than later.

5.0 POTENTIAL SCENARIOS

International governance of DSI is spread over various agreements and institutions, resulting in international governance gaps. The private ordering of knowledge and changing physical structures as the world moves from physical property sharing to online public DSI knowledge sharing, poses challenges for knowledge mobilization. Much, if not all, of the international governance network in existence, is designed to deal with the sharing of resources, applicability of traditional knowledge and appropriate access and benefits sharing. Online digital publicly accessible resources represent a transformative technological shift, resulting in governance gaps. If physical access no longer matters, what benefits can be, or should be, expected to be shared?

The governance of ABS as it relates to DSI, is not a material governance conundrum, but an informational governance challenge. Online digital repositories of genomic sequence information, for example, are an intangible public or common pool good that lack international governance. Given the current governance environment and the contemporary discussions on the subject, should nothing truly revolutionary occur, we anticipate that there are four options for moving forward.

First, given the lack of governance capacity in this space, an existing international institution could 'move into' this space and claim governance. The practical feasibility of this may be limited, given that WIPO has invested efforts for close to 20 years to reach a definition for a genetic resource, without success. For an international institution to 'move into' this space, would require a substantial investment in terms of time and resources, with a less than optimal likelihood of success. This is not to suggest that the premise of doing so is unwise, rather such a move would require considerable deliberation, with a clear vision of the process required to move forward. Institutions that require consensus, may be most restricted in their ability to move successfully into this governance gap, allowing those that govern by judgement (such as the WTO's Dispute Settlement Mechanism) or by majority opinion to be better situated for such a move.

Second, this governance gap could be viewed as a 'greenfield' space, whereby an entirely new organization, institution or convention is discussed, negotiated, agreed to and ratified. Again, citing WIPO's near two decades of effort to satisfactorily define genetic resource, suggests this approach may be problematic. The Doha Round of WTO trade negotiations, which began in 2001 and continue today, exemplify the risk of consensus-based organizations getting bogged down in indecision and conflict. Given the sensitivities of ABS and the connectivity to TK, we are hard pressed to see this approach providing a rapid resolution to the DSI governance gap.

Third, collaboration through existing mechanisms could be employed to reach consensus more rapidly than searching for a greenfield solution. The international governance architecture has grown increasingly complex over recent decades and one approach to resolving the consensus requirement of a new agreement would be for existing organizations to agree upon a new governance mechanism, whereby all signatories to the principal organizations involved would be signatories to the new mechanism. For example, a country joining the WTO agrees to comply with the SPS, TBT and TRIPS agreements, and the commitments are mutually reinforcing. The amount of effort invested by the FAO, WIPO and the CBD in the space already, suggests these three may be best positioned to collaboratively address the governance gap.

Fourth and perhaps the simplest or most desirable/realistic option, is to let the status quo exist. This is a complex topic, where the path forward is far from clear, even more so following The Court of Justice of the European Union ruling on genome editing mutagenesis technology. This option allows a developer, either public or private, to engage in a one-off research contract with the owners of genetic resources. This should not be treated as an expectation of DSI utilization, given the public good, open access nature of DSI.

Improved food security may be the benefit that is widely shared.

As innovations transition the world away from TK and physical resource access to DSI, gaps in the existing governance network are created by the disembodiment of property and knowledge. The potential for benefit sharing is eroded by not moving forward. However, moving forward requires compromise and the acceptance of new protocols. As knowledge is increasingly digitized in the plant world, physical access continually becomes less of an issue, creating a governance quandary for ABS. Realistically, a global solution to this governance gap is unlikely in the short-term (the next decade) and the speed at which science moves, may mitigate this as an issue as innovative means of benefits sharing are identified. Improved food security may be the benefit that is widely shared.

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APPENDIX 1

Business/Economic Abbreviations

IPPC: International Plant Protection Convention
ISO: International Organization for Standardization
OECD: Organisation for Economic Co-operation and Development
OIE: World Organization for Animal Health
SPS: Sanitary and Phytosanitary measures
TBT: Technical Barriers to Trade
WTO: World Trade Agreement

Environmental Abbreviations:

BONN: Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization
CBD: Convention on Biological Diversity
CPB: Cartagena Protocol on Biosafety to the Convention on Biological Diversity
NP: Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS) to the Convention on Biological Diversity

Intellectual Property:

TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights
UPOV: International Union for the Protection of New Varieties of Plants
WIPO: World Intellectual Property Organization

Societal Abbreviations:

CGIAR: Consultative Group for International Agricultural Research

CODEX: Codex Alimentarius
DivSeek: Community driven effort to unlock crop diversity
FAO: Food and Agriculture Organization of the United Nations
GCDT: Global Crop Diversity Trust
ILO: International Labour Organization
ITPGRFA: International Treaty on Plant Genetic Resources for Food and Agriculture
UN: United Nations
UNDRIP: United Nations Declaration on the Rights of Indigenous Peoples
UNESCO: United Nations Educational, Scientific and Cultural Organization
Plants
WHO: World Health Organization

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