

International agreements may impact genomic technologies

Modern plant biology relies heavily on genetic sequence information from species with a diversity of origins. Could proposed changes to the terms of use of this digital sequence information threaten the development of new crop varieties and improvements in global agriculture?

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Plant genomic technologies, including gene editing and synthetic biology, make it possible to understand, change and create plant traits in a manner that is beneficial for food security. Realizing the promise of these technologies depends, at least in part, on access to (and use of) digital sequence information from a rich diversity of plant varieties^{1,2}. There is an intense debate in the international community about appropriate terms of access and use of digital sequence information derived from plant materials for developing new varieties. At present, much digital sequence information is freely available, however, there is a push to subject it to the terms of access and benefit-sharing that are applicable to physical plant resources at present. It is critical for those utilizing plant genomic technologies to be aware of and engage in these debates, and to comply with potentially shifting requirements. A failure to do so risks reputational harm as well as potential opposition to any new varieties developed.

Agreements address physical resources

Access and benefit-sharing of physical plant genetic resources are governed variously by the 1993 Convention on Biological Diversity (the Convention)³, the related 2014 Nagoya Protocol⁴ to the Convention and the 2004 International Treaty for Plant Genetic Resources in Food and Agriculture (the Plant Treaty)⁵. Among other things, these agreements obligate a user of physical genetic resources to share certain defined benefits, including monetary payments, that are derived from access and use. As drafted, these international regimes tie access and benefit-sharing obligations to the use of physical genetic resources and do not address digital sequence information⁶, which the Convention defines collectively as “genomics and related information that can be derived from physical genetic materials”³.

The Convention is the lynchpin of the international system for establishing access and benefit-sharing for genetic resources.

It came into effect in 1993 as a part of an effort to counter the privatization of biological resources that resulted from the advent of biotechnology and the increased availability of proprietary protections for living organisms⁷. Under the Convention, anyone wishing to obtain genetic resources from their country of origin must obtain prior informed consent from the relevant authorities and establish mutually agreed terms for sharing “benefits arising from the utilization of [those] genetic resources”. In this context, parties to the Convention can pass national laws and set their own terms for access to and use of genetic materials. Those seeking genetic materials must be aware of these national laws to ensure compliance.

The Convention was amended by the Nagoya Protocol, which is intended, in part, to clarify the utilization trigger in the Convention so that parties are aware of the activities that trigger benefit-sharing obligations. The Nagoya Protocol outlines the arrays of benefits that can satisfy this obligation. The terms of the Convention and the Nagoya Protocol apply to access and use of all genetic resources held by signatory countries, except those “plant genetic resources for food and agriculture” that are instead subject to the Plant Treaty.

The Plant Treaty carves out facilitated access to a set of 64 crops from the Convention, in recognition that ready access to these plant genetic resources is critically important for food security. This facilitated access makes the plant genetic resources subject to the Plant Treaty available to any party under a non-negotiable Standard Material Transfer Agreement in exchange for specified benefit-sharing. Under the terms of the Plant Treaty, countries accept that they cannot apply additional terms to the transfer of such material. Notably, facilitated access applies only to the 64 identified crops for use in research, breeding and training for food and agriculture. Access to, and use of, genetic resources from plants not included on the list, or use of the

64 crops on the list for other purposes, remain instead subject to the Convention/Nagoya Protocol and mutually agreed terms with a country of origin.

Unclear status of sequence information

Both the Convention/Nagoya Protocol and the Plant Treaty tie benefit-sharing to physical resources, and not to the use of digital sequence information. To this end, the Convention and the Nagoya Protocol require benefit-sharing where there is “utilization of genetic resources”, while the Plant Treaty ties benefit-sharing to “use of plant genetic resources for food and agriculture”. Both the Convention and the Plant Treaty define genetic resources as “genetic material of actual or potential value”. Genetic material, is, in the case of the Convention, “any material of plant, animal, microbial or other origin containing functional units of heredity” and in the Plant Treaty, simply “any material of plant origin containing functional units of heredity”. Neither agreement defines functional units of heredity, however, the term is presumed to refer to genes and DNA⁸. It could be argued that the use of the word ‘containing’ in the definition of genetic material indicates that these functional units of heredity are not themselves included in the definition of genetic material.

The Nagoya Protocol was intended to clarify activities that trigger benefit-sharing under the Convention, among other goals. To do so, it offers a definition of the utilization of genetic resources that is complex, and incorporates the terms ‘biotechnology’ and ‘derivative’, from the Convention. Thus, according to the Nagoya Protocol:

- Utilization of genetic resources means “research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology”
- Biotechnology comprises “any technological application that uses bio-

logical systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use”

- Derivative refers to “a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity”

The net result is that benefit-sharing obligations are triggered by any technological application that uses a naturally occurring biochemical compound such as “aromas, biochemicals in cells, resins, and snake venoms” obtained from accessed genetic resources. There is no indication that this definition was intended to include digital sequence information⁹.

The Convention, Nagoya Protocol and Plant Treaty together set the international standards for access and benefit-sharing for plant genetic resources but not all countries are parties to all of these agreements. The United States only recently became a party to the Plant Treaty¹⁰, and has not ratified the Convention or the Nagoya Protocol; conversely, China is a party to the Convention and the Nagoya Protocol but not the Plant Treaty. Materials accessed from non-party countries are de facto not subject to access and benefit-sharing obligations, although there may again be national laws that apply.

Lack of obligations raises tensions

At present — and except where national laws dictate otherwise — it is possible to access and use digital sequence information from plants that are subject to the Convention, the Nagoya Protocol and the Plant Treaty without triggering benefit-sharing obligations.

This lack of benefit-sharing is unsatisfactory to many countries and groups, and has become deeply controversial. There is a sense that the open availability of digital sequence information undermines the quid pro quo of access and benefit-sharing provisions that were carefully negotiated in the Convention, the Nagoya Protocol and the Plant Treaty. Critics see the use of digital sequence information as a way to do away with the need for plant genetic resources, and to allow for commercialization without benefit-sharing. In this sense, plant genomic technologies seem to exacerbate the divide between developing, biodiversity-rich countries and the developed world that has access to technological tools¹¹.

The practice of generating and using digital sequence information has already been branded ‘digital biopiracy’ and individuals and organizations involved

in research and development are being targeted as bad actors by civil society organizations^{12–14}. This development has come as a surprise to many in the plant genomics research community, who are motivated by a desire to make the benefits of digital sequence information available to all with a goal of enhancing food security.

Wide discussions over sequence data

The impact of digital sequence information for the Plant Treaty permeated discussions at the recent Governing Body meeting held in Rwanda in October–November 2017. Participants’ opinions diverged over whether the utilization of such information should trigger benefit-sharing and the net result for the Plant Treaty if it did not¹⁵. The challenge posed by digital sequence information also informs efforts underway to revise the Plant Treaty Standard Material Transfer Agreement. Proposed revisions would require payment to the benefit-sharing fund for access to plant genetic resources, rather than based on ultimate utilization. To some degree, such a change would resolve the issue of tracking the use of digital sequence information derived from plant genetic materials. Ultimately, and reflecting the significance of the challenge, the parties agreed to include a focus on “the potential implications of the use of ‘digital sequence information’ on genetic resources for the objectives” of the Plant Treaty at the next Governing Body meeting in 2019, and in the meantime to solicit input from “contracting Parties, other governments, relevant stakeholders and individuals with relevant expertise”¹⁶.

Parties to the Convention and the Nagoya Protocol have similarly launched a process for considering the implications of digital sequence information¹⁷. At the 2016 Conference of the Parties (COP13), the Convention established an Ad Hoc Technical Expert Group, which has now received comments from interested parties, including those using plant genomic technologies¹⁸. The Expert Group will report to the Convention’s Subsidiary Body on Scientific, Technical and Technological Advice, which will then issue a recommendation for the next Conference of the Parties in November 2018.

In the absence of collective action, individual countries have already begun implementing their own rules for the use of digital sequence information, as permitted by the Convention and the Nagoya Protocol. For example, Brazil now requires parties seeking access to genetic resources to share benefits arising from the utilization of digital sequence information¹⁹. The existence of country regimes means that tracking use is already obligatory in certain circumstances.

The role of digital sequence information is also being productively addressed in other contexts, including the World Health Organisation’s PIP Framework. The PIP Framework, which was developed to ensure access and benefit-sharing of pandemic influenza viruses, has undertaken a process to ensure that genetic sequence data associated with these viruses are subject to the same obligations. It is considering both ‘upstream’ obligations and a ‘downstream’ track-and-trace system to monitor compliance²⁰. It is possible that these efforts will inform the activities of the Convention and the Plant Treaty.

Potential shifts of compliance landscape

Given this current activity, the terms for access and use of digital sequence information may change. Compliance for those using plant genomic technologies could be complex if the Convention and the Plant Treaty decide to apply existing benefit-sharing regimes to the use of digital sequence information. A genomics researcher may sequence all or part of hundreds of plant genetic resource samples, coming from multiple sources, in an effort to understand one or more plant traits of interest²¹. This process yields massive quantities of data, which may then be reviewed and analysed to identify patterns and differences of interest. Practically speaking, it is extremely labour intensive to track the nature and scope of utilization of this information from individual materials in any final product, particularly if individual genetic resources are subject to different benefit-sharing obligations¹⁰. There is anecdotal evidence that some in research and industry are already avoiding the use of certain plant genetic resources to avoid the potential of having to engage in this tracking.

At the same time, non-compliance raises significant reputational risks. There is a clear willingness to call out individual researchers and entities for biopiracy, and to publicly question the intentions of those using plant genomic technologies, including gene editing and synthetic biology. It is possible that such efforts could affect the acceptance of products arising from plant genomic technologies, in a manner akin to the response to genetically modified organisms. Civil society opposed genetically modified organisms at least in part because of a perception that applicable biosafety regulations did not adequately address public concerns²². It is similarly possible that concerns about benefit-sharing in the context of the Convention, the Nagoya Protocol and the Plant Treaty may strengthen public opposition to use of genomic technologies.

The next few years will be important for determining the role of digital sequence information in benefit-sharing regimes. Parties to the Convention, the Nagoya Protocol and the Plant Treaty are focused on the issue and engaging with stakeholders. Those using plant genomic technologies should stay apprised of the discussions, participate to the appropriate degree and ensure compliance with national and international regimes as they evolve. The future of plant genomic technologies may hinge on these debates. □

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Published online: 4 January 2018

<https://doi.org/10.1038/s41477-017-0087-4>

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Acknowledgements

The author acknowledges the support of Genome Canada and Genome British Columbia. This article is for informational purposes only and does not constitute legal advice. The views expressed are the author's alone and not of Sidley Austin LLP.

Competing interests

The author declares no competing financial interests.