The International Treaty
ON PLANT GENETIC RESOURCES FOR FOOD AND AGRICULTURE

Research Study 3

Analysis of the transaction costs occurring for the user, under the SMTA of the International Treaty on Plant Genetic Resources for Food and Agriculture, and the EU Regulation on Implementation of the Nagoya Protocol

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BACKGROUND

1. The Governing Body, in Resolution 5/2013:

   "Look[ed] forward to the entry into force of the *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization* and its full implementation, in harmony with the Treaty, in the interest of the conservation and sustainable use of biodiversity;

   "Again, call[ed] on Contracting Parties to ensure that any legislative, administrative or policy measures taken for the implementation of both the Treaty and the Convention on Biological Diversity (CBD) or its Nagoya Protocol, are consistent and mutually supportive."

2. The Working Group to Enhance the Functioning of the Multilateral System of Access and Benefit-sharing, at its first session:

   "noted that the Nagoya Protocol would probably come into force in the near future and agreed that it will be crucial to continue to stress the special features of plant genetic resources for food and agriculture. In this context, the Working Group provides a unique opportunity for the Treaty community to work together to strengthen its mechanisms for access and benefit-sharing so that the key role of the Treaty in the International Regime of access and benefit-sharing is fully respected by all forums and processes."

3. The Working Group accordingly requested that the Studies take into account the interface between the Treaty and the Nagoya Protocol.

4. Discussions with members of the seed industry showed that there is much apprehension regarding the regulatory burden for the seed industry that is likely to result from legislation for the implementation of the Nagoya Protocol, at national and regional level, even for breeders who are not using any materials accessed in accordance with the provisions of the Convention on Biological Diversity. These matters were raised, in particular, in relation to the possibility of substantially reducing transaction costs for users of Article 6.11, as discussed in IT/OWG-EFMLS-1/14/3, *Background on the work undertaken by the* Ad Hoc *Advisory Committee on the Funding Strategy, and its further development*,[1] , paragraphs 84–96.

5. It is important to be clear: the perceived additional transaction costs falling upon users do not derive from the CBD itself, and few breeders and seed companies access materials under use-licenses issued within the framework of the CBD. It arises rather from the implementation of Nagoya Protocol at national level, pursuant to, in particular, Articles 15 and 16, on compliance with domestic legislation, and Article 17, on the monitoring of the utilization of genetic resources. The regulatory pressures arise when added burdens are imposed, for the sole purpose of ensuring that benefits due under CBD use-licenses are paid.

6. The Treaty and the CBD are in harmony, one with another, and Article 4.2 of the Nagoya

[1] At http://www.planttreaty.org/sites/default/files/OEWG-EFMLS_1-14-w3_en.pdf

Protocol provides that:

> "Nothing in this Protocol shall prevent the Parties from developing and implementing other relevant international agreements, including other specialized access and benefit-sharing agreements, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol".

7. Moreover, Article 8c provides that:

> "In the development and implementation of its access and benefit-sharing legislation or regulatory requirements, each Party shall:
>
> "Consider the importance of genetic resources for food and agriculture and their special role for food security."

8. Because of the apprehension of seed industry, the comparative analysis contained in this document was made of the transaction costs involved in accessing and using materials under SMTAs — including in the context of a revisited Article 6.11, and under regulations established for the implementation of the Nagoya Protocol, at national level — in the light of the possible revisiting of Articles 6.7 and 6.11 of the SMTA, as discussed in document IT/OWG-EFMLS-1/14/3. The only such implementing regulation, to date, is the *European Union Regulation on Compliance Measures for Users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union*,[2] and this was therefore taken as the model, for the analysis.

[2] At http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32014R0511.

Transaction Costs Article 6.7 and a revised Article 6.11 of the SMTA, and the EU Regulation on implementation of the Nagoya Protocol and under the SMTA[3]

Nature of costs	SMTA Art. 6.7.	SMTA Art. 6.11 (revised)	EU Regulation/Nagoya Protocol
I. PRE•CONTRACT			
(a) Identification of material and, if applicable, of traditional knowledge associated with the material • Administrative costs	• Most Treaty material is described on searchable websites • No separate identification of TK is needed (Art. 9.2 (a) of the Treaty)		• GR, described under the NP Art. 2.2 (cfr. Art. 4.4) is most often not already identified or described • Most TK (Art. 2.4) is not already identified or described, and may be held by a different person
(b) Characterization of material • Administrative costs	• Material exchanged under the Treaty is usually accompanied at least by Passport Data; morphological and agronomic data is often also available		• Unless material is obtained from a Registered Collection, characterization has to be performed by the user
(c) Establishment of contact for GR and, if applicable, for TK • Administrative costs	• Direct request to the collection containing the material of interest, easily identifiable through the Treaty website • No request for TK is needed n.a. n.a.		• The NFP and/or the NCA(s) (Art. 6), or the responsible person for a "Registered Collection" (Art. 4.7) must be identified. There may be different NCAs for GR and TK, and more than one in each case (see section V.2. of this table) • There may be several NCAs in one MS: risk of operational delay due to confusion, overlapping and the sub-division of competences; • The process of obtaining material from any country without a defined NCA risks being lengthy; there is the additional risk/cost of obtaining PIC from an authority that later turns out not to have been the appropriate one
(c) Obtaining PIC(s) • Administrative and legal costs	n.a.; The use of materials from the MLS assures Providers and Recipients of the legality of the transfer of material, and clarifies benefit-sharing obligations n.a.; The acceptance/signature of an SMTA is sufficient		• Due Diligence in obtaining GR and TK must be exercised and documented, within national Law of Provider Country (Art. 4.1) • Separate PICs for GR and TK may be required; Extra costs are likely in the case of PIC bring needed for TK, as this usually goes beyond the user's first contacts

[3] The acronyms used are listed at the end of this table.

Nature of costs	SMTA Art. 6.7.	SMTA Art. 6.11 (revised)	EU Regulation/Nagoya Protocol
II. CONTRACT			
(a) Conclusion of MAT(s) and contracts • Administrative and legal costs	• The BS provisions in the SMTA are standard, and do not require negotiation • The only decision the Recipient must make is whether to choose the Art. 6.7/6.8 or Art. 6.11 payment option, and inform the GB) • Contracts are accepted is by signature, click-wrap on line, or through shrink-wrap provisions		• Negotiation of conditions for bilateral ABS and further terms and conditions, if needed (Art. 4.2);
(b) Legal consultancy • Legal costs	n.a.		• During negotiation of case-by-case MAT provisions, the provider country's laws and regulations require substantial legal expertise.
(c) Obtaining an IRCC • Administrative costs	n.a.		• Following the completion of PIC and MAT contract(s) an IRCC must be obtained from the NCA
(d) Communication and archiving of documents • Administrative costs	n.a.; The Provider informs the GB, and has no further responsibility • The Treaty's Data Store then maintains information on SMTA, under strict confidentiality		• The IRCC must be submitted to the ABS-CHM (Art. 7) • Users will need to archive a copy for internal documentation and legal clarity • Three or more documents (PIC/MAT/IRCC for GR, and often for TK as well) must be archived for each acquisition of material
III. POST•CONTRACT **1. Administrative costs**			
(a) Record keeping and archiving of documents • Administrative costs	• All SMTAs are archived by the Secretariat of the Treaty • Records of all crosses with SMTA material must be kept • Transfers to subsequent users require issuing of SMTAs, which need to be reported to the GB	• No need to record crosses • No SMTAs nor reporting needed for transfers amongst members of the "6.11 club"; • SMTAs must be issued and reported for transfers to non-members of the "6.11 club"	• PIC and MAT or equivalent documentation, must be kept for 20 years, including all subsequent contracts, reports and other documentation

Nature of costs	SMTA Art. 6.7.	SMTA Art. 6.11 (revised)	EU Regulation/Nagoya Protocol
III. POST•CONTRACT **1. Administrative costs (continued)**			
(b) Reporting on BS • Administrative costs	• An annual report to the GB is required, if there are sales of a product incorporating SMTA material, stating the payment due, and the type of restrictions imposed on the product	• An annual report to the GB is required on sales of products belonging to the crop or crops for which a company is a "6.11 subscriber", stating the payment due and the type of restrictions imposed on the product	• At the final development stage of the product, due diligence must be demonstrated, and the necessary documentation submitted to the NFP (Art. 7.2) – see also section V.2. of this table; • Individual MAT contracts will involve different reporting obligations, deadlines, etc.
(c) Reporting to the MS and the EC, in the case of that funds are received for research • Administrative costs	n.a.		• Declaration of due diligence (Art. 4 and Art. 7.1)
(d) Compliance/ Dispute settlement	• Simple, clear dispute settlement procedures: in case of alleged or suspected non-compliance, the user will initially be approached by the Secretary of the Treaty, and if the matter is not resolved, mediation or legally binding arbitration follows		• NCAs may check possession of relevant information, on the basis of third party concerns, or a "risk-based" plan. This may involve "on the spot checks" (Art. 9.3 (b)). This could be very disruptive • The user must disclose all documentation required, give further information that may be requested by NFPs, NCAs or other persons in charge of checks

III. POST•CONTRACT **2. Legal costs**			
(a) Benefit-sharing obligations • Legal costs	• Mandatory; throughout the commercialization of a Product incorporating SMTA material Clearly set-out rules regarding non-monetary benefit-sharing: • The Recipient makes available all non-confidential information and results of research concerning the material (Art. 6.9 SMTA); • After expiry of IPR on the Product incorporating SMTA material, the Recipient is encouraged to make a sample of the Product available to the MLS (Art. 6.9 SMTA)	• Mandatory; renewable periods of 10 years	• The terms and conditions must individually stipulated in a MAT contract, and may include monetary and non-monetary benefits
(b) Applicable Law • Legal costs	Art. 7 of SMTA stipulates that the only applicable law is binding international mediation and arbitration		• The variety of applicable law implies the need to engage legal expertise with appropriate knowledge of the laws of the Provider Country or Countries, on a case-by-case basis

Nature of costs	SMTA Art. 6.7.	SMTA Art. 6.11 (revised)	EU Regulation/Nagoya Protocol
(c) Subsequent use by the same user • Administrative costs	n.a.; All research and breeding activities are allowed		• any "further use" that was not specified in the original MAT contract must be re-negotiated, with attendant legal costs
(d) Subsequent use by another user • Administrative costs	• Transfer to a subsequent user of the original "material under development" requires the issue of a SMTA, to be reported to the Treaty secretariat	• Transfers between members of the "6.11 club" require no SMTA • Transfers to non-members of "6.11 club" require an SMTA, to be reported to the Treaty Secretariat	• New PIC and MAT contracts are required • A subsequent user is bound to the terms and conditions negotiated by the previous user, which might limit subsequent research and breeding activities • The IRCC must assure due diligence and transfer all relevant documents to subsequent users (Art. 4. 3 (a) and (b))
IV. FIXED COSTS AND UNCERTAINTIES **1. Legal uncertainty**			
(a) Benefit-sharing in the case of the crossing of materials under different contracts • Administrative and legal costs	• Materials under different SMTAs may be crossed at will; the benefit-sharing obligations are on products, and do not increase no matter how many SMTA materials have been used • The crossing of materials under SMTAs with materials MAT contracts will create legal uncertainty		• The crossing of materials under SMTAs with materials MAT contracts will create legal uncertainty • The crossing of materials under different MAT contracts will create legal uncertainty, and necessitate complex renegotiation of contracts in different provider countries • This may also require the renegotiation of different PIC agreements as well, if TK is involved
(b) Enforcement in the case of the crossing of materials under different contracts • Legal costs	Materials under different SMTAs may be crossed at will; no such disputes can arise		• Compliance monitoring and dispute settlement will involve a number of provider countries, which raises questions of jurisdiction, choice of law, and the simultaneous interpretation of the provisions of a number of non-standard contracts
(c) Implications for companies operating across national boundaries • Legal costs	SMTAs are not subject to national law		• Legal uncertainties increase for companies operating across national boundaries
(d) Material of unknown/ disputed origin • Legal costs	All Treaty materials are obliged to the Treaty only, so their origin is immaterial		• Uncertainty of origin requires discontinuation of use (Art. 4 (5))

Nature of costs	SMTA Art. 6.7.	SMTA Art. 6.11 (revised)	EU Regulation/Nagoya Protocol
IV. FIXED COSTS AND UNCERTAINTIES			
2. Overheads and fixed costs			
(a) Overheads • Administrative and legal costs	The issuance of an SMTA requires minimal legal expertise	Simplification of Article 6.11 further reduces the need for legal expertise	• The complexity of working under the Nagoya Protocol will probably require the company to retain permanent legal staff, in both the provider and the user countries, and retain frequent specialised consultancies • Extra permanent administrative staff will probably be needed, included for archiving documentation
(b) Participation in a Consultation Forum • Administrative costs			Although voluntary (Art. 15), companies may need to devote considerable staff time to the forum, in order to deal with uncertainties

The current situation	Problematic aspects
V. OTHER LEGAL AND PROCEDURAL UNCERTAINTIES OF RELEVANCE TO PLANT BREEDING	
General observations: This section identifies a number of uncertainties that may discourage potential users from using materials, either with the EU Regulation itself, as the MS establish and implement their national Regulation. These uncertainties raise the risk of substantial legal and administrative costs and delays	
1. Aspects to be resolved within the EU Regulation	
Art. 5: The EC will set up and publish a Register of Collections authorized to distribute material under PIC regulations	• The identification of these Collections is up to the individual MS • The criteria for qualification as Collections are not precise • The decision and communication to the Commission depends on the individual MS, and times are unpredictable
Art. 6: The EC will publish a list of national responsible persons (National Focal Points, National Competent Authorities) in charge of implementing the NP and the EU Regulation	• The decision and communication to the Commission depends on the individual MS, and times are unpredictable
Art. 7 Monitoring Compliance on due diligence in the case of receiving research funds: • No timeframe is stipulated in the Regulation as to when the EC will establish implementing acts • The EC has yet to to define the term, " final stage of development" of a Product (Art. 7.6)	• The lack of definition of key terms such as "final stage of development" of a product will create uncertainty and delays

Art. 8 Definition of catalogue of "Best Practices": • The EC will set up the catalogue as basis of the "due diligence requirement", by which users to be able to ensure that material has been obtained in accordance with national legislation or regulations, in and avoid possible avoid non-compliance	• The uncertainty regarding due diligence measures until publication of this catalogue will hinder investment in plant breeding, if materials under the Nagoya Protocol are to be used • Uncertainty will arise from the parallel publication of two different catalogues of "Best Practices" (Art. 8.6)
Art. 9 Checks on User Compliance and Best Practice: The EC will elaborate a "risk-based periodical work plan" for controls by NCAs	• Until the risks involved are established, investment in plant breeding is unlikely, if materials under the Nagoya Protocol are to be used
Preamble: Simplified measures The EC will establish simplified measures for "due diligence" and "best practices" and in the general context, taking into account the situation of SMEs, the academic sector, genebanks, etc., with a focus on cost reduction for administrative burdens (Preamble (23), (28), (33))	• Uncertainty regarding the nature of these measures, whether or not they can effectively facilitate operations by users, and the time frame for their development, will hinder investment in plant breeding, if materials under the Nagoya Protocol are to be used
2. Aspects left to the responsibility of Member States	
Art. 5) Identification of Collections to be included in the Register of Collections • Each MS will choose the national Collections to be included in the Register • The modalities of the controls of the functioning of the collections to be included are not defined yet, nor have the "remedial measures" which MS might need to take in the event collection does not prove to meet the qualification criteria.	• The use of materials from genebanks and other *ex situ* collections is likely to stall, until the list has been established • There is uncertainty regarding the possible consequences for those users who have obtained material from a collection that fails to meet the qualification criteria (interruption of utilization and need to renegotiate PIC and MAT? cf. Art. 4.5)
Art. 6 Definition of National Competent Authorities: So far, only a few MS have established one or more National Competent Authority (communicated on the CBD website)	• Delays in designating NCA will create uncertainty, and postpone investment in plant breeding, if materials under the Nagoya Protocol are to be used
Art. 9. Checks on User Compliance: • In addition to checks by NCAs as part of a "risk-bases periodical work plan", "on the spot checks" can be carried out • NCAs or MS can take appropriate "interim measures" — re-negotiation of PIC, confiscation of illegally obtained material, interruption of research	• The uncertainties regarding "on the spot checks" and "interim measures" which may result in a lack of investment in plant breeding, if materials under the Nagoya Protocol are to be used
Art. 11 MS will publish a list of penalties for infringements of Art. 4 and 7	• It is uncertain that MS van publish lists of penalties by the target date of 15 June 2015), and, until they have, it will result in a lack of investment in plant breeding, if materials under the Nagoya Protocol are to be used

Acronyms used in this table

ABS: Access and Benefit Sharing
BS: Benefit sharing
CHM: Clearing House Mechanism
CP: Contracting Party to the Treaty
EC: European Commission
GB: Governing Body of the Treaty
GR: Genetic Resources
IRCC: Internationally Recognised Certificate of Compliance
MAT: Mutually Agreed Terms
MLS: Multilateral system of Access and Benefit-sharing
MS: Member State of the European Union
NP: Nagoya Protocol
NCA: National Competent Authority
NFP: National Focal Point
PIC: Prior Informed Consent
RC: Registered Collections
TK: Traditional Knowledge