A LEGAL PERSPECTIVE ON OPTIONS FOR THE EXCHANGE OF ANGRS INCLUDING STANDARD AND MODEL MATERIAL TRANSFER AGREEMENTS AND CLAUSES

Carlos M. Correa[1]
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Object and purpose

Material transfer agreements (MTAs) are bilateral (or plurilateral) contracts whose object characteristically includes the handing out of samples of biological materials (seeds, embryos, cells, etc.) from the supplier to the recipient party. They are commonly used whether property rights in the materials are claimed or not (e.g. materials in the public domain held in gene banks). The use of MTAs was pioneered by industry, but nowadays they are widely used by public entities and research institutions; they may adopt the form of a formally negotiated contract with the signature of contracting parties, or be contained in letters or statements accompanying a shipment of materials[2].

Although MTAs encompass, by definition, the transfer of the possession over materials from one party to another one, they may differ in respect of the purpose of the transfer. The latter may include one or more of the following:

- Biosprospecting
- Safekeeping
- Research
- Breeding
- Training
- Multiplication/production

Typical clauses

MTAs normally contain a number of specific clauses that spell out the rights and obligations of the parties and a number of 'boiler plate' clauses that are common to most private contracts. For instance, the Bonn Guidelines identified the following 'access and benefit-sharing provisions**'** in MTAS**:**

1. Description of genetic resources covered by the material transfer agreements, including accompanying information
2. Permitted uses, bearing in mind the potential uses, of the genetic resources, their products or derivatives under the material transfer agreement (e.g. research, breeding, commercialization)

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[1] Professor, University of Buenos Aires, Argentina. Special Advisor on Intellectual Property and Trade, South Centre, Geneva.

[2] See VICTOR RODRIGUEZ,FRIZO JANSSENS, KOENRAAD DEBACKERE and BART DE MOOR, 'Do material transfer agreements affect the choice of research agendas? The case of biotechnology in Belgium', *Scientometrics, Vol. 71, No. 2 (2007).*

3. Statement that any change of use would require new prior informed consent and material transfer agreement
4. Whether intellectual property rights may be sought and if so under what conditions
5. Terms of benefit-sharing arrangements, including commitment to share monetary and non-monetary benefits
6. No warranties guaranteed by provider on identity and/or quality of the provided material
7. Whether the genetic resources and/or accompanying information may be transferred to third parties and if so conditions that should apply
8. Definitions
9. Duty to minimize environmental impacts of collecting activities.

The 'boiler plate' clauses include, *inter alia*, the following:

-duration
-non-compliance
-effects of termination
-applicable law
-jurisdiction
-notifications
-signature.

Although common to most contracts, some of these clauses may be difficult to negotiate, such as the applicable law and the courts competent to settle any disputes regarding interpretation or compliance of the contract (arbitration is generally an easy way out, but it may be more costly than judicial procedures).

Typically, MTAs include restrictions regarding the type or purpose of permitted uses of the received material and regarding the dissemination of research results. Some MTAs' clauses may have significant implications regarding the direction or scope of allowed activities. For instance, restrictions on research 'imposed by providers to protect their scientific or technological lead, to slow the dissemination of undesired results, to allow time to negotiate a patent, or resolve disputes over ownership of intellectual property' may erode the research freedom of recipients[3], and consequently affect scientific and technological progress.

Standardization and model contracts or clauses

Given the specific objects and limited possible purposes of an MTA, there is some room for their standardization or for the development of model MTAs or clauses.

A 'standard' MTA would apply in all circumstances. It may contain optional clauses but, in principle, would not allow negotiating parties to introduce new provisions or change the existing ones. A standard contract may be applied when one of the parties has sufficient bargaining position to impose it on the other party, or when its use is mandated by national or international law.

[3] Id.

A ‘model’ contract provides a framework that the parties may adapt to the specific circumstances of the case. The availability of a model contract might speed up and facilitate negotiations, but would not prevent the parties from crafting and agreeing upon different terms and conditions.

‘Model clauses’ offer a still more flexible option, as parties may pick and choose those they think are appropriate and agreeable for a particular transaction.

An outstanding example of a standard MTA is the Standard Material Transfer Agreement (SMTA), adopted by the Governing Body of the International Treaty on Plant Genetic Resources for food and Agriculture to implement the rights and obligations provided under the Multilateral System created by the Treaty. Although it contains some options (e.g regarding calculation of monetary payments) it is to be entered into *as is*, without modifications or reservations. This rigidity is functional to the need of implementing the rights and obligations of providers and recipients of PGRFA consistently with the Treaty provisions.

Some institutions have also set out standard MTAs to provide materials in their possession. In the USA, for instance, the National Institutes of Health (NIH) published in 1995 the Uniform Biological Material Transfer Agreement (UBMTA).

Some model MTAs have been elaborated to facilitate negotiations and deal with the diversity of and, in some cases, uncertainty about regulations regarding prior consent and benefit sharing. For instance, the Biotechnology Industry Organization (BIO) developed *Guidelines for BIO Members Engaging in Bioprospecting* and a “Model Material Transfer Agreement” that is intended to provide

> an outline for a transfer agreement that is consistent with the best practices set forth in the Guidelines. This Model may be incorporated into a Bioprospecting Agreement; it may be the basis for an transfer agreement entered into after the completion of collection activities undertaken pursuant to a Bioprospecting Agreement; or, it may take the place [4]of a Bioprospecting Agreement when a BIO Member seeks a specific regulated genetic resource or a group of regulated genetic resources from an *ex situ* holding.

The adoption of model clauses offers a more flexible option than standard or model contracts. Notably, the recently adopted 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 (Nagoya Protocol) provides for the development of model clauses for MTAs (article 15). Such clauses could be general and apply to any type of genetic resources (cross-sectoral models), or be adapted to particular sectors of biodiversity (sectoral models).

[4] See BIOTECHNOLOGY INDUSTRY ORGANIZATION, *Suggested Model Material Transfer Agreement*, available at

Possible options for the exchange of ANGrs?

The exchange of AnGR has generally taken place under contracts subject to private law. MTAs are, hence, of particular importance for AnGRs. In this field, the physical possession of the animals or their germplasm is generally sufficient to maintain control over particular features and innovations. This is one important difference with the area of PGRFA where this is far more difficult, as seeds can be reproduced once they have disseminated, unless this possibility is limited by hybridization or other techniques.

There are a number of reasons that might suggest the convenience of standardizing MTAs for AnGrs exchange[5]. One of such reasons is the time and cost involved in negotiating bilateral agreements. This can be cumbersome, indeed, particularly for small farmers/companies, particularly in developing countries. Moreover, a fairly drafted standard MTA might contribute to protect the weaker or less experienced party in the negotiation. In this regard, it has been found that while there has been a massive exchange of AnGrs North-North, and that transfer of such resources North-South and South-South has also been important, 'movements of livestock germplasm from South to North have been rare in the past century, and in most cases the economic benefits to both North and South have been relatively small'[6]. This pattern of exchange may, however, change in the future.

A standard MTA for AnGRs exchange, if adopted, should have to include, as a minimum, provisions regarding:

a) Identification of the AnGR and associated information to be transferred;

b) Transfer conditions, including guarantees, if any;

c) Permitted and excluded uses;

d) Price and payment modalities;

d) Other modalities of benefit sharing (e.g. access to information, participation in research, etc.).

If the adoption of a standard MTA were deemed desirable, a it number of questions would arise, namely as to which institution should establish it and how to make it effectively enforceable. A standard MTA could not be binding unless its use is legally required by national laws or an international treaty.

A standard MTAs might be established at the national level. However, unless there is a strong coordination among countries and a *uniform* standard is adopted, a diversity

[5] S.J. Hiemstra, A.G. Drucker, M.W. Tvedt, N. Louwaars, J.K. Oldenbroek, K. Awgichew, S. Abegaz Kebede, P.N. Bhat & A. da Silva Mariante (2006), Exchange, Use and Conservation of Animal Genetic Resources. Policy and regulatory options,Centre for Genetic Resources, the Netherlands (CGN), Wageningen University and Research Centre, Wageningen.
[6] Id, p. 5.

of nationally mandated agreements might not facilitate but rather create obstacles to the international exchange of AnGrs. Another possible option would be the development of a binding international agreement that mandates the use of a standard MTA (as in the case of the SMTA for PGRFA).

Model MTAs or clauses thereof would be easier to develop as non-binding guidelines to facilitate the exchange of AnGrs. Given the different circumstances, type of potential parties (profit and non-profit) and different objects (blood samples, embryos, gene sequences) that MTAs may refer to, a set of model MTAs rather than a single model contract may be elaborated. The Nagoya Protocol may provide the framework for the adoption of model clauses at the national level, as contemplated in article 15 of the Protocol.