

Tools to implement the Nagoya Protocol on Access and Benefit Sharing in microbiology ABS, an intrinsic preoccupation of the World Federation for Culture Collections (WFCC)

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WFCC welcomes the Nagoya Protocol on Access and Benefit Sharing. WFCC consider that the Protocol is an opportunity to reinforce appropriate *ex situ* conservation of the microbial realm and facilitated access to key type and reference strains.

Most culture collections were started by scientific institutions or individual scientists, some of them more than 100 years ago; when stable long-term *ex situ* conservation of microbes was almost fiction. Today 586 culture collections in 68 countries are registered with the World Data Centre for Micro-organisms (WDCM) of the World Federation for Culture Collections (WFCC¹). One of the aims of the WDCM is optimal transparent dissemination of information. WFCC members contribute daily to the study, exploration and *ex situ* conservation of microbiological resources vital for humankind. WFCC is organized in a cooperative spirit, best illustrated by its program of “endangered collections” that tries to secure stock of microbial specimens doomed to be lost by lack of funding.

Since the mission of culture collections is to provide facilitated access to fit-for-use (technically and legally) characterised microbiological resources, it is not surprising that several initiatives to translate proactively the rules into practices were taken by the culture collections community. The outcomes of these various initiatives represent a set of coherent and complementary tools to implement the ABS concept. Although developed before the Nagoya Protocol they are still valid and provide relevant solutions for microbiologists. These solutions will be improved now that the Nagoya Protocol proposes a more precise legal framework for compliance.

Some contributions of the culture collections to the practical implementation of the ABS concept are:

1. The **Code of Conduct MOSAICC**² (Micro-organisms Sustainable use and Access regulation International Code of Conduct). MOSAICC recommendations facilitate access to microbial genetic resources (MGRs) and help partners to make appropriate agreements when transferring MGRs, in the framework of the Convention on Biological Diversity (CBD) and other applicable rules of international and national laws. MOSAICC is a tool to support the implementation of the CBD at the microbial level; it can also serve as a model when dealing with genetic resources other than MGRs.

2. The **Material Transfer Agreement (MTA)**³. MTA is a generic term that includes very short shipment document, simple delivery notice, standard invoice containing minimal standard requirements, or more detailed specific contract including tailor-made mutually agreed terms. All these documents can be designated as MTA as long as they contain at least:

- information about the *in situ* origin or the source of the microbiological material;
- information about provider and recipient;
- mutually agreed terms for the access to and the transfer of MGRs, the access to and the transfer of technology, the fair and equitable sharing of the benefits as well as for technical and scientific co-operation.

According to the use and intended distribution of the MGRs, mutually agreed terms can be either very short or very detailed. It is also advisable to strive towards the development of sector-based Standard MTA (sMTA) such as the one designed for the International Treaty for Plant Genetic resources for Food and Agriculture (ITPGR). sMTA adapted to the bilateral framework of the Nagoya Protocol can be inspired by the ITPGR sMTA which is used in a multilateral system. The European Culture Collections Organisation (ECCO) is striving towards such a model MTA with a standard core completed with facultative provisions. Such regional model MTA can foster the exchanges of microbial material in a uniform legal system.

3. Besides facilitating access to microbiological resources through uniform access and distribution rules, it is also necessary to ease their sound utilization. The mere static concept of ownership must be adapted to the requirements of the Nagoya Protocol. Full private ownership implies exclusive property and the right to sell or lease this exclusive property and all the other rights. However, this concept applies poorly to biological resources when the same material is held by different stakeholders (collectors, isolators, institutes, research groups, etc.). In general, innovation in life sciences is characterized by a diffuse process of “exploration” of microbiological resources. Forms of non-exclusive property, such as the sharing of resources among public and private research institutions or collaborative databases are thus common in the intermediary stages of the innovation process. There is thus a need for flexible property rights management tools.

The innovative concept of “**bundle of rights**”⁴ is rooted in intellectual property rights but scales the implementation of IPR according to the stakeholders’ socio-economic needs and goals. It can also take into consideration the role of traditional knowledge. This dynamic model of ownership management moves away from the static concept of ownership towards a flexible allotment of rights. Ownership constitutes a “bundle” of use and decision rights that are attributed to a number of stakeholders / economic agents. It is a set of operational and collective choice rights defining respectively who decides upon the use that one can make of a resource, and who decides upon the future exercise of the rights on the resource. Such scheme allows multi-ownership of a gradual level of use and decision rights. These rights can begin with basic access rights, encompassing research delivering outputs to the public domain, distribution on to third parties, exploitation rights to develop intellectual property and its ownership which may include reach through rights. Furthermore, the application of the “bundle of rights” makes possible the enforcement of the “sovereign rights of States over their natural resources” without prejudice to private rights. Unambiguous allotment of rights in advance will facilitate rightful benefit sharing “along the chain of use”.

4. The WFCC has developed a pioneering database system in the **World Data Centre for Micro-organisms**⁵ by registering the culture collections through a unique acronym and numerical identifier in its official list and urging them to catalogue their microbiological resources. The culture collection acronym and its unique number facilitate access to data in multiple sources: scientific, technical, administrative, etc., for any kind of use: research, conveyance, resources conservation, etc. In effect once an organism is deposited in a WFCC member collection and assigned a number it can be traced right through all publications it is mentioned in, including patent files. Combining the WDCM registration system of culture collections and the use of more recent technology of electronic markers called “**Globally Unique Identifiers (GUIDs)**”, it is possible to set up a robust system to organise transfers of (micro)biological items, tracking the flow of resources and related information. This system⁶ also facilitates the application of ABS since it can potentially retrieve all kinds of information about microbiological resources, including information related to the location and movements of the resource.
5. Almost all BRC's keep track of the history of their resources, from the point of deposit, back to the initial point of isolation. This linear information however, only gives a fragmented view on the complete path the strains have followed. The **StrainInfo.net**⁷ envisions the establishment of a technology platform that works towards the use of multi-perspective integrated information in a broadened context. At the heart of this portal lays an Integrated Strain database, a curated central repository that provides a complete and correct view on the synonymous labels assigned to biological specimen during their lifetime. This data repository is constructed automatically through the seamless integration of label equivalence information as it is disseminated through the online catalogues of CC and BRC's. The Straininfo.net portal acts as an information broker between all online catalogue entries of the BRCs that have a given strain in their holdings; it extracts all history information of a strain as it is fragmentarily recorded over all these data sources. The StrainInfo.net portal adds to the commonly used strain numbers a more persistent identifier; in order to incorporate it within a larger namespace that provides extended unicity. As a result of incorporating the unique identifiers maintained by the StrainInfo.net portal within well-established global network identification infrastructures, the flexibility and interoperability of the identifier will no longer be related to its use to indicate biological resources but can possibly be linked to additional services that work completely independent of the StrainInfo.net system.
6. Common rules of access to MGRs and related data can be part of a process to reconstruct “commons” in microbial data, information and material. That is to establish “**microbial commons**” for the exchange of (micro) biological material which would provide basic common use principles for access to both material and information. This development will be complementary to the national regulations on ABS and to existing IPR laws, as it will constitute a demarcated space where material and information are relatively freely accessible provided that the outputs are returned to this open space, to be shared again. Inside this space access and benefit-sharing are “commonly shared”. Outside this demarcated space, access and benefit-sharing will be governed by ordinary national and international laws, including IPR and specific Nagoya Protocol inspired regulations. The WFCC supports similar views on such “microbial commons”. Considering that fair and equitable benefit sharing depends upon

the usage and activities undertaken with the resource, the benefits for most research and education activities should extend to depositing in collections, publication of associated data including experimental results, and making both material and associated information widely and easily available to stakeholders including the (source) country of origin. If the MGRs are made available with the purpose of commercial exploitation then other ways of sharing could apply such as access, milestone and royalty/license payments, or mechanisms such as IPR related patent and royalties could be activated.

7. Having organized the legal framework and the technical issues paves the way to benefit sharing but ultimately, to reach a fair deal requires reliable figures. One cannot reach a quantitative deal without having a good estimation of the socio-economic, ecological and scientific **value of the microbiological resource** that is “traded”. The WFCC has participated in the MOSAICS⁸ project which advises further work on appropriate methods to appraise the multiple values of microbiological resources, in such a way that these can be translated in economic terms. Methods to value ecological items such as ecosystems exist but at present there is no reliable way to value biological items as such. In the case of micro-organisms, the inherent value is not easily defined. In many cases, there is no identifiable inherent value in the microbe until a lot of scientific work has been done to investigate the metabolic pathways of the organism and determine if it has any unique feature. More specific economic studies on test cases are necessary to adapt existing methods or develop new ones to appraise the value of microbiological items and express it in monetary terms. Such studies could conciliate the economic and the ecological aspects

The mechanism and definition of what is fair and equitable benefit sharing depends upon the usage and activities undertaken with the resource.

For most research activities, depositing in collections for distribution for research and education, publication of associated data including key elements of experimental results, giving a clear link to the source material, and making it available to stakeholders is as far as the benefits should extend for this use. The culture collection provides added benefit as the material is made available back to the (source) country of origin. Supply fees for biological resources for use in research would not be considered a benefit to share as such fees are essential to ensure the collections sustainability and therefore the continued availability of the deposited resources. The supply fee covers only part of the long-term storage and delivery of materials.

However, if the resources are made available with the purpose of commercial exploitation then access, milestone and royalty/license payments may be required. Currently, the levels of these are set by imperfect market forces. They could be preset for a consortium of supply collections at a level that respects the input value of the materials and that satisfies the principles of the Nagoya Protocol. Another option may be that benefit sharing is triggered by end use; for example a link to patents can be made when the link is retained via the original WDCM unique identifier for deposits made as part of the patent process. Not all research and development work will result in patents but if citing the WDCM number is part of the process the link to source country is made.

To achieve a balanced implementation of the Access and Benefit Sharing concept, from a practical perspective, taking into consideration the technical developments, the World Federation for Culture Collections pleads for the development of a simple, cost effective and efficient multi-purpose conveyance system that integrates tracking the biological material as well as collecting, managing, and exploiting related information.

The implementation of the concept of “bundle of rights” to allot the right and duties to entitled stakeholders, the use of Global Unique Identifiers to convey transfers of microbiological items combined with an appropriate valuation of the microbiological items make it possible for fair and equitable transaction embedded in MTA between provider and users of microbiological items. Building on decades of WFCC efforts in cooperative networking and pioneer work in IT, these new tools are the latest contribution of the culture collections to facilitate access to genetic resources.

However, it remains the responsibility of all stakeholders, including lawmakers, to make the system work and secure access to genetic resources enabling fair benefit-sharing whilst facilitating the objectives of the CBD and the Nagoya Protocol.

¹ Visit <http://www.wfcc.info>

² See <http://bccm.belspo.be/projects/mosaicc/index.php>

³ See recommendations about MTA in MOSAICC at <http://bccm.belspo.be/projects/mosaicc/d/code2009.pdf> and the core MTA model issued by the European Culture Collection Organisation at <http://www.eccosite.org/>

⁴ Dedeurwaerdere Tom. Understanding ownership in the knowledge economy: the concept of the bundle of rights. BCCM News Edition 18 - Autumn 2005. See <http://bccm.belspo.be/newsletter/18-05/bccm03.htm>

⁵ See <http://www.wdcm.org>

⁶ See http://bccm.belspo.be/projects/mosaics/reports/files/ics_report.pdf

⁷ See <http://www.straininfo.net>

⁸ See <http://bccm.belspo.be/projects/mosaics/>