

# HOW WILL THE NAGOYA PROTOCOL AFFECT OUR DAILY WORK?



The Nagoya Protocol<sup>1</sup> on “Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization” came into effect on 12 October 2014 and the implications of this need to be appreciated by all mycologists involved in the collection and maintenance of fungal material. This is the legally binding instrument for implementation at the national level of the Convention of Biological Diversity (CBD) of 1992, which entered into force on 29 December 1993. The CBD has three objectives: (1) the conservation of biological diversity; (2) the sustainable use of its components; and (3) the fair and equitable sharing of benefits arising from its utilization. A basic principle of the CBD is that it recognizes the sovereign rights of countries over their own biological resources and the so-called ‘genetic resources’ contained therein.

Access to genetic resources in a country that is Party to the CBD (i.e. one that has signed and ratified the CBD) requires Prior Informed Consent (PIC) from the competent authority in that country and settling on Mutually Agreed

Terms (MAT) between provider and user. Parties are, however, free to determine if access to genetic resources within their own territories will be subject to such requirements or not. But every Party must assure that, within its territory, genetic resources originating from other Parties are utilized in accordance with the CBD and that benefits arising from the utilization of these genetic resources or traditional knowledge associated with genetic resources are shared fairly and equitably. The genetic resources include those contained in environmental samples, living and dead biological specimens, fungarium specimens, DNA extracts, and other derivatives. The Nagoya Protocol was adopted by the 10th Conference of the Parties (COP10) on 29 October 2010 in Nagoya, Japan, and entered into force in 2014. The Protocol provides guidance for Parties to implement their national access and benefit sharing (ABS) legislation, and effectively achieve the third objective of the CBD.

## Implementation of Access and Benefit Sharing (ABS) legislation: the EU Regulation as an example

To govern ABS in the European Union, Regulation (EU) 511/2014<sup>2</sup> was adopted by the European Parliament and the Council on 16 April 2014. It entered into force on 9 June 2014, and applies since the

Nagoya Protocol entered into force for the Union (12 October 2014). Key Articles 4, 7 and 9 of this Regulation, however, apply from 12 October 2015. Article 4 lays down the obligations of users in the EU, such as to “exercise due diligence”, i.e. to ascertain that genetic resources (and associated traditional knowledge) utilized have been accessed in accordance with applicable ABS legislation. Further obligations include the sharing of benefits arising from the utilization of the genetic resources in agreement with MAT and in accordance with legal requirements, and to transfer and utilize genetic resources (and associated traditional knowledge) only in accordance with MAT (if required), and to seek, keep and transfer to subsequent users the internationally-recognized certificate of compliance (IRCC), information on the content of the MAT for subsequent users, etc. Furthermore, users are obliged to keep the information relevant to ABS for 20 years after the end of the period of utilization. Art. 7 of the Regulation deals with due diligence declaration requirements for users and how Member States should monitor user compliance, while Art. 9 describes how the Member States are to carry out checks on user compliance. Recipients of research funding utilizing genetic resources and users of genetic resources bringing products to the EU market will have to make due diligence declarations. Detailed procedures will be settled in the Implementing Acts which are expected to enter into force in October 2015.

The importance of biological collections for research and development is recognized by Art. 5 of the Regulation. It offers

<sup>1</sup><https://www.cbd.int/abs/>

<sup>2</sup>Regulation (EU) No511/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 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; <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32014R0511>



Dr H.-D. Shin collecting cercosporoid fungi in South Korea.

biological resource centres within the EU the possibility to apply for admittance of their collections (or part thereof) to a Register of collections. Researchers obtaining a genetic resource from a registered collection will be considered to have exercised due diligence as regards the legality of access, and thus would likely benefit from less administrative burden and more legal certainty. Whether the Register will become a success is difficult to predict. For collections to qualify for the Register they will have to invest in order to meet administrative demands, and it is uncertain if they will see any return on such investments. Registered collections could receive more requests for material, but at the same time researchers expect that the Nagoya Protocol is going to cause a reduction in their research activities on genetic resources, as collecting and sharing material will become more difficult, time-consuming, and costly. This could also result in a reduction of numbers of strains researchers will deposit in or order from the public collections.

## Scope and how research could be affected

The scope of the Nagoya Protocol is still not fully clear. It is certain that the Protocol does not affect human genetic resources and

material collected in areas beyond national jurisdiction (e.g. the high seas, Antarctica). As regards the temporal scope, at least for the European Union it has been made clear now that only material accessed in a Party to the Nagoya Protocol (i.e. collected *in situ*) after the entry into force of the Nagoya Protocol for the Union (i.e. 12 October 2014), is considered to be in scope of the Regulation. It is not unlikely that some Parties will adopt a wider temporal scope, which then may also include “new use” of materials collected earlier in the country of origin, and for example deposited in *ex situ* collections. As regards the utilization of genetic resources, the definition provided in Art. 2 of the CBD, which reads “to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology”, needs further clarification. The European Commission has explained that for research activities in order to be in scope of the Regulation 511/2014, there has to be an element of development involved (“research and development are cumulative requirements”), but what this will mean for research practices in different sectors remains obscure<sup>3</sup>. This may become clearer when the foreseen sectorial guidance is provided by the Commission based on consultations with stakeholders in these sectors.

For research involving material that is (potentially) within scope of the Nagoya Protocol, it is advisable to check whether any restrictions or requirements are applicable regarding PIC, MAT or MTA (if such is available) covering the material, or in general in national legislation of the country of origin of the material (at the time of collecting) or in the legislation of the country where the work will be conducted (at the time it is to be conducted). The same is advisable before transferring materials to third party users, as this is may be subject to restrictions or not allowed at all.

Researchers who acquire biological material for research should always ascertain that it has been accessed lawfully. Even if from the onset of a project it is clear that use will be limited to non-commercial purposes, such as phylogenetic and taxonomic research or other descriptive work, this could be important. For example, when strains are to be deposited in a public collection located in a country that is a Party, the curators will have to assess the status under Nagoya of any material offered for deposit. The curator will need at least as a minimum the following information: the geographic origin

of the strain (at least the country of origin, if applicable), the date of collecting the source samples *in situ*, and the person(s) who collected the source samples (including the legal entity on behalf of which the collecting was done). And, where such is required (for future transfers for example) by applicable ABS legislation, the depositor will have to provide all available documents relevant to ABS at the time of deposit. This is crucial for in order to provide the necessary legal certainty for both the collection preserving the strains and the users who will acquire these strains from the collection. The collection will provide these strains to third parties under the same conditions as they were received by the collection.

## Where to find information

The ABS Clearing House (ABSCH)<sup>4</sup> database has recently been set up. Here, each Party should provide information on relevant national legislation and policy measures. Parties are also committed to upload in the ABSCH any issued IRCC, i.e. the collecting permits or equivalents, information on mutually agreed terms, and checkpoint communiqués sent or received. Many country pages in the ABSCH are still empty at this time. Most of the 59 Parties to the Nagoya Protocol (there are now in total 92 signatory countries) still have to put in place national ABS legislation, and are not yet able to deal with requests for PIC. Documents which are accessible in the ABSCH are not always available in English. It may be hoped that the situation will soon improve. All Parties do provide contact information of National Focal Point staff, and these persons can be expected to answer specific questions. It should be noted that some countries have had CBD-based legislation in place since before Nagoya, under which permits are required for collecting *in situ* biological resources, as for example Brazil. Also, the export of genetic resources from the country of origin may be illegal without a proper Material Transfer Agreement (MTA).

<sup>3</sup>European Commission (2014) Questions and answers on access and benefit sharing. EC MEMO-14-411 ([http://europa.eu/rapid/press-release\\_MEMO-14-411\\_en.htm](http://europa.eu/rapid/press-release_MEMO-14-411_en.htm)). Brussels, 10 June 2014.

<sup>4</sup><https://absch.cbd.int/>

## Collections continue efforts to provide legal certainty and harmonize their practices

Since the entry into force of the CBD, microbial culture collections or “biological resource centres” have worked to reach compliance and harmonise practices. MOSAICC<sup>5</sup> developed a first voluntary code of conduct that provided a set of model clauses for PIC and MAT for providers and recipients of microbial genetic resources, and MTAs for the deposit in public collections (also referred to as material accession agreements) and supply to users. The European Culture Collection’s Organisation (ECCO)<sup>6,7</sup> developed the “ECCO-Core MTA”<sup>8</sup> in 2009. The Core MTA answered the need of collections to have a harmonized MTA that settles terms for use of supplied microbial materials, and also effectively raises awareness with the users of microbial genetic resources about their obligations under the CBD, especially with regard to benefit sharing. Now, these initiatives are being worked up to assure

compliance to the Nagoya Protocol, and the Microbial Resources Research Infrastructure (MIRRI)<sup>9</sup> is developing a best practice for ABS. By delivering transparency to users and providing countries (countries of origin of accessioned materials), public collections

aim to contribute to the enhancement of trust among the various stakeholders in the ABS arena.

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<sup>5</sup>Microorganism Sustainable use and Access regulation International Code of Conduct (<http://bcm.belspo.be/projects/mosaicc/>). A version that was updated in 2011 is provided at the BCCM website.

<sup>6</sup><http://www.eccosite.org/>

<sup>7</sup>Fritze D (2010) A common basis for facilitated legitimate exchange of biological materials, proposed by the European Culture Collections’ Organisation (ECCO). *International Journal of the Commons* 4: 507–527. URN:NBN:NL:UI:10-1-100222.

<sup>8</sup>Janssens D, Tindal B, Green P, Garay E, Fritze D, *et al.* (2009) The ECCO core Material Transfer Agreement for the supply of samples of biological material from the public collection. <http://www.eccosite.org/>.  
Art. 7 of this standard MTA states: “If the RECIPIENT desires to use the MATERIAL or MODIFICATIONS for COMMERCIAL PURPOSE(S), it is the responsibility of the RECIPIENT, in advance of such use, to negotiate in good faith the terms of any benefit sharing with the appropriate authority in the country of origin of the MATERIAL, as indicated by the COLLECTION’s documentation.”

<sup>9</sup>Microbial Resource Research Infrastructure (MIRRI) is an EU funded project (grant agreement no. 312251) that aims to build one pan-European infrastructure for microbial collections that will more effectively facilitate access to high-quality microorganisms, their derivatives and associated data and services, for research, development and applications; [www.mirri.org](http://www.mirri.org).

## IMA FUNGUS ACCEPTED BY SCOPUS

# Scopus

On 11 May 2015, we learnt that *IMA Fungus* had been accepted for inclusion in Scopus, following an evaluation by the Content Selection & Advisory Board (CSAB). In notifying us of this decision,

the following comment was made: “Excellent journal that was a clear omission from SCOPUS”. A content feed will be established, and the journal loaded as soon as the issues have been processed for indexing.

Owned by Elsevier BV, Scopus is the world’s largest abstract and citation database of peer-reviewed literature: scientific journals, books, and conference

proceedings. It now covers over 21 000 journals and 86 000 books. It consequently delivers a comprehensive overview of the world’s scientific output, and features smart tools to track, analyze, and visualize research. We therefore anticipate that this inclusion will raise the international profile and visibility of the journal, which we expect to be reflected in increased citations.

## THE “GOLDEN MYCOLOGICAL TRIANGLE” – an option to foster international collaboration in biodiversity research and applied mycology

The “Research and Innovation Staff Exchange (RISE)” scheme constitutes an element of the Marie Skłodowska-Curie Actions that are funded by the EU in the course of the Horizon 2020 programme.

This funding scheme appears especially attractive for networking between public research infrastructures, as well as between industrial companies and academic institutes.

If successful, such grants can provide the partners with ample opportunities for staff exchange. In the secondments, not only PhD students and postdoctoral researchers, but even technical and administrative staff



Partners meeting in Utrecht, April 2015: (left to right) Marc Stadler (HZI), Pedro W. Crous (CBS), Margarita Hernandez (CBS), Alejandra Giraldo (CBS), Lily Eurwilaichr (BIOTEC), Jennifer Luangsa-ard (BIOTEC), Lucile Wendt (HZI), and Jan Dijksterhuis (CBS).

can participate. Secondments for up to 12 months per person are being funded between the private and public sector in different EU member countries, as well as for international staff exchanges between public institutions (i.e. between EU and Non-EU member countries). The financial contribution by the EU covers travel costs, bench fees and management activities, but notably, not salaries. It is also not possible to arrange secondments between academic partners or between industrial partners inside the EU, and only persons that have a full time contract and have been working in the sending institution for at least six months can be considered as candidates for the secondments.

In Spring 2014, a consortium comprising the CBS-KNAW Biodiversity Centre (Utrecht, The Netherlands), the department of Microbial Drugs of the Helmholtz Centre for Infection Research (HZI, Braunschweig, Germany) and the National Center for Genetic Engineering and Biotechnology (BIOTEC, Bangkok, Thailand) decided to file a proposal under the acronym GoMyTri (Golden Mycological Triangle), which has received funding (EU-RISE Project H2020) and runs from January 2015 for four years. The project is being co-ordinated by the HZI and governed by a steering committee

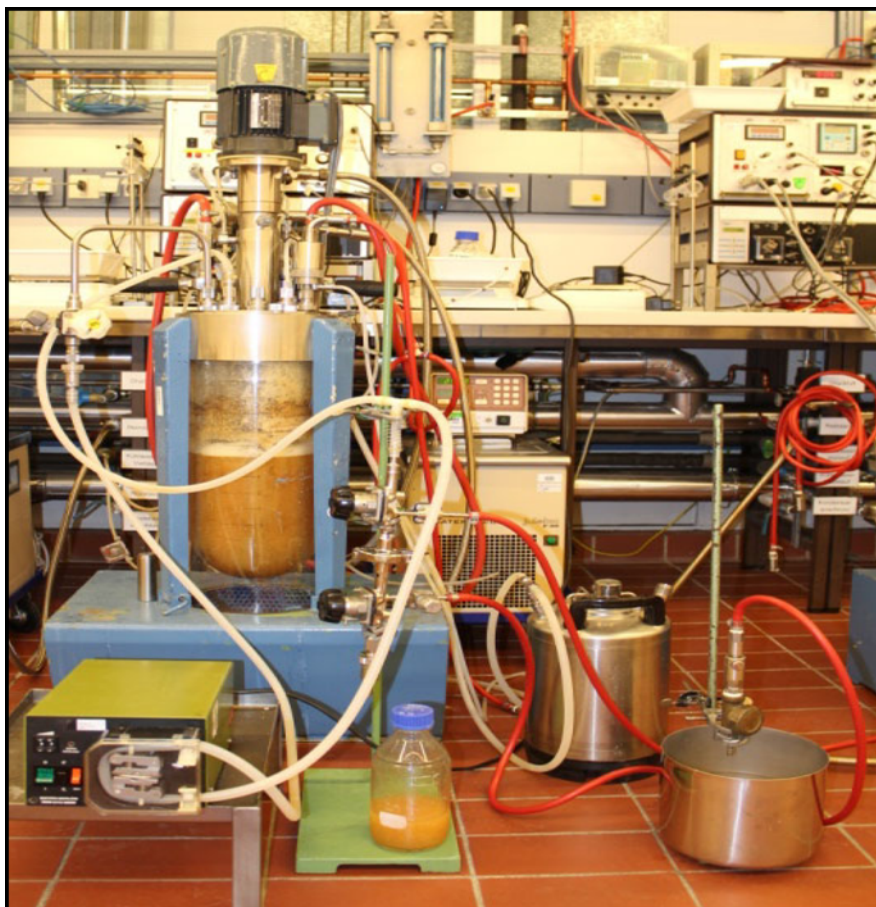
comprising representatives of all partner organisations.

The cooperation is intended to explore the mycological and microbiological biodiversity of Europe and south-east Asia, in particular with regard to the search for badly needed new antibiotics and other biologically active substances. The working plan includes activities such as the systematic exploration of fungal biodiversity by using modern molecular phylogenetic and chemotaxonomic techniques, as well as genome sequencing, in conjunction with classical microbiology. The focus of the research will be endophytes (e.g. *Botryosphaeriaceae*, *Xylariales*), invertebrate-associated ascomycetes (*Cordycipitaceae* etc.), as well as marine fungi and fungal-like organisms. In addition, some basidiomycete cultures will also be studied. The taxonomic expertise of the partners will be used to pre-select the most promising organisms. Mycologists will be trained in the core disciplines of natural product screening, such as fermentation, extraction, bioassay-guided fractionation and analytical chemistry, in the laboratories of BIOTEC and HZI. On the other hand, natural product chemists will get acquainted with field work and mycological taxonomy, and there will be ample opportunity for the participating scientists to exchange

know-how on innovative techniques for fermentation and downstream processing. The PhD students and postdocs at the partner institutes can even participate if they are funded by stipends. Therefore, a number of young scientists from all over the world, who are currently working at the partner institutes will also be able to profit from the project. For instance, two Colombian postdocs from CBS and Kenyan PhD students from HZI, will participate in the research activities with the Thai partner.

Several bureaucratic obstacles had to be overcome before the working programme could start. In particular, this concerned the implementation of the rules of the CBD/ABS and the so-called “Nagoya protocol” (see pp. (3)–(5) in this issue), which do not facilitate international collaboration and the training of young scientists on aspects of biodiversity research. However, the grant agreement and other respective contracts were finally signed and now the actual work can start.

A natural product library will be generated and tested in various bioassays that are established at the respective partner sites. For creation of this library, the taxonomic know-how of the partners, above all in CBS, will be important. Interesting bioactive metabolites can be produced at a large scale and optimised by methods of



Stirring fermentor (10 L scale) for fungal fermentation broths to obtain large amounts of bioactive fungal compounds. Photo by Benjarong Thongbai (guest PhD student at HZI).



Thailand field work.

medicinal chemistry by the biotechnological and chemical departments of the German and Thai partners. Methods for in-depth biological characterization and elucidation of the biochemical mode of action are also readily available within the consortium, and the isolated strains will also be evaluated for their potential as biocontrol agents.

However, the project will also have a strong taxonomic aspect, considering the expertise of the consortium. Hence, it can be expected that numerous new species that even produce previously unknown compounds will be discovered and described. The project could even result in the discovery of novel fungal lead compounds, in particular

in the areas of novel anti-infectives, anticancer agents, and agrochemicals.

The GoMyTri Kick-off meeting was organized during the CBS Spring Symposium week in late April 2015 in Utrecht and Amsterdam, including the meetings of the ICTF and the IMA Executive Committee. This appeared practical as the PIs of all partner institutions are actively engaged in the international mycological community. A preliminary work plan was discussed and the project has already started with some German delegates who went to southern Thailand for fieldwork and are now working on isolating fungi from the material collected in the BIOTEC facilities. Two postdocs from The Netherlands will join the group in Thailand in the summer of 2015, and the first secondments of the Thai partner will be realised in the autumn.

Several further field excursions, staff exchanges, and workshops, are planned until 2018, which should allow the partners to further increase and optimise their interactions and gain interdisciplinary skills. In the medium term, the project is aimed at establishing an internationally visible strategic cooperation, including other departments of the institutions involved, as well as further collaborations with other parties. This means that the partners will be applying for further funding, such as personal grants for the young scientists involved and other measures in the framework of the EU H2020 programme and in other international funding schemes that provide funding for salaries of staff, and where larger consortia including additional partners from the extensive scientific networks of the current GoMyTri protagonists could also participate.

The primary aim of this news item is to alert other mycologists to this funding opportunity and to encourage them to form their own consortia, especially as the H2020 RISE funding scheme is not restricted to any particular scientific sector. Since fungi are playing a major role in many other fields of research that are highly prioritised by the EU and worldwide, ranging from the bioeconomy and biotechnology to agriculture and food safety, it should be relatively easy to identify additional topics that could be a starting point for additional joint applications.

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