Sharing Microbial Genetic Resources Internationally in Compliance to CBD Norms: an Indian Scenario

Yogesh Shouche

MCC

MICROBIAL CULTURE COLLECTION

National Centre for Cell Science, Pune

www.nccs.res.in/mcc

History of Culture collections

Prof Frantisek Karl

KRÁL'S BAKTERIOLOGISCHES LABORATORIUM. PRAG.
I. KLEINER RING 11.

Král's bakteriologisches Museum
WIEN IX /2.
Zimmermannsgasse Nr. 3.

DER GEGENWÄRTIGE BESTAND
DER KRÁL'SCHEN SAMMLUNG
VON
MIKROORGANISMEN

MÄRZ 1911

History in India

- In 1941 National Collection of Type Cultures started at Indian Institute of Science by Prof. M. Sreenivasaya on suggestion of Dr. Shanti Swarup Bhatnagar
- In 1951, it was transferred to Biochemistry Division of National Chemical Laboratory today know as National Collection of Industrial Microorganisms
- Today there are 31 culture collections registered with WDCM

Microbial Culture Collections

There are 714 culture collections in 72 countries and regions registered in WDCM.

Source: http://www.wfcc.info/ccinfo/statistics/

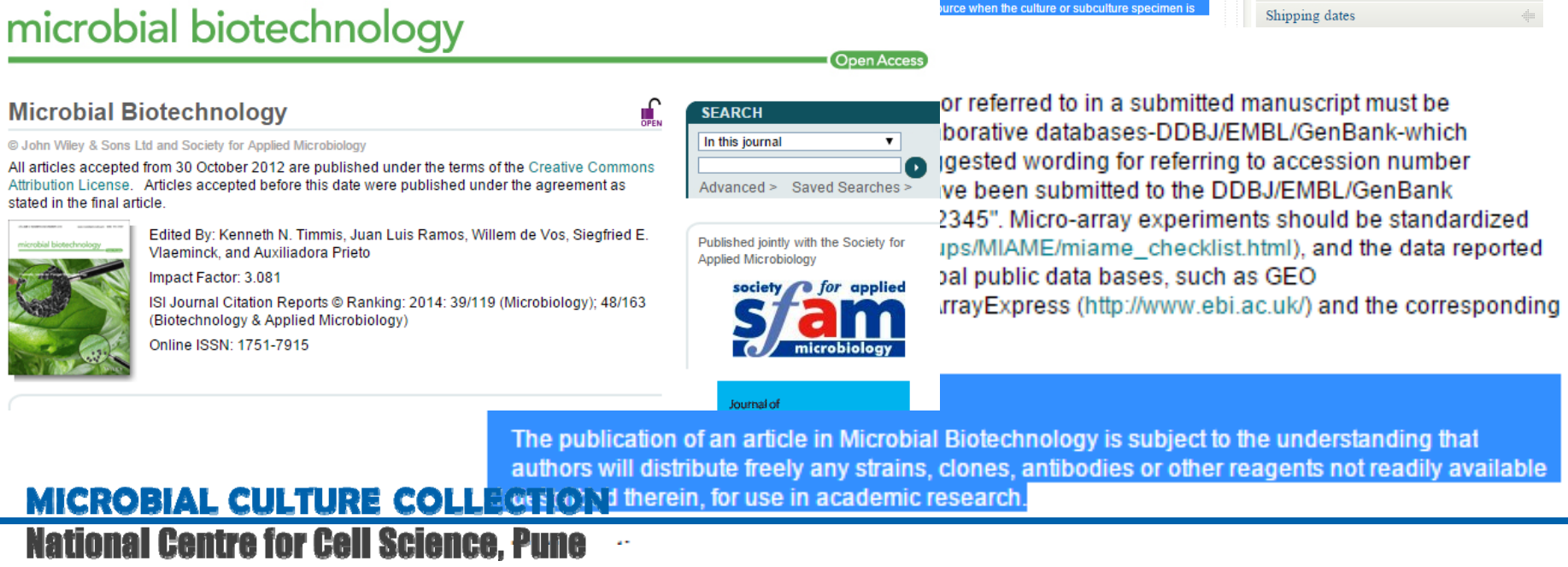
Microbial Culture Collections

- These culture collections hold nearly 2.5 million microbial strains.
- 58.3% of which are preserved with the culture collections of only five countries
- With a total of 1.9 lakh cultures India is placed at third position after USA and Japan.

Microbial Culture Collections

- Microorganisms are required for teaching, research and quality control.
- Conservation of Biodiversity and Biosecurity
- Microorganisms have frequently been isolated and exploited for industrial, environmental and agricultural applications over long period of time.

Why deposit cultures



MICROBIAL CULTURE COLLECTION
National Centre for Cell Science, Pune

Need for the deposition of cultures in culture collections outside India

Rule 30

International Code for the Nomenclature of Prokaryotes 2015

For the name of a species to be validly published, it must conform with the following conditions.

(1) It must be published in conformity with Rules 27 and 28b.
(2) It must be published as a binary combination consisting of a genus name followed by a single species epithet (see Rule 12a).
(3) (a) Up to 31 December 2000, before publication of the name of a new species, a culture of the type strain (or, if the species is non-cultivable, type material, a photograph or an illustration, see Rule 18a) should be deposited in at least one of the permanently established culture collections from which it would be readily available. The designation allotted to the strain by the culture collections should be quoted in the published description.

(b) As of 1 January 2001, the description of a new species, or new combinations previously represented by viable cultures must include the designation of a type strain (see Rule 18a), and a viable culture of that strain must be deposited in at least two publicly accessible culture collections in different countries from which subcultures must be available. The designations allotted to the strain by the culture collections should be quoted in the published description. Evidence must be presented that the cultures are present, viable, and available at the time of publication.

Sharing Microbial Genetic Resources Internationally

- Historically, microbial cultures were frequently gifted, exchanged informally/formally without restrictions among research groups and culture collections.
- To utilised them for educational and research purposes.
- There was no international legal regime to regulate access to genetic resources and to promote the sharing of benefits arising from the commercial and scientific uses.

Convention on Biological Divesity

- Entered into force from 29th December 1993
- Has 150 signatories
- Main objectives
  - The conservation of biological diversity
  - The sustainable use of the components of biological diversity
  - **The fair and equitable sharing of the benefits arising out of the utilization of genetic resources**

Nagoya Protocol

The *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS) to the Convention on Biological Diversity* is a supplementary agreement to the Convention on Biological Diversity. It provides a transparent legal framework for the effective implementation of one of the three objectives of the CBD: the fair and equitable sharing of benefits arising out of the utilization of genetic resources.

The Nagoya Protocol on ABS was adopted on 29 October 2010 in Nagoya, Japan and entered into force on 12 October 2014, 90 days after the deposit of the fiftieth instrument of ratification. Its objective is the fair and equitable sharing of benefits arising from the utilization of genetic resources, thereby contributing to the conservation and sustainable use of biodiversity.

Article 15 of CBD . Access to Genetic Resources

1. Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.

2. Each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention.

National Biodiversity Authority

Establishment of National Biodiversity Authority

8.(1) With effect from such date as the Central Government may, by notification in the Official Gazette, appoint, there shall be established by the Central Government for the purposes of this Act, a body to be called the National Biodiversity Authority.

Functions and powers of National Biodiversity Authority

18.(1) It shall be the duty of the National Biodiversity Authority to regulate activities referred to in sections 3, 4 and 6 and by regulations issue guidelines for access to biological resources and for fair and equitable benefit sharing.

(2) The National Biodiversity Authority may grant approval for undertaking any activity referred to in sections 3, 4 and 6.

Regulation of Access to Biological Diversity

Certain persons not to undertake Biodiversity related activities without approval of National Biodiversity Authority

3. (1) No person referred to in sub-section (2) shall, without previous approval of the National Biodiversity Authority, obtain any biological resource occurring in India or knowledge associated thereto for research or for commercial utilization or for bio-survey and bio-utilization.

(2) The persons who shall be required to take the approval of the National Biodiversity Authority under sub-section (1) are the following, namely:

(a) a person who is not a citizen of India;

(b) a citizen of India, who is a non-resident as defined in clause (30) of section 2 of the Income-tax Act, 196 1;

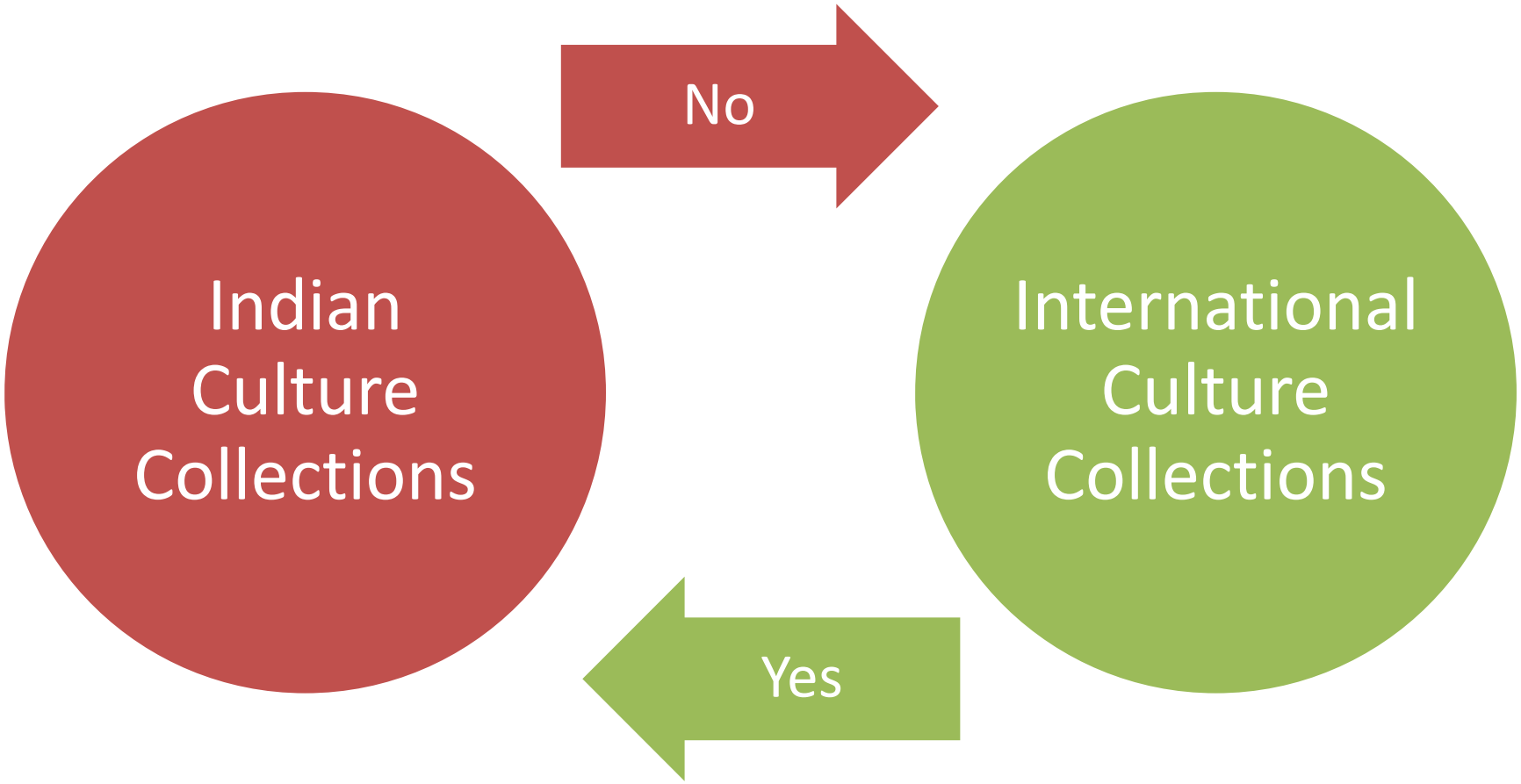
14. Procedure for access to biological resources and associated traditional knowledge

(1) Any person seeking approval of the Authority for access to biological resources and associated knowledge for research or for commercial utilization shall make an application in Form 1.

(2) Every application under sub-rule (1) shall be accompanied by a fee of ten thousand rupees in the form of a cheque or demand draft drawn in favour of the Authority.

(3) The Authority shall after consultation with the concerned local bodies and collecting such additional information from the applicant and other sources, as it may deem necessary, dispose of the application, as far as possible, within a period of six months from the date of its receipts.

Sharing Microbial Genetic Resources



Discussions on Microbial Taxonomy in NBA Meetings

Action: Secretary

Agenda 13. 12: Facilitating approvals for taxonomic research

The matter was deliberated at great length. The Scientist concerned was also given opportunity to enlighten the authority. Considering the importance of identification of new taxa/species by our scientists, the proposal of IMTECH/CSIR was approved. Dr Naresh Kumar suggested that the provisions may be applicable to all organizations undertaking similar research work. It was also decided that the concerned scientist/organization/Institution should clearly indicate in the MOU that in case the material deposited in the designated Repositories is accessed for commercial purposes, the same will be subject to benefit sharing arrangements as per the Biological Diversity Act. It was also suggested that the effort should be made by the ICAR to get international recognition for NBAIM, Mau, (UP) as International Repository. Dr Ghosh suggested that CSIR may also be requested to get the collection at Pune recognized and to this effect he presented the following account:

Minutes of 13th authority meeting on 28th January 2009

Dr Anil Gupta emphasized that India should take lead in establishing state of art laboratory facilities/ repository for microbial diversity in SAARC region in Bhutan which will satisfy the requirement of depositing one sample of taxa, for publication work of taxonomic research in the Designated National Repositories in other countries.

It was agreed that a committee under the chairmanship of Director, NBPGR, with Directors of BSI and ZSI and Dr.A.K.Ghosh as members may discuss the matter in a meeting before March 2009 and come out with recommendations.

A notification to that effect shall be put up by the NBA/MOEF. Till a view is taken on the matter, it was agreed that all such proposals relating to taxonomic research may be considered on case by case basis as was done for IMTECH's proposal in this meeting.

Problems for Indian Microbial Taxonomists

Dear Dr. Joshi,

Many thanks for your submission to International Journal of Systematic and Evolutionary Microbiology.

I have checked the revised version of this paper and I observed some deficiencies that should be corrected. I will contact you later when I prepare the complete file.

In the mean ld like to contact you concerning the certificate documents from the culture collections. During the IJSEM Editorial Board meeting that we had last week we discusse about this matter and it was decided that according to the Prokaryotic Code of Nomenclature the culture collections should indicate on their certificates that the strain is available without any kind of restriction. For that reason it would need thay you supply the JCM certificate in such terms. I imagine the IJSEM Editorial Office has already contacted you on this matter, but in any case I am remembering you this point.

Besides, we also discussed the problems associated to the supply of strains from some culture collections that may have to be addapted to national rules, such as it seems that may happens with some culture collections located in India. They have problems to supply strains abroad of India and/or for freely distribute them for their use by third parties. For that reason, the agreement was that we recommend to authors that in this case they might deposit the type strain of the new taxon on a third culture collection locate in another different country. Thus, I am contacting you in order to fulfill this recommendation and ask you to deposit the strain in another culture collection and suppy an additional certificate of deposit. This is of course a recommendation but we hope you will agree with this decision and accept it. In the meantime I will prepare the comments concerning your paper and send them to you for further consideration.

Yours Sincerely,

Antonio Ventosa
Editor
International Journal of Systematic and Evolutionary Microbiology

Problems for Indian Microbial Taxonomists

Dear Dr.
Thank you for your e-mail. The "problem" is not that the DSMZ can not accept the strains, but that we need to make sure that the strains are being sent to us legally. I appreciate the problem and have suggested that you clarify this issue within the collection/institute and with the National Biodiversity Authority. If you send the strains to the KCTC and they accept them you essentially have the same problem, are you allowed to export the strains?

Best wishes
Dr.

- Gentle reminder (3)

Subject: Re: Gentle reminder

Dear Dr.
I am sorry, but the whole situation with India is very complex. The wording from the minutes you sent were very helpful and helped me to find additional texts. The problem is that the minutes indicate that a particular solution was being looked at for certain collections in India, but not neccessarily all of them.

I have become aware of a colleague in an institution in India facing disciplinary/legal action because he sent strains out of India illegally. In additional the DSMZ is now required to check that material it is accessing is in compliance with laws resulting from the Nagoya Protocol.

I suggest that you check in the MCC that the collection has written permission from the National Biodiversity Authority to sent strains out of India. A copy of the letter would be appropriate.

Thinking about sending strains to another collection when a manuscript has already been submitted is not the best solution. We know that there are several collections that do not check the identity of what they are sent, with the result that others have to document later that the wrong strain has been deposited, with consequences for the original publication. The DSMZ checks all incoming strains and that takes time.

Best wishes
Dr.

Problems for Indian Microbial Culture Collections

- In absence of any clear guidelines in the NBA document regarding supply of cultures outside India, such requests are not entertained.
- Failure to provide type strains/reference strains to investigators outside India put Indian culture collections in an embarrassing situation with the prospect that cultures deposited in these culture collections will not be recognised by international scientific journals/organisations for deposit of strains mandatory for publications in reputed journals.
- India, thus, loses their standing in international scientific community.

Problems for Indian Microbial Culture Collections

Firstly, the refusal by the MTCC to provide strains to other countries, which were submitted to the collection with the aim of receiving a certificate of deposit by a depositor for the subsequent publication of the description of a novel taxon, is in contradiction with Rule 30(3a) of the Code requiring availability of type materials in public collections. The importance of the rule was emphasized once again in the current recommendations on description of prokaryote taxa (Tindall *et al.*, 2010). The MTCC is clearly familiar with these requirements; a statement in its certificates of deposit claim, 'This strain is available in the publicly accessible section of the MTCC and restrictions have not been placed on access to information concerning the presence of this strain in the MTCC', but, nevertheless, the MTCC declined our requests for the strains. It is understandable that IJSEM editors do not have authority to order the MTCC or other collections to submit strains abroad, but, at least, IJSEM could prevent such situations by rejecting acceptance as valid of certificates of deposit from collections which do not follow the rule.

To find a reason for the discrepancy, efforts to acquire the strains were made, but the type strains of *B. aerius*, *B. aerophilus* and *B. stratosphericus* were not available. They were absent in the JCM catalogue. The strains were listed in the MTCC catalogue, but they were also not available; according to a response by the MTCC curator to the request for strains, sending these strains abroad was not permitted. The search for other sources of strains, includ-

Liu et al., 2015 Int J Syst Evol Microbiol 65: 3228-3231, doi: 10.1099/ijsem.0.000408

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Dear Prof. Milton and Tindall

Recently I was received a mail from IJSEM regarding deposition of taxonomic cultures in Indian Culture collection, as suggested we need to deposit culture in third collection apart from two. Since last three or fourth this matter was quite discussed with National Biodiversity authority of India (NBA) by all the culture collection present in India. And recently NBA has issued a circular in National news papers (attached) dated 1.10.2015 page No.19 regrading the biological resources access by the abroad researchers , and it was quite clearly stated that abroad researcher can access the Indian type culture available in Indian culture collection by filling the form one (Form I) and paying some fee of NBA as mentioned forms can be accessed at (http://nbaindia.org/content /26/59/1/forms.html). From this circular, it states that, it is not restricted the supply of biological resources to

Dear Dr. Dastager,

Thank you for your e-mail and passing on information on the outcome of meetings of the Indian NBA, who are clearly approaching this issue in a constructive fashion.

Please note that the current situation in India is that a body external to the collections (ie the NBA) have to be consulted before a strain can be sent and this is one of the stumbling blocks.

Best wishes

Dr. Brian J. Tindall

Chair

What other collections do

- Most of the international culture collections are supplying microbial strains under agreement applies to the use, handling, distribution and any disposition of the microorganism supplied by the collection, and addresses the identified key points like traceability, fair and equitable benefit sharing, intellectual property rights, quality, and safety and security .

Sharing Microorganisms by Major Culture Collections

Culture Collection	Country	Supply	Agreement
American Type Culture Collection (ATCC)	USA	Global	MTA (material and progeny may only be used by the purchaser for research purpose). Any Commercial Use of the Biological Material is strictly prohibited without ATCC's prior written consent.
Belgian Co-Ordinated Collections of Microorganisms (BCCM)	Belgium	Global	MTA (a limited non-exclusive license to use the MATERIAL under the terms and conditions specified). The RECIPIENT shall not sell, lease, license, lend, supply, distribute or otherwise transfer the MATERIAL to any others, save those involved in LEGITIMATE EXCHANGES.
Bioresource Collection and Research Center (BCRC)	Taiwan	Global	MTA (applicant may use the Biological Material only for research purposes other than Commercial Use). Any Commercial Use of the Biological Material or Modifications is prohibited without FIRDI's prior written consent.
Centraalbureau voor Schimmelcultures (CBS)	The Netherlands	Global	MTA (applies to the use of the MATERIAL in any lawful manner for the purpose of scientific research, teaching or quality control purposes or any such other purposes agreed in writing with CBS). RECIPIENT shall not sell, distribute, lend, or otherwise transfer the MATERIAL to any others, save those involved in LEGITIMATE EXCHANGES.
China Center of Industrial Culture Collection (CCIC)	China	Global	MTA (may use the CICC Material in any lawful manner for the purpose of scientific research, teaching or quality control purpose agreed with CICC's prior written consent). Purchaser shall not sell, lend, distribute or transfer the CICC Material to others.
Collections Coordonnées Marocaines de Micro-organismes (CCMM)	Morocco	Global	MTA (material and its progeny is to be used solely for teaching and academic research purposes). The recipient shall not further distribute the material, its progeny or its derivatives to third parties, without prior written consent from the depositor and notification of the CCMM.
German Collection of Microorganisms and Cell Cultures (DSMZ)	Germany	Global	MTA (applies to the use, handling, distribution and any disposition of the MATERIAL supplied by the COLLECTION, and addresses the identified key points like Traceability, Fair and Equitable Benefit Sharing, Intellectual Property Rights, Quality, and Safety and Security).

Sharing Microorganisms by Major Culture Collections

Culture Collection	Country	Supply	Agreement
Centre for Agriculture and Biosciences International (CABI)	UK	Global	MTA (use of the genetic resource provided by CABI and all replicates and derivatives are for research or teaching purposes only). The Customer shall not distribute, sell, lend or otherwise transfer the Genetic resource to any third party.
Japan Collection of Microorganisms (JCM)	Japan	Global	MTA (the RECIPIENT shall obtain a written prior permission for the usage of the BIOLOGICAL RESOURCE for any other purposes than the purpose specified in the MTA). The RECIPIENT shall not distribute, resell or otherwise dispose of the BIOLOGICAL RESOURCE to any third party.
Korean Agricultural Culture Collection (KACC)	Republic of Korea	Global	MTA (Recipient will not distribute, sell, lend or otherwise transfer the KACC materials to third parties for any reason). Recipient will fulfill the obligations under the Convention on Biological Diversity (CBD) concerning fair and equitable benefit sharing with these materials.
National Collection of Agricultural and Industrial Microorganisms (NCAIM)	Hungary	Global	MTA (RECIPIENT may use the MATERIAL in any lawful manner for the purpose of academic scientific research, teaching or quality control purposes or any such other non-commercial purposes). RECIPIENT shall not sell, distribute or propagate for distribution, lend, or otherwise transfer the MATERIAL to any others, save those involved in LEGITIMATE EXCHANGES as defined above.
Philippine National Collection of Microorganisms (PNCM)	Philippines	Global	MTA (MATERIAL, including any progeny, portions and/or unmodified derivatives therefore is being provided for RESEARCH AND ACADEMIC PURPOSES ONLY). Recipient shall not distribute, sell, lend, or otherwise transfer, the Material or its Replicates for any reason. Any third party requesting a sample shall be referred to the PNCM.
Spanish Type Culture Collection (CECT)	Spain	Global	MTA (provide microorganisms for test, reference, bioassay, control and training purposes). No commercial application; no Intellectual Property Rights (IPR) related to MGRs, derived technology and information; recipient has to follow the standard test and reference procedures.

WFCC tools for the implementation of Nagoya Protocol

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.

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.

WFCC tools: WDCM and GUID

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 system[6] 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.

WFCC tools: StrainInfo.net

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 [illegible] completely independent of the StrainInfo.net system.

WFCC tools: Value of microbiological resource

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 MOSAICS[8] 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

Existing NBA regulation	Microbial culture collections seeking
NBA regulation 19. (1) Any person referred to in sub-section (2) of section 3 who intends to obtain any biological resource occurring in India or knowledge associated thereto for research or for commercial utilization or for bio-survey and bio-utilisation or transfer the results of any research relating to biological resources occurring in, or obtained from, India, shall make application in such form and payment of such fees as may be prescribed, to the National Biodiversity Authority.	The microbial culture collections and microbial taxonomist are seeking one time approval to share "type strains" of microbes with the international researchers only for the purpose of research and after signing a material transfer agreement.

Proposed Solutions

- Exchange of Microbial Genomic Resources between DNRs in India notified by MoEF, and recognized culture collection in other countries that are used as reference strains in taxonomy research. This is expected to expedite such transactions with proper safeguard of national interest.
- Such an exchange should follow the guidelines designed by NBA for this purpose and should be done under MUTUAL TRANSFER AGREEMENT (MTA) between the recipient and the DNR. This MTA should have the approval of NBA.
- Any exchange of cultures /strains outside India should only be done through DNRs.
- Reference microbial cultures used in taxonomy research and for quality control purpose can also get exemption by putting them with Biological resources normally traded as commodities under section 40 of NBA rules.

Thank You!

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