

Microbial Commons: Overview of the Governance Considerations – A Framework for Discussion

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24. Microbial Commons: Overview of the Governance Considerations—A Framework for Discussion – Tom Dedeurwaerdere⁵¹

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Exchanges of microorganisms among culture collections, laboratories, and researchers worldwide have historically occurred in an informal way. These informal exchanges have facilitated research activities, and, as a consequence, science and exploitation of microbial resources have advanced rapidly. During the last decades of the twentieth century, this situation has changed. Major drivers of this transformation are the increasing commercial pressures from biotechnology firms active in microbiology and the introduction of new legislation on the use of and access to biological resources. As a result, the access and distribution of genetic resources are now more strictly regulated and, therefore, exchanges are becoming more and more formalized.⁵²

Before addressing these issues, let me make a brief note about terminology and, in particular, about the meaning of “commons” because the term is used very differently by legal scholars and by economic scholars. To clarify, I use the consensus definition that came out of a workshop organized by the Center for the Study of the Public Domain at Duke Law School. In that workshop there was a great deal of discussion about the definition because the term comes from natural resource management, but has now moved into the field of the Internet and the science commons. Therefore, an approach was needed that covers both shared resources that are depleted upon use, which are designated as common pool resources, and shared resources which are not, such as ideas, which are pure public goods. The workshop came up with a very simple standard definition. A commons is a resource shared and managed in common by a group of people. The group of people can be very small, like a club in the sense discussed by Minna Allarakhia⁵³ this morning, or it can be at the level of a community or even multiple countries.

The concept, as defined, includes both the semicommons, which is a partially restricted area of exchanging resources and digital data, and a fully open commons. Those distinctions can be evolving for the same resources; materials may remain in a semicommons for six months or a year and then come into the full commons.

With that in mind, I would like to give some examples of the benefits of global and regional exchange of microorganisms in a commons, provide an analysis of the patterns and norms of exchange, and then examine the institutional design implications for the development of research friendly formal institutional arrangements.

I will begin by examining some existing practices where broad worldwide sharing of materials and information provides key benefits to both public and private actors. Well-known examples of the worldwide sharing of biological resources involve microbial materials in the field of food and agriculture. In the early 1950s, stem rust (race 15B)

⁵¹ Presentations slides available at http://sites.nationalacademies.org/xpedito/idcplg?IdcService=GET_FILE&dDocName=PGA_053743&RevisionSelectionMethod=Latest.

⁵² See also, T. Dedeurwaerdere. Global microbial commons: institutional challenges for the global exchange and distribution of microorganisms in the life sciences. *Research in Microbiology* 2010;161(6):414-421.

⁵³ See Chapter 20 within this publication.

devastated the US and Canadian wheat crops, leading to estimated losses of around US 3 billion (in 2007 dollars). This disease prompted the organization of the first international nursery trial to test wheat lines for resistance in seven countries. As a result of this international breeding program, stem rust was brought under control by the mid-1950s.

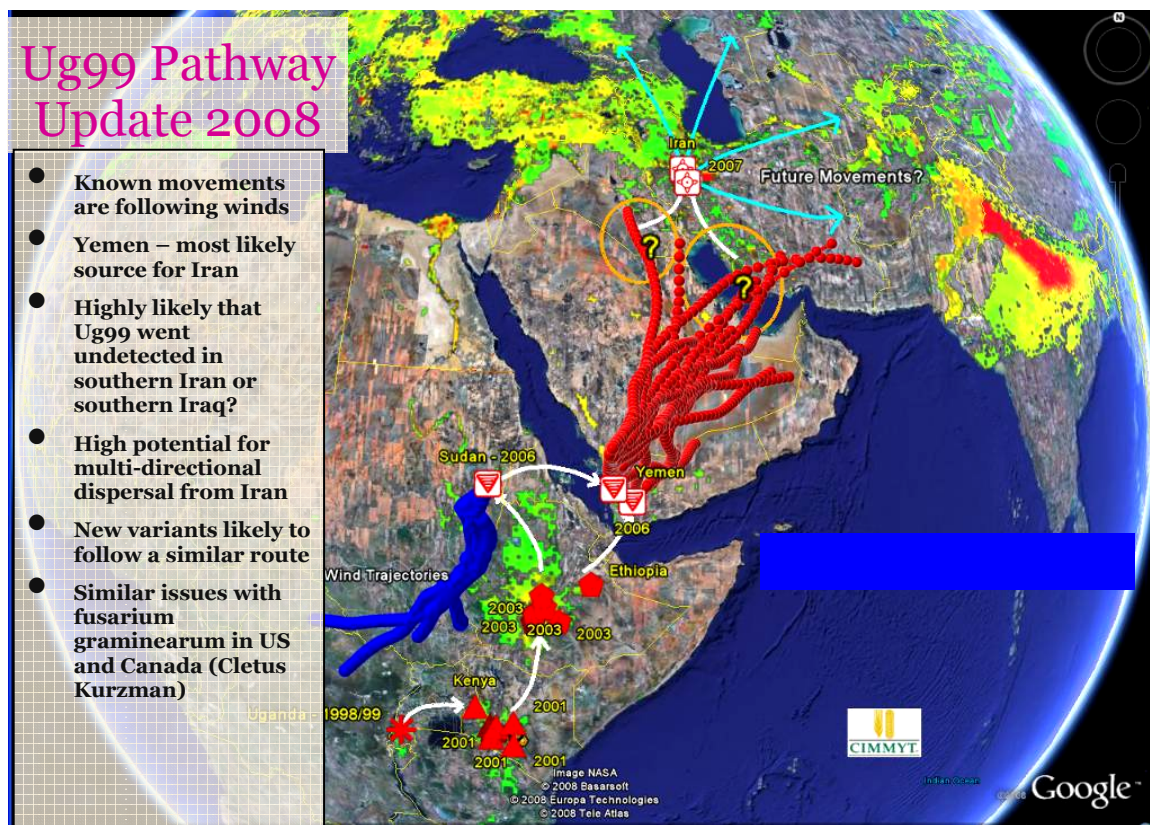


FIGURE 24–1 Path of a disease outbreak.

SOURCE: Amri Ahmed, 2nd microbial commons expert workshop, Brussels, March 25, 2009.

This success was one of the motivating factors to establish the Consultative Group on International Agricultural Research (CGIAR), which coordinates international breeding programs for the main food crops based. This in turn led to the Green Revolution, golden rice, and other agricultural breakthroughs.

What is interesting is that the disease is back again. Figure 24–1 shows the path of a recent epidemic of stem rust spreading from Uganda since 1999. So we are faced here with an evolving biological reality—there is a race going on in which microbial pathogens evolve and make previous crop improvement programs obsolete. The microbial pathogen population of *Puccinia graminis* has been evolving and a new program of international collaborative research is needed to bring stem rust under control in East Africa and the Middle East.

An important lesson from these programs is that it is only possible to derive the benefits for disease diagnostics and crop improvement if one can gather and identify the microbial materials from all the places where the diseases are, which requires collaborative DNA sequencing arrangements of the main materials, and track down all

the existing scientific information required to identify the mutations of the pathogens that are responsible for the disease.

There are many other examples of research with microbial resources where the end results require not just one local study but a large collaborative project. One such case is the use of microbial ferments in food processing, such as yoghurt.

By gathering all the strains of yogurt of a great number of the farmers' markets in Georgia, public sector researchers were able to design uniform starter cultures for the dairy industry in Georgia, whose milk products are known to possess special pro-biotic properties. They were able to develop a standardized yogurt product by collecting all the strains, analyzing the genetic sequences, and then selecting the strain that was most useful. Again, this was a major collaborative project with direct social benefits.

In the commercial context, let us briefly examine bio-prospecting outside national jurisdiction, which can still be done in places like Antarctica or the open seas. These are areas where any company can go and harvest valuable microbials.

For example, companies active in Antarctica have collaborated on a website (www.bioprospector.org), which shows innovations based on microbials from Antarctica. All the ice cream companies are there because they are interested in microbes that can affect the freezing point. The bioportal shows an incomplete list, but it already does demonstrate that the private sector has a big interest in accessing microbials throughout the world. It is a list of examples where benefits have been transferred from a public commons, with shared use of a whole range of resources and digital information, to private sector innovation.

These three examples aim to illustrate how emerging groups and cooperative networks, both from the public and private sector, are trying to produce benefits from global and regional exchange to the broader society. This symposium has highlighted a number of other interesting initiatives involving emerging cooperative networks trying to provide such benefits, but overall, these initiatives are still disjointed and involve many ad hoc arrangements. As yet, no overall vision of an integrated infrastructure has emerged.

For the design of a worldwide microbial commons, a more systematic approach that is based on a set of agreed rules between the collections, the users and the provider countries, is needed. The main issue that has to be addressed in this context is the creation of a better fit between the formal institutional arrangements required for building a global science infrastructure and the norms and goals of the microbial science communities. In particular, to foster wide acceptance and thereby accelerate scientific progress, any formal arrangement needs to be committed to facilitate the exchange of materials and need to be easy to implement by regulatory bodies, as well as both parties involved in the exchange (providers and recipients). This raises a double set of problems. On the one hand, institutional frameworks that rely excessively on monetary incentives or formal control can crowd out the social norms of communalism and the intrinsic values that drive scientific communities. This is especially relevant for the bulk of microbial resources that are exchanged for public research purposes. On the other hand, without a formal arrangement of some kind for regulating the exchanges, the benefits of the infrastructure might be restricted to the most advanced researchers, who organize exchanges on the basis of networks of personal relationships. The goal of further harmonization of the institutional frameworks should therefore be to provide the broadest access possible to essential research materials—within the constraints set by biosecurity

and quality management requirements, while preserving the community norms which motivated the practice of exchange to start with.

Let us discuss some of the available institutional options. One option is the adoption, on an international level, of a set of legally binding rules to govern transactions involving microbial resources. This would potentially alleviate many of the problems caused by the lack of standardization and agreed formal rules which characterize the current system of exchange. The development of a fully fledged international regime takes time however, and, in the light of the threats to the commons and the public good benefits that may potentially be lost, it is urgent to work on interim solutions for putting the global microbial commons on a sound legal basis.

In the area of the microbial commons, there are some emergent examples of such interim solutions which might lead to the building of a global commons. It is interesting to see that those are appearing throughout the world. It is not a north-south divide. For microbiology collections in Thailand, for example, the institutional arrangement is based on two Material Transfer Agreements (MTAs): one for regular distributions, and one for what they call legal or legitimate exchange among culture collections. In the case of the latter, as long as the strains circulate among the pool of more than 600 culture collections who are members of the World Federation of Culture Collections, anyone can redistribute it within that same network.

Russia is adopting the same approach, as is the European Culture Collection Organization. One could envision extending this approach beyond just exchanges among culture collections, to encompass also type strains and reference strains held by qualified research collections, because those are basic research materials that everybody needs, whether they are in the commercial or the public sector.

A third model is the clearinghouse model, where only information is shared and not the materials. In an information clearinghouse, all the information on available strains is put on a common bioportal, and people get the materials from the most nearby places or where the license conditions are the most open. One can go onto each website and see the different conditions the culture collection imposes. This clearinghouse model has been developed for research into Huntington's disease by Science Commons, for example (cf. Science Commons MTA project, <http://sciencecommons.org>). Finally, you have the public domain, as in the case of bioprospecting in Antarctica and the high seas. That is also a commons. But there, you do not need contracts. It is unregulated and in the open.

How should principles of governance be designed for this whole galaxy of projects and emerging initiatives? We need to move from a disjointed set of bottom-up initiatives towards an integrated, but still distributed, infrastructure. The research question that needs to be answered is: How can we create the best possible fit between the governance of scientific infrastructures, on the one hand, and the normative practices and needs of the microbial research commons, on the other?

In short, there are trade-offs and many complex social mechanisms to be considered in designing the governance rules. It has to be done in a way that keeps and reinforces the existing normative practices, but that also adds new mechanisms for coordination wherever needed. That is the challenge that we have in front of us. What are those norms and collaborative practices that must be taken into account when thinking about governance?

Currently, more than half a million microbial samples, which have been collected in various countries, are distributed throughout the world every year by the public *ex-situ*

collections that are members of the World Federation of Culture Collections alone, mostly for the marginal costs of distribution. Each of these collections contains a very substantial set of unique materials. An average of 40 percent of the strains in the WFCC that are referenced on StrainInfo (www.straininfo.net) are unique. Intense collaboration and exchange amongst culture collections is a necessary consequence of this situation. It is difficult to estimate how many *ex-situ* materials are exchanged between research collections outside the WFCC collections on an informal basis, but it is fair to say that the volume of materials exchanged between these collections is probably even greater.⁵⁴

In order to get a better picture of the institutional arrangements within the microbial commons, a set of original surveys and interviews were conducted in 2005 and 2009. In 2005 Stromberg et al.⁵⁵ surveyed the 499 public collections that were members of the WFCC at that time (119 completed survey forms). In 2009 Dedeurwaerdere et al.⁵⁶, undertook a quantitative assessment of the entire accession database of a geographically representative set of 9 major collections over 3 years (2005, 2006, 2007 : totalling more than 15,000 single accessions), conducted semi-structured interviews with administrators of these collections, organized a short complementary email survey on access and benefit-sharing measures with 238 WFCC collections (43 completed questionnaires), and completed 16 in-depth phone interviews with scientists from both public and laboratory culture collections.

The quantitative assessment of the databases of the 8 major collections showed that for 6 collections more than 98 percent of all the deposits of 2005 to 2007 came in without restrictions, in spite of the use of formal deposit forms by these collections. For the other 2 collections around 85 percent came without restrictions. The overall experience was that after formalizing the process, the vast majority of deposits were still done without restrictions. The lesson is that people not only operate on the presumption that their work is part of a global research infrastructure, but when you ask them to sign a form, they are willing to give up their proprietary interests as well, in exchange for the benefits from making the microbial material available for follow on research and publication purposes. The collections we examined were selected from a set of major collections throughout the world, some in the United States, some in Europe, and some in Asia and South America. We did not see any exceptions to this behavior.

It is also worth noting that the depositors to those culture collections often come from other countries. Researchers in India or Brazil are regularly depositing to collections in the United States, Europe, and Japan. Even for the deposits done by national researchers, if you look at the country of origin of the material that is deposited, 60 to 75 percent of those materials come from other countries. So the people are collecting and depositing throughout the world.

⁵⁴ Dedeurwaerdere T. Institutionalizing Global Genetic Resource Commons: Towards Alternative Models for Facilitating Access in the Global Biodiversity Regime. 2010

⁵⁵ Stromberg, P., Dedeurwaerdere, T., Pascual, U., 2007. An empirical analysis of ex-situ conservation of microbial diversity. Presented at the 9th International BIOECON Conference on "Economics and Institutions for Biodiversity Conservation", Kings College Cambridge, 19-21 September 2007. Available on line at <http://www.bioecon.ucl.ac.uk/10chapters9.htm>.

⁵⁶ Dedeurwaerdere, T., Iglesias, M., Weiland, S., Halewood, M., 2009. Use and exchange of microbial genetic resources relevant for food and agriculture. CGRFA Background Study Chapter No. 46. Commission on Genetic Resources for Food and Agriculture, Rome. Available on line at <http://www.fao.org/nr/cgrfa/cgrfa-back/>.

There is a great deal of material deposited in the World Federation of Culture Collections (WFCC) collections that comes from in house laboratory and university research collections. It is expensive to maintain the strains. The informal research collections do not have the money to do that, so typically upon publication they will put the materials in a WFCC collection. However, there is also a lot of exchange between WFCC collections. The survey found that on average 20 percent of the strains acquired in 2005 by 119 WFCC culture collections came from other WFCC culture collections, and 10 percent of distributed materials went from WFCC collections to other WFCC culture collections. Those are the high-value and unique research materials. This is how a collection fills in its own gaps in order to have all the type strains and remain up to date. This “conditional reciprocity” between the culture collections—I can order unique materials at other WFCC collections because I also distribute my own unique materials under open access conditions—is very strong, and that is an important fact to take into account.

Regarding digital information, our study of open access publishing in the field of microbiology found that about 30 percent of the academic literature is in full open access journals⁵⁷. However, that figure includes hybrid access, which means that the information is available both through purchased open access and by subscription. The prices to purchase open access can be quite high, so full open access is still not prevalent in this field.

What are the implications for governance principles that one can draw from these surveys? I offer three.

The first is that you will need a governance framework driven at least in part by the scientific community. It should not be driven by a government entity only. The main reason for this is that most decisions on governance require deep knowledge of the technical specifics of the field. Regarding issues like prior informed consent or quality management, although these do have a regulatory component, the decisions require thorough knowledge of the scientific aspects.

The second principle is the need for multi-level governance. This requirement arises primarily because of the extreme heterogeneity between the collections and the various research environments. Some of the collections produce international public goods. The World Health Organization’s network of microbial laboratories supporting research on H1N1 is a case of a global public good. Others produce just regional or trans-regional public goods, that is, they operate as knowledge hubs that are very strongly integrated with a local or regional microeconomic environment. We saw an example of this in the dairy industry in Georgia, where the goal was to have new starter cultures for the national yogurt industry. They did the genetic sequencing locally and then looked in GenBank to compare the sequences. So they accessed the global infrastructure, but overall the sharing of microbial material occurred on a regional basis. That is quite common in this field.

The third principle is the need for specialization and cooperation. To understand this need, it is sufficient to recall that, on average, 40 percent of the strains in each WFCC collection are unique. Thus if you want to solve the stem rust disease discussed above,

⁵⁷ Reichman, J.H., T. Dedeurwaerdere, and P. F. Uhlir. Designing the microbial research commons: Global intellectual property strategies for accessing and using essential public knowledge assets (Cambridge Univ. Press, forthcoming 2013).

you probably will need access to pathogenic strains from many places, and some unique strains will probably be in collections far away. Thus we need specialization and cooperation.

The implementation of these principles needs to be articulated to the regulatory frameworks developed at the international level. Therefore, there are some fora where representation of the microbial science community is a key issue. For instance, the discussion on access to knowledge going on at the World Intellectual Property Organization will be crucial for building common ground between developing and developed nations on open-access infrastructures. There are also the discussions concerning access and benefit sharing for microbial materials taking place in the Convention on Biological Diversity and in the FAO's Commission on Genetic Resources for Food and Agriculture, which have been addressed in other presentations at this symposium.

Here the key message is that there are limits to a voluntary scheme such as a microbial commons for an international access and benefit-sharing regime. Even if the microbial research commons would contribute to access and benefit sharing through a standard material transfer agreement and a compensatory liability scheme, it remains a voluntary regime, so people can always decide whether to join the research commons or, if they have microbial materials with a very high commercial potential, to go in a different direction and step out of the commons. Major contributions for addressing these problems can be expected from international agreements between competent science ministries that oversee the collection on measures that provide for a standardized solution to benefit-sharing with the original providers of the strains to culture collections and support further standardization of the license conditions used in the various MTAs.

These and other considerations lead us to think about the possibility of further formalizing the informal exchange practices in the microbial commons and developing a sound legal and institutional framework for the operations of the collections. This in turn can support the further development of a fully digitally integrated research infrastructure building upon and extending the emerging global initiatives in the microbial commons.