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Dimensional Analysis of International Regulations of Biological Matter. Genetic Resources and Agrobiodiversity

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Developments in biotechnology, molecular genetics, intellectual property regimes and access to genetic resources and related information over the last two decades are rapidly changing the conditions for public research. The emerging "proprietary science landscape" is comprehensive (Table)

Adding the Nagoya protocol to the above presented box gives indeed food for thought as regards how all these agreements–several of them legally binding–may work in everyday life for scientists, farmers and in trade. These conditions are global and comprise an *evolving new global legal regime related to all biological matter*. Here we will refer mainly to three international treaties (several others also matter see box above) that have considerable bearings on public research, namely:

- the Biodiversity convention/CBD + the Nagoya Protocol
- the WTO-agreement and its annex on trade related intellectual property rights/TRIPS
- and the FAO international treaty on plant genetic resources for food and agriculture/FAO-IT.

The two latter have (different) provisions for intergovernmental enforcement and sanctions, while the first (CBD) leaves this subject to national legislation. In short the CBD means nationalization of genetic resources (previously seen as part humankind´s common heritage), TRIPS sets minimum standards for what must be protected as intellectual property/IP and the FAO-treaty stipulates multilateral access and benefit sharing/ABS rules for some 50 crop genera of high country interdependence and for global food security. In short the new subsequent regulatory regimes on access and ownership means an enclosing of the biological and genetic commons. In this zero sum game the public domain is continuously reduced as more and more of the commons are proprietized. Thus a move from being free public good to private, corporate or state property. Biological common rights are thus replaced with regulated/discriminating access.

CBD 1992/93	TRIPS WTO 1994	FAO-1T PGRFA 2001/2004	UPOV 1978/91	W1PO IGCGRTKF 2000	Cartagena Biosafety Protocol/ 2000
National sovereignty SNL Art 15 PIC/MAT Art 8j Protection of TK ABS - Bonn Guidelines/ Nagoya protocol	Mini-standard for IP (time limited) Art 27.3(b) *Sui generis*–protection Microorganism Microbiological processes Plant varieties _____ Patent Copyright Trademark Trade secret Industrial designs Integrated circuits Databases * Novelty/ non prior art * Innovative step * Industrial appl'n Morality, Ordre public	Multilateral access to ca 50 crop genera Standard MIA Art 9.3 Farmer's Rights SNL Farming system knowledge Landraces Farmer varieties SNL	Plant Variety Protection PVP (time limited) * New * Distinct * Uniform * Stable Common knowledge Public domain Extant varieties Farmer's privilege SNL Breeder's Exemption SNL	Protection of TK CO/DO in IP-application International ABS regime Standardized PIC/MAT regime	Transboundary movement of LMOs Art 10 Right to delay import subject to further scientific biosafety check Art 17 Unintentional transboundary movements and emergency measures _____ IPPC/1997 Art V, VI, VII regarding phytnsanitary requirements in shipping of plant material

Source: CG Thornstrom, 2012

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The emerging new legal regimes have deep impact on the freedom to operate/FTO for public science. In fact for public (and in fact also private sector) research we can summarize this in an equation: IP+ABS=FTO or in other words –***proprietary science***. Thus if we marry IP with ABS, how to create a viable offspring that has considerable FTO for science and scientists? In the following we will focus mainly on plant genetic resources. Animal genetic resources fall under CBD provisions while human genetic resources is subject to different other legal provisions mainly conventions and protocols under the World Health Organization.

Moving into a global legal can of worms?

In a study (CGIAR GRSS 2010:21) the following observation was made as regards microbial and insect genetic resources "… more than 53,000 accessions of living microorganisms or cell cultures and an astounding collection of insects and other arthropods numbering about 420,000 are collectively held in the CGIAR Centers. The … survey also contacted 28 worldwide bio resource centers, of which 26 responded showing more than 7 million accessions of living and nonliving materials." So which is the *legal status* of these 7 million accessions in the context of CBD, FAO-IT, TRIPS and UPOV? The GRSS-study gives the following answer (Ibid page 22): "…most collections of non-crop genetic resources are used by researchers to develop their activities and sometimes specimens are exchanged with partners, without due regard to IP or the access and benefit sharing regulations. Can these accessions be regarded as Global Public Goods? Or are they only genetic resources for current research? It seems that a serious discussion is needed as basis for further investment on conservation, capacity building, and infrastructure or to establish connections with local institutions and international repositories for the maintenance of the specimens that are indispensable for the research projects."

The CBD is one of the fastest approved international legally binding agreements. Negotiations started late 1987 and the final text was endorsed in Rio 1992 and entered into force in December 1993. The CBD places every living cell and its derivatives on the planet (with the exception of humans) under national sovereignty where access by other parties to the Convention is subject to the PIC/MAT procedures as adopted in different national legislation. The negotiations for an exception covering plant genetic resources for food and agriculture started already in 1983 (10 years before) and resulted in the FAO-IT 2001 which entered into force in 2004. In the history of international treaties the link between CBD and FAO-IT is an almost hilarious one. Policy making is an extremely complex game, especially when advanced genetics, evolution/genetic drift and legal matters are to be usefully –and fairly politically correctly- combined. To expect that the discussions around genetic resources for food and agriculture led by national ministries of agriculture (starting on larger scale in the 1970´s) would have influenced the discussions on implementing benefit sharing under CBD would be naïve And still: during the late part of that period a similar negotiation process was on, led by national ministries of the environment to establish another internationally binding agreement which adopted in October 2010 by parties of the CBD – the Nagoya-Cali Protocol on Access and Benefit Sharing (GRSS 2010:3).The CGIAR GRSS study (2010:70) makes the following observation of the Protocol´s text: "While a certain degree of creative ambiguity is a hallmark of international accords, the text of the Nagoya protocol has left experts puzzled about what exactly has been agreed on for many critical issues, including the substantive and temporal scope of the agreement and the application of the definitions – derivatives and utilisation, giving rise to a range of partially conflicting interpretation."

Agrobiodiversity and the Nagoya Protocol

Agrobiodiversity concerns biological material and associated knowledge regulated under half a dozen different international treaties. Here it is extremely important to note that all the different regulatory regimes use concepts that either overlap or criss-cross over different legal regimes. The UPOV–and FAO-IT legal languages are specific as regards the concepts **scope of protection** and **rights conferred** (*Seeding solutions* vol 2 page 10 and 95) and very different from the more political languages used in the CBD and the Nagoya protocol. In the European Commission process (September 2016) the Nagoya–protocol assumes six 'biological categories': cosmetics, plant breeding, biocontrol, pharmaceuticals, food and feed, biotechnologies. But these general concepts do not lend themselves easily to legal specifications. Living biological matter: plants, animals, microbes etc are all part of evolution and their life cycles do certainly not respect certain given national borders in their life cycles. Further inherited traits are not necessarily specific for a certain species. Still further it is unclear whether the definition of genetic resources in the Nagoya protocol

includes sequenced data deposited in public international databases. On top of this biological and medicinal model organisms are international – and thus outside the Nagoya provisions. Wild relatives of cultivated crops fall under the FAO-IT. But for example India urged in early 2012 that such material collected in India after enforcing of the Nagoya protocol should be made available on Nagoya-provisions – not those of the FAO-IT. Still another challenge is to clear and safely beyond any doubt make sure that a microorganism is unique on a unique sovereign country's territory. While in reality microorganism through winds, ocean currents, international trade (fruits/vegetables), migration of insects, migrating birds, animals and humans continuously cross national borders it is in reality very difficult or completely impossible to identify a single national origin – as assumed/required in the Nagoya protocol.

Further the Nagoya protocol assumes (like the CBD article 8j) easily identifiable traditional groups, that are in full legitimate control of their stable homelands and which 25 years after the entering into force of the CBD all of them now have effective smart/smooth PIC/MAT-procedures for Prior Informed Consent and Mutually Agreed Terms. In reality so far very few such smoothly organized procedures are in place in most indigenous communities or most countries. Many countries members of the Andean Pact have enacted draconian access legislation. The challenge is how to find smooth and effective PIC/MAT-procedures when each member country may have 20-50 indigenous groups/tribes with their own ´national´ territories. And where the same "Nagoya material" may occur on the territory of several of these groups/tribes/countries. So far few or even no successes have been achieved at the scale expected in national and international legislation. Thus the COP of the CBD has over decades made few successes. The Nagoya protocol is a politically negotiated compromise. Focusing on static/stable mixes of stable species. Assuming stable and easily defined local communities and effective government structures. In reality impossible to translate into workable and effective access/transfer procedures that respect interests of local communities and increase and facilitate scientific and commercial exchange. Another challenge is the concept of **intangible genetic information** making it possible to digitalize a whole genome and "beam" it to another location – thus no longer in need of the biological matter ***in situ*** as the CBD/Nagoya assumes. Given these realities my own university Swedish University of Agricultural Sciences proposed to the Swedish government that Sweden shall **revoke** ratification of Nagoya protocol.

Concluding Remarks

The CBD is one of the fastest negotiated international agreements. It took less than 6 years and adopted in Rio 1992. It took another two decades to negotiate the subsequent Nagoya protocol. May introduction of the concept ***agrobiodiversity*** facilitate overview and rationalization/slimming of obligations under different treaties? The FAO-IT and the Global Diversity Conservation Trust have still not yet reached enough long-term and secured funding. And the CGIAR is facing rapidly shrinking core funding through its "Window 1". The upcoming 1st International Agrobiodiversity Congress scheduled for ICAR in New Delhi in November 2016 may be a proper and timely forum to reconsider the overloaded and underfunded international regulatory regimes now increasingly blocking scientific progress globally. Here I would recommend a recent PhD-Thesis ca 450 pages (2014) by Dr Frantzesca Papadopoulou at the Dept of IP and Market law Stockholm University Faculty of Law entitled: **Opening Pandora´s Box Exploring Flexibilities and Alternatives for Protecting Traditional Knowledge and Genetic Resources under the Intellectual Property Framework** (available at: http://www.diva-portal.org/smash/record.jsf?pid=diva2%3A694432&dswid=-4339).

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Footnote: Agribiodiversity and antagonistic threats

In January 2009 the European Commission published its report on Chemical, Biological, Radiological and Nuclear security. The Swedish Ministry of Rural Development instructed SLU to appoint a classified group of senior scientist tasked to look further into possible antagonistic threats – called bioterrorism to Swedish food and agriculture. The present author was–due to his studies of agricultural research in Germany during the Nazi-era 1933-45 tasked to start and chair this group 2009-2013 and of which he still is a member. For details please consult: http://online.liebertpub.com/toc/bsp/11/S1