The Nagoya Protocol: Compliance

Implications of the E.U. law for Microbiologists
Nagoya Protocol
Compliance

In this talk I will outline:

The role of compliance
How developed countries will respond
The EU Law on Compliance
What it means for you &
What is being done to help through the development of the Global Catalogue & the ABS CHM
Compliance

Why the Protocol?
No substantive implementation of the agreed access regime (per the Bonn Guidelines) unless developed (user) countries agree to legally binding requirements to ensure that provider’s PIC and MAT terms are honoured in user countries

= Legally binding obligations for access and for utilisation agreed via the NP
Common outcome: legal certainty
COMPLIANCE OPTIONS

NP Art 15 – must act to provide that GRs used in your country were obtained in accordance with rules of the provider
Actions must be: appropriate, effective and proportionate
Response to breaches must also be appropriate, effective and proportionate
Countries must cooperate on allegations of breaches of ABS
COMPLIANCE OPTIONS

NP Art 16 Similar obligations where TK associated with GRs is used
  – NB ‘as required” means abiding by other countries ABS requirements

NB Art 17- Checkpoints
  Every country must have one
  Must collect info re Cert of Compliance
  Must put collected info onto CHM & to provider
Options

Possible Checkpoints:
- When users apply for a patent
- When users import a sample
- When users publish research results
- When recipients of gov’t research funds report on research
- When users apply for product registration
- When users apply for a research permit
Art 15 & 16 Options

Require grantees to abide by ABS law of the GR providing country

Disclose in patent applications the source of GRs and TK used to develop an invention.

Disclose PIC and MAT when seeking research partners

Make it an offence to import or utilize unlawfully obtained GRs & Associated TK
Art 15
& 16 Options

Set standards for academic publication and award of degrees

Funding support for research journals to be conditional on adoption of disclosure standards

Disclosure at point of import or export

Bind all government agencies and gov’t research bodies or bodies receiving financial support
Option choices

Checkpoints at the end of the development process eg product registration may be burdensome on Industry which would have to do retrospective analysis.

Securing compliance at the outset is least-cost and most effective.

Border controls have limited effect as GRs may be reduced to electronic data and just emailed.
E.U. Compliance Law

See handout copy of the Law

Key points:

• Became Law on 12 June 2014
• Becomes operational on 12 October 2015
• Binds all 28 Member states
• Applies to all researchers in the 28 Countries &
• affects international collaboration
E.U. Compliance

The EU Compliance regime is the new legal environment in which significant amounts of non-commercial and commercial research are undertaken within the EU.

Affects research partners outside the E.U.

Will have a powerful normative effect on other countries.
E.U. Compliance Law

EU is the largest group (28) of developed or user countries in CBD. Its compliance regime will likely set a de-facto global standard.

Contains innovations, eg:
- Registered collections
- Due diligence
- Recognition of best practice
Regime covers 8 key areas:

- User obligations (Art 4)
- Registers of collections (Art 5)
- Focal points and competent authorities (Art 6)
- Monitoring compliance (Art 7)
- Recognizes best practices (Art 8)
- Checks on Compliance (Art 9)
- Penalties (Art 11)
- Co-op & support (Arts 12,14)
Key Scheme Features

User Compliance:
- Do due diligence to verify provider’s terms of access and use are met
- Must comply with MAT
- Must, seek, keep and transfer International Certificates of Compliance
  - If no Cert, then find evidence of PIC and MAT
  - If no evidence then get PIC and MAT

Or Stop Use
E.U. Scheme Features

**Due diligence** met if:

- Obtained from a Registered Collection
- PGRFA material obtained using ITPGRFA standard material transfer agreement
- Users must keep records for 20 years after last use.
- Special rules with health emergencies
- PIC & MAT needed for market approval of GR derived products
E.U. Scheme Features

Monitoring:

Recipients of research funding **requested** to declare they do due diligence

At final product development stage users must declare to NCA they met their user obligations and must submit documentary proof - which will be sent to ABS CHM (and provider NCA if needed).
E.U. Scheme Features

Best Practice

EU Commission empowered to grant recognition of best practice
It must establish an online register of its recognised best practices and those adopted by the COP/MOP
E.U. Scheme Features

Checks on user compliance:

Requires member state NCAs to conduct checks that users are undertaking due diligence and monitoring obligations.

Notes user non-compliance risk reduced where best practice adopted.

NCA MUST issue a notice of remedial action if a user is delinquent.
Time to pause
Registers of Collections

Concept Origins:
Many collections are state owned
Some had already developed CBD compliant best practice (eg Common Policy Guidelines)
Australia trialed accrediting institutions eg National Botanic Gardens & Australian Institute of Marine Science in 2005 and Brasil has done the same
Registers of Collections

Origins:

Article 8 (a) simplified procedures for non-commercial research – out of a concern to foster taxonomic and other public good research

Public institutions generally require less oversight compared to private ones

Collections potential to deliver CBD /NP Plus - i.e. treat all their collection as if subject to CBD and soon CBD/NP
Register of Collections

Collections comparative advantages:

Able to deliver legal certainty

Deliver reduced compliance cost for users

Greater transparency

Familiar with best practices & tracking

Can readily adopt common transfer and acquisition forms and procedures

Enhanced standing with 3\textsuperscript{rd} parties

Reduce access cost for researchers
Register of Collections - Benefits

Avoids collections being isolated from research into genetic and biochemical make-up of species

Will help integrate classical taxonomy with molecular taxonomy

Broaden range of research partners

Broaden range of possible sources of funding – public and private

Reduce perception that taxonomic and natural history museums are antiquated
Register of Collections

Kindled interest among non-EU countries in adoption of a similar system of registered, or accredited collections
Opens the door for countries to recognise registered collections as trustworthy ie deliver legal certainty
Opens the door to countries to consider development of mutual recognition where similar systems are established
Register of Collections

Can create a network of collections beyond the EU to foster research

Eg Work is now underway among microbial collections in Asia to establish such communities of institutions:

– Network of International Exchange of Microbes in Asia (NIEMA)
Implications for Microbiologists

Field collection:

Know what national ABS law applies in collection area

Check with applicable ABS National Focal Point or National Competent Authority

Know what national ABS law applies where your research is being conducted

Check with applicable ABS National Focal Point or National Competent Authority
Implications for Microbiologists

Field collection:

Check with your own Institution especially your Technology Transfer Department

If you are collaborating with a partner

– Check they are complying with their own national ABS laws and procedures

– Do they understand their obligations in country of collection?

– Do they understand their obligations in country of use?
Implications for Microbiologists

Field collection:

Do you need an ABS Permit?
Has it become an Internationally Recognised Certificate of Compliance?
Does your country or institution require you to have Internationally Recognised Certificate of Compliance for any material imported into your country or any third country where your material may be deposited?
Implications for Microbiologists

Ex-situ collections:

Is material accessed from an EU Registered Collection providing you with legal certainty?

Does the material come with an Internationally Recognised Certificate of Compliance?

Does your country or institution require you to use only lawfully obtained material?

Can the collection or research partner provide evidence of lawful possession?
Things to help

Electronic verification of Permits (IRCCs) will be available from the ABS CHM at the CBD in Montreal – free and any time.

Material obtained from EU Registered Collections comes with legal compliance protection.

Material obtained from institutions subscribing to best practices and standards can provide confidence to researchers.
Things to help

The TRUST Project is working to update Micro-Organisms Sustainable use and Access regulation International Code of Conduct (ie MOSSAIC) so give you the guidance you need.

TRUST stands for TRansparent User-friendly System of Transfer for Science & Technology. It aims at organizing the scientific, technical and administrative activities of culture collections and microbiologists in light of the Nagoya
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Finally:
The WFCC Global Catalogue of Microorganisms is a powerful tool for users and depositors of microorganisms. It shows who, what, when, and where strains come from, the conditions under which they were obtained ie P.IC M.A.T., I.R.C.C., what IP has been created and what has been published.
Things to help

Finally:
Along with the ABS CHM, the WFCC Global Catalogue of Microorganisms is a most useful tool to establish the legal provenance of microorganisms and the conditions for its use.
Conclusion

For practicing Microbiologists:

the introduction of the Nagoya Protocol on 12 October 2014 changes the way science will be conducted

Laws will be changed or updated
International standards will be rewritten
Material collected or used will have to be lawfully obtained

Microbiology leads the other sciences in being organised for this change
Thank you