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 3rd 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 **M**icro-**O**rganisms **S**ustainable use and **A**ccess regulation **I**nternational **C**ode of **C**onduct (ie MOSSAIC) so give you the guidance you need.

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Things to help

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 Mircobiologists:

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