The Nagoya Protocol

Proposed E.U. Compliance Regulation

Compliance

- Why the Protocol?
- No substantive implementation of the agreed access regime (per the Bonn Guidelines) unless developed (user) countries agree 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

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

E.U. Compliance

- EU is the largest group (28) of developed or user countries in CBD
- Its compliance regime will likely set a de-facto global standard
- Intended to come into force when NP becomes operational
- 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 (Art7)
- Recognition of best practices (Art8)
- Checks on Compliance (Art9)
- Penalties (Art11)
- 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
- User 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

- 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 complaint 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 a community of institutions:
  - **Network of International Exchange of Microbes in Asia (NIEMA)**

Conclusion

- **Success of Registered Collections**:
- Depends on sensitive implementation at EC level and at national level
- Only possible if there is strong engagement by collections at both levels
- Opportunity for collections to be core institutions for scientific research into biota and for their value to be properly recognised

Thank you