# 2014 年度 ABS 関連調査研究
# オーストラリア調査まとめ

ABS 学術対策チーム

森岡　一

期間
2014 年 7 月 28 日（日）から
2014 年 8 月 5 日（火）まで

内容

まとめ

オーストラリアも名古屋議定書実施のための制度を確立する活動を、連邦政府環境省を中心に行っている。オーストラリア連邦政府は名古屋議定書実施を法律ではなく、現行法の範囲内での改革を志向している。現在、国内措置案について、関係者（州政府、産業界、研究機関、先住民）のコンサルテーションを実施している。関係団体の反応もまちまちであるが、大筋は了解されているようである。行動規範の作成についてはコレクションから意見が出されている。

中心となる課題は、実施可能で省コストなチェックポイント制度を作ることである。チェックポイントは、オーストラリア国内のみならず国外の遺伝資源利用を監視する必要がある。ただし、連邦政府と州政府の調整が困難で、まだどこの機関がチェックポイントになるか決まっていない。

名古屋議定書実施制度は、EU 規則がベースになっており、Due diligence に類似した行動規範制度と信頼されるコレクション(Trusted Collections)制度がポイントである。利用国間で ABS 制度が異なると混乱するという考え方が働いている。

オーストラリアは連邦政府と州政府からなっており、ABS 制度も二重構造があり複雑である。連邦政府は生物多様性法 1999 を持っている。連邦政府の生物多様性法は、連邦政府の管轄下にある生物資源のみを対象としており、各州には及ばない。クイーンズランド州、北部準州、タスマニア州などで 2000 年初めから生物多様性法等独自の ABS 規則を定めている。環境戦略により各州の生物多様性条約への対応は濃淡がある。法律のない州では、政府許可なく取得が可能である。ウエスタンオーストラリア州では、鉱山開発などが盛んであるため、消極的である。また、それぞれの州の先住民政策も異なっている。

先住民アボリジニーに対する連邦政府の ABS 政策は二面ある。伝統的知識は、連邦政府の管轄権の及ばない範囲にあり、伝統的知識保持者の所持物であると考えている。連邦政府は表向き保護政策をとっているが、深入りしない、アクセスは当事者間の交渉にゆだねている。連邦政府は単に、その報告を受けて、それが法律に違反しない限りなにもしない。当然種族には管理委員会のようなものがあり、管理委員会の活動にすべてを依存している。

これでは現実の世界に対応できないという批判が出されている。現在オーストラリアには先住民と呼ばれるアボリジニーが約 800 部族いるといわれている。先住民が文明社会の法律、契約を理解しているはずはなく、契約交渉で衡平な立場にいるとは現実に考えにくい。多くは交渉相手の弁護士に言いくるめられ、不満が充満している。利益配分契約をしても、それを守られることは稀である。守られないという不満を訴える仕組みがないため、先住民は泣き寝入りするしかない。このような現状を改革するボトムアップの取り組みを行わない限り、オーストラリアにおける伝統的知識問題は解決できない。

オーストラリアでは生物多様性条約が成立する前から、いくつかの研究機関は、医薬品を目的としたバイオ探索研究を行っており、商用研究目的の契約経験は豊富である。名古屋議定書を実行するのに、アクセスと利益配分の面から特に困ることはない。研究所は活動方針が探索目的から保全目的に変わり、保存するサンプルをどうやって維持するか困っている。現在クイーンズランド州では Chemical Library を作って、そこで保存する計画を実

行している。

Griffith 大 Eskitis 研究所では、先住民の伝統的知識に高い敬意を払って接してきている。ある伝統的知識を使う場合、その保持者部族のみならず周りの部族に情報を公開し、同じ伝統的知識を使っている部族を探し、交渉することにしている。部族間で考え方が異なり、部族間紛争が起こることを避けるためである。伝統的知識の民俗学研究者の参加が必須であると Eskitis 研の経験上いえる。

目的

名古屋議定書の批准に向けたオーストラリアの進捗状況を把握することは重要事項である。オーストラリアはまだ名古屋議定書に批准していない。オーストラリアにおける名古屋議定書批准のための国内規則の議論経過情報を得ることにより、日本における国内措置、特に学術研究に対する監視制度設計に有意義な参考となる可能性がある。

オーストラリアは提供国と利用国の両面を持つ国であり、生物多様性条約に対する意識が高い。すでにクイーンズランド州を始めいくつかの州と連邦政府は生物多様性法を制定しており、その規則も定められている。しかしながら、報告書類の調査には限界があり、実際の運営状況、現在の各関連組織の考え方などは、実際に現地の関係者との意見交換が必要である。

今回、オーストラリアの生物多様性事情をオーストラリア環境省 ABS 担当官、Griffith 大学法学部、Griffith 大学生物資源探索研究所、オーストラリア国立大学法学者等から現状と今後の対応について調査する。

オーストラリアの遺伝資源へのアクセスと利益配分概要

オーストラリアの生物多様性条約の基づくアクセスと利益配分（ABS）政策は、2005 年より実行されている[1]。オーストラリア連邦政府の行政機構によれば、生物資源の所有権は、その資源が見つかる場所が連邦政府管轄地、州および準州政府管轄地、海域によって ABS 政策は異なる。複雑なのは、先住民所有地であり、それぞれの先住民の独自の考え方で運営されている。

州および準州政府は、クイーンズランド州、ニューサウスウエールズ州、オーストラリア首都特別準州、ビクトリア州、タスマニア州、サウスオーストラリア州、ウエスタンオーストラリア州、北部準州から構成されている。連邦政府は「環境保護生物多様性保全法 1999」[2]を定めている。それ以外に、クイーンズランド州[3]、北部準州[4]、タスマニア州は独自の生物多様性法を作っている。

2002 年、遺伝資源へのアクセスを効率化するため、ABS 実行制度についてオーストラリア全体で統一した方法を取ることに連邦政府と各州が一致した[5]。この共通アプローチにより、連邦政府と各州が ABS 法制度を定める際の一般的な原理を定めた。共通アプローチはボンガイドラインに準拠している。

連邦政府管轄地での ABS は、2000 年の「環境保護と生物多様性保全規則 2000」[6]に基づいている。この法律によれば、連邦政府からアクセスと利益配分に関する許可を取ることが必須である。非営利研究目的に関しては、「法的宣誓（statutory declaration）」[7]を行うことが要件の一つである。これは、規則・契約に従い活動を行うことを宣誓することである。

先住民で遺伝資源へのアクセスを行う時は、先住民からの「事前の情報に基づく同意（PIC）」と「相互に合意する条件（MAT）」の契約を事前に行うことが必須の要件である。利益配分契約について、連邦政府管轄地及び連邦政府管轄内の先住民との間の利益配分モデルを作成している。

現在、環境保護生物多様性保全規則に基づいて、許可と利益配分契約を結んでいるオーストラリアの研究機関には、グレートバリアリーフ海洋公園局、国立植物園、海洋生物研究所、南極局などがある。

現在、名古屋議定書批准のための国内措置を考えており、考え方はだされている。すでに関係者である産業界、コレクションなどにコンサルテーションを行っている。基本的には EU 規則と似たようなものになる。ただし、オーストラリア連邦政府は生物多様性法を持っているので、法律にすることはなく、他のアプローチを考えている。

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[1] http://www.environment.gov.au./topics/science-and-research/australias-biological-resources.
[2] http://www.cbd.int/doc/measures/abs/msr-abs-au-en.pdf.
[3] http://www.cbd.int/doc/measures/abs/msr-abs-au1-en.pdf.
[4] http://www.cbd.int/doc/measures/abs/msr-abs-au6-en.pdf.
[5] Nationally Consistent Approach for Access to and the Utilisation of Australia's Native Genetic and Biochemical Resources.
[6] Part 8A and Part 17 of the EPBC Regulations (www.austlii.edu.au/au/legis/cth/consol_reg/epabcr2000693/)
[7] Commonwealth of Australia：STATUTORY DECLARATION　*Statutory Declarations Act 1959.*

議論記録

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内容：
日本の名古屋議定書関連の活動についてセミナーを約 1 時間開催した。出席者 7 人、外務省関係者（WIPO 出向予定）が知的財産との関連について質問があった。日本の学術研究は、名古屋議定書実施に対応できる体制にあるのかという質問もあった。

学会誌などが PIC 番号等の記載を論文で表明報告する制度を考えているのかという質問があった。新規微生物は寄託機関への登録が必要で、登録の際入手先などを記載する必要がある。これが、学会関係で唯一の出所開示要求であるが、今後は学会誌などが、PIC 番号等の出所開示の記載を論文発表の際の要件とする可能性が検討されている。

日本の特許庁は名古屋議定書にどのように対応しようとしているのかという質問があった。特許要件としての出所開示には日本の特許庁は反対している。誤った特許付与にはデータベース作成を推薦しているし、国内の審査に利用している。特許出願は生物多様性条約にとって重要なステップ(非商用から商用)なのでなんらかの（確認）制度を考えなければならない。

その他の Dr. Rimmer との議論

オーストラリアの政治制度について
オーストラリアは連邦政府と西部オーストラリア州、南部オーストラリア州、北部準州、クイーンズランド州、サウスウエールズ州、ビクトリア州、タスマニア州、首都準州がある。連邦政府は国全体を管理・運営しているが、各州の専権事項については、各州が事情に応じて政策を立案し、実行できる。

オーストラリア連邦政府は、連邦法として環境保護生物多様性保全法 1999 を制定している。この連邦法は、連邦政府が管理している地域（国立公園、国立研究所）などの遺伝資源が規制されるが、州の所有物については州法が規定する。現在、クイーンズランド州と北部準州は独自の生物多様性法を持っている。複雑なのは、両方で管理している地域があることである。また、先住民は独自の所有権を持っており、連邦政府や州政府の管理は及ばないという政策を取っている。先住民の独自の委員会が取り扱いを決めることになっている。

課題は各州と連邦政府で別々の法律があることである。これは、各州でそれぞれ独自の環境政策があるからである。クイーンズランド州は保護にも熱心であるが、バイオテクノロジー開発にも力をいれている。クイーンズランド州は生物資源が最も豊富な州である。グレートバリアリーフの石炭開発にも力をいれている。北部準州では、赤道に近いので熱帯性の生物多様性に富んでいる。アボリジニー以外の独自の先住民もいるので保護が優勢である。西部オーストラリア州では天然資源開発（石炭、ガス、鉱物）開発が盛んである。陸上の生物資源には乏しいが、海洋資源はある。どちらかというと開発よりの政策を取っている。

連邦政府と地方州政府の間で、生物多様性条約関連について統一したシステムを作ることが必要になる。オーストラリア独自の生物資源へのアクセスと利用に関する統一アプローチ [8]の考え方がだされているが、それぞれの思惑のため思うように進んでいない。連邦政府は名古屋議定書の国内措置も統一した方法を取りたいと考えているようで、現在関係政府内で議論が進んでいる。

以上を考えると、PIC 制度は複雑である。連邦政府、州政府のどちらでもらうかは明確に決まっていない。へたをすれば先住民の PIC や土地所有者の PIC など 3-4 つの PIC が必要になるかもしれない

遺伝子特許について

米国で Myriad の乳がん遺伝子特許の無効判決がでたが、オーストラリアでも同じような遺伝子特許問題が高等裁判所で争われている。どのような判決がでるかによって遺伝子特許、遺伝資源特許の在り方がかわるのではないかと考えている。遺伝資源で DNA 解析などを行い、有用な遺伝子を見つけても、特許化することは難しいし、取れても限定的である。

合成生物学も生物多様性条約内では大きな話題になりつつあるが、オーストラリアの中では、まだそれほど大きな話題にはなっていない。ただし、Creig Ventor Institute の海洋資源探索活動は、オーストラリアで大変話題になっており、環境問題と関連して議論されている。

気候変動枠組条約と CBD の関係をもっと議論すべきである。気候変動がもたらす生物多様性への影響は大きい。気候変動条約と CBD はもっと密に議論を続けるべきである。

[8] Nationally Consistent Approach for Access to and the Utilisation of Australia's Native Genetic and Biochemical Resources.

CAMBIA[9]の活動は知っている。しかし、本当にオープンソース運動をやっているのか懐疑的である。ANU はアジア太平洋地域研究が盛んで、センター[10]がある。

[9] http://www.cambia.org/daisy/cambia/home.html.
[10] http://asiapacific.anu.edu.au/.

Mr. Ben Phillips

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面談内容

オーストラリア連邦政府管轄地での ABS 制度について

連邦政府管轄地でのアクセスと利益配分に関しては、細かな規定が環境保護生物多様性保全改正規則 2005(2)をもとに作成されている [11]。連邦政府管轄地とは、国立公園（Kakadu National Park, Uluru-Kata Tjuta National Park, and Booderee National Park）、排他的経済水域内の領海、大陸棚、首都準州などである。そこには、アクセス許可申請書のフォーム（参考資料）が添付されている。重要な点は、申請者の法の自己遵守の宣誓書を提出しなければならない点である。これに違反すると罰則がある。オーストラリアは簡便な方法として電子申請が可能である。

オーストラリアの名古屋議定書批准状況

オーストラリアのバイオ研究者もアクセスと利益配分に関してそれほど詳しいわけではなく、まだまだ普及教育が必要と考えている。その中で、名古屋議定書批准を考えていかなければならない。

名古屋議定書批准のためのモデル案を作成した。(参考資料)　オーストラリア全体で統一して実施できる制度を考えている。このモデル案を用いて関係者（植物園、博物館、コレクション）のコンサルテーションを行った。各関係者を集めたミーティングを開催し、意見交換した。印象では、大部分の関係者がモデル案に賛成したと考えている。特にオーストラリア海洋生物学研究所（AIMS）の賛成を得ている。

[11] http://www.environment.gov.au./topics/science-and-research/australias-biological-resources/permits

セクター毎、特にコレクションで、名古屋議定書批准のための行動規範を作ることを提案しているが、今後この点を重点的に関係者と詰めていく考えである。コレクションの行動規範ができれば、コレクションのシステムを名古屋議定書向けに改良するのに有効であると思われる。

EU 規則と同じ due diligence を取り入れる考えである。利用者側の制度は同じでないと、利用者が混乱する。公共資金で研究した時、その報告書に法的情報（PIC/MAT か）を記載することを求める。公共資金以外の資金のときどうするかまだ決まっていない。オーストラリアは公共資金が多いので問題ない。カナダの情報によれば、カナダはほとんど民間資金で遺伝資源研究がされているので、カナダではこのやり方は実効性がないといっている。

PIC 制度の作らない国（別段の決定）は、クリアリングハウス制度で公表されることになる。そうすれば、どの国に PIC が必要でないことが、情報がすぐわかることになる。ただし、念のため、PIC 制度を作らない国のフォーカルポイントから、PIC 不要証明書をもらうことはよいことと考える。

クリアリングハウスが認証したものについて、国際認証としてそのまま受け入れる。チェックポイントが PIC 内容、正当性を精査することはない。PIC 制度をこれから作る国は、現行の MOU などで証明してもらえればよいのではないか。今後、学会報告等で PIC 番号が必要になる可能性が高くなると思う。学会雑誌など（Nature や Science）なども遺伝資源に関連する研究の発表には PIC 番号などを記載する条件にする可能性が高い。PIC 制度がなく PIC を持っていなくても、PIC 不要証明書が必要になる。こういうことになれば、研究者の認識も変わると思う。

伝統的知識、先住民の取り扱いについて

伝統的知識の取り扱いは難しい課題である。伝統的知識は政府のものではなく保持者のものなので、政府が干渉することはないというのがオーストラリアの考え方である。オーストラリアには約 800 のアボリジニー種族がある。これを政府が管理することは不可能である。したがって、政府は利用者からの報告を受け、チェックし、一定の基準に合っていれば、報告を了解する。オーストラリア政府の PIC 許可は必要ないが、先住民からは当然 PIC は必要である。

先住民社会では、自身の所有物を利用したりさせたりする場合、法的な委員会制度がすでに確立されている。先住民の土地を利用する場合、委員会と相談し、許可を得ることが必要である。ただし、先住民所有地の地下資源について所有権が及ばないとする考えが一般的なので、石炭開発等で紛争が発生する。この委員会制度を遺伝資源の PIC 取得に利用することになる。ただし、似たような種族が多数いるので、どの種族にアプローチするのか難しい問題がある。種族間で紛争している場合は、同意を得ることは難しい。

現在、オーストラリア政府は、先住民に所有物、所有地を返還するプログラムを行っている。ただし、先住民のものかどうか判断することは、言葉だけで文書がないので、困難である。最近、100 年以上保存されていたアボリジニーの毛髪から DNA 解析され、他の民族と比較され、アボリジニーの祖先を探る研究がされたが、アボリジニーからは猛烈な反対運動が起こり、博物館に保存されていたアボリジニーの毛髪は返却された。

伝統的知識は無形であるので、その所有権を決定することは更に難しい。やはり、社会的責任からの政策的な取り組みが重要であり、国全体のシステムを変える取り組みとなる。

Dr. Graham Matheson

面談日：7 月 30 日(水) AM11:00-13:00
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専門：CIMTECH 創始者。クック島遺伝資源利用した伝統医薬や化粧品開発販売ベンチャー。クック島の伝統的知識保持者との PIC 取得や利益配分契約経験ある。

Dr. W.R. Walsh
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Dr. Matheson の CIMTECH の共同研究開発先。潰瘍研究をしている。

内容：
Cook Islands は他の太平洋諸国とは異なり、アクセスと利益配分制度は整っている。すでに、商用開発のための遺伝資源利用契約を結んだ経験を持つ。遺伝資源も豊富であり、住んでいる先住民も単一のマオリ族であるため、統治組織が明確である。伝統的な法体系 Koutu Nui を持っている。


**図 1　クック島の Raui 地区の海洋保護地域写真**
クック島の伝統的法組織Koutu Nuiによって統制されている。

Cook Islands は安全でフレンドリーな島である。住民の教育水準は高く、ほとんどの島民は英語をしゃべれる。クックアイランドは人口 14000 人、９０%以上がマオリ族である。北部はフラットであるが、南に 600m の山があり、生物多様性は富んでいる。

Cook Islands の環境省がフォーカルポイントになっている。ただし担当職員が 3 人しかいない。Elizabeth Munro（elizabeth.munro@cookislands.gov.ck）が環境省の生物多様性管理者である。アクセスと利益配分の管理を行っている。

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**図 2　クック島政府のナショナルフォーカルポイント Ms. Elizabeth Munro とその家族**

名古屋議定書を批准するため、現在アクセス法案を作成中である。名古屋議定書実施基金

（NPIF）の援助を受けている。法律は他の島との協調も必要である。伝統的知識の取り扱いが難しく、なかなか整備が進んでいない。

名古屋議定書は理想的ではあるが、現実に実践することは難しい。特に伝統的知識を用いる場合は、現在マオリ族の委員会 Koutu Nui の許可が必要である。これはマオリ族独特の伝統的法組織である。どのようにマオリ族にアクセスするかはフォーカルポイントが教えてくれる。

名古屋議定書によれば、研究活動にはマオリ族の参加が必須である。ただし、大学や研究所もなく、学術研究者もいない。遺伝資源を取り扱うにも、伝統的な方法を踏襲することが重要である。たとえば乾燥させたり、熱抽出させたりしてはいけないという伝統的知識があれば、それに従うべきである。これを怠り、単に溶媒抽出などをすると、活性成分が失われる可能性がある。

PIC 許可の条件として利益配分が最も重要である。利益配分として、共同研究者にマオリ族を入れることは当然と考えている。学会発表、特許にも共同研究者としてマオリ族の名前を入れることが求められる。学術研究の場合、商用化するときに改めてマオリ族の許可が必要である。研究発表する際にも許可がいる。

金銭的利益を重視するのは、マオリ族の生活向上に貢献しなければ研究の意味がないと考えているからである。学術研究でも金銭的利益は必要である。何らかの金銭的利益がなければ許可されない。そうはいっても、商品の販売による利益はそう簡単にはでないのが現実である。学術研究の金銭的利益は更に遠い。そこで、マオリ族に対して初期から利益を配分方法があるかよく考えるべきである。CIMTECH では、売上の利益を配分するのは当然であるが、それと同時に会社の資本金のマオリ族に分配している。そうすると参加意識が芽生える。

現在。傷の治癒に用いる薬草を現代医学に応用することを目指した医薬品を開発しているが、動物実験はできるだけ伝統的知識をまねた方法を取っている。西洋式のやりかたでは活性がでない場合があるからである。分析ではなく全体として利用することが重要であると考えている。

Matheson の会社 CIMTECH では、Cook Islands でしか使われていない遺伝資源を用いて研究開発している。したがって、サモアなど他の島から同じ遺伝資源について文句を付けられることはない。他の太平洋諸島では、同じ遺伝資源の利用を巡る争いがある。

開発に用いる遺伝資源の供給は栽培化をしており、野生のものではない。種子はマオリ族の専門家に選択してもらい、本物のみを栽培している。なぜなら、変異により亜種がいろいろできるので、活性を保つためなるべくオリジナルを維持している。

Professor Kamal Puri

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専門：遺伝資源あるいは関連する伝統的知識に関する知的財産側面の法学研究者、WIPO 教育プログラム実施

内容：
オーストラリア連邦政府の先住民アボリジニー政策は表面上熱心に行っているように見えるが、実際には表面的であり政府が深入りしない印象を受けるし、アボリジニーにインタビューしても政府に対する不満が多い。オーストラリア政府は産業界のいうことはよく聞くが、アボリジニーのいうことはできるだけ引き延ばし、うやむやにする態度であることは昔から変わりない。できるだけ避けて通る態度である。これでは、アボリジニーの現在の悲惨な生活が向上するとは思えない。

アボリジニーとなんらかの契約をして MAT を満足させることは基本的に不可能である。なぜなら、アボリジニーは西洋の契約についての概念が理解できず、自分たちの伝統的習慣法（おきて）にもとづいて判断している。西洋式契約について何も知らないアボリジニーと公正で衡平な利益配分契約ができるはずはない。公正でも、衡平でもない。アボリジニーは委員会組織などを作って自治を行っている。しかし、あくまで表面的で、実際には積極的に独自システムの改良、問題解決は行っていないし、そのような資金も存在しない。

オーストラリア、ニュージランド、パプアニューギニア、フィージーなど 39 の国を含む南太平洋地域で伝統的知識や伝統的文化表現に関する Model Law[12]を確立するプロジェクトをオーストラリア政府から資金提供を受けて 3 年＋1 年行った。最終版を 2002 年に作ったところ、オーストラリア政府とニュージランド政府を除く国は賛成したにも関わらず、両政府はまだこのプロジェクトは完成していない、もっと研究すべきであるという理由で報告書を最終化するのに反対した。両政府を除くいくつかの国は、この Model Law を基礎に各国の国内法を作ろうとしたが、いずれの国もその資金や人材はオーストラリア政府から援助を受けているので、いまだにドラフト段階で止まっている。オーストラリア政府が賛成し、資金を提供しない限り完成はできない。両政府は、できるだけ先延ばしにして、うやむやにする態度である。これでは南太平洋地区で名古屋議定書、特に伝統的知識を実施したくてもできない。

12 “REGIONAL FRAMEWORK for the Protection of Traditional Knowledge and Expressions of Culture”; http://www.forumsec.org.fj/resources/uploads/attachments/documents/PacificModelLaw,ProtectionofTKandExprssnsofCulture20021.pdf.

これを解決するにはトップダウンに頼っているだけではだめで、ボトムアップを強力に進めるべきである。たくさんの事例を分析し、そこからベストプラクティスを見出していくことが現実の問題を解決する有効な手段であると考える。

WIPO-QUT[13]プログラムを強力に推進している。世界の特許関係者を教育するプログラムであるが、アジアの多くの国から特許庁関係者が参加している。今度日本の特許庁からもプログラム参加者がある。今度 9 月に韓国で開かれる AIPPI の Working Group Q232[14] (Traditional Knowledge)でプレナリースピーチを行う。WIPO の事務局長 Francis Gurry は 30 年来の友人である。でんとうに大変興味を持っている。モダンローの原稿を見せたら、11 ページのレスポンスがあった。

[13] https://www.qut.edu.au/study/international-courses/master-of-laws-in-intellectual-property.
[14] https://www.aippi.org/download/commitees/232/RS232English.pdf.

Professor Ronnald J. Quinn

面談日：8 月 1 日（金）10:00 12:00 AM
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専門：動物、植物、微生物から有用化合物を探索する研究所の所長。アクセスと利益配分契約の経験豊富。

Dr Stuart Newman
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専門：Dr. Quinn のアシスタント、ABS 関係のマネージャを一人で行っている。ただしこの日が最後。クイーンズランド州の Queensland Compound library(ケミカルライブライの一種、同施設内設置）のマネージャに転職

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内容：

Griffith 大 Eskitis 研は生物多様性条約ができる前から、バイオ探索研究を行っており、アクセスと利益配分、特に利益配分に対して真剣に取り組んでいた。英国製薬会社 AstraZeneca とのプロジェクトで資金が入ったため施設が建設できた。Griffith 大学と AstraZeneca は 1993 年以来共同研究契約を締結し、植物及び海洋生物から新規な医薬品を探索する研究を実施した。主に Griffith 大学で一連の分離、抽出操作を行い、それには当初 17 名の技術者が当たっていたが 2000 年には 43 名に増加した。AstraZeneca はこの共同研究事業にすでに 2700 万オーストラリアドルを投資したと報告している。1998 年にこの事業が 2003 年まで延長されることが決定され、AstraZeneca は更に 3100 万オーストラリアドルを投資した。Griffith 大学は上市された化合物に対するロイヤリティを利益配分として受けることになっている。この共同研究事業によって、Griffith 大学や周辺の研究機関の探索技術が向上し、新知見が得られた。例えばクイーンズランド州の博物館[15]では海洋生物の収集を担当しているが、この共同事業のおかげで 37 種の植物新種を発見することができた。更に、僻地における海洋環境保護に貢献することができた。原始林における雑草の侵食状態を記録することにより、原始林の管理が容易になるなどの成果をあげた。

オーストラリアで最初に生物多様性法ができたのがクイーンズランド州である。連邦政府より古い歴史がある。クイーンズランド州では、バイオベンチャーを中心にバイオ探索研究が盛んに行われてきた歴史がある。クイーンズランド州の生物多様性法は少し使い勝手が悪い。利益配分がちゃんと考えられていない面がある。BioProspect Limited (BioProspect と略)は、オーストラリア人が生物多様性条約に基づいて自身の資金で経営を行っている[16]。もし、資金援助者などがついていると独立性が失われ、衡平性が保てないと考えているからである。特に製薬企業の資金を受ければ、その意向に沿った探索研究を行わなければならなくなり、そうなれば、合理的な運営はできない。BioProspect では、生物遺伝資源へのアクセスは持続可能なアクセスに限定し、研究に必要な最小量しか採取しない方針である。また、希少植物の抽出は、栽培化など持続可能と判断されたとき以外は行わない。大量に試料が必要な後期研究段階では、栽培可能な試料に限定される。

BioProspect は、アクセスと利益配分に関する契約を西オーストラリア州とクイーンズランド州と結んでいる。契約によれば、BioProspect が抽出したサンプルを第三者機関の研究のため移転できることになっている。BioProspect の利益配分に対する考え方として、知的財産権は政府に帰するべきであると考えている。したがって製品販売を行う企業は政府からライセンスを受けることになる。ライセンスの見返りに、利益配分としてロイヤリティを両州政府に支払う。生物遺伝資源の収集・同定は政府機関の職員を使うことでより公平性、透明性を保つことにしている。生物遺伝資源探索研究から得られたロイヤリティなどの利益は、信託管理基金かプール形式で保管し、生物多様性保護あるいは生物相の持続可能な発展に貢献する伝統的知識の保護ために使われるべきであると考えている。

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[15] クイーンズランド州博物館：クイーンズランド州環境保護局の一部で、クイーンズランド州の植物資源の情報センターとして機能し、植物資源情報の収集活動を行う；
http://www.epa.qld.gov.au/nature_conservation/plants/queensland_herbarium/#about..

[16] BioProspect, “About the company”, http://www.bioprospect.com/.

州法に従うか、連邦法に従うかは取り扱う遺伝資源が誰に属しているかによって異なる。国立公園や AIMS など国立の研究機関などから入手する場合は連邦法に従う。州の植物園、博物館、州の大学等は州法に従う。

Eskitis 研は Griffith 大の中にあるが、完全に商用目的を意識した管理を行っている。商用開発を目的にしているため、企業との共同研究が主流である。管理部門の所属は、Griffith 大の産学連携本部であるが、他の産学連携事業とは性格が異なるので、特別扱いにしてもらっている。ただし、サインは Griffith 大の産学連携本部長が行う。

遺伝資源はクイーンズランド州植物園、博物館と協力して行ったのが最初である。いまでは、パプアニューギニアや中国など世界の遺伝資源を受け入れている。オーストラリア国立海洋生物研（AIMS）の海洋サンプルも受け入れている。現在、45000 サンプルを保存している。受け入れに際しては MAT を結ぶのが当然である。MAT は生物多様性条約発効以前から行っている。利益配分が最も重要な項目と考えており、商用開発で得られる利益の配分を明確にしている。クイーンズランド州植物園、博物館は州のものなので、利益配分は州政府に行っており、州政府の収入になる。

Eskitis 研では、入手した遺伝資源を乾燥、粉砕、抽出、活性測定、化合物同定、化合物ライブラリの作成を行っている。DNA 分析は行っていない。世界の製薬企業に化合物を供給したり、共同研究ということで、Eskitis 研で生理活性を調べたりしている。日本のベンチャーとの共同研究も行っている。企業とは MTA あるいはライセンス契約になり、それにはさまざまな利益配分条項がある。企業とクイーンズランド州とは直接契約は行わないで、Eskitis 研が仲介している。企業が州政府のスロー手続きを嫌うからである。

アボリジニーの伝統的知識を使う場合がある。その場合、保持者とは特別の契約を結ぶ。その際の利益配分は 50:50 である。これは米国の ICBG と同じ割合である。伝統的知識を使う際は、その部族のみならず周辺の部族にも知らせて、不満がでないようにしている。ウエスタンオーストラリア州で先住民の土地でガス開発計画が起こったとき、ある部族は賛成、他の部族は反対したため、部族間で紛争が起こった経緯がある。このようなことを避けるために、伝統的知識が関与する場合は慎重な契約を行っている。

Ms. Libby Evans-Illidge

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オーストラリア国立海洋生物学研究所で 30 年以上海洋生物の多様性研究。現在は同研究所で、生物多様性条約関係の研究所政策、原則などの立案担当。研究所の名古屋議定書対応のあり方

内容：

オーストラリア連邦政府は名古屋議定書の国内措置を策定している。すでに、モデルが環境省 Ben Phillips からオーストラリア国立海洋生物学研究所（AIMS）に示されているし、Griffith 大でミーティングも行った。オーストラリア政府の国内措置の考え方は EU 規則と似ていると考えている。

連邦政府の提示した名古屋議定書国内措置モデル案に対する AIMS の考え方[17]を発表した。AIMS の研究活動に影響を及ぼすため、名古屋議定書国内措置に強い関心を持ち、注目している。AIMS では 25 年のアクセスと利益配分活動実績がある。非常に効率的なコレクション管理システムをすでに開発しており、個々のコレクションに関するデータが一つのデータベースで管理されている。特に、採取許可、利益配分やその他の契約も一緒にひも付され保存されている。AIMS は、名古屋議定書の実施を通じてオーストラリアのバイオ探索研究に透明性の高い出所の合法性と遵守の制度を提供する試みに賛成する。AIMS の保存サンプル管理システムは新しい制度に適応したものであるので、いつでも実行可能である。

すべての遺伝資源サンプルの移転は、名古屋議定書国内措置のシステムに従わなければならないことは理解している。このことは、AIMS の現存するバイオリソースライブラリー管理システムの管理範囲を拡大することを要求しているように思われる。名古屋議定書で考えられているアクセスと利益配分に関するクリアリングハウスメカニズムにビルトインされた国際遵守証明（International Certificates of Compliance (ICC)）の考え方を AIMS は理解し、それを支持する。国際遵守証明は、遵守と合法性を証明する透明性の高い国際

[17] A submission on Australia's draft model for implementing the Nagoya Protocol in Australia. Submitted to the Department of Environment 27 June 2014.

的な仕組みであると考える。オーストラリア連邦政府は、国際遵守認証の発行に際し、アクセスと利益配分の許可プロセスの重複とリスクを最小限になるようにしていただきたい。

示された原則と将来できる実際のプロセス過程を分析した後ではあるが、AIMS は信頼ある機関（trusted collection）としての認定の申請を行いたいと考えている。そうすることによって、AIMS が現在保有するバイオリソースライブラリーやその他の収集物に対して、自ら国際遵守証明を発行することができると考える。

AIMS はチェックポイントシステムの利用を原則として支持するが、チェックポイントシステムの開発は、現存する報告義務制度に沿って行うべきであると考える。報告者に過度の負担をかけるべきではない。そうすることによって、研究者の管理的重荷を避けることができる。そのために、チェックポイントへの報告義務は、遵守、位置情報や国際遵守証明のデータ情報について、現存の報告システム（例えば公共資金報告、査読済出版）などで行うべきであると考える。

AIMS は連邦政府が資金提供している国立機関であるので、連邦政府の政策、方針に従う。しかし、AIMS の活動がクイーンズランド州中心なので、クイーンズランド生物多様性法に基づきクイーンズランド州と PIC/MAT 契約を行わなければならない。連邦政府と各州の方針が異なっていると、統一した方法を取ることは困難である。最近オーストラリア連邦政府が政権交代したため、国の方針が、環境より開発に変化した。環境省の ABS 陣容も縮小された。AIMS も国の方針変更に伴い、従来から行っているバイオ探索研究を行っていくことが難しくなった。一方、クイーンズランド州はもともとバイオテクノロジー開発志向が強い。このような状況では、オーストラリア全体で統一した考え方で名古屋議定書を実施することは困難と考える。

AIMS は生物多様性条約ができる以前から、PIC/MAT の考え方を持っていた。CBD 以前から利益配分契約を実施している。生物多様性条約以前の保存サンプルで MAT がないものは、消費して再度収集する際に MAT を結ぶようにしている。保存サンプルで MAT のないものはだれも使わなくなった。デッドサンプルとなる。保存サンプルには、その PIC/MAT 情報が一緒に保存されている。もともと第三者が商用開発することを想定しているので、第三者とは素材ライセンス契約（Material Licensing Agreement（MLA））を標準としている。また収集する際には、提供者に第三者移転を認めてもらっている。MLA は一種のライセンス契約であり、実施権を認めているだけであり、所有権はあくまで AIMS にある。したがって、サンプルからどんな派生物が開発されたとしても、AIMS の権利は継続する。第三者は起源の提供者と PIC/MAT を結ぶ必要はない。AIMS がその責任を持つ。

課題は、このような利益配分契約をしても、それを 20 年も管理し、開発をフォローすることは大変難しい。政府なら更に困難であろう。オーストラリアでは chemical library (depository)構想があり、天然化合物を集中管理する方針である。現在 Eskitis 研に設置されており、オーストラリアで分離された化合物を保存し、分析し、第三者に移転する。その管理を Eskitis 研が行っている。今後ここがアクセスと利益配分管理の中心となっていくだろう。

オーストラリア政府の方針が変わり、海洋生物から有用物質を分離する事業は縮小傾向にある。そのため、過去に分離した化合物や抽出物を保存してくれる機関を探して移管している。一つはオーストラリアの Eskitis 研の Chemical Library であり、もう一つは米国

NIH/NCI のデポジトリーである。NCI の David Newman と共同研究関係にある。

公海からの収集はわずかである。したがって国連海洋法条約（UNCLOS）のことはあまり考慮にいれていない。しかし、UNCLOS では生物多様性の課題は重要であり、議論に参加したことはある。ただし、公海での生物資源の取り扱いはなかなか決まらないのではないかと予想する。そもそも UNCLOS の基本的考え方が生物多様性条約とは異なる。欧州の PharmaSea の取り組みに関心がある。南極にも採取に行くことはあるが、活動自体はわずかである。

AIMS の研究所はオーストラリアに 3 か所ある。Perth、Darwin、Townsville である。それぞれ違った環境にあるので、違った海洋生物を研究し保存しているが、情報は共有されている。AIMS は海綿から Halichondrin 系の抗ガン剤を発見したが、第三者が興味を持って開発を引き受けてくれない。まだ動物実験も行っていない。日本の企業がやってくれないか紹介してほしい。HalichondrinB の開発に大変興味を持っている。

12 月 12 日に開かれるシンポジウムに参加を要請したところ、招待を受ければぜひ参加したいということであった。オーストラリアの名古屋議定書実施の実情の話をすることができるということである。

Professor Charles Lawson

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CBD アクセスと利益配分に関する法的理論研究者。AIPPI 経由 Spruson & Ferguson 山本様紹介。

内容：

オーストラリアでは政治的に生物多様性制度は確立している。ただし、現実の世界は異なり、多くの問題点を抱えている。問題の一つは、連邦と州で生物多様性制度について異なる考え方を持っており、オーストラリア全体で統一した制度となっていない。クイーンズランド州で最初に生物多様性法を導入したが、その内容は複雑である。適用されるのは州の管理する地区のみであり、そこの遺伝資源を利用する場合 PIC/MAT が必要である。個人所有の土地が大部分であるので、作物のようなものは、個人から許可を得れば MAT であり、それ以上のことはない。だれも州の管理地にわざわざ行くことはない。もし、ニューサウスウエールズ州にも同じようなものがあれば、法律がないのでそちらにいく。

名古屋議定書を施行するのに最大の問題はチェックポイントであると考える。その他はすでに法律として整備されているので大きな問題はない。現在、連邦政府の環境省がどのような名古屋議定書施行システムを作るか関係者にモデルを示してコンサルテーションをしているところである。チェックポイントを州に置くのか、連邦政府の環境省に置くのか大きな問題である。ニューサウスウエールズ州、ウエスタンオーストラリア州、サウスオーストラリア州には生物多様性法はないので、チックポイント機能は果たせない。コレクションがチェックポイントになることも難しいのではないか。報告者と管理者が同じではチェックにならない。連邦政府にチェックポイントを作ったとしても、州政府組織との連携がうまくいくのか疑問である。

国立海洋生物研究所は国立機関なので、もし利益配分があったとしても連邦政府の収入になり、研究所に直接利益配分されることはない。いまのところ、探索研究で商用まで行った例はないはずなので、利益配分は受けていないはずである。国立海洋生物研究所の本来の目的は環境保全であるが、その活動には資金が必要であるが、それを自ら行うバイオ探索の利益配分から受けることはないので、モチベーションが低くなるのはしかたがない。

Griffith 大の Eskitis 研が古くからバイオ探索研究を行っている。設立当時、Astrazeneca から研究所設立資金を出してもらった経緯がある。Astrazeneca がなければ、Eskitis 研はなかったことになる。いまでも Astrazeneca との関係は続いていて影響力があるので、その他の製薬会社は手を出しにくいのではないか。Eskitis 研の企業との契約はすべて秘密であり、公開されることはないのでよく理解していない。他の企業が Eskitis の保存化合物を使おうと思っても、その結果が Astrazeneca に漏れる恐れが多いので、共同研究をやりたがらないと思う。40000 点のサンプルをそろえたが、そこから医薬品が販売されて利益配分を受けているという報告はない。Eskitis 研は Griffith 大に属しているので、利益配分があれば Griffith 大に入ることになる。

生物多様性条約では、提供国の提供者と MAT を結ぶのが決まりであるが、第三者に移転する際にどのような契約をするかは規制していない。したがって、第三者とは当事者間の契約で自由にできる。極端なことを言えば利益配分しなくてもよい。そのような事態は現実にないが、問題は派生物の範囲をどこにするかで利益配分が異なる。受け取った遺伝資源と全く異なった派生物が商品になった場合、どの範囲でどの程度の利益配分をするかは、ライセンスサー（研究者）とライセンシー（企業）の間の決め事であるはずである。この第三者との契約内容によって、最初の提供者が受ける利益配分は大きく影響を受ける。第三者契約における提供者の地位についてもっと議論する必要があるのではないか。現実には医薬品などは、ほとんど成功しないので、利益配分を研究者側が受けることも現実的ではないし、まして提供者が受けることは皆無であるであるので、真剣な議論はあまり行われていないのが残念である。

伝統的知識は大変難しい問題である。オーストラリアには約 800 の先住民部族があり、それぞれ違った言葉、伝統を持っている。ひとつの部族から伝統的知識を使う交渉をしても、となりの部族がそれに反対すると使えない。伝統的知識利用の PIC をどのように考えるか検討を続けなければならない。伝統的知識のデータベースを作る試みがあるが、うまくいかない。協力的な部族もあるが、秘密であると非協力的な部族も多い。言葉しかなく文字がないので、おなじような話でどの話が正当な伝統的知識か不明である。伝統的知識の対象とその所有者が明確でなければ法律として機能しない。

日本の漢方と中国の関係は大変興味がある。資料を送ってほしい。

参考資料

名古屋議定書実施のためのオーストラリア連邦政府のモデル提案

A Model for Implementing the Nagoya Protocol in Australia

What is the Nagoya Protocol?

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (the Protocol) is a global agreement that implements the access and benefit-sharing obligations of the Convention on Biological Diversity (CBD). It was adopted in October 2010 and will come into force when ratified by 50 countries.

The Challenge

Genetic resources from plants, animals and microorganisms are increasingly valuable in the development of specialty enzymes, enhanced genes, or small molecules. These products can be used in many areas, including crop protection, drug development, production of specialised chemicals, biotech innovation and industrial processing.
The Protocol aims to ensure the fair and equitable sharing of benefits arising from the use of genetic resources. Finding a practical way to do this has been challenging and few countries, other than Australia, have implemented an access system that welcomes and encourages research. Lack of a coherent global standard has also resulted in a high level of uncertainty, creating obstacles to biodiversity research.

The Protocol's Benefits

The Protocol establishes a legally-binding framework that helps biotechnology and other researchers access genetic resources in return for a fair share of any benefits from their use. This provides the R&D sector with the legal certainty they need to invest in biodiversity-based research. Indigenous and local communities may also benefit through the Protocol's requirement of prior informed consent for the use of their traditional knowledge associated with genetic resources.

A Workable, Cost Effective System

Proper implementation of the Nagoya Protocol will maximise benefits from research based on genetic resources and associated traditional knowledge. The Government aims to develop a workable, ethical and cost-effective way to implement the Protocol in Australia. The aim is to increase certainty for both users and providers of genetic resources and associated traditional knowledge. When implemented, the Nagoya Protocol will affect the operations of those who use genetic resources and associated traditional knowledge.

☐ The principal effect will be to enhance transparency in the use of genetic resources and associated traditional knowledge, enabling users to demonstrate that these resources are sourced legally.

- ☐ International standards in access and certification will enable users of these resources to be satisfied that the resources they use were legally acquired.
- ☐ User countries will be obliged to take measures on compliance and the use of these resources in their country, while provider countries will need to meet new standards in providing access.

Certainty for Users and Providers of Genetic Resources

All countries have the right to determine access to their genetic resources, and many countries already regulate their collection and use. Parties to the Protocol must ensure that genetic resources and associated traditional knowledge used in their country are acquired legally in the country from which they were sourced.
The Nagoya Protocol makes it easier to find out how to access genetic resources, and to provide evidence demonstrating their legal acquisition. This increases legal certainty and confidence in the use of genetic resources by users and providers.
Under the Protocol, regulations for access to genetic resources will need to meet new standards of transparency, timeliness and legal certainty. Regulations must be published on the Protocol's website, and be clear on how permission to access genetic resources can be obtained.
Australian legislation that requires a permit for the collection and use of genetic resources meets the standards required by the Protocol. Users of genetic resources from Australia will need to be able to demonstrate that they have obtained that permit. Users of associated traditional knowledge will need to be able to demonstrate that it was obtained with prior informed consent and on mutually agreed terms, and in accordance with applicable laws.

Implementing the Protocol Internationally

An Access and Benefit-sharing (ABS) Clearing House website will be established to publish access legislation and associated permits. Other countries implementing the Protocol will recognise published access permits as International Certificates of Compliance (ICC). ICCs will play an important part role in establishing provenance of genetic resources and associated traditional knowledge.

- ☐ Australia proposes to recognise ICCs as evidence of legal acquisition of genetic resources and associated traditional knowledge

Parties need to monitor the use of genetic resources at one or more checkpoints and establish appropriate measures to effectively deal with non-compliance. Australia's implementation of the Protocol will give provider countries the assurance of compliance they need, which will assist researchers in accessing resources in those countries.

Implementing the Protocol in Australia

Scope of the Protocol

☐ Australia proposes to implement compliance measures only in relation to genetic resources and associated traditional knowledge acquired after the Protocol comes into effect in Australia

For some ex-situ collections, such as existing bio-resource libraries, this means that they would not have to provide provenance details for material acquired before the Protocol comes into effect. However, to maximise the usefulness of their collections for research, such collections may prefer to administer their whole collection to meet Protocol's standards.

☐ Australian measures would not apply to:

- resources acquired in jurisdictions that do not meet the relevant provider standards;
- resources acquired beyond national jurisdiction; and
- resources acquired under another specialised international ABS system, such as the Multilateral System of the International Treaty on Plant Genetic Resources for Food and Agriculture

Australia's Approach

In order to meet Protocol obligations as a user country, some changes are required to legislation.

Australia proposes to:

☐ Support and facilitate the development of Codes of Conduct that are consistent with the Nagoya Protocol for different user sectors. Codes of Conduct would document reporting obligations as well as standards for, and the circumstances where, due diligence processes should be undertaken.

☐ Require an agreement between users of associated traditional knowledge and the Indigenous people providing that knowledge that is negotiated in accordance with a specific code of conduct—either a community protocol, the AIATSIS Guidelines for the Conduct of Research in Indigenous Studies or a sui generis Code developed in consultation with Aboriginal and Torres Strait Islander people. The Australian Government does not have jurisdiction over access to associated traditional knowledge, and would not be a party to mutually agreed terms for its use.

☐ Recognise trusted institutions which opt and qualify to be accredited to provide genetic resources. These institutions would be required to demonstrate a due diligence and administrative standard that provides a warranty for the legal acquisition and use of genetic resources.

☐ Establish a checkpoint that requires recipients of Commonwealth government funding for research using genetic resources and/or associated traditional knowledge to report on and provide evidence for the legal provenance of those resources. In the case of the use of associated traditional knowledge held by

Australian Indigenous people, reports would include evidence of an agreement with the holders of that knowledge.

☐ Create an offence within the Environment Protection and Biodiversity Conservation Act to use illegally acquired genetic resources and/or associated traditional knowledge:
   a. where use is reckless to the source; and
   b. where genetic resources and/or associated traditional knowledge were obtained in contravention of provider measures (where such measures are available on the ABS Clearing House website and meet the standards required by the Protocol).

It would not be an offence if:
   a. due diligence was conducted in accordance with an agreed code of conduct, and
   b. on the available evidence, it is reasonable to believe that the genetic resources and/or associated traditional knowledge were legally obtained.

An International Certificate of Compliance or equivalent would be taken as evidence of legal acquisition, as would obtaining the resources from a 'trusted institution'.

☐ Provide audit powers to the Commonwealth to monitor, using a risk-based approach, the use of genetic resources and/or associated traditional knowledge for potential breaches of the above offence.

A person or institution in good standing with the relevant code of conduct would be regarded as being of low risk for audit purposes.

☐ Provide an option for remedy to allow a user of genetic resources to remedy the legal status of potentially illegally acquired resources with written permission of the source country, and on established mutually agreed terms. If this cannot be negotiated, it would remain an offence to continue to use the resource.

Interaction with International ABS Schemes

The European Union is a major user of genetic resources and associated traditional knowledge. It intends to enact Union-wide legislation to implement the Protocol by July 2014.
Proposed European regulation would oblige users of genetic resources to check that genetic resources and associated traditional knowledge have been accessed in accordance with the applicable legal requirements in the source country.
Due diligence obligations on users would be monitored to ensure compliance with the Nagoya Protocol. It is highly likely that the European model will set the standard for other industrialised users of genetic resources.
This will have implications for Australian researchers using genetic resources, whether native or exotic, in collaboration with EU researchers or where seeking to access

European commercialisation pathways.
A primary objective in implementing the Nagoya Protocol in Australia is to ensure that Australian research, and research involving Australian genetic resources or associated traditional knowledge, continues to have access to international research, development and potential commercialisation opportunities.

Glossary

ABS means access and benefit-sharing in relation to the use of genetic resources and associated traditional knowledge.
A genetic resource is any material of plant, microbial or other origin containing functional units of heredity which is of actual or potential value.
An International Certificate of Compliance is a permit or equivalent, issued in accordance with the standards of the Protocol, which is made available on the ABS Clearing House Mechanism website.
Use/utilisation of genetic resources means to conduct research and development on their genetic and/or biochemical composition.
User countries are countries where genetic resources and traditional knowledge are used for research and development activities.
Provider countries are countries where genetic resources are sourced.

Further information[18]

オーストラリアの遺伝あるいは生化学的資源のアクセスと利用に関する全国統一アプローチ

Nationally Consistent Approach for Access to and the Utilisation of Australia's Native Genetic and Biochemical Resources

Foreword:

For centuries people have utilised plants, animals and microorganisms (genetic and biochemical resources) to produce food, treat human disease, and in other ways deliver benefits to communities. Modern biotechnology can play a vital role in this process by enabling sophisticated research to be undertaken in relation to the genetic and biochemical resources.

Australia is rich in resources that could be used in scientific and technological research and that have the potential to be developed into commercial products – Australia's biodiversity is estimated to represent 10% of the total biodiversity of the planet.

As Australia is a signatory to the Convention on Biological Diversity, each jurisdiction recognises its responsibility to develop frameworks for access to and utilisation of genetic and biochemical resources consistent with this Convention. Accordingly, in providing opportunities for the ecologically sustainable and ethical use of its biological diversity it has a responsibility to ensure the fair and equitable sharing of the benefits arising from the use of those resources. Such frameworks must also respect indigenous peoples' special knowledge of that biodiversity. It is important to ensure

[18] http://www.environment.gov.au/biodiversity/science/access/biological-diversity.html.

that indigenous peoples' have the choice and means to share their knowledge on fair and equitable terms.

Australia is now poised to take advantage of its substantial research infrastructure, its mega biodiversity and its stable, developed economy to expand into being a significant biotechnology provider through the development of valuable bio-products including pharmaceuticals, agrochemicals, disease control and bioremediation products.

Recognising that biological resources don't respect jurisdictional boundaries, and the need to develop an efficient and equitable system for those seeking access, regardless of the jurisdiction, we are keen to ensure that our responses are consistent and compatible, while meeting our individual needs.

Accordingly, we have agreed to this set of principles, to underpin the development or review of legislative, administrative or policy frameworks in each jurisdiction. These principles are based upon world's best practice, through the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization adopted earlier this year in The Hague by the 6th Conference of the Parties of the Convention on Biological Diversity. They also deliver on important elements of the National Strategy for the Conservation of Australia's Biological Diversity.

All Australians will benefit from a nationally consistent approach for access to, and utilisation of, Australia's biological resources.

Introduction

This nationally consistent approach complements actions already taken by Australian Governments to conserve and protect biodiversity. It underpins future action by governments when developing, or reviewing, legislative, administrative or policy measures on access and benefit-sharing.

Australia ratified the Convention on Biological Diversity in 1993. The Convention has three primary objectives, the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising from the use of genetic resources. This nationally consistent approach, addresses that third objective of the Convention and in particular responsibilities set out at Articles 1, 3, 6, 8(j), 10(c) 15, 16 and 19.

Australia's governments have committed themselves to implementing the National Strategy for the Conservation of Australia's Biological Diversity (the National Strategy) as a matter of urgency. Objective 2.8 (Access to genetic resources) of that National Strategy states:

> *"Ensure that the social and economic benefits of the use of genetic material and products derived from Australia's biological diversity accrue to Australia."*

This nationally consistent approach addresses that objective.

The work being undertaken at Commonwealth, State and Territory level recognises the need to foster biotechnology and capture its benefits for the Australian community, industry and the environment. An important outcome will be providing certainty to the industry and scientific communities that are seeking access to genetic and biochemical resources throughout Australia.

Additionally, the nationally consistent approach makes a significant contribution to achieving Objective 1.8.2 (Use and benefits of traditional biological knowledge) of the National Strategy, which states:

> *"Ensure that the use of traditional biological knowledge in the scientific, commercial and public domains proceeds only with the cooperation and control of the traditional owners of that knowledge and ensure that the use and collection of such knowledge results in social and economic benefits to the traditional owners. This will include:*
>
> a. encouraging and supporting the development and use of collaborative agreements safeguarding the use of traditional knowledge of biological diversity, taking into account existing intellectual property rights;
> b. establishing a royalty payments system from commercial development of products resulting, at least in part, from the use of traditional knowledge."

The National Strategy identifies the need to achieve greater consistency in approaches between governments. The nationally consistent approach exemplifies this by providing an integrated framework within which jurisdictions can develop measures that meet their needs.

Goal

To position Australia to obtain the maximum economic, social and environmental benefits from the ecologically sustainable use of its genetic and biochemical resources whilst protecting our biodiversity and natural capital.

The nationally consistent approach

Preamble

The Commonwealth, State and Territory Governments of Australia,

- respecting our responsibilities under the Convention on Biological Diversity;
- accepting the invitation of the Conference of the Parties to use the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization when developing measures on access and benefit-sharing;
- aware of our commitments under the National Strategy for Ecologically Sustainable Development;

- reiterating our commitment to work with stakeholders to provide ecologically sustainable access to native biota;

- declaring our intention to capture the benefits of biotechnology development for Australia through equitable benefit sharing;

- delivering on the objectives of the National Strategy for the Conservation of Australia's Biological Diversity;

- endorse the General Principles underpinning development or review of legislative, administrative or policy frameworks or other mutually agreed arrangements in Australian jurisdictions for access to biological resources.

General Principles Underpinning Development or Review of Legislative, Administrative or Policy Frameworks in Australian Jurisdictions for Access to, and Utilisation of, Australia's Native Genetic and Biochemical Resources.

Such frameworks shall:

1. give effect to Australia's obligations under the Convention on Biological Diversity in relation to access to Australia's native biological resources;

2. be consistent with Australia's responsibilities and interests arising from other international agreements;

3. develop terms of access to resources that encourage local, national and international investment in Australia's biotechnology R&D capabilities, including, biodiscovery research, bioprocessing and product development;

4. be consistent with:
   a. National Competition Policy;
   b. the *Trade Practices Act 1974*;
   c. the *Native Title Act 1993*;
   d. the National Strategy for the Conservation of Australia's Biological Diversity; and
   e. the Intergovernmental Agreement on the Environment

5. facilitate the ecologically sustainable access and use of biological resources;

6. enable the fair and equitable sharing of benefits derived from the use of Australia's genetic and biochemical resources;

7. recognise the need to ensure the use of traditional knowledge is undertaken with the cooperation and approval of the holders of that knowledge and on mutually agreed terms;

8. enhance biodiversity conservation and the valuing of biodiversity by ensuring that, as appropriate, some of the benefits derived from all access to and use of the genetic and biochemical resources are, where possible, used for biodiversity conservation, in the area from which the resources were taken;

9. introduce terms and conditions of access to Australian resources that Australia would be prepared to meet if applied by other countries;

10. ensure that all applicants for access to resources are treated fairly and without prejudice, with all applications judged against transparent criteria and according to law;

11. be developed in consultation with stakeholders, indigenous peoples and local communities;

12. facilitate continued access for non-commercial scientific research, particularly taxonomic research;

13. be integrated into biotechnology development policies and strategies to ensure the continued development of these industries in Australia; and

14. recognise the differences between commercial scientific research and non-commercial scientific research and their needs.

Common Elements of Access and Benefit-sharing Arrangements Established in Australian Jurisdictions

The following are elements to be taken into account, as far as is practical and appropriate, in the application of the General Principles when developing or reviewing access and benefit-sharing systems established within Australian jurisdictions.

1. Any person or organisation seeking access to the genetic or biochemical components of publicly owned or managed native biota would be required to seek permission from the relevant authority, or authorities, in the relevant jurisdiction/s.

2. The framework would require:

    a. that the collection of native biological material is undertaken in an ecologically sustainable and ethical way; and

    b. equitable sharing of benefits between access providers and applicants, examples include:

        i. agreement to share research outcomes with the provider or to make research outcomes available to the public through publication or related activities; or

        ii. negotiation of a legally binding benefit sharing agreement between the access provider and the person, institution or corporation seeking access.

3. So as to facilitate biodiscovery and maximise certainty:

    a. processing of applications for access should be timely;
    b. transaction costs should be minimised;
    c. model contracts and dictionaries of contractual terms for benefit-sharing agreements should be developed;
    d. information should be provided in a clear, readily-accessible and reliable manner;
    e. reassurance should be provided that arrangements do not alter existing property or intellectual property law;
    f. access permissions should allow flexibility in their scope and duration; and
    g. online application processing and information provision should be used where possible.

4. Certainty should be maximised by providing a legal basis for access and benefit sharing.

5. Transparency and accountability should be supported by:

    a. disclosure of all criteria against which access is granted;
    b. appropriate integration of decision making into administrative review systems; and
    c. making public information about benefit-sharing agreements where consistent with commercial, privacy and cultural confidentiality.

6. To minimise duplication, frameworks should allow for possible exemption of public collections administered consistently with these Principles. This may include, for example, institutions such as botanic gardens or herbaria that are participating institutions in the international Common Policy Guidelines for implementation of the "Principles on Access to Genetic Resources and Benefit Sharing for Participating Institutions".

7. That in granting access, the decision maker should be able to attach conditions aimed at ensuring ecological sustainability and such conditions may include the application of collection protocols.

8. In granting access and determining conditions, environmental assessment of possible impacts should be consistent with assessment systems established within jurisdictions. Regard should be given to the application of the *precautionary principle*, namely that "where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation".

9. In the development of model contracts consideration should be given to the *Suggested Elements for Material Transfer Agreements* found at Appendix 1 of the *Bonn Guidelines on Access to Genetic Resources and Fair and Equitable*

*Sharing of the Benefits arising out of their Utilization* together with Appendix II, *Monetary and Non-Monetary Benefits.*

10. That the scope of possible benefits available from access to, and the ecologically sustainable use of, genetic and biochemical resources as illustrated in Appendix II of the Bonn Guidelines should be made available to all stakeholders by way of explanatory documentation or other means, for example made available on the internet.

11. When seeking to maximise consistency with other Australian jurisdictions, regard should be given to the value of:
    a. the use of common terms wherever possible;
    b. agreement on appropriate deterrent penalty levels for similar offences;
    c. collaboration in the development of model contracts and contractual terms;
    d. establishing links between web based on-line information sites;
    e. developing consistent public information material;
    f. the use of joint benefit-sharing contracts where intended biodiscovery collection involves crossing jurisdictional borders;
    g. the adoption of common collection protocols where possible;
    h. sharing of common experience;
    i. collaborating in the development of whole of government policy positions in relevant international fora;
    j. collaborating when considering common issues such as the ownership of resources and the possible application of frameworks to private land; and collaborating in the development of contract monitoring and access compliance procedures.

オーストラリアの生物多様性条約関連規制

Environment Protection and Biodiversity Conservation Act 1999[19]

Environment Protection and Biodiversity Conservation Amendment Regulations 2005 (No.2)[20]

Environment Protection and Biodiversity Conservation Regulations 2000[21]

Northern Territory of Australia Biological Resources Act 2006[22]

Queensland's Biodiscovery Act 2004[23]

**図 3　オーストラリア先住民アボリジニー**

[19] http://www.cbd.int/abs/measures/measure.shtml?id=6588.
[20] http://www.cbd.int/abs/measures/measure.shtml?id=44185.
[21] http://www.cbd.int/abs/measures/measure.shtml?id=25417.
[22] http://www.cbd.int/abs/measures/measure.shtml?id=39039.
[23] http://www.cbd.int/abs/measures/measure.shtml?id=7807.

オーストラリア連邦政府管轄地におけるアクセスと利益配分手続き

PIC 手続き

Name of applicant.

| | |
|---|---|
| **Title** | |
| **Name** | |
| **Position** | |
| **Institution/ Organisation** | |
| **Business address** | |
| **Postal address** | |
| **Australian Business Number (ABN)** | |
| **Phone** | |
| **Fax** | |
| **Email** | |

Full name, business address and postal address, and contact details of each person to whom the permit is to be issued.

| | **Co-applicant 1** | **Co-applicant 2** | **Co-applicant 3** |
|---|---|---|---|
| **Name** | | | |
| **Institution/ Organisation** | | | |
| **Business address** | | | |
| **Postal address** | | | |
| **Phone** | | | |
| **Fax** | | | |
| **Email** | | | |

Details of the relevant qualifications or experience of each person proposing to take the action (i.e. access biological resources under this permit).

| **Name** | **Relevant Qualifications or Experience** |
|---|---|
| | |
| | |
| | |

Research purpose (see **Note 1**): Please check one

☐ The application is for **NON-COMMERCIAL** purposes

OR

☐ The application is for **COMMERCIAL** or **POTENTIALLY COMMERCIAL** purposes (see **Note 2**)

Title of the proposed action.

When will the action be taken?
**Date/s: From:** _____ **To:** _____

Are the details of this project confidential? YES ☐ NO ☐

Provide a description of the action (see **Note 3**), including the objectives (see **Note 4**), and describe methods to be used to comply with these Regulations and to minimise environmental impact on native species and the collection location (see also question 17).
**Objective:**
**Description of Action:**
**Minimise Environmental Impact:**

Provide details of where the action will be taken, including the latitude and longitude of the location area. Please also attach a location map or proposed route of voyages on a separate sheet to your application.
**Location /s:**
**Latitude / Longitude:**
**Map Attached:** ☐

Do you intend to re-collect at this location? YES ☐ NO ☐
If so, when and how often? .....

How is the access to be undertaken?
**Vessel / Vehicles:**
**Equipment:**

List the name of each access provider (see **Note 5**) and provide a copy of written permission to access biological resources from each access provider.
**Access Provider:**
**Written Permission Attached:** ☐

List the biological resources to which you are seeking access, including the amount of biological resources you propose to sample. If unknown, please provide a description of sampling methods and the quantity and type of organisms likely to be collected using those methods.

| Common name | Taxon. (to the most specific taxonomic level known) | Amount/number/volume (as appropriate) |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

| Common name | Taxon. (to the most specific taxonomic level known) | Amount/number/volume (as appropriate) |
|---|---|---|
| | | |

Identify the use(s) you propose to make of the biological resources.
**Use:**

Identify how access to these biological resources will benefit biodiversity conservation. Specify any likely benefits for the access area.
**Conservation Benefit:**

Identify any listed species (under the *Environment Protection and Biodiversity Conservation Act 1999*) that will be affected by the proposed action (see **Note 6**).

| Listed species | Amount/number/volume proposed to be sampled |
|---|---|
| | |
| | |

Describe the methods by which you will minimise the impact on listed species identified in Question 17 of the proposed action.

Proposed location(s) of taxonomic duplicate – you must offer duplicate samples of specimens to an Australian public institution that is a repository of taxonomic specimens of the same order or genus as those collected, for permanent loan.
**Australian public institution:**

List any other applications for permits (or list permits issued) made in relation to the research activity (see **Note 7**)
**Other Permits:** [Include date of application, title of application, permit number & expiry date (if a permit was issued)].

Identify the use (if any) that is proposed to be made of Indigenous people's knowledge in determining the biological resources to be accessed or the particular areas to be searched.

Provide details of any agreements (if any) made with Indigenous persons in relation to use of specialised information or information otherwise confidential to the indigenous people of the area.
[Include as a minimum, the date the agreement was made, who it was made with, if it was approved by a Land Council or other body representing the indigenous community, and what has been agreed to].

Provide details of any person not already named on this form on whose behalf access is sought or who proposes to use the samples obtained.

| Name | Institution address | Purpose of access |
|---|---|---|
| | | |

| | | |
|---|---|---|
| | | |

Complete and sign (in the presence of a witness) the following declaration in relation to this application.

On behalf of myself and each proposed permit holder I (FULL NAME)……hereby -**DECLARE** as follows-

Neither I, nor any of the proposed permit holders, have been convicted[24] of, or are subject to proceedings for, an offence under:
the EPBC Act or Regulations another law of the Commonwealth or a State or Territory about the protection, conservation or management of native species or ecological communities;
section 6[25] of the *Crimes Act 1914* or sections 11.1. 11.4 or 11.5[26] of the Criminal Code, in relation to an offence under a law mentioned in a) or b) above; or
a provision of a law of a State or Territory that is equivalent to a provision mentioned in (c) above.

I am authorised to complete this application on behalf of all proposed permit holders. The information and statements contained in this application are correct to the best of my knowledge.
Full Name:……

Signature:……Date……/……/……

In the presence of

Full name of Witness:……

Signature:……Date:……/……/……

[24] Part VIIC of the *Crimes Act 1914* includes provisions that, in certain circumstances, relieve persons from the requirement to disclose spent convictions and require persons aware of such convictions to disregard them.

A person is taken to have been convicted of an offence if, within 5 years before the application is made, the applicant:

a) has been charged with, and found guilty of, the offence but discharged without conviction; or
b) has not been found guilty of the offence, but a court has taken the offence into account in passing sentence on the applicant for another offence.

[25] Section 6 of the *Crimes Act 1914* deals with being an accessory after the fact.

[26] Sections 11.1, 11.4 and 11.5 of the *Criminal Code* deal with attempts to commit offences, inciting to or urging the commission of offences by other people and conspiracy to commit offences.

a) If the application is for **NON-COMMERCIAL** purposes you will need to complete and sign (in the presence of a witness) the following Statutory Declaration form.

Commonwealth of Australia

# STATUTORY DECLARATION

*Statutory Declarations Act 1959*

*1 Insert the name, address and occupation of person making the declaration*

[1]I, [*Insert the name, address and occupation of person making the declaration*]

make the following declaration under the *Statutory Declarations Act 1959:*

*2 Set out matter declared to in numbered paragraphs*

[2]That in relation to the application by [*insert proponent institution/company and name/s of principle researchers*] for access to biological resources under Part 8A of the *Environmental Protection and Biodiversity Regulations 2000* entitled [*insert title of application*] for [*insert proposed action*]:

I am authorised to make this declaration for and on behalf of [*insert proponent/s institution/company*] (referred to as 'the applicant for the permit'); and

the applicant for the permit does not intend to use the biological resources, to which the proposed action relates, for commercial purposes; and

the applicant for the permit undertakes to give a written report on the results of any research on the biological resources to each access provider; and

the applicant for the permit undertakes to offer, on behalf of each access provider, a taxonomic duplicate of each sample taken to an Australian public institution that is a repository of taxonomic specimens of the same order or genus as those collected for permanent loan; and

the applicant for the permit undertakes not to give the sample to any person, other than the institution mentioned in paragraph (d) above, without permission of each access provider; and

the applicant for the permit undertakes not to carry out, or allow others to carry out, research or development for commercial purposes on any genetic resources or biochemical compounds comprising or contained in the biological resources unless a benefit-sharing agreement has been entered into with each access provider.

I understand that a person who intentionally makes a false statement in a statutory declaration is guilty of an offence under section 11 of the *Statutory Declarations Act 1959*, and I believe that the statements in

this declaration are true in every particular.

3

*3 Signature of person making the declaration*

*4 Place*
*5 Day*
*6 Month and year*

Declared at [4] on [5] of [6]

Before me,

7

*7 Signature of person before whom the declaration is made (see over)*

8

*8 Full name, qualification and address of person before whom the declaration is made (in printed letters)*

*Note 1* A person who intentionally makes a false statement in a statutory declaration is guilty of an offence, the punishment for which is imprisonment for a term of 4 years — see section 11 of the *Statutory Declarations Act 1959*.
*Note 2* Chapter 2 of the *Criminal Code* applies to all offences against the *Statutory Declarations Act 1959* — see section 5A of the *Statutory Declarations Act 1959*.

**A statutory declaration under the *Statutory Declarations Act 1959* may be made before–**
(1) a person who is currently licensed or registered under a law to practise in one of the following occupations:

| | | |
|---|---|---|
| Chiropractor | Dentist | Legal practitioner |
| Medical practitioner | Nurse | Optometrist |
| Patent attorney | Pharmacist | Physiotherapist |
| Psychologist | Trade marks attorney | Veterinary surgeon |

(2) a person who is enrolled on the roll of the Supreme Court of a State or Territory, or the High Court of Australia, as a legal practitioner (however described); or
(3) a person who is in the following list:
Agent of the Australian Postal Corporation who is in charge of an office supplying postal services to the public
Australian Consular Officer or Australian Diplomatic Officer (within the meaning of the *Consular Fees Act 1955*)
Bailiff
Bank officer with 5 or more continuous years of service
Building society officer with 5 or more years of continuous service
Chief executive officer of a Commonwealth court
Clerk of a court
Commissioner for Affidavits
Commissioner for Declarations
Credit union officer with 5 or more years of continuous service
Employee of the Australian Trade Commission who is:
(a) in a country or place outside Australia; and
(b) authorised under paragraph 3 (d) of the *Consular Fees Act 1955*; and
(c) exercising his or her function in that place
Employee of the Commonwealth who is:
(a) in a country or place outside Australia; and
(b) authorised under paragraph 3 (c) of the *Consular Fees Act 1955*; and
(c) exercising his or her function in that place
Fellow of the National Tax Accountants' Association
Finance company officer with 5 or more years of continuous service
Holder of a statutory office not specified in another item in this list
Judge of a court
Justice of the Peace
Magistrate
Marriage celebrant registered under Subdivision C of Division 1 of Part IV of the *Marriage Act 1961*
Master of a court
Member of Chartered Secretaries Australia
Member of Engineers Australia, other than at the grade of student
Member of the Association of Taxation and Management Accountants
Member of the Australasian Institute of Mining and Metallurgy
Member of the Australian Defence Force who is:
(a) an officer; or
(b) a non-commissioned officer within the meaning of the *Defence Force Discipline Act 1982* with 5 or more years of continuous service; or
(c) a warrant officer within the meaning of that Act
Member of the Institute of Chartered Accountants in Australia, the Australian Society of Certified Practising Accountants or the National Institute of Accountants
Member of:
(a) the Parliament of the Commonwealth; or
(b) the Parliament of a State; or
(c) a Territory legislature; or
(d) a local government authority of a State or Territory
Minister of religion registered under Subdivision A of Division 1 of Part IV of the

*Marriage Act 1961*
Notary public
Permanent employee of the Australian Postal Corporation with 5 or more years of continuous service who is employed in an office supplying postal services to the public
Permanent employee of:
(a) the Commonwealth or a Commonwealth authority; or
(b) a State or Territory or a State or Territory authority; or
(c) a local government authority;
with 5 or more years of continuous service who is not specified in another item in this list
Person before whom a statutory declaration may be made under the law of the State or Territory in which the declaration is made
Police officer
Registrar, or Deputy Registrar, of a court
Senior Executive Service employee of:
(a) the Commonwealth or a Commonwealth authority; or
(b) a State or Territory or a State or Territory authority
Sheriff
Sheriff's officer
Teacher employed on a full-time basis at a school or tertiary education institution

## Feedback

In order to assist in developing more efficient systems, please provide an estimate of the time taken to complete this application form.

| Hours | Minutes |
|---|---|

Do you have any other feedback about the administration of your permit?

## Contact details

The completed permit application can be emailed to grm@environment.gov.au or posted to:

Protected Area Policy and Biodiscovery Section
Department of Sustainability, Environment, Water, Population and Communities
GPO Box 787
CANBERRA ACT 2601
AUSTRALIA

Note 1

*Purpose*

Non-Commercial purpose: the biological resources sampled will not be used for research for commercial or potentially commercial purposes. You must complete the attached Statutory Declaration (see Question 24).

**Commercial or potentially commercial purpose:** the biological resources sampled are to be used for research which has potentially commercial pharmaceutical, agricultural, industrial or other application (for example, screening for bioactivity).

Note 2

If an applicant wishes to obtain access to biological resources for commercial purposes or potentially commercial purposes, then they will need to have entered into a Benefit-Sharing Agreement (BSA) with the access provider, before a permit can be issued. An application fee of AUD$50 is also payable.

Applicants for an access permit for commercial purposes are advised to contact the us at: grm@environment.gov.au for further information.

The model Benefit-sharing Agreement (Commonwealth areas) must be used as the basis of any agreement for biological resources taken from Commonwealth areas.

Note 3

*Description of Action*: describe the methods which will be used to sample the biological resource(s) and conduct the research more generally. Detail what equipment will be used in and outline why the research methods are the most appropriate to minimise impact on the environment and the species being sampled. Include reference to research codes of conduct or ethics approvals where appropriate.

Note 4

*Objectives of Research:* describe the objective(s) of the research project and any background information to place the project in context.

Note 5

*The Access Provider* is the entity that administers the area in which the research is to be conducted. Access providers are defined in section 8A.04 of the regulations and may include: native title holders; Commonwealth agencies; and owners of land leased by the Commonwealth. For Commonwealth terrestrial and marine protected areas the access provider is usually the Director of National Parks. There may be several access providers depending on the area the research is to be conducted in.

We can assist you in identifying access providers and facilitating access, contact us at: grm@environment.gov.au

Note 6

Any listed species to be sampled **MUST** be specified. Listed EPBC species can be found at: http://www.environment.gov.au/cgi-bin/sprat/public/sprat.pl

Note 7

Include any Australian, State or Territory Government permits associated with the research permit.

**Note:** Research in a Commonwealth marine or terrestrial protected area requires a permit. Information on permits for protected areas can be found at: environment.gov.au/parks/permits/index.html.

Applicants planning to export samples need to obtain a permit. Further information can be found at: environment.gov.au/biodiversity/trade-use/permits/index.html.

オーストラリア国立大学での講演

Australian National University

PUBLIC SEMINAR

## Clean Tech Law Seminar Series 2014

## The Nagoya Protocol: Japan, access to genetic resources and academic research

**Tuesday 29 July 2014** 12–1 pm

**Dr Hajimu Morioka** ABS Task Force Team for Academia, Intellectual Property Unit, National Institute of Genetics, Japan

Hosted by **Dr Matthew Rimmer**, ARC Future Fellow, ACIPA, ANU College of Law

**Phillipa Weeks Staff Library** ANU College of Law, Building 5, Fellows Road, The Australian National University, Canberra

The Nagoya Protocol will be in force on 12 October 2014. The Japanese government has been discussing implementation of the Nagoya Protocol and will decide a monitoring system soon.

Under this regime, Japanese academic institutions conducting research activities using genetic resources have to prepare to comply with the Nagoya Protocol and domestic monitoring measures for their academic research. To support and promote these activities, the ABS Task Force Team for Academia was established in 2012.

The ABS Task Force Team for Academia is enabling research utilisation of genetic resources. Survey and individual consultation indicate more efforts are necessary for not only researchers but also internal supporting organisations to undertake appropriate ABS conduct.

To ensure self-compliance for the Nagoya Protocol rules, we are creating practical guidelines for research institutions, research projects, researchers themselves, research administrators and other supporters, and collections. Using the guidelines, we have started a training course to foster ABS specialists in the institutions.

Dr Hajimu Morioka has been the Team Leader of the ABS Task Force Team for Academia under instruction of the Ministry of Education, Culture, Sports, Science and Technology (MEXT). Before joining to the team, Morioka had worked for 37 years in a private company, conducting R&D activities, strategic R&D planning and managing intellectual properties of the company. During his IP carreer, Morioka had engaged in ABS discussion groups in the Japan Bioindustry Association (JBA), the AIPPI, and the Institute of Intellectual Property (IIP).

*The views expressed in this seminar are those of the presenter and do not necessarily represent the views of The Australian National University.*

*The Clean Tech Law Series is supported by the Australian Research Council.*

Presented by

ACIPA

ANU College of Law

RSVP online by Monday 28 July

Click here to RSVP

Enquiries T 6125 1096
This lecture is free and open to the public

**図 4　オーストラリア国立大学での講演**

# Current Situation of Academic Researches using Genetic Resources in Japan

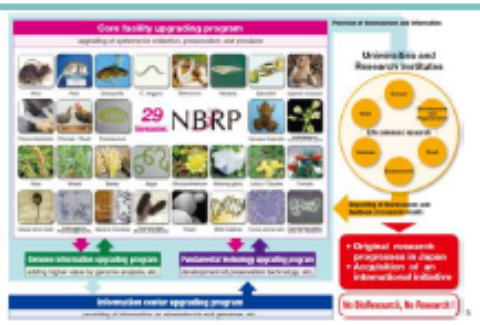
For Australian Colleagues
July , 2014

Hajimu Morioka
ABS Task Force Team for Academia
Intellectual Property Unit
National Institute of Genetics

## Major National Academic Bioresource Centers in Japan

- National BioResource Project under MEXT
  - Management: National Institute of Genetics (NIG)
  - 28 genome information upgrading programs, 10 fundamental technology upgrading programs
- Riken BioResource Center under MEXT
  - Management: Riken
  - a core repository of biological experimental materials
- National Bioresource Center under METI
  - Management: National Institute of Technology and Evaluation (NITE)
  - To expand collections of microbial resources and to perform taxonomic characterization for academic research and industrial applications
- NIAS GeneBank under MAFF
  - Management: National Institute of Agrobiological Sciences (NIAS)
  - To participate in collaborative activities with other countries in relation to surveys and research related to agricultural related genetic resources
- Research Center for Medicinal Plant Resources under MHLW
  - Management: National Institute of Biomedical Innovation (NIBIO)
  - To perform research and development on technology related to the cultivation and breeding of medicinal plants
  - To cultivate and preserve more than 4,000 species and groups of medicinal plants

## National BioResource Project (NBRP)

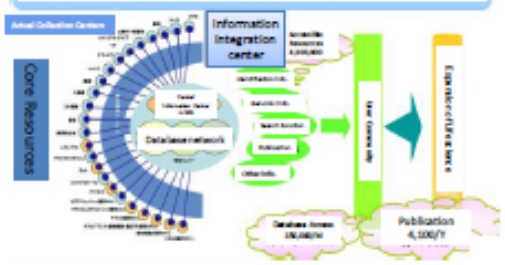



## General Outline and Purposes of NBRP

- A national project financially supported by the Ministry of Education, Culture, Sports, Science and Technology (MEXT)
- The first and second terms: since FY2002 to FY2011, Third term has started from FY2012
- Purpose
  - To collect, preserve, and provide for life sciences research
- Functions
  - Establishment of collection, preservation, and provision of bioresources such as experimental animals, plants, and microorganisms
  - Enrichment of genome information
  - Development of fundamental technologies for preservation
  - Reinforcement of functions of the information center

## Information Center Upgrading Program

Construction of databases of whereabouts information, genetic information, and biological characteristics of bioresources that are gathered at the core facilities, and public relations of the NBRP through its home page is upgraded




## Whole Genome Sequencing of Coelacanths known as "living fossils"

- Three specimens from Tanzania, one from Comoros) and one from Indonesia under CITES conditions
- The genome is ~2.74 Gbp, genetic diversity among the individuals was extremely low

## Establishment of ABS Task Force Team for Academia

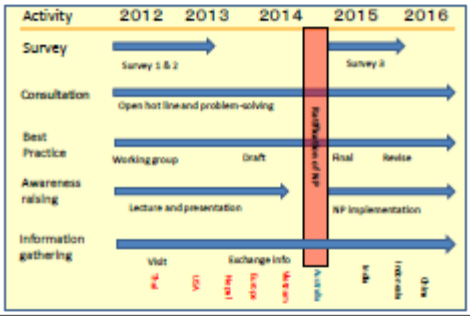
Our TEAM

Ministry of Education, Culture, Sports, Science and Technology (MEXT)

## ABS Task Force Team for Academia

URL:http://www.idenshigen.jp/en/index.html

## Current Activities of the Team




## Survey of Academic Researchers

1. Period: February to April, 2012
2. Purpose :
   - To investigate actual situation of bioresource researches in academic institutions
   - To know what researchers themselves consider about access and benefit-sharing when they conduct research activities
3. Survey Subject :
   - 76 Japanese researchers in 42 institutions, who are using genetic resources for research purposes
4. Findings :
   - Valid responder : 28 researchers in 23 institutions
   - Valid responder ratio: 37%

## Summary of Survey Opinions from Researchers

- It is difficult and time-consuming to conclude PIC and MAT with providing countries because domestic laws relating to CBD are not clear
- It is necessary to form information service system which provides status of CBD related laws and systems in providing countries
- It is necessary to give researchers awareness raising lectures and to set up a guideline relating ABS

## Summary of Consultation

- Access
  - Materials brought by students from providing countries
  - Materials obtained from intermediaries or amateurs
  - Marine genetic resources isolated from the high see
  - Genes synthesized from DNA database
  - Transfer of domestic genetic resources to European countries
- Utilization
  - Change of utilization from non-commercial to commercial purposes
  - How to make databases and ex situ collection in providing countries?
- Benefit-sharing
  - What is monetary benefit-sharing in academic research?
  - What is necessary for patent application ?

## Consulting Case 1:
A Researcher of Providing Country Brings Research Samples for Own Research in Japan

- A researcher in providing country has collected herbal samples from several indigenous groups
- He brings samples from his country to Japan and conducts research with Japanese collaborator
- He makes publication and patent application of outcomes

Who and from whom PIC/MAT obtained and how to divide benefit sharing ?

## Consulting Case 2:
Genetic resources difficult to obtain PIC

- Medicinal plants obtained at market in a providing country
- Microorganisms isolated from foods imported from a providing country
- Microorganisms isolated from yellow dust flying from China
- Pathogen isolated in Japan from a patient travelling many Asian countries

## Lectures at Universities

- Presentations since April 2012
  - ABS only
    - 21 universities
    - About 30 attendee in average
  - ABS and Cartagena
    - 4 universities
    - About 100 attendee in average
- Presentation at Scientific Meeting
  - 5 meetings
- Lecture course for graduate students
  - Kyoto Institute of Technology: Society and Law

## Development of ABS Guidance for Academic Research

## Development of ABS Guidance for Academia

- Formation of expert group in our Task Force
  - Law professors: 2
  - CBD activists: 1
  - Business-academia cooperation officer: 1
  - Professional lawyer: 1
- Guiding documents
  - Bonn Guidelines
  - Swiss Academy of Science: Access and Benefit Sharing Good practice for academic research on genetic resources
- Currently for open discussion
  - 10th Anniversary Symposium of Intellectual Property Association of Japan (February 23, 2013)

## Purposes to Design ABS Guidance for Academia

- Focus on supporting and promoting organizations in institutions
  - It is difficult for a researcher to fulfill legal requirements
  - Involvement of research promotion, coordination and tech transfer organizations in institutions is essential for ABS matters
  - It is necessary to establish principles or strategy for environmental conservation in research institution
- Design to use for risk management in research institution
  - For social responsibility, human rights, and ethical standard
  - For determination of responsibility in the organization
- Do not include specific domestic monitoring measures in Nagoya Protocol
  - Japanese monitoring measures will be included after determined
- Annex PIC procedure, contract examples, case study and Q&A

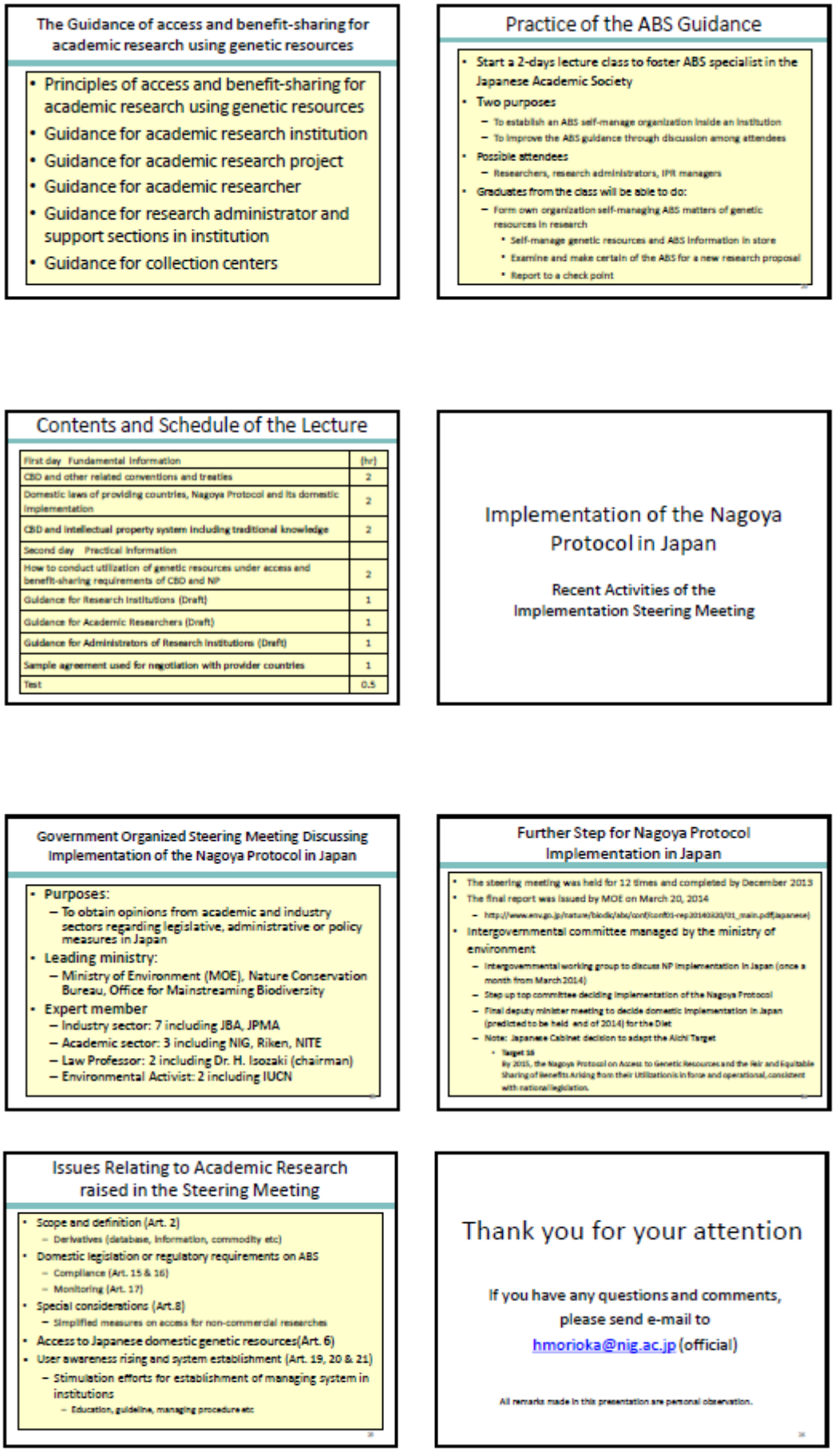



図 5　オーストラリア国立大学での講演内容

CIMTECH

**Towards Access and Benefit-Sharing Best Practice**
***Pacific Case Studies***

Report written and prepared by Dr Daniel Robinson, Senior Lecturer, Institute of Environmental Studies, The University of New South Wales, Australia. Dr Robinson is also a Research Associate of Natural Justice.

## *Case 2:* The Cook Islands CIMTECH – Koutu Nui Agreement

Dr Graham Matheson, a medical researcher brought up in the Cook Islands, observed the traditional application of plant-based extracts for treatment of bone fractures and other medical and therapeutic applications, by members of his community, friends and family.
Matheson later trained as a medical practitioner and in 2000 undertook research towards his PhD at the Orthopaedic Research Laboratories at UNSW. In 2003 he developed a proposal for the investigation and potential commercialisation of medical and therapeutic remedies based on plant extracts and associated traditional knowledge and took it to the Cook Islands.
Dr Matheson reached a benefit-sharing agreement with the Koutu Nui – a lawfully recognised assemblage of chiefs charged with overseeing the cultural impacts of modern lawmaking (Sissons, 1998). Dr Matheson's research led to the establishment of the company 'CIMTECH' which incorporates the Koutu Nui as a shareholder.

### The biodiscovery and research activities

Dr Matheson undertook a study of pharmacological effects of traditional Cook Islands methods of bone healing at the UNSW Orthopaedic Research Laboratories. He is conducting cell culture experiments, testing on small mammals, fractionation and isolation of active ingredients, and quantification of the effects.
This research, which initially focused solely on bone and wound healing, has also led to a number of practical cosmetic applications. Consequently, Matheson and CIMTECH have filed for a number of patents4 covering three distinct areas: bone and cartilage treatment, wound healing, and skin care treatments. For the promotion of wound healing and the treatment of skin disorders, the CIMTECH patents list bio-active extracts of one or more of *Vigna marina* (Burm.) Merr., *Cocos nucifera* L., or *Terminalia catappa* L. in compositions and extracts providing therapeutic and cosmetic uses. For the promotion of healing of bone and cartilage injuries, the patents claim a bioactive extract of *Hibiscus tiliaceus* L. and therapeutic compositions related to this.

### Conformance with ABS principles, legislation and permits

Initial engagement for 'research access' with the Cook Islands government began in 2003. Pilot study funding was sought from the Ministry of Health (Peri Vaevae, Roro Daniel and Denise Rairi) in March 2003. They advised that Dr. Matheson seek aid funding for the project from other sources. Representatives of the Ministry of Culture, the Aid Coordinating Committee (Edwin Pitman) and the Ministry of Finance and Economic Development were also approached by Dr Matheson and Dorice Reid (cMay

2003). Having no objections to the research and expressing no interest in involvement in the research, they also suggested external grant funding to support it. No regulations, permissions or permits were advised for the project – A National Research Policy and process for obtaining research permits was established later in 2006. With no other options, Dr Matheson personally funded the pilot studies with some resourcing from UNSW (Matheson, pers. comm. 2012). While the Cook Islands have since established a research permit requirement for foreigners, Dr Matheson would also be exempt from this, given that he is a Cook Islander.

4 Filed in Australia in May 2009 (and with the PCT in November) "Methods and compositions for the promotion of wound healing" AU 2009901952; Filed in Australia in December 2009 (and the PCT in May) "Methods and composition for bone and cartilage repair" AU 2009906034; Filed in Australia in November 2010 "Methods and compositions for the maintaining and improving the health of skin" Australian Provisional Patent No. 2010904905; and filed in Australia in November 2010 "Methods and compositions for the treatment and prevention of skin disorders" Australian Provisional Patent No. 2010904906

### Access/prior informed consent procedure followed

Matheson also sought prior informed consent from an appropriate and lawfully recognized indigenous representative body – the Koutu Nui (established in written law in 1972 under an amendment to the 1968 House of Ariki Act) – prior to any research activity. The intended research was informed in detail in submissions to the Koutu Nui. In (cMarch) 2003 the Koutu Nui executive met, returned with questions, and then reconvened at an annual general meeting in June 2003 to unanimously approve the project.

The Koutu Nui provided a bottle of Vairakau Ati prepared by Taunga Ngateina Ngapare and handed to Dr Matheson by Dorice Reid (cMay 2003). This arrived too late to be used in the pilot research, but was felt to be extremely important to the Koutu Nui that they hand over the Vairakau Ati as proof of their commitment. This is also reflected in the wording of the Deed of Confirmation and Assurance, the Koutu Nui shareholding, and share in ownership of IP (CIMTECH is the patent assignee, of which the Koutu Nui are a shareholder).

The Taunga of the Koutu Nui did not provide the TK/GRs used, but rather Graham developed his own formula based on various pieces of information from family and friends, with their approval. Graham obtained plants from within 100m of his home. A solution derived from the plants was carried to Australia for testing (in order to avoid issues relating to the importation of plant materials through customs and quarantine into Australia) (Matheson, pers. comm, 7/3/12).

### Consultation with relevant parties

As noted in the above sections, Dr Graham Matheson consulted both government and the Koutu Nui as deemed to be the primary stakeholders to engage. Notably, Dr Matheson's submissions to the Koutu Nui were also communicated to a number of Taunga (traditional healers) who were members of the Koutu Nui, prior to establishment of an agreement.

### Terms of benefit-sharing agreements

Matheson reached a benefit-sharing agreement with the Koutu Nui under mutually agreed terms. A company: Cook Islands Medical Research and Development (CIMRAD)

was incorporated with Matheson and the Koutu Nui equal share-holders. This was agreed to be the vehicle through which the R&D would be commercialized, with the Koutu Nui agreeing to take responsibility for the allocation of monies it received, as a shareholder, for the benefit of the Indigenous inhabitants of the Cook Islands (Matheson-Koutu Nui Deed, 2003).

An Australian company, CIMTECH, was also subsequently established to take advantage of grant opportunities, for tax reasons, and for the protection of intellectual property (Australia is a signatory to World Intellectual Property Organization agreements allowing the filing of international patents). The new company incorporated the Koutu Nui and UNSW (which provided financial and institutional support towards the development of intellectual property) as shareholders: CIMTECH is owned by an Australian trust whose beneficiaries include the Koutu Nui and Matheson family, with no royalties owed, but rather their interests represented by a shareholding in CIMTECH and the potential for dividend payments upon the sale of products by CIMTECH. The Koutu Nui were informed that further investment required for R&D and commercialization of CIMTECH's products would dilute their shareholding and they agreed to these terms (Matheson-Koutu Nui Deed, 2003). This was confirmed in a meeting with the current President of the Koutu Nui, Turi Maria Henderson (Henderson, pers. comm. 6/3/12).

**Summary of monetary and non-monetary benefits**

| Monetary (USD) | Non-monetary |
|---|---|
| Koutu Nui shareholding value estimated to be worth at least $150,000 (after personal investment by Matheson of $300,000). | Expected contributions to the local economy through the laboratory and processing facility in Raratonga, sales, marketing and tourism (use of product in spas and hotels). |
| Anticipated dividend payments to the Koutu Nui via the shareholding in CIMTECH. | Research directed towards priority health care needs – bone and wound healing. |
| Research income to CIMTECH: $264,000 in grants received from the Australian Government, and $74,000 from UNSW. | Physical technology transfer of machinery to the processing facility and laboratory. |
| Employment of 12 people on a part time basis in the Cook Islands (expected to expand upon launch of the cosmetic product) | Joint ownership of patents assigned to CIMTECH (of which the Koutu Nui are shareholders) |
| Investment in CIMTECH: $560,000 in preseed investment in 2010 and a further $800,000 in 2011 for further R&D. | Improved livelihood security for staff (through employment). |
| | Social recognition regarding Cook Islands traditional medicine, and particularly for recognition of the role of the Koutu Nui as a cultural authority involved in conservationoriented practices |

| | |
|---|---|
| | like Raui. |

**Tangible impacts derived from these benefits**

Although further testing and analysis is required to determine the therapeutic effects and safety of the treatments for wound and bone healing (requiring significant external funding), CIMTECH is on the verge of launching their skincare line in 2012. CIMTECH has now completed construction of a processing facility and laboratory on Rarotonga. The facility includes equipment for shredding the plants, pressing and extracting the infused oil, filtering/separating the oil solution, and has systems in place for quality control.

The preparation of skincare products is currently providing some part time employment for 12 people and this is expected to grow as the product comes to market. The processing facility in Raratonga has the potential to be also used to process other plant products to derive essential oils, thus providing for other spin-off products (Romagnino, pers. comm. 5/3/12).

It is anticipated that the Koutu Nui (which currently has a limited budget of approximately $10,000 NZD/$8000 USD per year for its activities) will derive monetary benefits that will further its work promoting and educating about Raui (customary no-take marine conservation zones, see front cover images). The Koutu Nui is also involved in aged care and other charitable activities that could be expanded with further income. In addition, the Koutu Nui have been involved in the primary, secondary, retail and knowledge aspects of the production and revenue chain to date (confirmed by Henderson, pers. comm, 6/3/12). All agricultural production and supply is agreed to be undertaken by Cook Islanders in the Cook Islands. To date, preliminary production and processing of the essential oil solution for prelaunch sample products and gifts has occurred.

図 6: The CIMTECH Facility in Avarua, Rarotonga

図 7: Bottles of cosmetic active ingredient solution produced in the CIMTECH Lab

## Products of the research and development

CIMTECH is preparing to launch a skincare line entitled 'Te Tika' which has the literal meaning of 'truth and integrity'. As noted on CIMTECH's website: "TeTika skin care range has been developed with CIMTECH's BioActive Cook Islands oil. This natural product is based on Australian scientific research and incorporates traditional Cook Islands medicines to create a unique skin care range that has regenerative and anti-aging effects." (CIMTECH, accessed 14/5/2012). The launch of the Te Tika range by the company occurred on 8th August at the Pacific Resort in Rarotonga, Cook Islands. Samples of the skincare products have also been prepared as a gift from the Cook Islands to the Queen of England for her Diamond Jubilee (Romagnino, pers. comm. 5/3/12).

## Challenges and lessons

The CIMTECH-Koutu Nui agreement provides an example of the importance of engagement with Indigenous groups prior to research, sufficiently informed about intent and risks, with an up-front agreement on the terms of benefit-sharing. The former Koutu Nui President, Ruby Dorice Reid, was quoted saying that the research was a first for the Cook Islands and would provide a new industry: "It is such an important venture for us. We are really proud and excited that this traditional medicine can help people throughout the world. And the people of the Cook Islands will also receive a great deal of benefit from it" (Reid, cited by Smith, April 2011).

Through the ability to diversify their R&D, CIMTECH have been able to bring a product to market quicker than they would if solely focused on pharmaceutical therapeutics (and thus share benefits earlier). The establishment of processing facilities, laboratories and investment in the Cook Islands demonstrates willingness to ensure inclusion of Cook Islanders in the value chain of the skincare products. This should provide a broader range of longer term (monetary and non-monetary) benefits than through a narrower royalty-sharing model.

The case also highlights the possibility of 'home-grown' R&D by Pacific island nationals. This needs to be considered when drafting conditions of research permits – countries must decide if they want to regulate only foreign biodiscovery activities (as per the current conditions of the Cook Islands permit system) of if they should require permits for all biodiscovery research (as per the permit system in PNG).

A number of the plants used are found in different parts of the Pacific and there are likely to be different traditional uses of them, particularly common plants like coconut. However, the traditional knowledge related to wound and especially bone healing in this case appears to be unique to the Cook Islands, as ethnobotanist Art Whistler (1994, p157) notes:

In Tahiti, the Cook Islands, and the Marquesas, the flowers, either fresh or boiled into a paste, are used as a poultice for sores, cuts, boils and swellings. The Cook Island Maoris use the bark, together with coconut bark or crushed husk, to make an infusion for bathing fractures.

Last, the case study raised a question about who represents 'traditional knowledge-holders' in the Cook Islands. This is a complex question in many Pacific nations. Within the Koutu Nui are a number of Taunga who ultimately endorsed the

agreement with Dr Matheson. Some discussions in the first Pacific ABS workshop organized by the ABS Capacity Development Initiative and DSEWPaC from 19 to 22 March 2012 in Nadi, Fiji have suggested that it may also be useful for a formalisation of Taunga networks to represent traditional medicinal practitioners, such that there is a clear consultation framework for PIC relating to traditional medicines in the future.



図　8　CIMTECH　の製品

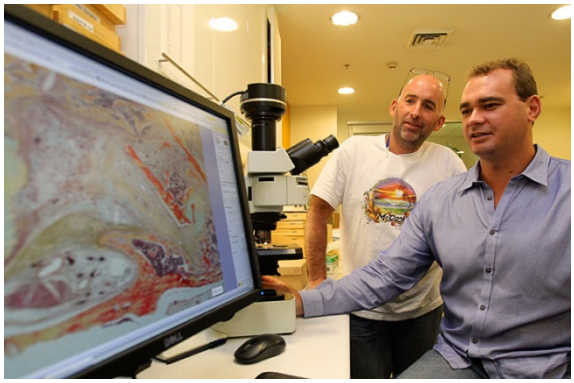


図 9 Drs. Walsh & Matheson

Eskitis 研究所の Nature Bank

保持しているサンプル数

| 地域 | サンプル数 |
|---|---|
| 中国南部地域植物 | 6,545 |
| パプアニューギニア植物 | 5,743 |
| オーストラリア植物 | ＞20,000 |
| オーストラリア海洋生物 | ＞9,000 |


**図 10 Griffith 大学 Eskitis 研究所**


図 11　Eskitis 研究所のパンフレット

オーストラリア海洋生物研究所（AIMS）の標準素材ライセンス契約（MLA）

# MATERIALS LICENCE AGREEMENT　NON-COMMERCIAL RESEARCH

This Agreement is entered into by **THE AUSTRALIAN INSTITUTE OF MARINE SCIENCE** (ABN 78 961 616 230) a body corporate established under the *Australian Institute of Marine Science Act 1972 (Cth)* of Cape Ferguson, via Townsville, Queensland 4810, Australia ("**AIMS"**) and the **RECIPIENT** for the licensing of certain materials as follows:

**DETAILS**

**TERM:**

| | | | |
|---|---|---|---|
| **Commencement Date:** | | **Expiry Date:** | |

**AIMS:**

| | | | |
|---|---|---|---|
| **AIMS Representative:** | | **Telephone:** | |
| **Address for Service:** | 1526 Cape Cleveland Road, Cape Cleveland, Qld 4810. | **Fax:** | +61 7 4772 5852 |
| | | **Mobile Phone:** | |
| **Mailing Address:** | PMB3, Townsville MC, Qld 4810 | **Email:** | |

**RECIPIENT:**

| | | | |
|---|---|---|---|
| **Full Legal Name:** | | **ABN:** | |
| **Mailing Address:** | | **Telephone:** | |
| | | **Fax:** | |
| | | **Mobile Phone:** | |
| **Address for Delivery of Materials:** | | **Email:** | |
| | | **Contact Person:** | |
| | | **Custodian:** | |

**DESCRIPTION OF MATERIALS:**

| | |
|---|---|
| **Definition::** | |
| **Quantity:** | |
| **Packaging:** | |
| **Mode of Transport:** | |

**APPROVED PURPOSE:**

| | |
|---|---|
| **Approved Purpose:** | Non-commercial use of Materials, relevant AIMS IP and Intellectual Property arising from use of the Materials and Derivatives associated with the research activities outlined below. |
| **Details of Non-Commercial Research Activities:** | |

**SPECIAL CONDITIONS (to the extent of any inconsistencies between the Special Conditions and the attached Terms and Conditions, these will override the attached Terms and Conditions):**

| | | |
|---|---|---|
| **Insert:** *Note - f there are any Special Conditions or* | 1. | |
| | 2. | |
| | 3. | |

| | | |
|---|---|---|
| *variations to the Terms and Conditions, please refer matter to CSG* | 4. | |

**EXECUTION PAGE**

AIMS agrees to grant to the RECIPIENT a licence to receive and use the Materials and the parties agree to accept certain other rights and obligations on the Terms and Conditions attached to and forming part of this Agreement.

| | |
|---|---|
| **Signed** for and on behalf of **THE AUSTRALIAN INSTITUTE OF MARINE SCIENCE:** | **Signed** for and on behalf of **FLINDERS UNIVERSITY :** |
| Signature of Authorised Officer: _____ | Signature of Authorised Officer: _____ |
| Print Name: _____ | Print Name: _____ |
| Date: _____ | Date: _____ |
| In the presence of: | In the presence of: |
| Signature of Witness: _____ | Signature of Witness: _____ |
| Print Name: _____ | Print Name: _____ |

Definitions & interpretation

In this Agreement, descriptions and terms referred to in the Details section have the meanings respectively there appearing. In addition:

**"Confidential Information"** means all know-how, Intellectual Property, financial information and other commercially valuable or sensitive information in whatever form, including inventions (whether or not reduced to practice), trade secrets, methodologies, formulae, graphs, drawings, samples, biological materials, devices, models, business plans, policies, information regarding future products and any other materials or information which a party regards as confidential, proprietary or of a commercially sensitive nature that may be in the possession of a party or its employees or officers, whether transmitted orally, in writing or by electronic means, directly or indirectly or via a third party associated with the disclosing party, and whether disclosed before or after the Commencement Date, and includes all information in or relating to the Materials, Derivatives and Results, provided that Confidential Information does not include information which:

(a) is now in the public domain, or enters the public domain after the Commencement Date, through no fault of the receiving party;

(b) can be shown by contemporaneous records of the receiving party to have been known to the receiving party at the time it is received pursuant to this Agreement;

(c) is provided to the receiving party by a third party after the Commencement Date, lawfully and without violating any restriction on its disclosure; or

(d) is independently developed by the receiving party without using any Confidential Information of the other party.

1.2 **"Derivative"** means anything (excluding Results), derived by the Recipient from or using the Materials and where appropriate the Derivatives, including without limitation:

(a) improvements, developments, modifications, structural or functional analogs and homologs of the Materials;

(b) expression products, replicates and progeny of any of the above; and

polynucleotides coding for any of the above;

1.3 "**Details**" means the matters set out in the Details section on the front pages of this Agreement.

1.4 **"Intellectual Property"** means statutory, general law and any other proprietary rights in respect of copyright and neighbouring rights, all rights in relation to inventions, patents, plant varieties, registered and unregistered trade marks, registered and unregistered designs, circuit layouts and rights to require information to be kept confidential, but does not include moral rights that are not transferable.

1.5 **"Results"** means all information, Intellectual Property, intellectual assets, data and knowledge arising from the Recipient's use of the Materials and any Derivatives.

**Interpretation**

Headings are for convenience only and do not affect interpretation.

The Details, Terms and Conditions and any schedules or attachments together constitute this Agreement.

The singular includes the plural and conversely, and a gender includes all genders.

A reference to any legislation or to any provision of any legislation includes any modification or re-enactment of it, any legislative provision substituted for it and all regulations and statutory instruments issued under it.

SUPPLY OF THE MATERIALS

AIMS agrees to provide the Recipient with the Materials in the quantity and in the packaging, and by the Mode of Transport, set out in the Details. The Recipient is solely responsible for all transport, insurance and any other costs incurred in supplying and/or using the Materials and to the extent that these are paid for by AIMS will reimburse AIMS within twenty-eight (28) days of written request.

The Recipient acknowledges that the Materials have been developed or acquired by AIMS, are the sole and absolute property of AIMS and are of considerable value, both in terms of research use and in their actual or potential commercial applications.

USE OF THE MATERIALS

The Recipient must only use the Materials for the Approved Purpose.

The Recipient agrees to keep the Materials secure, confidential and under the personal care and control of the Custodian for the Recipient. If the Custodian for the Recipient named in the Details changes, the Recipient must notify the full name and contact addresses of the replacement Custodian for the Recipient and the reason for his or her replacement no later than three (3) days after the change becomes effective.

The Recipient must not without the prior written permission of AIMS:

sell, loan or otherwise provide or give physical possession of any of the Materials or any Derivative to any third party;

use the Materials or any Derivative for any purpose other than the Approved Purpose; or

use or store the Materials or any Derivative in any location other than in the laboratory of the Custodian for the Recipient and under his or her direct supervision.

Subject only to clause 4.6, the Recipient warrants that the research that will be conducted pursuant to this Agreement is non-commercial and that no person or entity that carries on or proposes to carry on any business holds or at any time will hold any option, licence or other rights to the use or commercialisation of the Materials or any Results or Intellectual Property arising from the Derivatives.
The Recipient must ensure that its use of the Materials complies with all relevant laws, codes of practice and ethical principles applicable in Australia and any other country in which the research by the Recipient takes place. In particular, the Recipient must not use the Materials or Derivatives in any research or trials involving human subjects without AIMS' prior express consent in writing. To the extent of any inconsistency between the laws, codes of conduct and ethical principles of Australia and the laws, codes of conduct and ethical principles of another country, the laws, codes of conduct and ethical principles, (as the case may be) of Australia shall prevail.

OWNERSHIP & INTELLECTUAL PROPERTY RIGHTS
AIMS is to be the owner of the entire right, title and interest in the Materials, any Intellectual Property rights subsisting in them at the point of transfer and any Derivatives.
The right of the Recipient to use the Materials and Derivatives under this Agreement is non-exclusive.
Nothing in this Agreement or the use of the Materials by the Recipient gives the Recipient any licence of or other proprietary or non-proprietary interest in any Intellectual Property rights of AIMS in relation to the Materials beyond the non-exclusive licence to use the Materials and Derivatives, created by this Agreement.
AIMS gives no warranty that any use of the Materials and/or Derivatives will not infringe the Intellectual Property rights or other rights of any third party.
The Recipient is to be the owner of all Results including Intellectual Property rights created by the Recipient after the date of this Agreement as a result of the use of the Materials and Derivatives by the Recipient in accordance with this Agreement. The Recipient grants AIMS a non-exclusive licence to use any Results and Intellectual Property rights so created by the Recipient for non-commercial purposes free of any charge, fee or other payment.
If the Recipient wishes to commercialise or have commercialised any Results or Intellectual Property rights arising from its use of the Materials or Derivatives, or otherwise deal with any Derivative for any commercial purpose, it must first enter into an appropriate agreement with AIMS. The parties agree to negotiate in good faith with a view to concluding such an agreement on terms reasonably acceptable to both parties.
If AIMS wishes to commercialise any Results including Intellectual Property created by the Recipient from the use of the Materials or Derivatives it must first enter into an appropriate agreement with the Recipient. Both Parties agree to negotiate in good faith with a view to concluding such an agreement on terms reasonably acceptable to both parties.

PUBLICATIONS
(a)The Recipient will provide AIMS a copy of any publications (including media releases) arising from the use of the Materials and Derivatives thirty (30) days in the case of scientific publications and fourteen(14) days in the case of media releases prior to public release or release outside of the Recipient's workplace which cannot be so published or released without AIMS' prior written consent which will not be unreasonably withheld or delayed for longer than 30 days and 14 days as the case may be.
(b)Where the intended publication is a student thesis it will be unreasonable for AIMS to withhold or delay consent unless AIMS can establish within 30 days of receipt of the request for publication that AIMS' Intellectual Property Rights or Confidential information would be adversely affected by the publication.
(c)Failure by AIMS to respond within the time limits specified in this clause 5.1 will be deemed to be a consent.
The Recipient agrees to acknowledge the role of AIMS in any publication arising out of the Recipient's use of the Materials and Derivatives (including without limitation the provision of the Materials pursuant to this Agreement) and, where any significant advice or recommendations have been provided by an employee of AIMS, the Recipient further agrees to acknowledge the authorship of that person.
The Recipient will not use AIMS' name or logo without AIMS' prior written consent.

CONFIDENTIALITY
The Recipient must treat the Materials as Confidential Information and restrict access to the Materials to those researchers who are directly involved in the Approved Purpose and who are placed under an obligation to observe the terms of this Agreement.
Each party will treat the terms of this Agreement and all Confidential Information owned by the other party as confidential. Each party's obligation of confidentiality will survive expiration or termination of this Agreement and will continue until the Confidential Information is disclosed to it lawfully becomes part of the public domain.

REPORTING

(a)The Recipient will provide Reports of the Results to AIMs in accordance with requirements set out in the Details.
(b)AIMS will keep such Reports confidential subject to any AIMS' rights described in clause 4.

LIABILITY & INDEMNITY
AIMS gives no warranty that the Materials are fit for the Approved Purpose, or that they have any particular qualities or characteristics. The Recipient acknowledges that the Materials are experimental in nature and that the speculative nature of scientific research is such that it is unreasonable to expect AIMS to give any assurances to the Recipient as to the performance of the Materials, the Derivatives or the Results.
To the extent permitted by law, all implied warranties and conditions relating to the supply of the Materials to the Recipient are excluded or, where such an exclusion is prohibited by law, liability under any such implied conditions and warranties is limited to the extent permitted by law. The Recipient indemnifies AIMS, its officers, staff, contractors, representatives and agents against any loss or liability arising out of or relating to the Recipient's possession, use, storage or transport of the Materials, however that loss or liability may arise.
For the avoidance of doubt, the fact that AIMS has reviewed a description of the Recipient's research does not constitute any advice by AIMS, or any endorsement of such research.
The Recipient indemnifies AIMS and its officers, staff, contractors, representatives and agents against all loss, liability, damage (whether to persons or property), costs and expenses (including without limitation legal expenses), claims, demands, suits and other actions arising out of the Recipient's acceptance, use and disposal of the Materials and/or Derivatives and publication or disclosure of the Results arising from the use of the Materials and/or Derivatives.

EXPLOITATION OF THE MATERIALS
Nothing in this Agreement prevents AIMS from exploiting the Materials or any derivatives or distributing, or licensing the Materials or any derivatives to any third party, including both profit and non-profit organisations.

TERMINATION & ASSIGNMENT
The Recipient may terminate this Agreement at any time by giving 14 days written notice to AIMS
In addition to its rights at common law , AIMS may immediately terminate this Agreement by notice in writing given to the Recipient if the Recipient :
(a) enters into liquidation or has receiver or manager appointed or enters into a scheme of arrangement with any of its creditors;
(b) breaches this agreement which is not in the reasonable opinion of AIMS capable of rectification;
(c) breaches this Agreement and does not rectify it to the satisfaction of AIMS within 14 days after receiving notice from AIMS requiring it to do so;
(d) engages in dishonest or fraudulent conduct; or
(e)fails to perform its obligations under this Agreement for more than 60 days due to an event beyond its control that AIMS did not cause.
The Recipient must either return the Materials and/or the Derivatives to AIMS or destroy the Materials and Derivatives (to be determined at AIMS' discretion) at the Recipient's cost upon the earlier of:
demand by AIMS;
termination or expiration of this Agreement; and
once the Materials and/or Derivatives are no longer required for the Approved Purpose.
The Recipient's rights under this Agreement are not assignable.
DISPUTE RESOLUTION
If a dispute arises out of or related to this Agreement no party may commence court or arbitration proceedings (other than proceedings for urgent interlocutory relief) unless it has first complied with this clause.
A party to this Agreement claiming that a dispute has arisen under or in relation to this Agreement must give written notice to the other party specifying the nature of the dispute. On receipt of that notice by the other party the parties' representatives must endeavour in good faith to resolve the dispute expeditiously and failing agreement within 7 days must use informal dispute resolution techniques such as mediation, expert evaluation or determination or similar techniques agreed to by them.
If the parties do not agree within 7 days of receipt of the notice referred to in this clause as to the dispute resolution technique and procedures to be adopted, the time table for all steps in those procedures, and the selection of compensation of the independent person required for such a technique, then the parties must mediate the dispute as to which the President of the Law Society of Queensland or his nominee will select the mediator and determine the mediator's remuneration. The mediator will determine the procedure for mediation which so far as is reasonably capable of application shall be based on the Rules of Arbitration of the International Chamber of Commerce.
GENERAL
Any notice under this Agreement may be served by hand delivery or by being forwarded by prepaid post to the address of the party or to such other address as may be notified in writing by the party from time to time and in

the case of service by post is deemed to have been received within four days after posting. Notices may be served by facsimile transmission or e-mail and are valid if in fact received, as demonstrated by a valid transmission report or notification of delivery to the recipient's computer.

This Agreement contains the entire agreement of the parties with respect to its subject matter. It sets out the only conduct relied on by the parties and supersedes all earlier conduct by the parties with respect to its subject matter.

This Agreement may be varied only by written agreement signed by both parties.

No waiver by AIMS of any provision of or right, remedy or power of AIMS, and no amendment to this Agreement, will be effective unless it is in writing signed by AIMS and any such waiver will be effective only in the specific instance and for the specific purpose for which it is given.

No failure or delay by AIMS to exercise any right, remedy or power under this agreement or to insist on strict compliance by the Recipient with any obligation under this Agreement, and no custom or practice of the parties at variance with the terms of this Agreement, will constitute a waiver of the right of AIMS to demand full compliance with this Agreement.

If any provision of this Agreement is unenforceable or invalid for any reason, the relevant provision will be deemed to be modified to the extent necessary to remedy such unenforceability or invalidity or, if this is not possible, then such provision will be severed from this agreement, without affecting the enforceability or validity of any other provision of this Agreement.

This Agreement is governed by the laws of Queensland and Australia without regard to conflicts of laws principles, and the parties submit to the non-exclusive jurisdiction of the courts of Queensland and Australia.

Each signatory to this Agreement warrants that he or she has authority to bind to this Agreement the party that he or she is stated to represent.

オーストラリア海洋生物研究所（AIMS）の標準素材ライセンス契約（MLA）の説明文書

Explanatory Notes – Non-commercial Material License Agreement

To access samples from the AIMS bioresources library.

AIMS has materials from a variety of jurisdictions, and the Terms and Conditions of the ABS agreements AIMS has with those jurisdictions varies. The MLA template includes terms that ensure any use of the material is consistent with our obligations in these ABS agreements with source jurisdictions. In essence – AIMS has an obligation to maintain control and accountability over the physical Material and any physical Derivatives (which includes any gene banks, crude extracts, partially purified compounds and purified secondary metabolites (=compounds) and chemical-derivatives of those compounds, microbes, fermentation products from those microbes, etc, etc, etc.). So, while we are not able to transfer complete rights to the physical material (and derivatives), we are able to grant licenses to allow others to use the material for agreed purposes – which is why the MLA is a license agreement, and not a transfer agreement. AIMS gives the Recipient a non-commercial license, for free, to take AIMS Material, make Derivatives, and evaluate them all.

In doing this – the Recipient will generate Results. In the MLA, the term Results captures the data, IP and all knowledge that the Recipient will create while evaluating the Material and Derivatives. As it is the IP which is the important commodity for commercialisation, this gives the Recipient important certainty, however the Recipient does not have the right to commercialise that IP without entering into a further agreement.

Although the MLA is a non-commercial agreement, AIMS understands that there is usually intent to identify commercial value in the samples. This MLA allows a period for evaluation of AIMS materials, prior to entering into a commercial arrangement. Note that the need to negotiate commercial terms is anticipated in the MLA – through the terms that commit AIMS to negotiate in good faith in the event that the Recipient wants to commercialise their Results. If doing this requires stronger rights to the Material or Derivatives then we would incorporate that into the appropriate license agreement at that time. AIMS wants the Recipient to be successful!

AIMS asks that in return for facilitating free access to material for evaluation, AIMS is provided with a licence to use the IP generated for non-commercial research. This is consistent with one of our key benefit sharing obligations – to maximise the non-monetary benefit of new knowledge about biodiversity, and disseminate that knowledge when doing so does not compromise commercial opportunities. Confidentiality obligations in the MLA protect the Recipient's IP. It is possible that AIMS may seek to publish *aspects* of results in such a way that individual data is not identifiable, for example in the recent PLoS ONE paper that used data to inform gross trends in bioactivity across Australia. This paper used over 18000 data points and advanced computational modelling to generate the trends that were reported (Phylogeny Drives Large Scale Patterns in Australian Marine Bioactivity and Provides a New Chemical Ecology Rationale for Future Biodiscovery http://www.plosone.org/article/authors/info%3Adoi%2F10.1371%2Fjournal.pone.0073800;jsessionid=F90AB4B68AD3CD1F37912720BF98FA55). This is the sort of study which would benefit from inclusion of Results, but this would only occur with a Recipient's consent and (hopefully) participation. In the unlikely event that AIMS would seek to commercialise a Recipient's IP, AIMS must negotiate a commercial agreement with the Recipient.