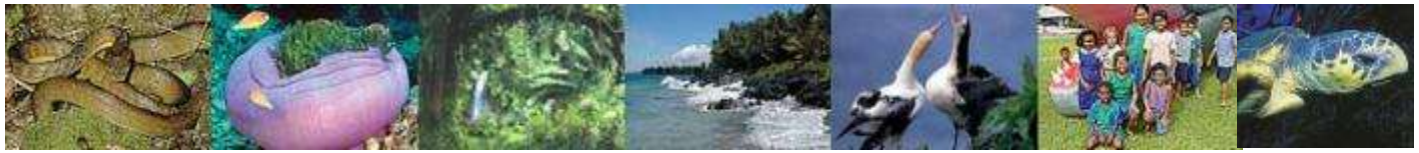
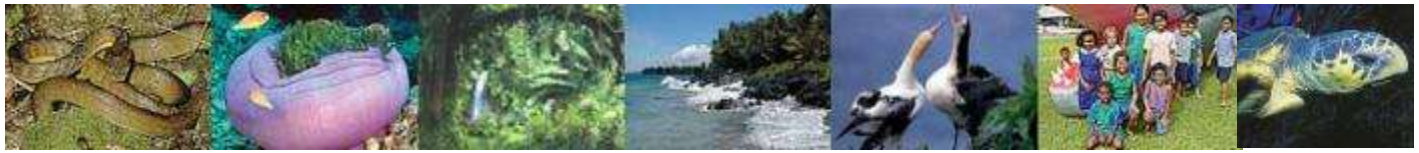


Training on Mutually Agreed Terms: Contracts for Making ABS Possible 5-8 August 2014, Nadi, Fiji

Introduction

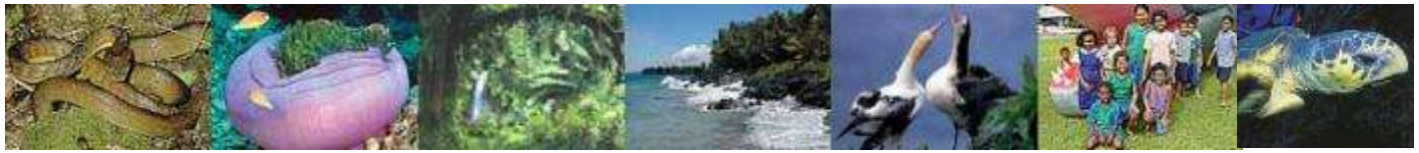
Clark Peteru, John Scott, Coral Reef Research Foundation (Palau)

South Pacific Regional Environment Programme



CBD Definitions

- Biodiversity
  - Means the variety of all life on earth: plants, animals, and microorganisms, the genes they contain and the ecosystems they form
- Genetic resources
  - Means any material of plant, animal, microbial or other origin containing functional units of heredity, of actual or potential value [Human GR excluded]; Biochemicals
- Bioprospecting
  - The obtaining of samples of biological or other material containing genetic material from areas within national jurisdiction for the purposes of research, conservation, commercial or industrial application of the genetic material



ABS in Practice

Different genetic resources

Animal, plant, microbial

(in-situ and ex-situ)

Used for different purposes

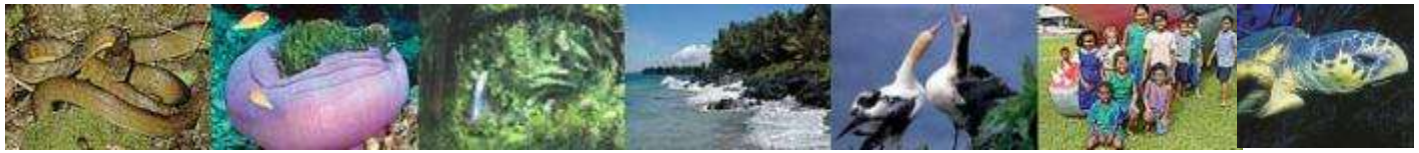
Research and/or commercialization

Different users operating in different sectors

- Pharmaceuticals
- Seed and crop protection
- Personal care and cosmetics
- Botanicals and horticulture

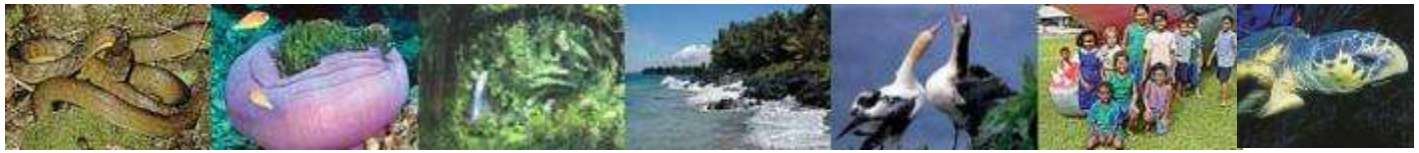
A large number of actors involved

(Rarely one provider and one user (e.g. intermediaries))



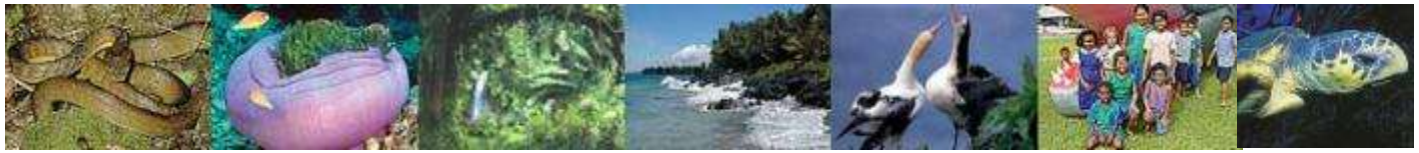
How did we get to Nagoya

- Pre-CBD
- CBD 1992
- Bonn Guidelines 2002
- Nagoya Protocol 2010



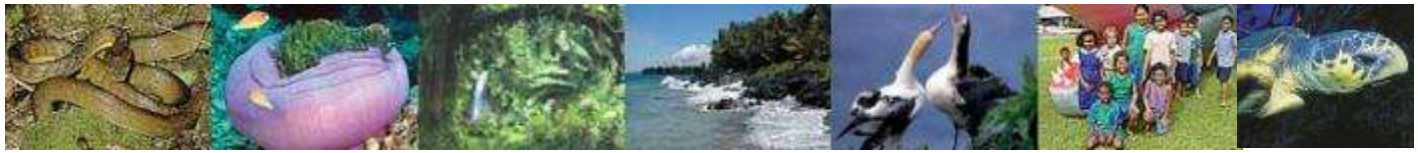
Pre-CBD

- Colletion of genetic resources without adequate compensation and sometimes without persmission ("common heritage")
- 1950s traditional farmers complain about practice of professional plant breeders within the forum of the FAO with little success
  - (recognition at the international level but compensation to be dealt with at the national level)
- 1980s the debate surfaces in the forum of the CBD and a solution is found



CBD: an international "solution"

- In force 1993, signed by most countries
- Natural resources are a matter of national sovereignty: good news for source countries (but not necessarily source communities)
- Need to have in place an access procedure for legitimate users wanting to access your genetic resources: a concession to users. This procedure should favour the provider but not be burdensome for the user.
- Good for tropical countries (PNG 4%)



CBD Provisions

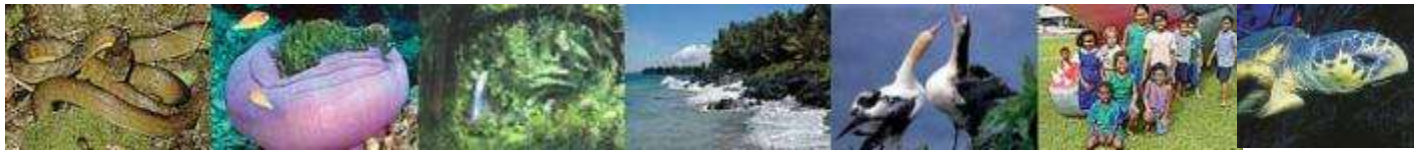
Four fundamental principles underpin the International Regime:

Sovereign rights over genetic resources

Facilitate access to genetic resources

Prior informed consent

Mutually agreed terms



Access and Benefit Sharing (ABS)

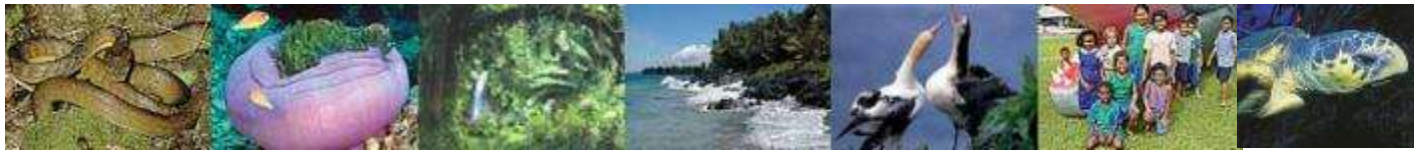
1 Access given by owners of genetic resources to those wanting to use it

- Prior informed consent (PIC)
- Mutually agreed terms (MAT)
  traditional ecological knowledge (TEK)
  Intellectual property rights (IPR) patent & sui generis law

2 Benefit sharing by the user for using the genetic resource

A quid pro quo

Conservation; self-interest to conserve and then to continue conserving.



ABS in Practice

Prior Informed Consent (PIC)

Provider of GR (+/- associated TK): (National Competent Authority, ILCs)

User of GR (+/- associated TK): (Industry, Research Institutes, Universities)

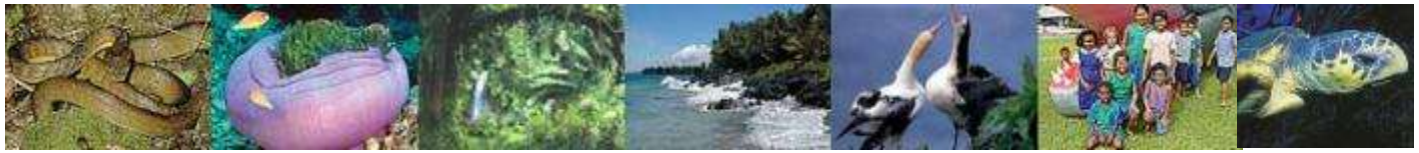
Intermediaries in either provider or user country:

e.g. Research Institutes, Universities, Botanical Gardens, Ex situ Collections

Mutually Agreed Terms (MAT) between Provider and User

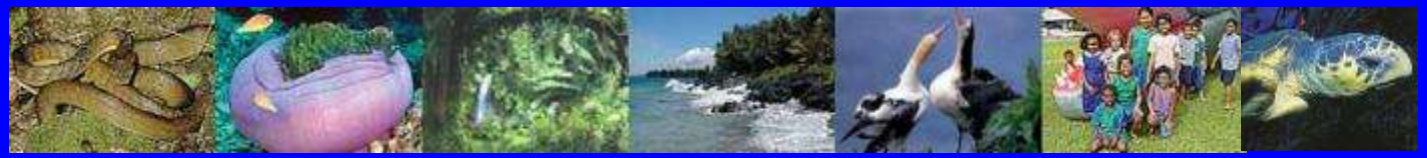
- Non-commercial or commercial utilization of GR (+/- associated TK): e.g. basic research, research and development, development of new pharmaceuticals, biotechnological products
- Benefit-Sharing (monetary & non-monetary): e.g. royalties, technology transfer, training

South Pacific Regional Environment Programme



Bonn Guidelines, 2002

- assist Parties, Governments and other stakeholders in developing overall access and benefit-sharing strategies, and in identifying the steps involved in the process of obtaining access to genetic resources and benefit-sharing.
- to help when establishing legislative,administrative or policy measures on access and benefit-sharing and/or when negotiating contractual arrangements for access and benefit-sharing.
- voluntary, not legally binding. Bilateral and suits countries with low biodiversity

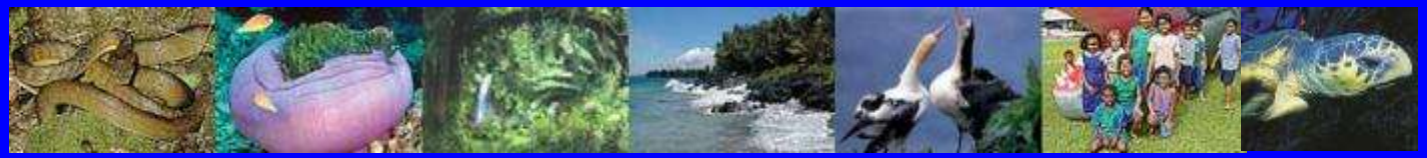


The Search for Drugs from Nature

- The plants and animals of the oceans and lands have had millions of years to develop through evolution chemical compounds to protect or benefit themselves, and defeat their neighbors in competition for space.

- The galaxy of naturally occurring chemical compounds, known as “natural products”. Many of these compounds have been used as medicines for centuries by people all over the world. Many of our prescription drugs today have their origin in traditional medicine.

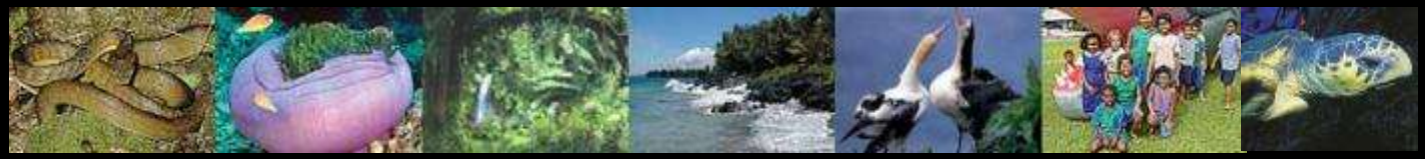
- This galaxy of chemical compounds in nature provides a source of new compounds to test for bioactivity. Many of the existing compounds organic chemists have never imagined, much less been able to make to test for drug activity.

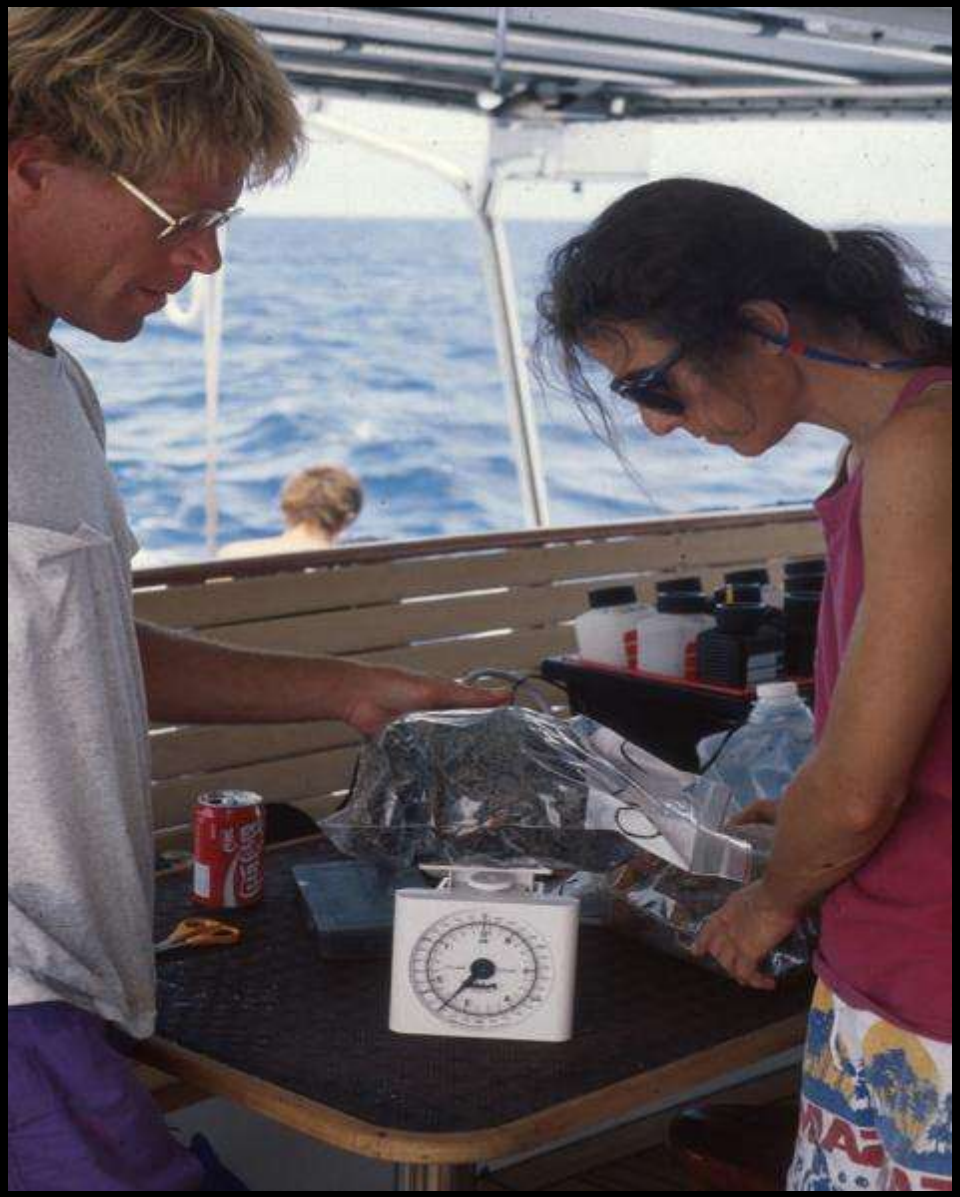


How do you go about discovering a new cancer treatment drug from nature?

- Collection
- Extraction
- Testing the raw extract in vitro
- Purifying the compound
- Determining the chemical structure
- Testing with pure compound vitro
- Animal and human testing
- Production


MAF
KAHAROA





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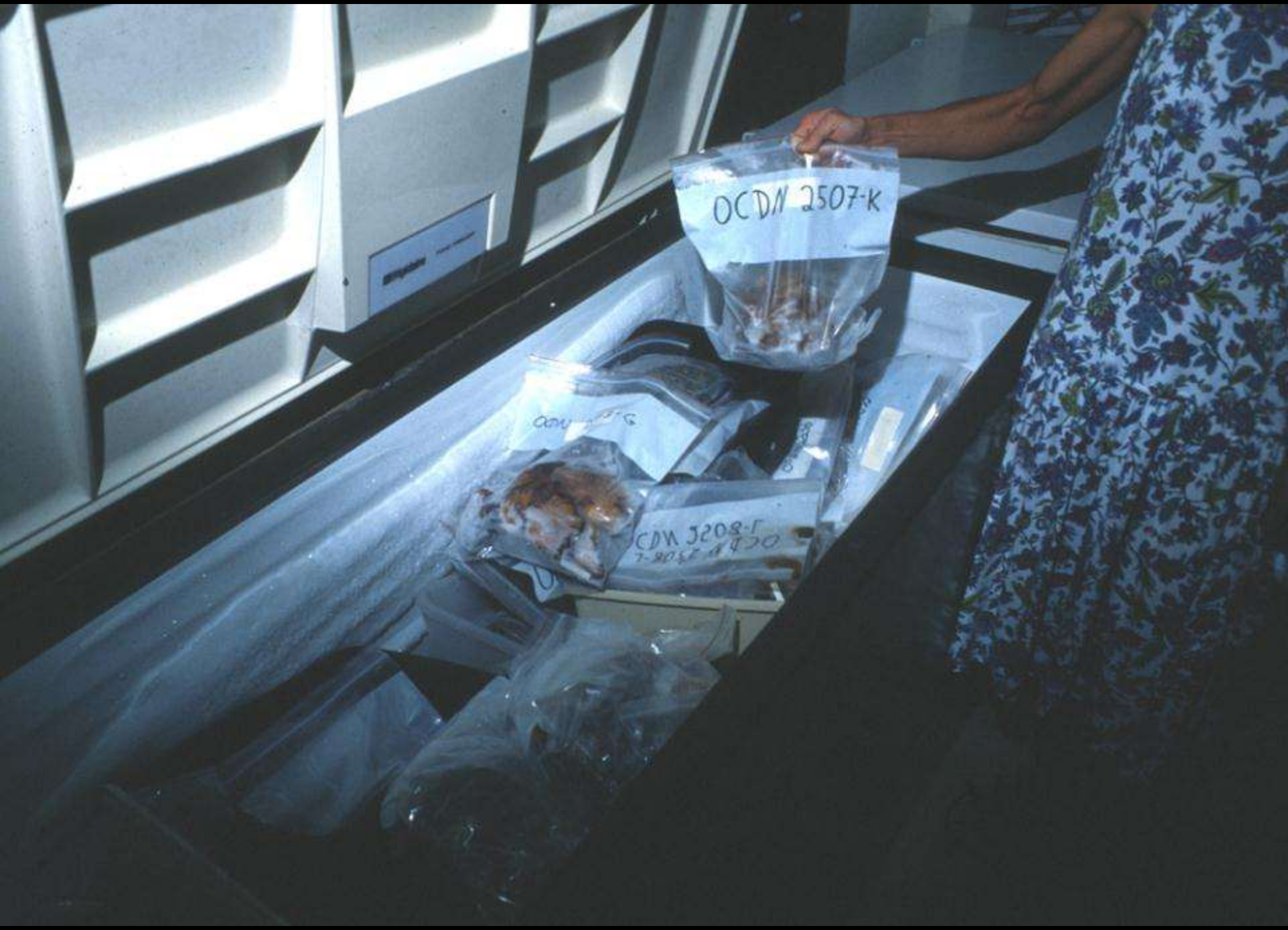
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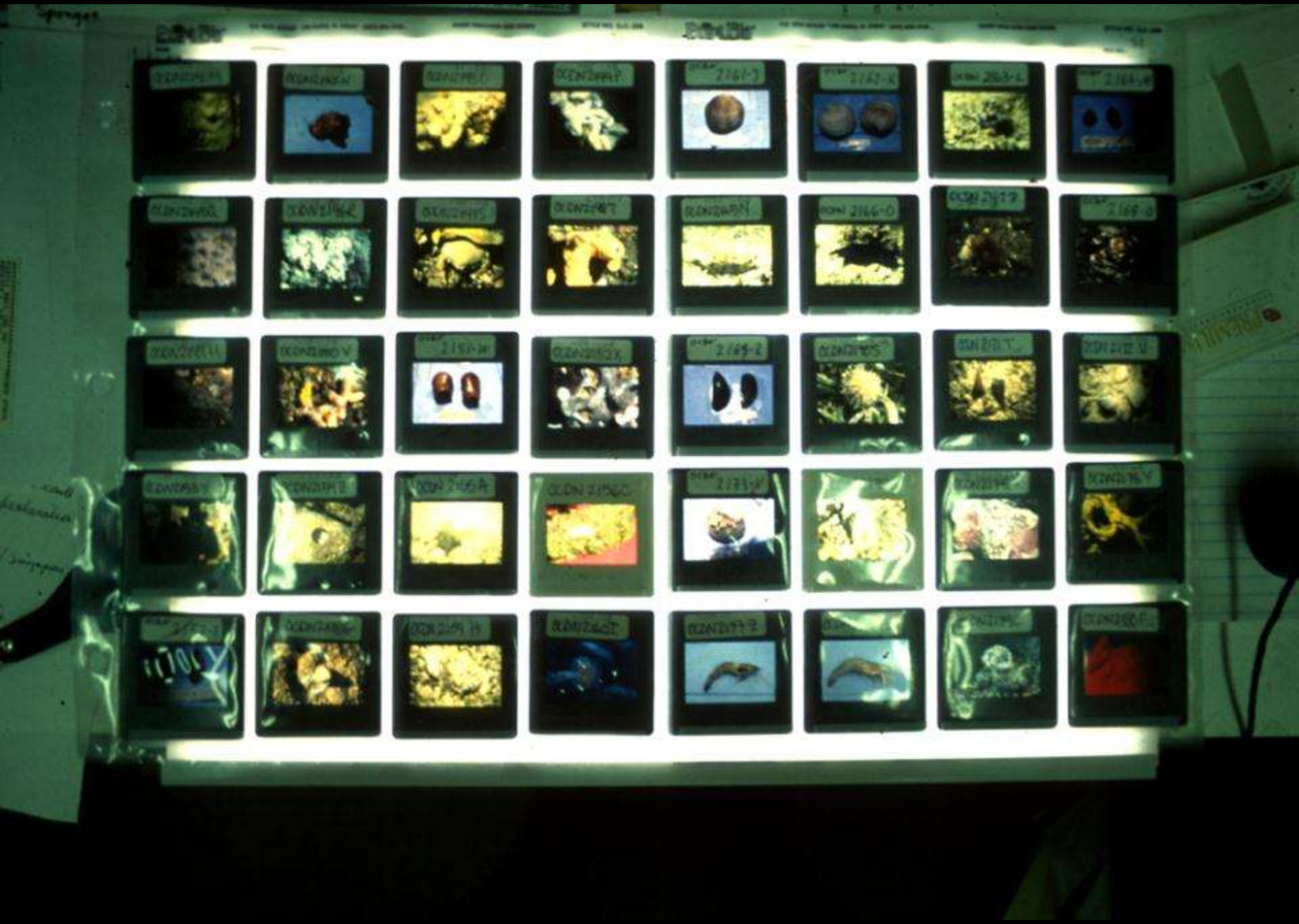
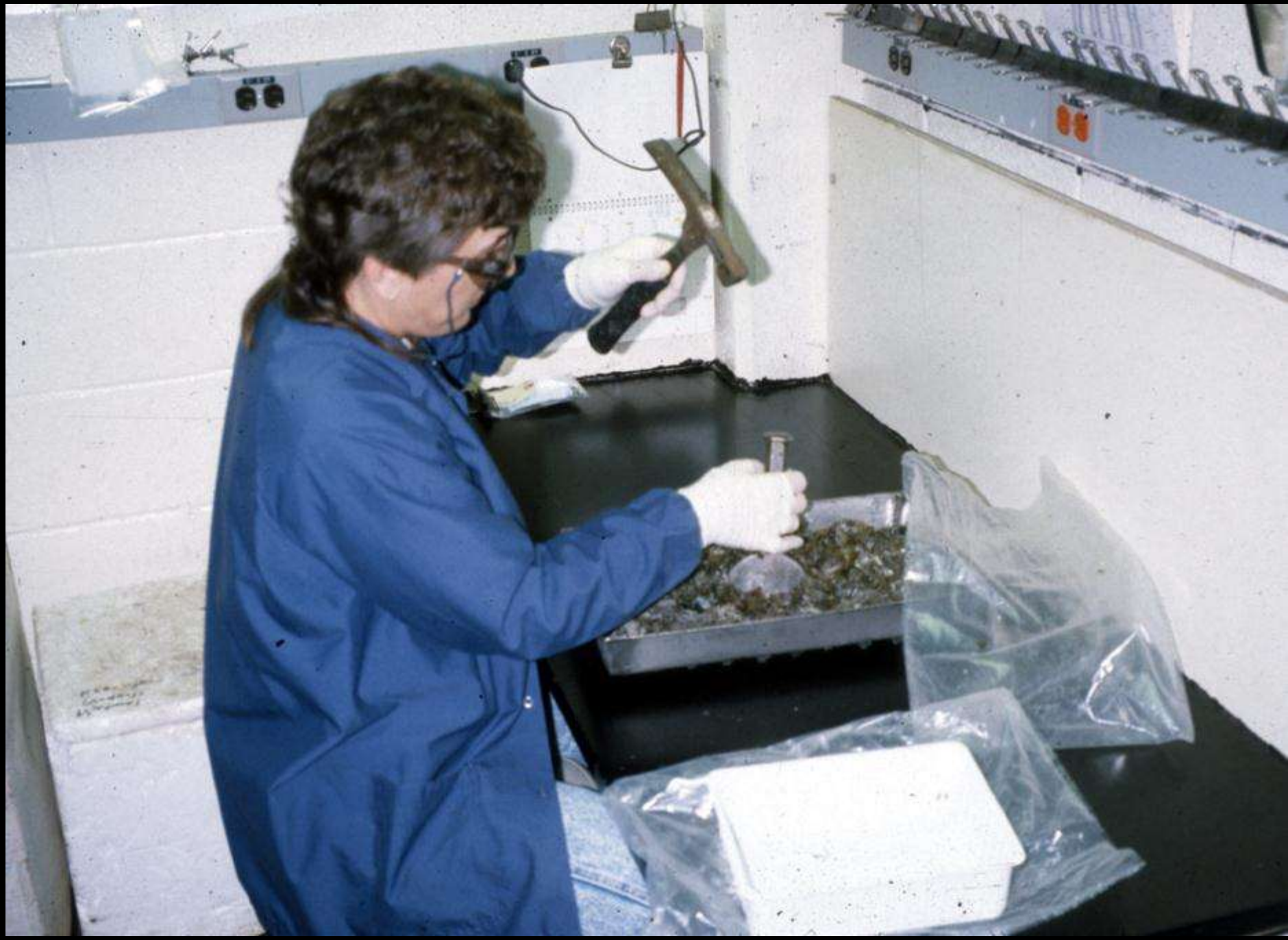
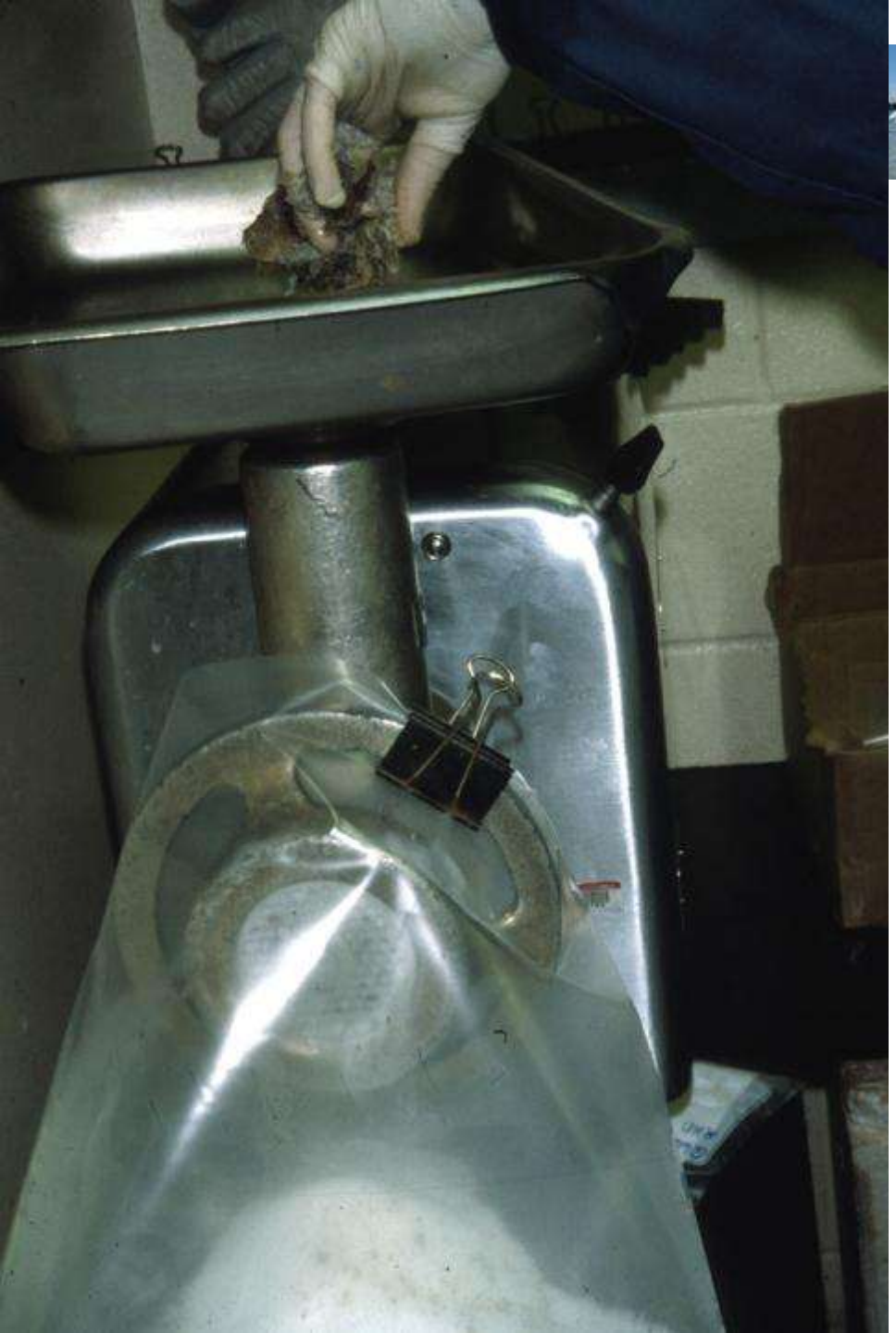


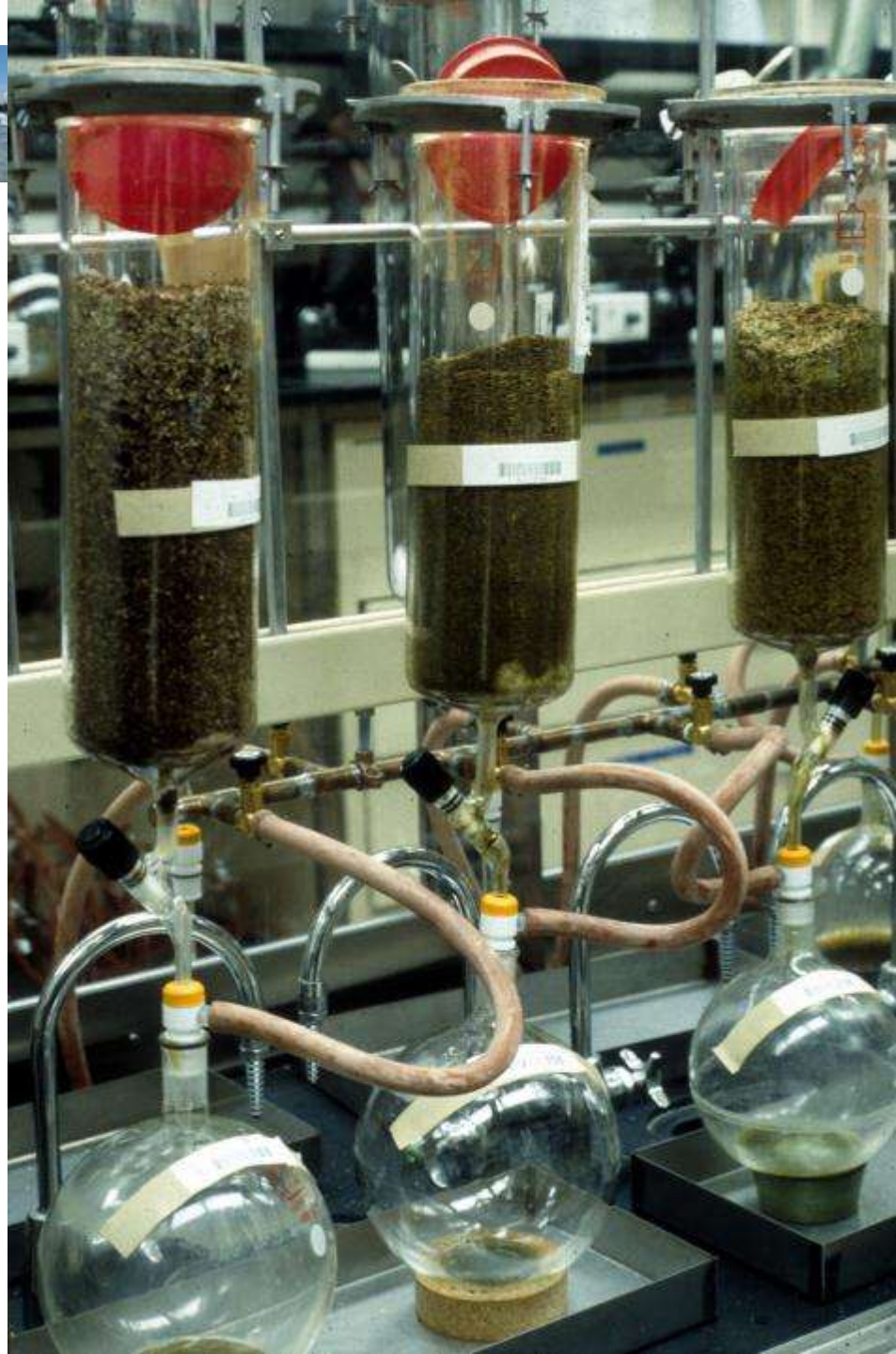

Vanuatu
YJ-AVI8
AIR VANUATU

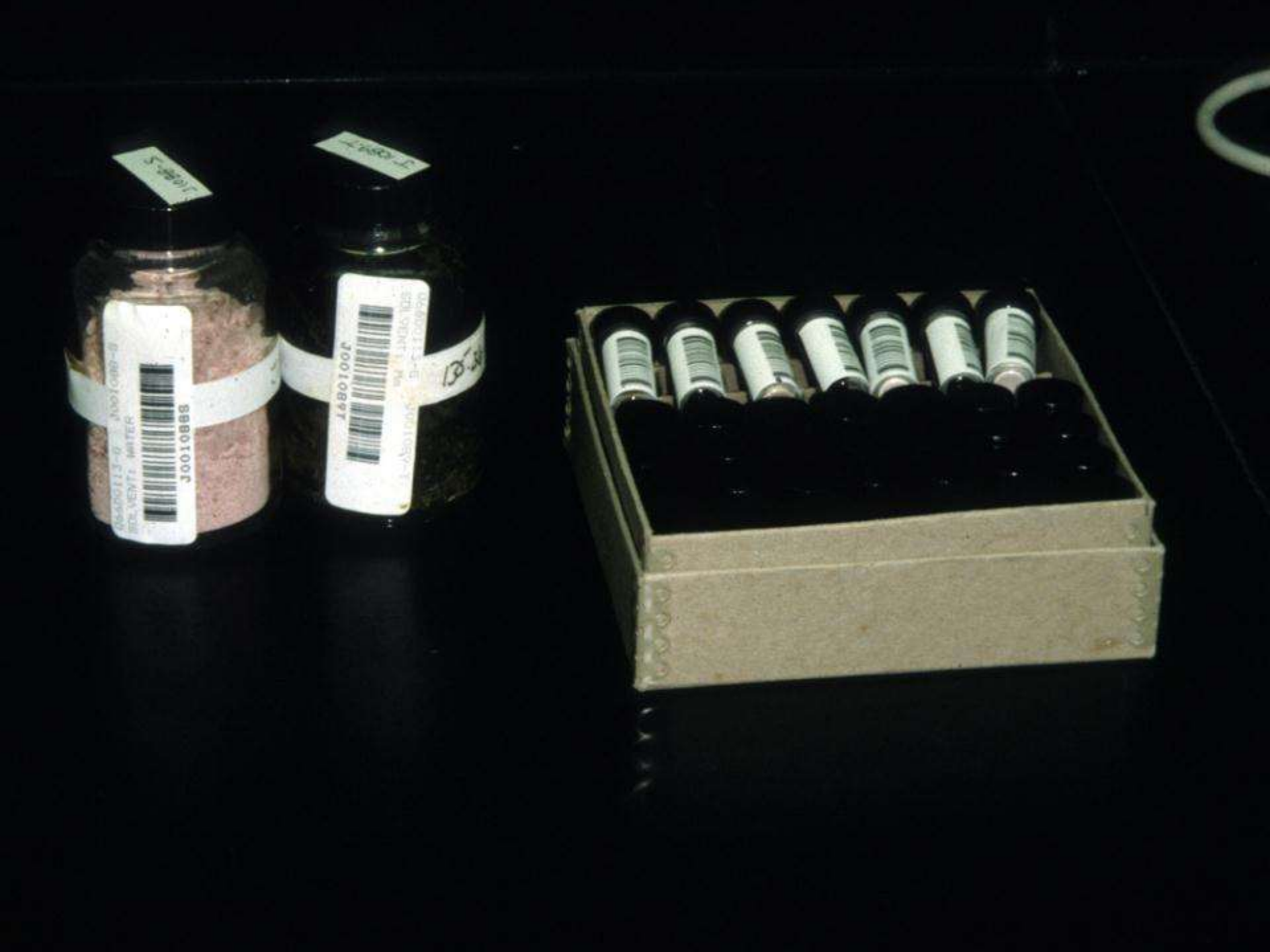

EXIT


A
B
D
E





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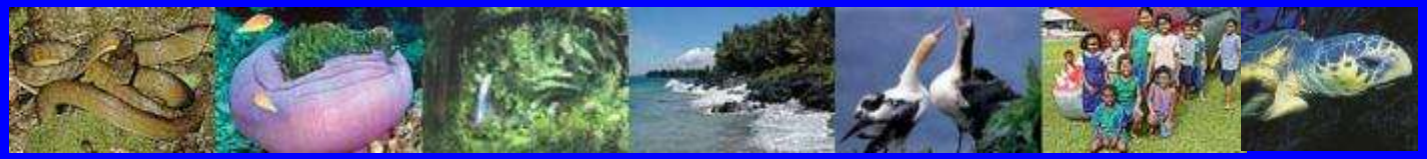
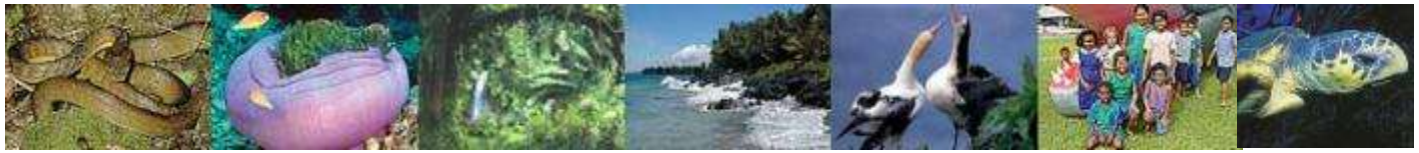


Policy Considerations for Marine Bioprospecting

Important Considerations

- 1) Who are you dealing with?
- 2) Where does their funding come from?
- 3) What samples are they going to collect and how much?
- 4) What are they going to do with the samples?
- 5) Who would have access to them in the future?
- 6) What are the institutional policies on benefit sharing and IPR for the samples?
- 7) What will be the reporting requirements and follow up for the samples?
- 8) What benefits are to the host country?



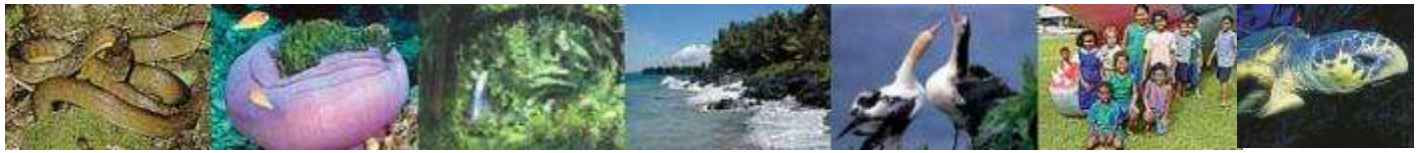
Traditional Knowledge

Basic issues and concepts:

- articles 15, 8(j) and 10(c)
- Interface of community level law / practices / procedures, domestic law and international law
- What is traditional knowledge associated with genetic resources?
- How to ensure PIC of indigenous and local communities
- Capacity of ILCs to negotiate MATs and enforce contracts

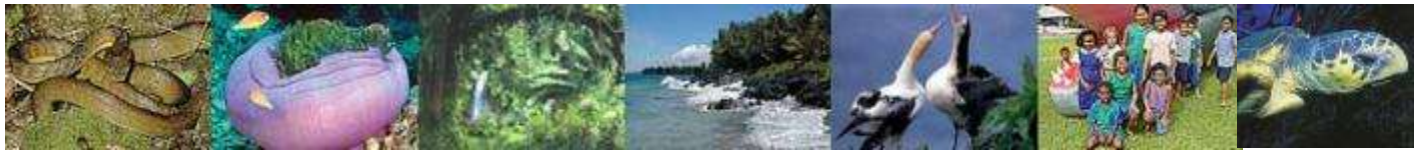
Broad areas under discussion

- Ensuring access in accordance with community level procedures
- Who grants PIC at community level and how can this be reflected to demonstrate compliance?
- Ensuring benefit-sharing
- Assistance to support community level decision making and compliance mechanisms



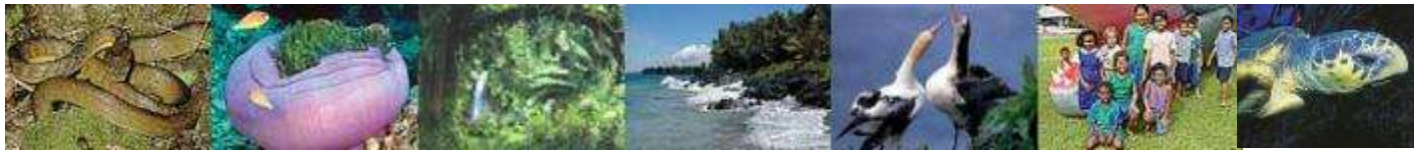
TK in the context of ABS

- **TK associated to biodiversity and GRs**,
- Exs: knowledge and practices related to the use of plants and herbs for medicinal purposes,
- traditional knowledge and practices of biodiversity conservation and sustainable use, such as knowledge of landscape/seascape management, of domesticated and wild species, of weather patterns, knowledge related to the conservation and sustainable use of genetic resources,
- traditional water and soil management
- traditional farming techniques and agricultural knowledge, practices and innovations



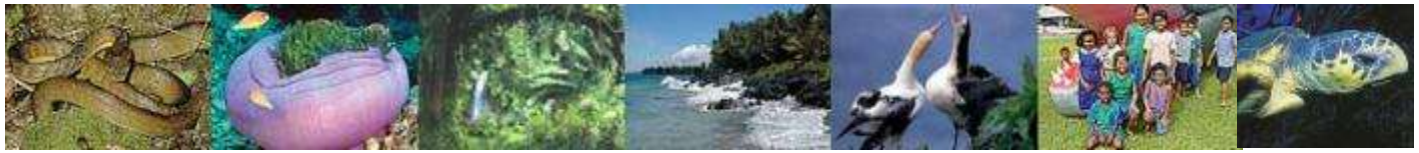
TK in the context of ABS

- **Collective knowledge** may belong to two or more indigenous peoples. Some TK might be shared by different indigenous and local communities, even by different indigenous and local communities in different countries
- Nonetheless, a particular individual member of a community, such as a certain traditional healer or individual farmer, might hold specific knowledge



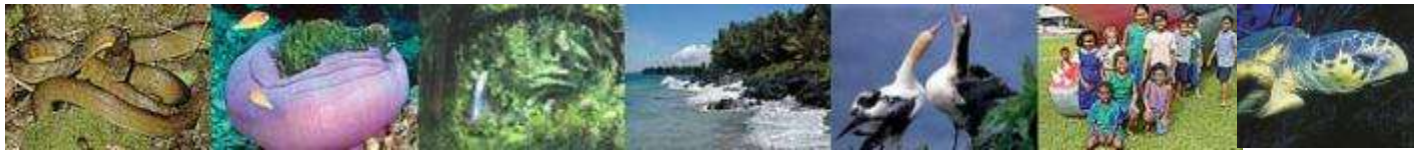
Prior Informed Consent

- Consent obtained by the applicant
- From the country or source (community, family, etc)
- After disclosing fully the intent and scope of bioprospecting activities
- In a language and process understandable to the country or source
- Prior to any bioprospecting taking place



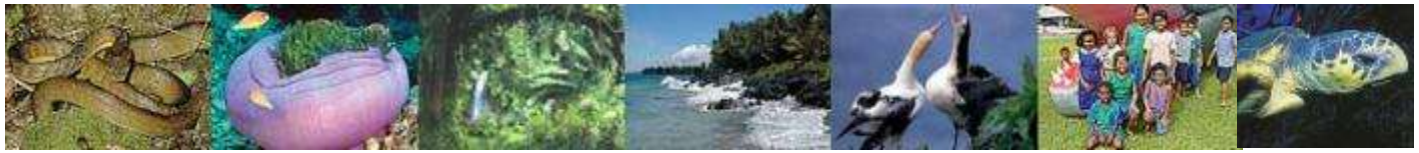
Mutually Agreed Terms (MATs)

- Per sample cost (refer to benefit sharing provisions)
- Non-destructive harvesting
- Purpose for which the material is to be used
- Whether EIA or SIA to be undertaken
- Compensation for use of TK (public domain issue)
- Restriction on release of TK to a third party
- IPRs over products of research
- Report back of research results
- Situations in which the agreement can be cancelled, etc.



The need for legal protection

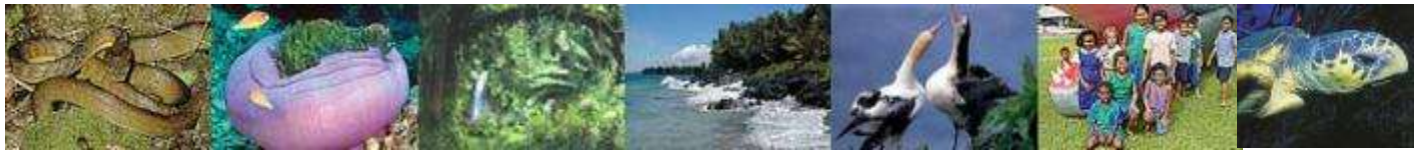
- From 5000-10000 candidate compounds, only one may make it through the full drug production process. May last up to 15 years costing $250-$570 million
- A need to protect a product or process for which much time and effort has been or will be expended
- The inventor needs to be rewarded for his invention and copycats discouraged



Intellectual Property laws

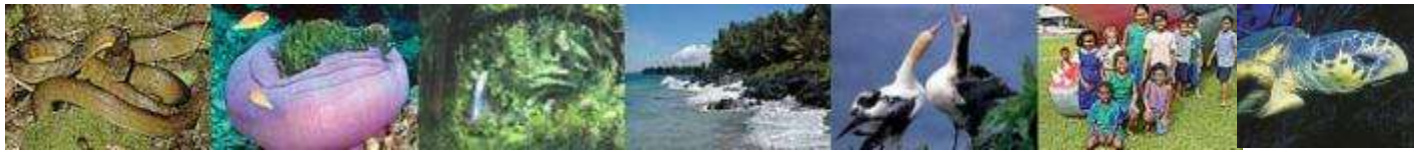
- Industrial patent (WIPO)
- Plant patent
- Plant breeders rights (WIPO/UPOV)

A time-limited monopoly over your invention. The invention needs to be disclosed (cf trade secret).



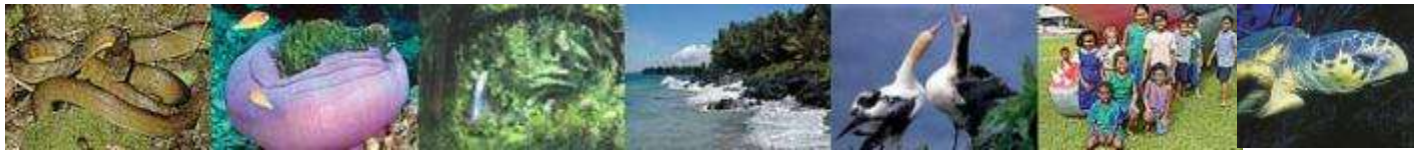
BENEFITS

- Per sample fee; recollection fees
- Milestone payments
- Co-ownership of patents
- Shares in a company
- Royalties
- Technology transfer: hardware, software
- Capacity building: training of locals
- Employment of locals



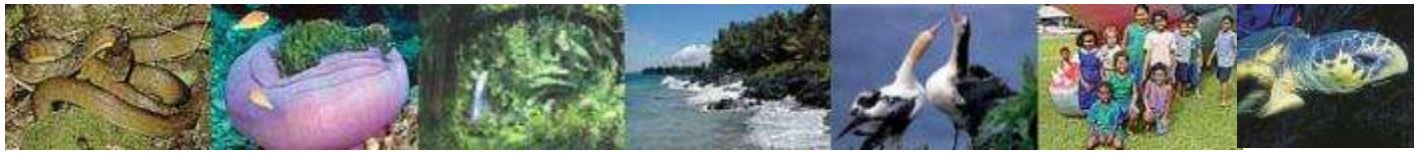
Access Procedure

- Who owns the genetic resources?
- Governments are Parties to the CBD and are required to identify a CNA.
- What will the extent of Government's involvement be in the Access Process?
  - Supervisory on behalf of resource owners: ie, facilitate transactions, arrange for obtaining permits and allowing for the free play of market forces, but, eg, (i) ensure a fair bargain is struck (ii) screen for GR of "national interest"; etc.
  - Total involvement



A legal regime

- Objective
- What GR to cover
- Who owns the GR
- Role of Govt
- What body should deal with applications
- What info will be required
- Who will grant the permit
- Who will police the permit
- What terms should be negotiated in an Agreement
- How will the Agreement be enforced
- Is there an interim policy

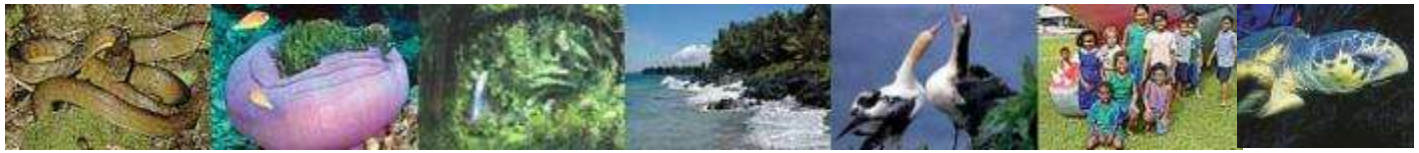


Plant Genetic Resources for Food and Agriculture

International Treaty and Multilateral System

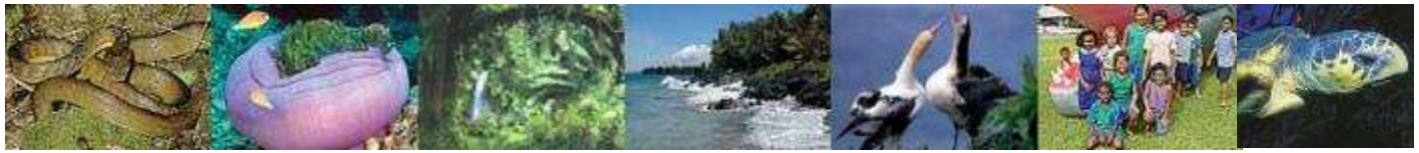
Annex 1 Crops

South Pacific Regional Environment Programme



Breadfruit

THE NEW TREE OF LIFE: Acting Prime Minister, Fonotoe Pierre Lauofo, accepts a cheque of US$12,240 (T$29,000) from the sales of a Samoan breadfruit cultivar as a result of a landmark benefit-sharing agreement entered into six years ago. The cheque was presented by Dr Diane Ragone, the Director of the Hawaii-based Breadfruit Institute of the National Tropical Botanical Garden (N.T.B.G) earlier this week. The money is the result of two years of tree sales.



Contracts

Formation

- Parties have capacity to contract
- Intention to create legal relations
- Breach of contract
- Purpose of the contract
- Remedy: damages – put plaintiff in position should have been in
- Work contracts as an illustration..
- Falealupo covenant