



# Implications of Access and Benefit Sharing Frameworks for Collections and Utilisation of Marine Genetic Resources

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With thanks to Oonagh McMeel and Thomas Vanagt



**45%**

From existing partner collections

**>110,000 screening events**

**> 700 active dereplicated extracts**

**Active, non toxic, novel chemistry**

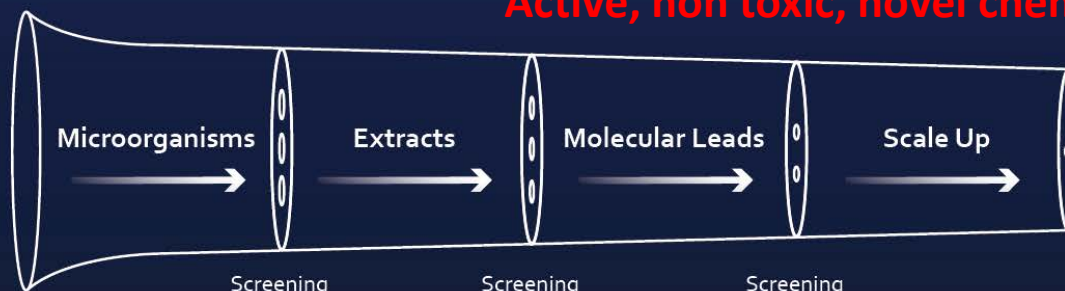


**55%**

New samples from cold/hot/deep habitats

**At 30 Months:**

Up to -6,000 metres



Screening

Screening

Screening

Microbial Library

Extract Library

Molecular Families



**13,689**

**Strains**

**>14,000**

**Active Extracts**

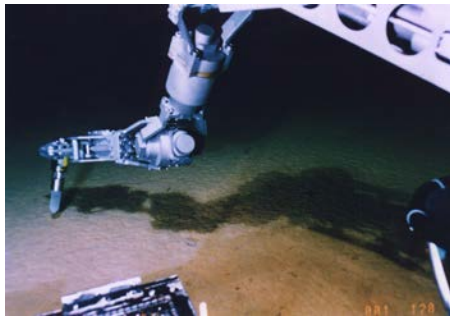
**>80**

**Active Compounds**

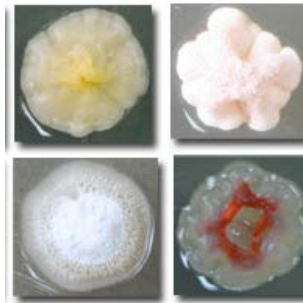
**1**

**Drug Lead**

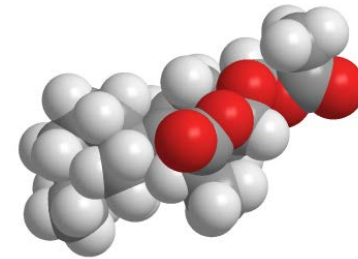
# The PharmaSea Pipeline



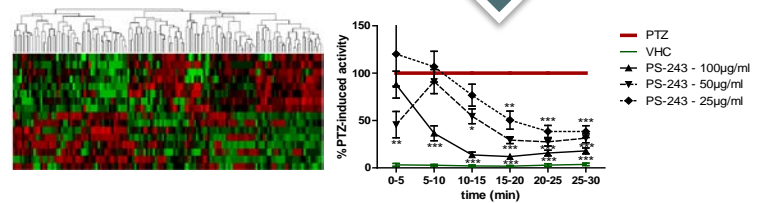
Sampling in ABNJ



MGR



Chemistry



Bioassay



Product



# PharmaSea is Working at the Science/Policy Interface

## Create Science/Policy Interface

MGR Practitioners  
Research /  
Industry



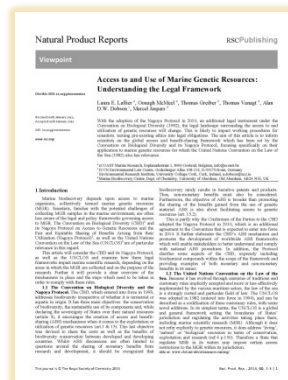
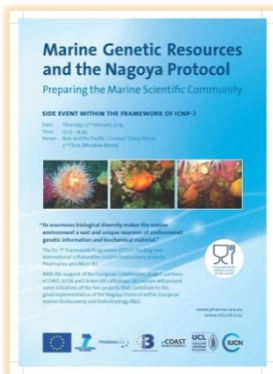
Legal Experts &  
Policy Makers

EC (DG MARE & DG ENV),  
UNDOALOS, CBD Secretariat,  
CIESM, ISA, CMS Secretariat

Inform Policy

Awareness  
Raising

Share best practice



# United Nations Convention on Laws of the Sea (UNCLOS)

**UNCLOS:** *‘peaceful uses of the seas and oceans, the equitable and efficient utilization of their resources, the conservation of their living resources, and the study, protection and preservation of the marine environment’*

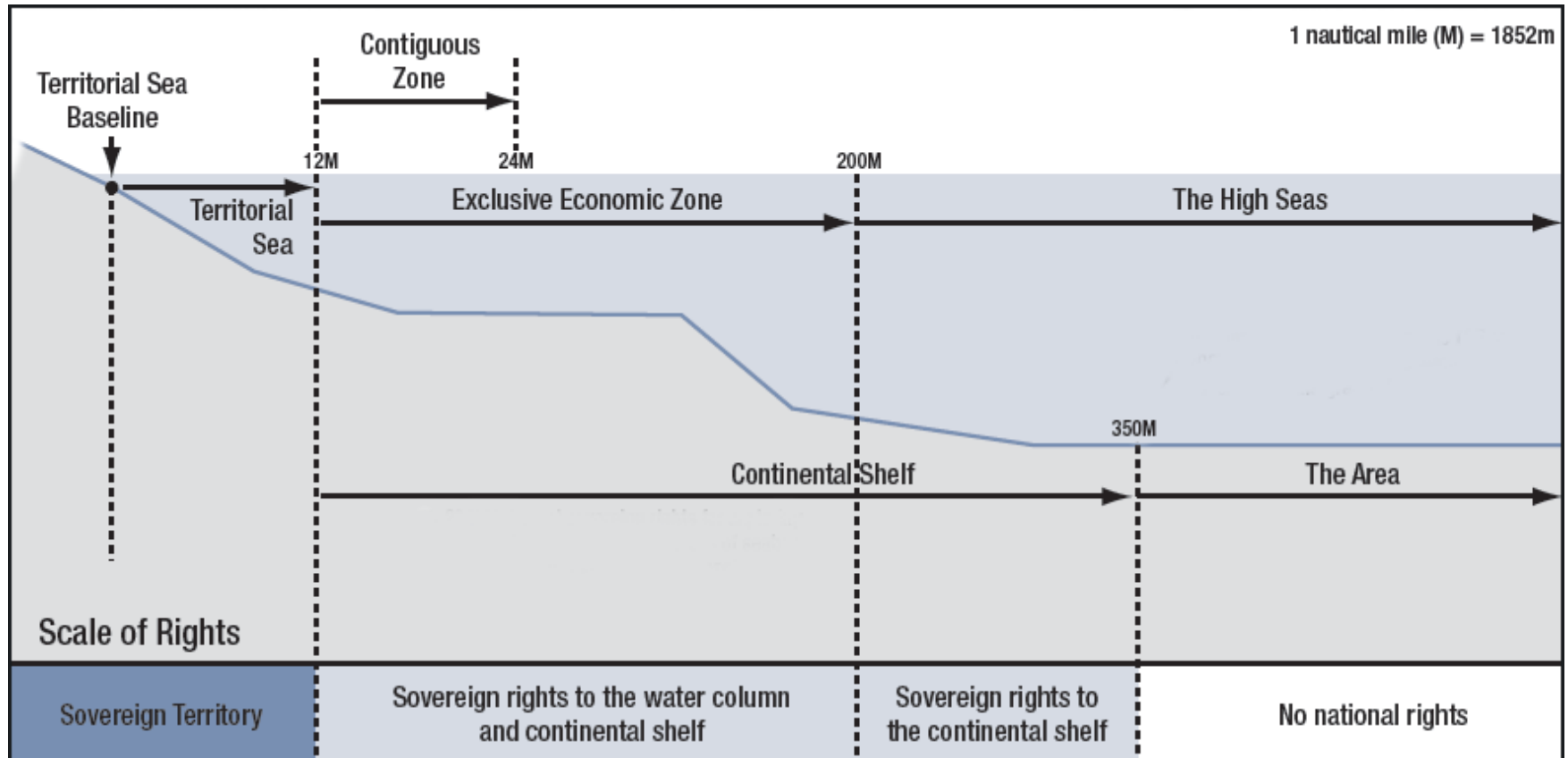
**BUT:** No mention of ‘Marine Genetic Resources’ UNCLOS Part XI only applies to “resources” defined as non-living, mineral resources

## **Conflicting Elements:**

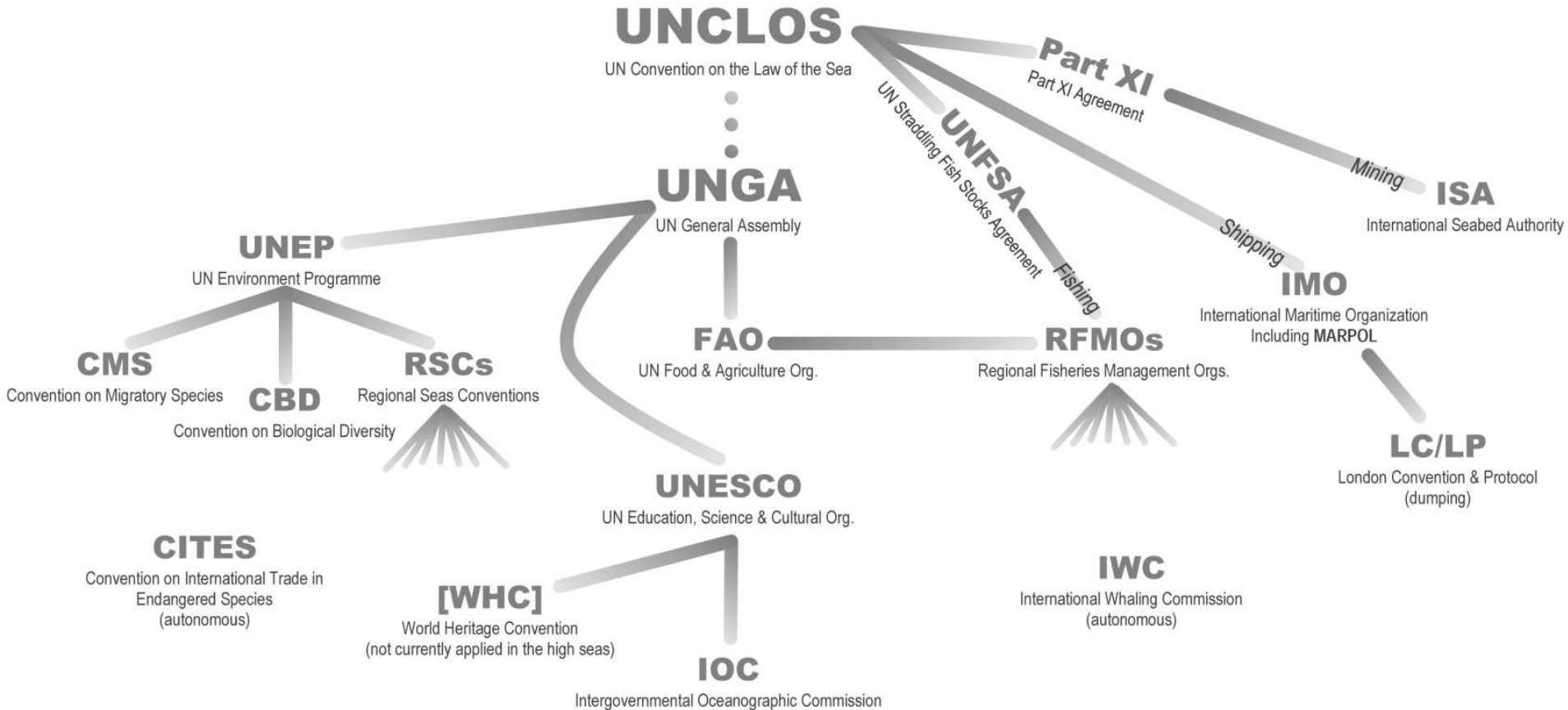
**Freedom of the High Seas:** Freedom to conduct Marine Scientific Research – requires sharing of results

**Common Heritage of Mankind:** No state shall claim sovereignty over any part of the area or its resources (incompatible with IP protection?). Implies equitable sharing of benefits?

# UNCLOS Definitions



# UNCLOS Relationships to Other Bodies



## The Process so Far

1982

- **UNCLOS** Excludes marine genetic resources, but allows freedom of marine scientific research

1996

- “The Deepest of Ironies” by Lyle Glowka raises this issue

2000s

- “Ad-hoc open ended working group to study issues relating to the conservation and sustainable use of marine biological diversity beyond areas of national jurisdiction”



## The Process so Far

2015

- Decision to “develop an international legally-binding instrument under UNCLOS”

2016

- Preparatory Committee (4 x 2 week sessions) open to all UN member states and observers to develop elements of a draft text for an implementing agreement.

2017-

- intergovernmental conference, to consider the recommendations of the preparatory committee on the elements and to elaborate the text of an international legally-binding instrument

# The Package Deal

Conservation and sustainable use of marine biodiversity in areas beyond national jurisdiction, in particular, together and as a whole:

- marine genetic resources
- sharing of benefits
- area-based management tools
- marine protected areas
- environmental impact assessments
- capacity building and the transfer of marine technology

# Definitions

**Bioprospecting (Oxford English Dictionary):** “the search for plant and animal species from which medicinal drugs and other commercially valuable compounds can be obtained.”

**Bioprospecting** is the discovery of compounds and associated ideas from genetic resources to develop novel biomedicines, biomedical research tools, antifoulants, catalysts, nutraceuticals, cosmeceuticals, etc. **Unlike seabed mining, marine genetic resources are not mined.**

**Marine Genetic Resources:** Term has no meaning to biologists and is not defined in UNCLOS but is taken to mean the Nagoya Equivalent:

“Marine genetic material” means any material of plant, animal, microbial or other origin, **found in the marine environment**, containing functional units of heredity ;

“Marine genetic resources” means **marine** genetic material of actual or potential value”

# Input into the Process – Tools for Negotiators



**An International Instrument on Conservation and Sustainable Use of  
Biodiversity in Marine Areas beyond National Jurisdiction**

**Matrix of Suggestions**

**16 December 2015**

# Input into the Process – Before and During the PrepCom



## IUCN Intervention on MGRs for Informal WG

Thank you Mr. Facilitator. We would also like to congratulate you on your appointment.

Speaking from the scientific perspective, we would like to add a few points to the discussion for your consideration. We believe that the provisions of the Agreement on marine genetic resources should be informed by science and scientific practice so that they can be more realistically implemented.

## Differing Opinions

**USA, Norway and others:** Freedom of the high seas is paramount

**G77 & China:** common heritage of mankind applies

**EU:** seeking pragmatic solutions

# PharmaSea Advice to Policy Makers at the UN

**Early 2014 – APPLE** meeting on biodiversity beyond national jurisdiction

**June 2014** – Side event at the UN Ad-Hoc Open Ended Working Group on BBNJ, UN, NY

**November 2015** – Tarrytown NY, presentation of the IUCN matrix to members of the IA Preparatory Committee (PrepCom)

**February 2016** – Centre for International Law, Singapore, BBNJ workshop

**March 2016** – Ugandan UN Mission, NY, advice on BBNJ to African Union

**March 2016** – Advice to G77 on BBNJ

**April 2016** – Advice to Peru, Chile and Ecuador at Peruvian UN Mission

**April 2016** – Side event at PrepCom on the Science and Business of Marine Genetic Resources

**April 2016** – IUCN/PharmaSea Workshop at NYU Law School on Challenges and Options for Addressing Marine Genetic Resources in Areas Beyond National Jurisdiction

# PharmaSea at the UN – Side Events



Ad Hoc Open-ended Informal Working Group to study issues relating to the conservation and sustainable use of marine biological diversity beyond areas of national jurisdiction



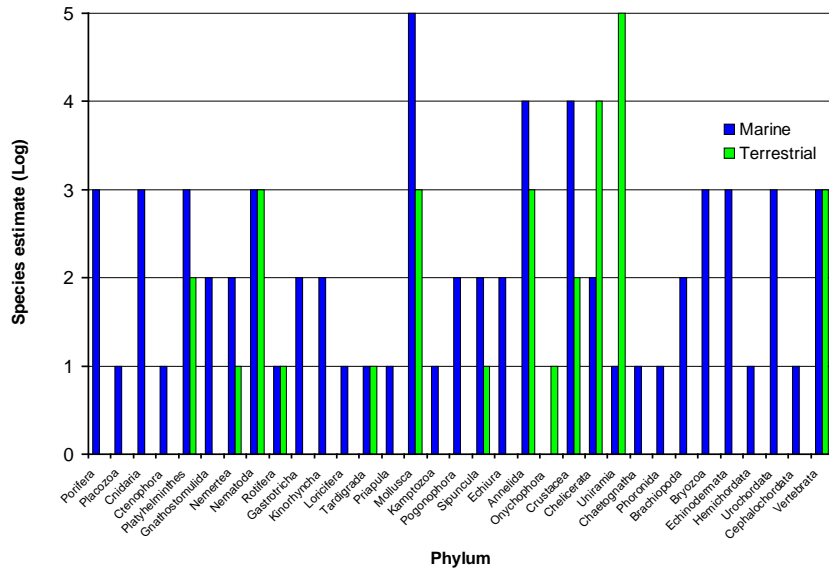


# Examples of Scientific Advice Provided

- Diversity of marine genetic resources
- Current good practice in marine bioprospecting
- Examples of successful exploitation of marine genetic resources
- Realistic benefit scenarios
- Traceability
- Benefit sharing scenarios
- Capacity building ideas
- Scientific advances that might affect implementing agreement

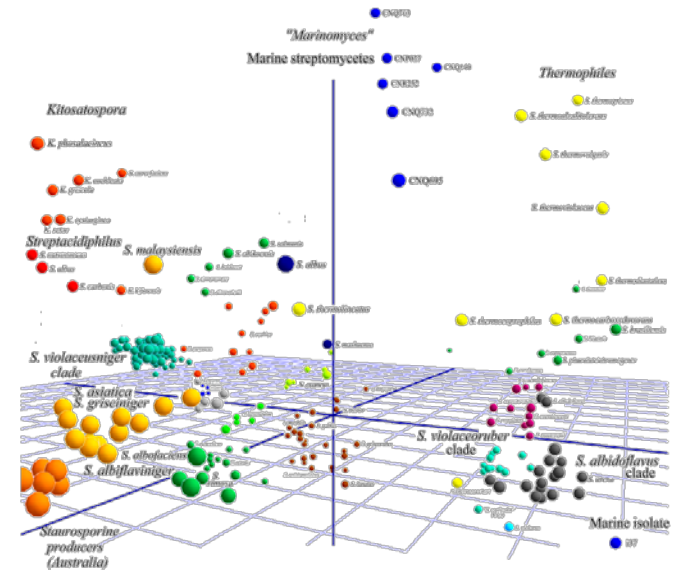
# Marine Genetic Resource Diversity

## Animal Diversity



Of the major divisions of animal life ~20 have no representatives on land

## Microbial Diversity

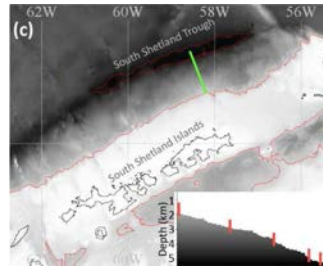


There is no clear estimate of marine microbial diversity or its economic value

# Notification & Reporting Requirements

Application

- Cruise plan



Award

- Feasibility
- Checks



After Cruise

- Cruise report

VESSEL	CRUISE DATE	SAMPLING GEAR	DIVS #	SAMPLE NUMBER	LATITUDE	LONGITUDE	DEPTH	SAMPLE TYPE	DESTINATION
Scotia	09/02	18/0/2015	Van Leen Grab	3 09195_VV_3A	52 016624N	15 540300W	1210.4	SED Su16amp	JAIFARS
Scotia	09/05	18/0/2015	Van Leen Grab	3 09195_VV_08	52 048247N	15 540300W	1304.6	SED Su16amp	JAIFARS
Scotia	09/05	18/0/2015	Van Leen Grab	3 09195_VV_3A	52 046249N	15 538200W	1203.8	SED Su16amp	JAIFARS
Scotia	09/05	18/0/2015	Van Leen Grab	3 09195_VV_08	52 046249N	15 538200W	1203.8	SED Su16amp	JAIFARS
Scotia	09/05	18/0/2015	Water/Larvae	1 09195_WL_1_1	52 013110N	15 535790W		Amphipods	P183TAF1
Scotia	09/05	18/0/2015	Water/Larvae	1 09195_WL_1_10	52 013110N	15 535790W		Amphipods	P183TAF1
Scotia	09/05	18/0/2015	Megacore	2 09195_MC_2_3A	52 005879N	15 530200W		SED Su16amp	JAIFARS
Scotia	09/05	18/0/2015	Megacore	2 09195_MC_2_10	52 010087N	15 530200W		SED Su16amp	JAIFARS
Scotia	09/05	18/0/2015	Megacore	2 09195_MC_2_04	52 005879N	15 530200W		Bacterial Mat	JAIFARS
Scotia	09/05	18/0/2015	Megacore	2 09195_MC_2_08	52 005879N	15 530200W		Bacterial Mat	JAIFARS
Scotia	09/05	18/0/2015	Megacore	2 09195_MC_2_04	52 005879N	15 530200W		Bacterial Mat	JAIFARS
Scotia	09/05	18/0/2015	Megacore	2 09195_MC_2_08	52 005879N	15 530200W		Bacterial Mat	JAIFARS
Scotia	09/05	18/0/2015	Megacore	2 09195_MC_2_04	52 005879N	15 530200W		Bacterial Mat	JAIFARS
Scotia	09/05	18/0/2015	Megacore	2 09195_MC_2_08	52 005879N	15 530200W		Bacterial Mat	JAIFARS

- Starts with marine scientific research

## Where to report data?

- Nagoya Protocol clearing-house
- New clearing house linked to NP
- A new international organisation
- Onus on flag state/vessel operator?

NP already requires evidence that collection did not come from area under national jurisdiction

# Impact of Sampling

Trawling impact ranges from 0.005 to 0.009 km<sup>2</sup>

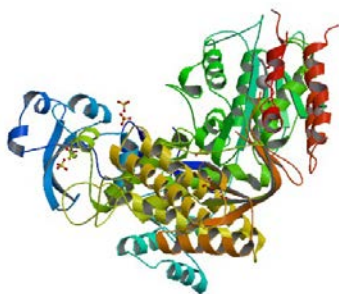
Gravity coring leaves a 10cm diameter hole that close within 1 h.

Mega coring in a typical cruise will impact ~0.5m<sup>2</sup> of seafloor

Removing 0.5m<sup>2</sup> of seafloor in ABNJ = 0.19cm<sup>2</sup> of Yellowstone national park



# Non-Pharma MGR Derived Products on the Market



Vent Polymerase – for DNA amplification

Origin: Vent bacterium (Naples, Italy)

**Production: Recombinant**

**Owner: New England Biolabs**



Cosmetic screening infra-red rays

Origin: Vent bacterium (location unknown)

**Production: Bacterial culture**

**Owner: Sederma (Croda)**

**Fuelzyme™-LF**

THE NEXT-GENERATION, HIGH-PERFORMANCE  
ALPHA-AMYLASE FOR MASH LIQUEFACTION

Fuelzyme – Enzyme used in biodiesel production

Origin: Deep sea bacterium (location unknown)

**Production: Recombinant**

**Owner: Verenium (BASF)**



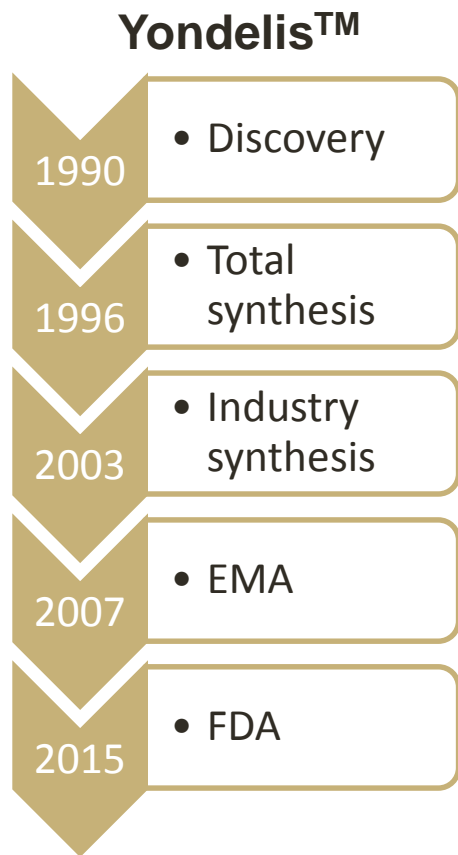
Anti biofilm agents

Origin: Red seaweed

**Production: Chemical Synthesis**

**Owner: XXXXX**

# Real Benefit Scenario



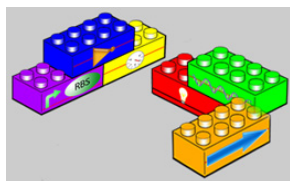
- Cost in 2014 to bring drug to market US\$2,558 M\* - >70% Clinical trials
- Typical industry royalties on natural products developed into drugs is 1-3%
- Halaven (Eisai), derived from a Japanese sponge makes US\$200 M per year – in principle yielding US\$ 2-6 M pa.
- Currently 7 approved marine drugs – total royalties would be US\$ 10-50 M.
- Blockbuster drug (> US\$ 1 Bn pa income) would yield US\$10-30 M pa
- Currently 7 approved marine drugs come from ~28,000 discovered marine compounds (1 in 4000 chance) – none are ‘blockbusters’
- All examples were discovered pre-CBD – not clear if actual royalties are being paid
- Other markets – nutraceuticals/cosmeceuticals, lower risk, quicker to market, lower investment and lower returns.

\*Tufts Study [http://csdd.tufts.edu/news/complete\\_story/cost\\_study\\_press\\_event\\_webcast](http://csdd.tufts.edu/news/complete_story/cost_study_press_event_webcast)

# Benefit Sharing

- Multilateral NOT Bilateral
- Most important benefits are non-monetary.

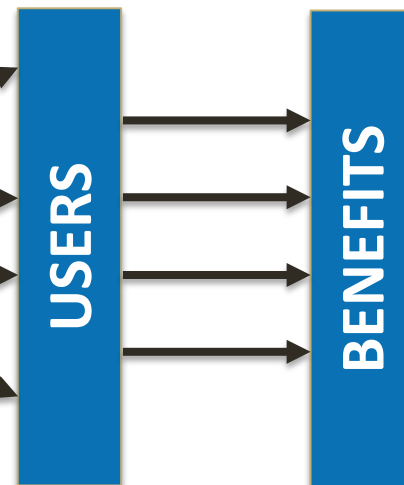
## Public domain approach



Biobricks

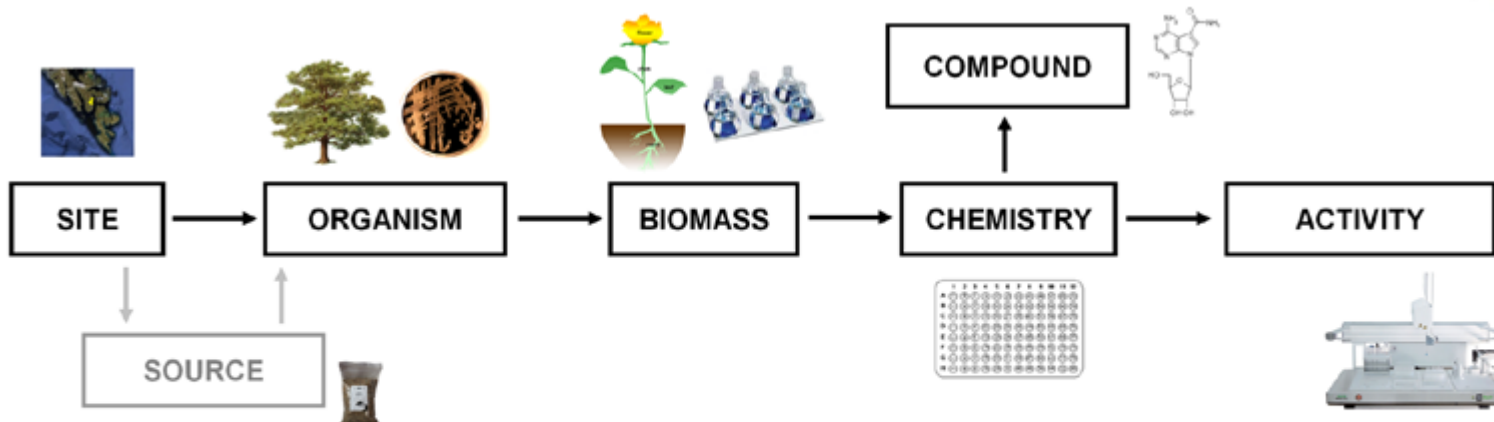
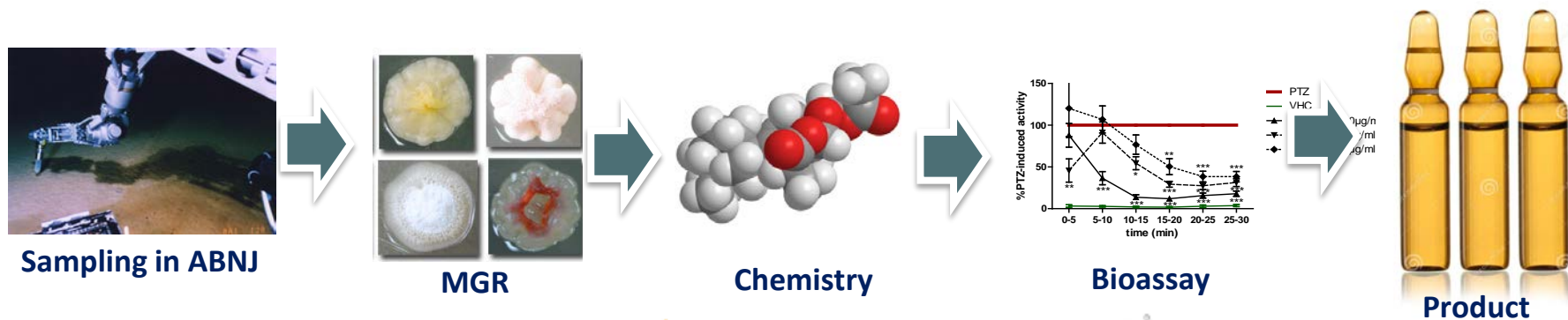


open source™



- Low cost
- Benefits will accrue locally
- All should be able to benefit from discoveries
- **Requires capacity building to ensure fairness**
- This approach will lead to greater innovation, transparency and openness

# Monitoring Sample and Data Flows



OpenNAPIS™

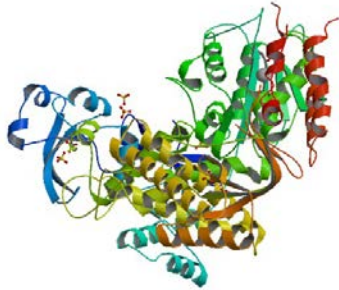
Functional Design

Possible to track sample from origin to exploitation (needs better databases)

White Point Systems, Inc.  
20100626



# Tracking Samples can be Tricky



## Vent Polymerase For DNA amplification



JB Article | Journal Info. | Authors | Reviewers | Permissions | Journals.ASM.org

J Bacteriol. 2012 May; 194(9): 2375–2376.  
doi: [10.1128/JB.00123-12](https://doi.org/10.1128/JB.00123-12)

PMCID: PMC3347054

### Genome Sequence of the Model Hyperthermophilic Archaeon *Thermococcus litoralis* NS-C

Andrew F. Gardner,<sup>✉</sup> Sanjay Kumar, and Francine B. Perler

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#### ABSTRACT

[Go to:](#)

The hyperthermophilic archaeon *Thermococcus litoralis* strain NS-C, first isolated in 1985, has been a foundational organism for archaeal research in biocatalysis, DNA replication, metabolism, and the discovery of inteins. Here, we present the genome sequence of *T. litoralis* with a focus on the replication machinery and inteins.

#### GENOME ANNOUNCEMENT

[Go to:](#)

*Thermococcus litoralis* strain NS-C was isolated from a shallow submarine hot spring at Lucrino Beach near Naples, Italy (1), and successfully grown in culture (14). Since then, *T. litoralis* has been the focus of studies on biocatalysis (10), archaeal metabolism (2, 3, 6, 7, 9, 11, 13, 17, 21), DNA replication (4, 5, 8, 12, 20), and protein splicing (15).

NCBI Resources How To

Genome

[Create alert](#) [Limits](#) [Advanced](#)

#### Thermococcus litoralis

Representative genome: **Thermococcus litoralis DSM 5473**

Download sequences in FASTA format for [genome](#), [protein](#)  
Download genome annotation in [GFF](#), [GenBank](#) or [tabular](#) format  
BLAST against *Thermococcus litoralis* [genome](#), [protein](#)

Display Settings: Overview

Send to:

#### Organism Overview

### Thermococcus litoralis

Thermococcus litoralis overview

ID: 12449

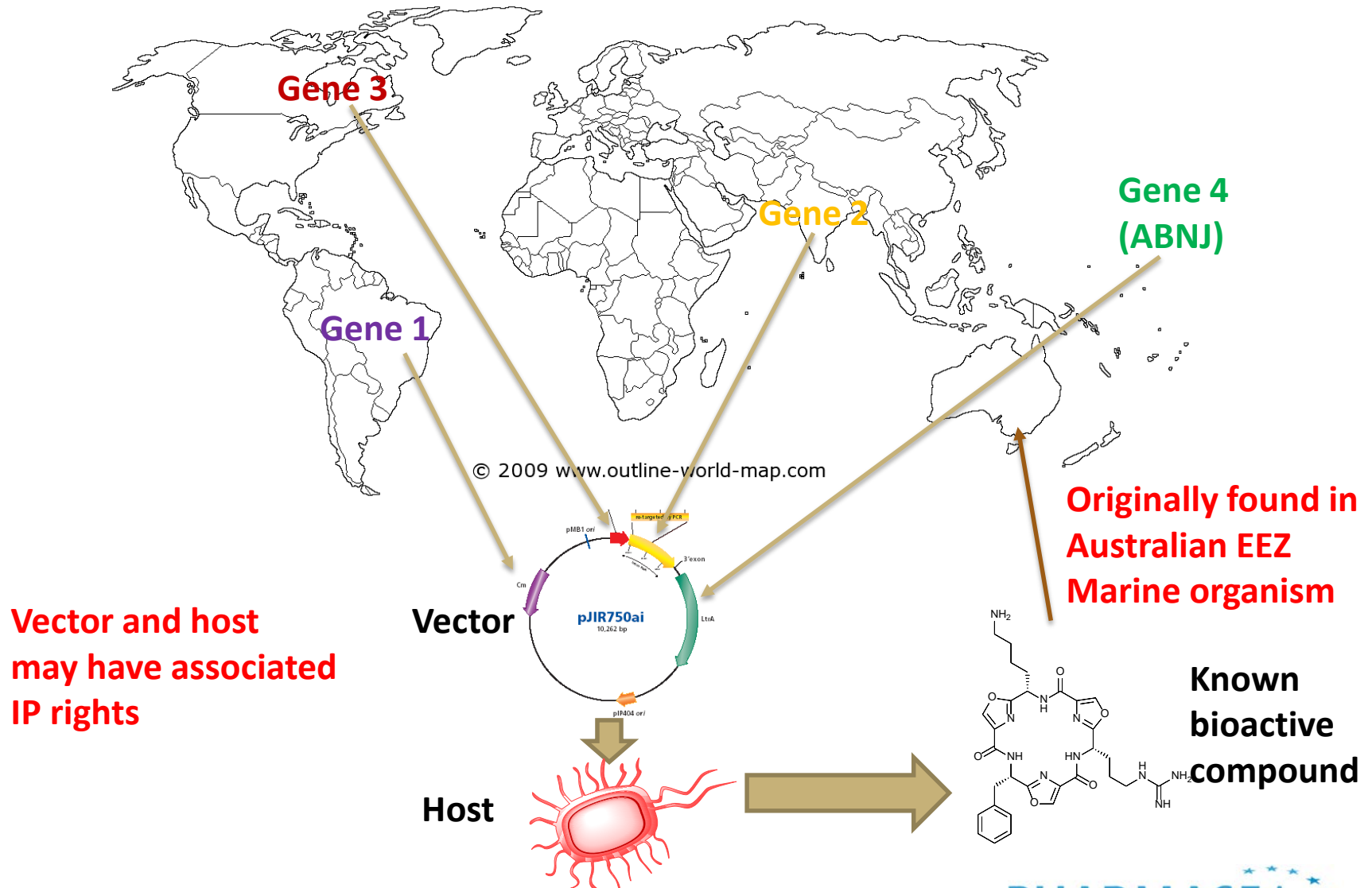
Lineage: Archaeal[545]; Euryarchaeota[344]; Thermococci[25]; Thermococcales[25]; Thermococcaceae[24]; Thermococcus[17]; Thermococcus litoralis[1]

England Biolabs, Inc.  
Complete Genome  
Type: Cocci  
Minimum Temperature: 85C, Temperature Range: Hyperthermophilic  
Life Relationship: Free Living, Trophic Level: Heterotroph  
Accession: [NC\\_000246.9](#) ASM24698v3 scaffolds: 1 contigs: 1 N50: 2,215,172 L50: 1 NA81925  
Genome length (Mb): 2.21517  
GC content: 2292  
GC%: 43.1

of the model hyperthermophilic archaeon *Thermococcus litoralis* NS-C. Gardner AF, et al. J Bacteriol 2012 May



# Synthetic Biology - Nightmare Scenario



# How You Can get Involved

- Contact your national delegation to the UN
  - Contact permanent mission to the UN in NY
  - Many are requesting advice but don't know who to ask
- Contact relevant Ministry in your Country
- Contact EU policy maker at DG-MARE representing your country in the EU Delegation to the UN
- Work with PharmaSea on developing networks and contacts
- Work with the IUCN on developing networks and contacts
- Through the European Science Foundation Marine Board
- Through EMBRC
- Through the Deep Ocean Stewardship Initiative
- **Please get involved – this will affect you!**

## Issues for Our Community

- **Provide reliable scientific and other evidence to ensure marine scientific research on marine genetic resources is not impeded.**
- Definitions (e.g. Marine Genetic Resources)
- Highlighting and agreeing on elements of good practice.
- Reporting and notification procedures: how will it be monitored/policed and by whom?
- Traceability becomes an issue as benefits may take a long time to be realised. Who will trace this?
- How can we manage expectations for financial returns?
- Can we make sure an implementing agreement is flexible enough to cope with scientific progress?
- **Light touch regulation which does not impose high bureaucratic burden is preferable.**

# Nagoya-O-Meter

Nagoya-like regime

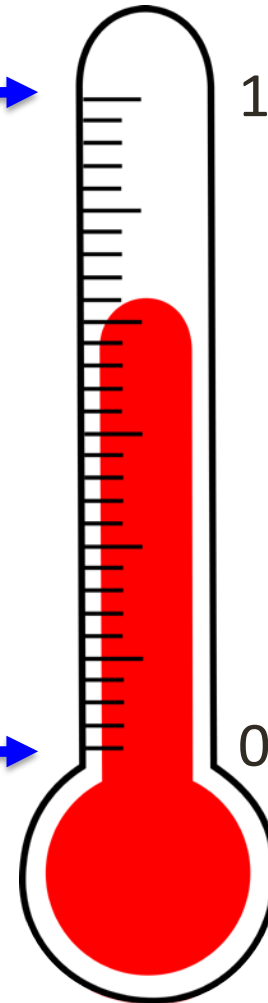


100% Nagoya

Public Domain Model



0% Nagoya



**Overly restrictive regime can damage progress of products (Australian example)**

# PHARMASEA



*“The research leading to these results has received funding from the European Union's Seventh Framework Programme (FP7/2007-2013 under grant agreement n<sup>o</sup> 312184)”*