

Access to Marine Genetic Resources and Benefit-sharing from Their Academic Use



REPORT OF MGR WORKSHOP IN JAPAN

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Report edited by:
Hajimu Morioka, Ph.D.
ABS Task Force Team for Academia in Japan
National Institute of Genetics

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List of Acronyms

ABNJ	Area beyond the National Jurisdiction
ABS	Access and benefit sharing
AORI	Atmosphere and Ocean Research Institute
AUNJ	Area under the National Jurisdiction
BBNJ	Biodiversity Beyond National Jurisdiction
CBD	Convention on Biological Diversity
CHM	Common Heritage of Mankind
CRADA	Cooperative Research and Development Agreement
DOALOS	Division for Ocean Affairs of the UNCLOS
DV	Drilling vessel
EEZ	Exclusive economic zone
EU	European Union
FDA	U.S. Food and Drug Administration
IODP	International Ocean Discovery Program
IPRs	Intellectual property rights
IRCC	Internationally recognized certificate of compliance
ISJ	Ichthyological Society of Japan
JAMSTEC	Japan Agency for Marine Earth Science and Technology
KCC	Kochi Core Center
MAT	Mutual agreed terms
MEXST	Ministry of Education, Culture, Sports, Science and Technology
MGR	Marine genetic resources
MSR	Marine scientific research
MTA	Material transfer agreement
NCI	National Cancer Institute
NIH	National Institute of Health
NMNS	National Museum of Nature and Science
NP	Nagoya Protocol
PIC	Prior informed consent
RV	Research vessel
UN	United Nations
UNCLOS	United Nations Convention on the Law of the Sea

Executive Summary

This report describes a recent workshop that focused on Access and Benefit-sharing (ABS) issues associated with scientific research utilizing marine genetic resources. Cases from a wide range of academic researches types including fisheries, ichthyologic, subseafloor biosphere and ocean bioprospecting, together with ocean ecosystems were presented with a focus on specific issues related to ABS across an international range of marine jurisdictions. Several practical issues such as understanding of ABS measures and use of biodiversity beyond national jurisdiction were additionally raised.

Legal frameworks associated with ABS governing marine scientific research, including the Convention on Biological Diversity and the United Nations Convention on the Law of the Sea were discussed for the use of marine genetic resources in the areas both within and beyond the national jurisdictions of a range of countries throughout the world. Experience with practical implementation of the Nagoya Protocol in marine scientific research was based on several experiences from delegates at the workshop, and some proposals for academic implementation of research findings from biodiscovery ventures were also discussed. Research and development of marine genetic resources in the areas beyond national jurisdiction were a focus from both commercial and non-commercial research viewpoints.

During panel discussions, ideas such as establishment of academic guidelines, codes of conduct; and benefit-sharing of marine scientific research outcomes; and continuing involvement of first-class scientists across international borders were elaborated. Comprehensive measures to reduce the heavy loads of paperwork associated with securing ABS approvals in order to facilitate sustainable access to marine genetic resources were also proposed.

Preface

The ABS Task Force Team for Academia is commissioned to support utilization of genetic resources in academic research in Japan and to raise awareness on and to promote compliance with the Convention on Biological Diversity (CBD) and the Nagoya Protocol. To achieve these tasks, the Team has organized a series of workshops discussing issues surrounding academic research on genetic resources. The first workshop was held in December 2014 and discussed access and benefit-sharing measures in taxonomic research areas. We invited prominent scholars from the Royal Botanic Garden of Kew and the Natural History Museum, London.

The second workshop was held in November 2015 and focused on marine genetic resources in sea areas under and beyond national jurisdiction. The ABS Task Force Team for Academia in Japan has been working on access and benefit-sharing for academic utilization of marine genetic resources. Since many academic researchers are dealing with marine genetic resources in Japan, the Team intended to promote such research activities and also the conservation of marine biodiversity.

The Team understand that there is political dispute regarding the legal

status of marine genetic resources in the area beyond national jurisdiction under the United Nations Convention on the Law of the Sea (UNCLOS), and that this legal dispute raises issues regarding scientific utilization of marine genetic resources in the area beyond national jurisdiction (ABNJ), and may influence the conservation of the global ocean in the future. This workshop intended to obtain opinions for the future contribution to the international negotiation of UNCLOS.

This report summarizes the second workshop dealt with marine genetic resources by inviting prominent researchers and scholars dealing with not only scientific researches but also legal affairs. Firstly, five cases from academic researchers were reported. Secondly, two scholars discussed legal issues relating to two conventions, i.e. the CBD and the UNCLOS. Thirdly, panel discussion was made focusing on academic marine biodiversity researches and compliance with two conventions. Several important outcomes were presented in the report.

Introduction

Japan is an island country surrounded by ocean containing habitats rich in marine biodiversity. Oceanographic research is very important and popular in Japan. Many scientists conduct research activities to elucidate marine biodiversity and contribute to marine industries.

To conduct biodiversity research activities in the sea, marine biological scientists and their colleagues in allied disciplines must be aware of two important conventions concerning the rules of the sea: UNCLOS and CBD. The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (NP) contains the latest instrument that provides formal structure about ABS of benefits associated with the utilization of marine genetic resources. It has been in force since 12 October, 2014.

Japanese researchers from marine science societies and institutions are getting to know the NP and are trying to comply with its implementation measures. However, there are still ambiguities in parts of the two conventions, especially the gap in rules between the two conventions in the ABS

protocols associated with maritime areas within national jurisdiction (AUNJ) and ABS in the areas beyond national jurisdiction (ABNJ).

Oceanographic scientists should consider the concepts and gaps in the two conventions and apply them to their research activities. To achieve and accomplish these considerations, marine scientists should discuss the issues and form their own opinions for the purpose of good research practices and contributing to conservation of biodiversity.

Purposes of the Workshop

This workshop was designed to disseminate knowledge of concepts and gaps of the UNCLOS and the CBD among Japanese marine scientists. In case reports, five researchers presented their scientific experience and achievements conducted in the AUNJ and ABNJ. They also raised issues regarding access and benefit-sharing for marine research in the two areas.

There was also a panel discussion after the presentations. Two prominent law scholars introduced concepts of the two conventions and how marine scientists should appropriately conduct research under these legislative tools. Issues of ABS in marine areas under the national

jurisdiction of a range of countries were discussed as well as how to deal with research activities in the ABNJ.

Another purpose of the workshop was attempting to collaborate to achieve uniform implementation practices of the NP in the marine research community. Thus, how academic researchers in other countries respond to the legislative or governance measures and issues surrounding implementation of the NP in the marine research field was discussed. A goal of the workshop is to form collaboration among participants from Japan and other countries and to achieve a kind of uniform implementation framework for practices relevant to NP in the wider international marine science society.

1. Case Report

Case 1: ABS for Fisheries and Marine Sciences

Presenter: Dr. Ikuo Hirono, Tokyo
University of Marine Science and
Technology

Discussions of NP Implementation in the Fisheries and Marine Sciences

The Fisheries and Marine Sciences Liaison Council for the Nagoya Protocol has been discussing implementation of the NP in fisheries and marine science societies of Japan. The council consists of several Japanese societies of fisheries and marine sciences and establishes a working group for the NP. Questions, suggestions, and opinions provided by members of the working group are related to marine science researches on biodiversity beyond national jurisdiction (BBNJ), and regulations of the UNCLOS.

Concerns are raised about regulations for conservation and protection of marine biological resources in Japan. A request from the group was raised indicating that for institutes, universities, and scientific societies to understand the NP, more frequent workshops or symposiums should be held by the Japanese government. Opinions of the working

group are that the Japanese government should not rush to ratify the NP, because many of providing countries have not yet prepared ABS rules and that the Japanese government should not ask for Prior Informed Consent (PIC) and Mutual Agreed Terms (MAT) certificates for researchers at the early stages such as grant application since there are several different steps in research. The group recommends establishing an ABS clearinghouse as a uniform information center in Japan.

Fisheries and marine science research programs are dealing with very diverse materials from fishes to shellfishes. Marine fishes, fresh water fishes, invertebrates, and algae are included as edible foods. And ornamental fishes and crustaceans, micro algae, and microorganisms are classified as nonedible foods. Some food materials are related to traditional knowledge. Hence, there is a diversity in purpose behind research programs and this needs to be taken into consideration with regard to permits through the NP.

The group has concerns about opportunities of obtaining research materials in regard to principles of the CBD. The origin of some research

materials come not only from overseas research activities, but also from landed marine product suppliers such as fish markets like Tsukiji where edible fishes are transferred from worldwide sources as well as regional and from pet shops suppliers, where Japan is known as one of the biggest pet importers globally. We understand it is necessary to follow the NP when we obtain research materials from overseas research activities. However, researchers don't know what kinds of permits are needed and how to get permission in other cases.

In addition, questions were raised about traditional fishing techniques and practices. Traditional fishing methods and their tools are known throughout the world. Can we conduct research activities using these traditional fishing methods without permission from holders and their government?

My Own Access Experiences in Research Activities (Ikuro Hirono, Tokyo University of Marine Science and Technology)

My experience in research activities in Thailand are as follows: We asked a researcher working in the Department of Fisheries of Thailand to get a certain certificate based on the Convention on Biological Diversity from the Thailand Government. The researcher asked his friend who is working at the competent

authority of the government. The authority said it is not necessary to get a certificate because of the joint research project between two countries. He confirmed this information with a high ranking officer of the Department. After confirmation and obtaining a certificate of the joint research participation, we immediately started to write an application for research permit. We received it from the National Research Council of Thailand (NRCT) after only two weeks of submission. However, it took a lot of time and effort to make a Material Transfer Agreement (MTA) with the Department. Since it generated a lot of claims and concerns regarding to making a similar agreement from European organizations, we had to solve these issues and apply them to an agreement with Japan also. This created a work overloaded and eventually forced delays.

There is another story about my experience of ABS. This story is not specific to fisheries science, but happens in other researches too. My friend in the Republic of the Philippines asked me to start a collaborative research project using genetic materials of the Philippines. Before we started the collaborative research, I needed to briefly analyze and characterize the materials beforehand to write a proposal. I asked her to send some DNA samples of target materials

for a preliminary work but she said it was impossible because she did not have a permission from the government to send their materials to Japan. Since then, she has not been able to submit permission to the government because we cannot write a research proposal without preliminary DNA data. My friends in Japan asked the government of providing countries to provide a permission for transferring research materials to Japan. However, it usually takes a very long time. Researchers in Japan feel that it is almost impossible to get permission from providing countries and then give up their research ideas. This kind of incidence regarding access to genetic resources happens very frequently around my research area.

My Opinions about Access Procedures

For promoting and accelerating research activities using genetic resources from providing countries, we must consider future directions as follows. We should consider how to reduce a heavy load of paperwork of researchers to get permission and to make agreements. To achieve this goal, first, it is necessary to establish a core center for obtaining permission from providing countries and making agreements under the principles of the CBD and the NP in each research area such as Fisheries Science, Agriculture Sciences, Veterinary Sciences,

Forestry Sciences, and Zoological Sciences. Second, it is important that dissemination of the rules and requirements of the CBD and the NP is made to academic researchers. To do so, it is necessary to hold meetings more frequently exchanging and discussing own experience.

Question and Answer

Question 1:

The Japanese Government has not established any user measures. If the user country rules would meet only minimum requirements of the NP, what do you expect would be problems for your research activities? If provider countries establish very full range of rules and meticulous guidelines in order to protect their rights under the Nagoya Protocol, how would you respond?

Answer 1:

Under the present NP, ABS depends on providing countries where the benefit could differ. There are and would be hundred kinds of rules and regulations in providing countries. If a hundred countries ratify the NP, we must individually comply with the rules of the member countries.

A Japanese Government role is just to

monitor the compliance of the relevant laws and rules of Japan. That is why measures should differ between Japan and providing countries. For example, the CBD has been effective since 1993, but some countries demanded retroactive application of the provisions. The Japanese Government can rule the retroactivity for monitoring. If we are to comply with the Japanese rules, then we would not be punished, but it is as far as we are in Japan. If we go to another country which adopts the retroactivity of the Convention far beyond 1993, then our names might be blacklisted or to be arrested if you enter such a country.

Question 2:

I frequently go to a pet shop to buy some jellyfish from the Philippines and some of the neighboring countries. I think that such materials bought from pet shops and from the Tsukiji Fish Market should not be used for research right now, but what is your prognosis for the future?

Answer 2:

The working groups I mentioned and also fisheries department of the academic institutions have been studying this issue. If we work on the issue individually, I think that there would be no change. Suggestions or discussions from more powerful organizations as a channel of

our opinions would hopefully raise the issue to the international conventions. If researchers could contact us, we would like to work with them so that their views could be communicated to the working groups.

Comment 1:

Your presentation is really valuable to see real life experience and how it differs from the theory of ABS under the NP, so I think that is incredibly valuable. The example you are giving of a fish market is one of the typical things that are probably going to disappear as a source for research under the NP and ABS regulations. Another example is a colleague who is going somewhere sampling in another country and we ask him to take some soil samples. I think these are the kind of things that are going to disappear since it is this kind of non-structured collecting of genetic resources.

I do have one comment on fishing gear examples that is potentially associated to traditional knowledge on fishing techniques. It is very important to note that the concept of traditional knowledge in the NP is explicitly stated as traditional knowledge associated to genetic resources, which means that traditional knowledge associated to the use of a fishing technique is definitely out

of scope of the NP, so we can do research on fishing techniques, that is completely out of any ABS regulations.

Case 2: Biodiscovery, Genetic Resources and the Nagoya Protocol: The Status Downunder

Presenter: Dr. Chris Battershill, Waikato University, New Zealand

The Australian Institute of Marine Science has developed a system for recording diversity, associated microbiology and ecological details such that results from screening activities and chemistry can be correlated with taxonomy. By using the smart discovery process, we improve odds ratio of discovery. This data is drawn from Australian and New Zealand experience in using the system. The likelihood ratio of drug discovery by haphazard collections is usually about 1: 100,000, and by combinatorial chemistry 1: 1,000,000+.

From the Australia NCI Collection Program, three FDA registered compounds were found from 5,000 samples and therefore odds ratio is 1: 1,500. From the New Zealand Shallow Water Collection Program, one drug and two late phase pre-clinical compounds are discovered from 1500 samples and therefore odds ratio is 1: 500. This

demonstrates the importance of identifying species to a high level of confidence and in understanding the chemical ecology of those organisms.

Following a relatively short effort in Australia and New Zealand a number of lead compounds have been discovered from marine genetic resources. The fact that not many of these have been followed up is due in significant part to the lack of national policies on biodiscovery and subsequent development in both countries. A case study based on Halaven (Halichondrin B) is discussed in detail to highlight the issues attendant in Australia and New Zealand regarding to biodiscovery policy and legislation/funding. The original discovery of Halichondrin molecules (that eventually led to the licensed drug Halaven) occurred in Japan, but it was a supply from New Zealand that permitted further preclinical testing and subsequent development of a synthetic analogue. The point is that both countries played a role in the development of the drug lead and both benefitted in a number of ways from that role. While New Zealand was not eligible for any royalties as may perhaps been provided by the Nagoya Protocol (because the original genetic resource was first discovered in Japan), nevertheless New Zealand science and scientists benefitted from playing a part in a successful drug

development program. The capacity built has led to other discoveries in that country (eg Peloruside A).

Australian Access and Benefit-sharing Regulation

We here report both Australian and New Zealand status of ABS legislation as well as comment on operational systems and practices. The NP and the new EU regulation provide for *ex situ* collections to play an intermediary role in assuring legal compliance. The EU Regulation 511/2014 includes process for registration of NP compliant collections, and users who are sourcing from a registered collection satisfy due diligence obligation. These new regulations are advantageous for Australia since a permit system for ABS has been already compliant in Australia. It may need minor amendments which may include recognition of trusted institutions, expansion of national competent authority, and establishment of checkpoints to ensure compliance which are associated with government research funding. In the case of non-compliance, it may be necessary to create an offence law, to establish audit powers and to provide option for remedy.

Ex situ collections in Australia may play an ABS role in biodiversity projects. Australian “trusted institutions” model

would provide an authority for *ex situ* collections to issue IRCC directly to the ABS Clearing House. They also provide “Economy of Scale” for collection and curation, sustainable supply and scaled re-supply, and legal certainty to commercialize.

A cross-regional *ex situ* collection may help to smooth out some of these cross boundary issues. It may become a common source to the end-user and can manage individual state interests. A cross-regional *ex situ* collection can carry provide cost-efficiencies in the overhead costs of sample control and house-keeping, centralising and maximising the non-monetary benefits of conservation information and data mining abilities for the future.

Best-practice sample management, especially the reference taxonomic voucher and information management for collection information plus sample handling information are imperative to make sure every sample and its screening results are collectable and reproducible. *Ex situ* collections can facilitate streamlined biodiversity supply and re-supply.

The NP also opens the way for new tools to monitor compliance through imposing checkpoints, tools for compliance without adding to risk and uncertainty.

Compliance should be demonstrated at points of research funding, IPRs licensing and publications. Geo-referencing will enable independent analysis of literatures and IPRs databases. Development of e-tools for compliance monitoring could be broadened.

However, this needs to be done in a way that doesn't create impediments to the pipeline. Besides using research funding, publications and IPRs processes may give an opportunity for a user to demonstrate their compliance. Providing countries can utilise e-tools and spatial information for their own monitoring.

The Australian Institute of Marine Science develops a database of geo-referenced information in publications about marine microbial natural products. For each paper, the source collected location was recorded with the flag of the senior author. And we click on any of these flags to get the citation of the paper. This sort of information could be routinely categorised in the many indexed databases for literature and IPRs, to facilitate this sort of e-analysis.

Biodiscovery gives enormous opportunity but becomes sensitive to increased risk, cost, and timelines. A pathway from genetic resources to product becomes

complicated and vulnerable. It's not just about money but non-monetary benefits can be immense. Legal certainty is central. The NP promises stronger legal certainty and provide a clear pathway to demonstrate legal compliance. An excellence of *ex situ* collections gives economy of scale in collection, curation, sustainable supply, and compliance as 'trusted institutions'. Checkpoints can provide compliance incentives.

New Zealand Access and Benefit-sharing Regulation

New Zealand has not yet signed and does not ratify the NP. For New Zealand there has not been much movement on developing policy leading to signing the NP since 2010. This is due to an urgent need to develop a national policy that takes into account traditional ownership rights and obligations. New Zealand awaits the decision on the Wai 262 which is a legislative process designed to examine such traditional rights.

Since New Zealand attended the Conference of the Parties in 2010, there has been little movement on international agreements while the country moves on internal legislative needs to recognise settlement of the past 'Treaty of Waitangi' (indigenous land and sea grievance issues) which has also become linked to an indigenous claim for

traditional ownership of resources through the 'Wai 262' Claim.

The Wai 262 Claim needs resolution before New Zealand can advance on NP deliberations. The Wai 262 Claim is the 262nd claim registered with the Waitangi Tribunal. The claim is about the place of Māori culture, identity and traditional knowledge in New Zealand's laws, and in government policies and practices. The Wai 262 Claim concerns who are responsible for Māori traditional knowledge, artistic and culture works, and the environment that created Māori culture. It also concerns important places, flora and fauna that are significant to Māori tribes' identity. The Wai 262 Claim seeks rights around indigenous flora and fauna and other traditional knowledge and IPRs over cultural idea, design, language and more.

Nighty eight tribes or Iwi have a legal right to have input into issues such as the NP. This figure indicates the complexity of the traditional ownership situation. As it stands, there is a need to consult Iwi for any intention of starting a biodiscovery process. However the legislative directive for this is vague.

A pathway for biodiscovery process is proposed by New Zealand government, but it is very general and has a long way to go to reach the levels of rigor that the

Australian system has for instance. The pathway suggests several reporting and permitting points such as notification to Environment Protection Agency, notification and agreement with Iwi, notification to Department of Conservation if in a protected area, and impact assessment for sensitive area.

In New Zealand checkpoints are not clearly identified. Checkpoints should possess tools for compliance without adding to risk and uncertainty. No internal funding can be gained without Iwi compliance. Demonstrated compliance to Vision Mātauranga is required for research funding. Project initiation and IPRs licensing need demonstrated compliance to Iwi protocols. It is therefore quicker to gain permits for access also if Iwi have been consulted and have formalised signoff.

It is possible however to carry out biodiscovery process outside of Iwi approval and this is probably happening albeit undesirable. In most instances the regulatory agencies become involved if the genetic material is hazardous, from a Marine Reserve or is rare species. Outside of these general constraints, the process is unclear. There is legislation for bringing a genetic material into New Zealand if it is deemed to be new, but little to control export.

For project initiation and IPRs licensing, compliance to rules of the Environment Protection Agency for hazardous materials, rules of the Ministry for the Environment for a genetic resource from marine reserve, and rules of the Department of Conservation for a rare species should be demonstrated.

Geo-referencing is encouraged to enable independent analysis of literature and IPRs databases. Development of e-tools for compliance monitoring is being considered. A uniform system should be developed for national bioresources repositories.

There is preliminary consideration about creation of metadata systems for tracking use and trade in genetic resources. The University of Waikato collects and stores Antarctic microorganisms, plants and marine samples, the Cawthron Institute collects marine micro algae and the National Institute of Water and Atmospheric Research (NIWA) stores marine macrofauna (now held at Trinity Biologicals).

Halichondrin B to Eribulin/Halaven® and Peloruside A

A case study of a new drug developed from compounds isolated from marine sponges of Indo-Pacific species is presented. It involves the marine genetic resources of three Pacific

countries, Japan, Palau and New Zealand, and presents a typically complex and convoluted pathway to market. This case study occurred prior to the Nagoya Protocol, but it had many near-fall-over points and it is useful to reflect on what implementation of the Nagoya Protocol would have done to the process.

Eribulin mesylate (Halaven®) is used for advanced breast cancer treatment. This drug is a synthesized derivative of Halichondrin B. Professor Hirata and Dr. Uemura of the Nagoya University discovered a compound named Halichondrin B from a sponge, *Halichondria okadai* in 1985. Further nine halichondrin derivatives were isolated at the University of Canterbury from 1989 to 1995. By 2006 a further six new halichondrins were isolated. These halichondrins demonstrated potency in full NCI-60 cancer cell lines, showing anti-tubulin activity.

Low material supply for pre-clinical and clinical development became a big issue and more amounts of compounds were demanded. Meanwhile, development of chemical synthesis reported in 1992 from Professor Kishi's group of the Harvard University. Total chemical synthesis produced Halichondrin B in very low yields. Halichondrin B and several intermediaries were provided to Eisai Co., a Japanese pharmaceutical company.

Fragments in the macrocyclic moiety showed best anticancer activity. Synthesis patents licensed to Eisai Co., but small quantities and expensive synthesis had still been in risk for further development.

New Zealand took a role to scale up supply of Halichondrin B circa 1995. Dr. Battershill (NIWA) and Drs. Blunt and Munroe (University of Canterbury) established collaboration to supply Halichondrin B under \$0.5M USD funding from NCI (\$0.25M in kind). Full distribution and abundance survey were done in collaboration with the Department of Conservation. As a result, limited range of distribution was identified, and new protected area was justified. And about 300 mg of Halichondrin B was isolated from collected 1 tonne of sponges. Developed aquaculture methods such as shallow water culture in collaboration with mussel farmers increased 50% greater yields. Capability for sustainable large-scale supply was developed and demonstrated in New Zealand industry.

The NCI in the U.S.A., Dr. Kishi and Eisai Co. compared the 2 best Eisai compounds (E7389 and E7390) and New Zealand Halichondrin B in a late-stage mouse tumor assay and found that E7389 showed outstanding results. Then under the CRADA program, Eisai Co.

continued to develop E7389 through phase 2 and 3 and resulted in successful launch into market as Halaven®.

The innovation and IPRs associated with Halaven® is ultimately audited directly through the original Japanese researchers and the development of the marketed compound. However, NCI's interest was the result of screening material from Palau and when they needed more materials to fully explore their interest. The NCI relied on materials to be readily supplied from New Zealand, combined with Eisai's synthetic compounds in a joint project to determine the worth of the final compound.

The Halichondrin B and Halaven® case indicates that it took 30 years and IPRs linked to Japan. But sponges isolated and supplied by Palau and New Zealand were also essential role for the development because the product is synthesised but significantly derived from the natural product. There are many non-monetary benefits as well as the monetary ones

We should consider this case from aspect of a post NP world. In the case, there are three points where marine genetic resources were used. A question is whether they would have needed an IRCC or not. Second is whether Palau and New Zealand should be entitled to

monetary benefits. Thirdly, how could NP implementation measures be used to facilitate the pipeline?

To provide a sustainable re-supply of Halichondrin B in quantity, NCI invested in a recollection and aquaculture effort. This resulted in huge boost to R&D capability and conservation benefit. A distribution and abundance survey discovered that the entire population of this species occurred in a limited range on the lip of the Kaikoura canyon where was in the middle of a trawl fishing ground and prompted a closure of that location to trawling. The joint venture that was developed for this re-supply project brought together industry, university and a public funded research agency in a unique collaboration. Some of the aquaculture was done in conjunction with existing aquaculture industry such as mussel farmers. The research suggests possible ameliorating some of the negative environmental impacts of mussel farming. This capability now being further developed in the supply of other bioactive compounds such as Peloruside A

As a post NP implementation, New Zealand received non-monetary benefits such as capacity building, \$5.0 M USD in research funding, research outputs, and many PhDs. Full distribution and abundance knowledge about this sponge

was obtained, and a new protected area was identified. We believe this is recognized as conservation benefits.

New partnerships between public research agencies, university and industry have been developed after the project. Large-scale supply of marine natural products through aquaculture is now progressing with *Mycale hentscheli* for Peloruside A. Mussel farmers are introduced to new high-value products.

Since Palau and New Zealand contributed to development and introduction of the new anticancer drug, Halaven®, Palau and New Zealand would be entitled to monetary returns as benefit-sharing. Monetary benefits as IPR royalties from Eisai Co. would be provided to the Nagoya and Harvard Universities and to the NIH. Should monetary returns not go to direct source countries as Palau and New Zealand? The NP implementation could be used to facilitate those monetary returns.

Question and Answer

Question 1:

What is the difference with European and Australian mechanisms for implementation of the NP?

Answer 1:

My understanding is that European and Australian systems are relatively similar. In Australia however there are 9 jurisdictions (State legislation and the overarching Federal or Commonwealth legislative process for waters outside the State territorial limits). Hence there are subtle variations on the legislative process.

Question 2:

I am a bit surprised that adopting or ratifying the NP in Australia and New Zealand would help towards creating legal certainty for the biotech sector and that they are waiting for this. The reason why I am surprised by this statement is because the general tendency in Europe's biotech industry is that by the fact that the EU ratified the NP and has the monitoring system, we are jealous of the situation of the United States of America which is not NP member state and is freedom to comply domestically with access legislation. I am surprised that that the biotech sector

in Australia and New Zealand is looking at this differently.

Answer 2:

Probably, I am oversimplifying. There are elements of the biotech sector in both countries that arguably are not keen on the NP. I guess my statement was more on behalf of certainly the governments and governance elements in both countries. And that is certain for New Zealand, in particular for Māori, because the NP is consistent with how they would see a way forward. Although it is not being just sensitive to cultural issues, this is actually significant in a commercial sense in that Māori entities are well resourced financially. They are looking to make substantial investments into new areas of research, new areas of industry and they are very strongly interested in marine biotechnology in particular. A mechanism by which there is a stated and agreed protocol for interacting internationally resonates very well with them.

**Case 3: Utilization of Genetic Resources
in Ichthyological Studies in Japan and
Access and Benefit-sharing under the
Convention on Biological Diversity**

***Presenter: Dr. Masanori Nakae, National
Museum of Nature and Science***

***Principles of ABS in the National
Museum of Nature and Science***

The three principal operations of the National Museum of Nature and Science (NMNS) under its mission are as follow:

(1) The Museum conducts surveys and studies about the history and present state of the Earth and its biosphere, and the history of science and technology, (2) The Museum collects specimens and other materials relevant to natural sciences and preserves them for future generations as a part of humanity's common heritage, and (3) The Museum puts its research results and collections to work creating opportunities for people to think about and develop interests in nature, science and technology.

The NMNS currently loans fish specimens to foreign ichthyologists for their research with an invoice without MTA. Reasons for this practice are 1) Japan has no ABS measures, 2) the NMNS wants to keep good relationships with all foreign researchers and promote

their studies, 3) few ichthyologists know ABS in details. But, the NMNS may introduce in the near future an appropriate measure for loans of fish specimen to comply with ABS regulations.

To deal with ABS in the NMNS, we have done so far several steps and continue them in future. At first, we must collect information on the convention and ABS regulations of providing countries, and then (re)studying them. It is necessary for the Research Department in the NMNS to frequently survey current situation of ABS regulations in providing countries, such as presence or absence of requirements of PIC and MAT. After getting updated information from providing countries, researchers and research staffs must familiarize such information. Then we make a basic principle for compliance with ABS procedures. In the near future, we will construct an internal system to comply with ABS regulations and will make guidelines or codes of conduct and toolkits such as a standard material transfer agreement.

In the process of such development, special considerations for loan and transfer of specimens in scientific studies should be realized early. Taxonomic studies can provide one of the most important source of information for

fundamental knowledge of biological diversity conservation. Since ABS regulations have been obviously disturbing such smooth transfer of specimens for taxonomic studies, a new concept of procedures promoting taxonomic studies and smoothing loan and transfer of specimens should be developed.

My Experience for ABS (Masanori Nakae, National Museum of Nature and Science)

It is also difficult to comply with ABS measures in a real international project. Some staff members of the NMNS are involved in the international research project titled “Establishment of Research and Education Network on Coastal Marine Science in Southeast Asia”. The fish team in the project has operated to clarify fish diversity in the countries that join the project.

But, the fish team has encountered some problems to carry out its research and to comply with ABS measures. It usually takes long time to make a MAT and obtain a PIC from a providing country even though requests to clarify fish fauna in a certain area come from an ichthyologist of a providing country. Unfortunately, some counterpart researchers in South Asia countries don't know in detail ABS measures in their own countries. It is therefore difficult in

keeping balance between compliance of access and benefit-sharing and smooth operations of the research. We hope that construction of special considerations in providing countries should be early realized for scientific researches, in particular, those producing biological diversity conservation benefits. This means; 1) obtaining PICs for scientific researches in both global common rule and Japanese legislative action, 2) benefits of outcomes of scientific studies using marine genetic resources existing without border, such as fishery resources of tunas, eels and Pacific saury, should be distributed in more than one country.

Implementation of ABS Measures in the Ichthyological Society of Japan (ISJ)

The ISJ has initiate coping with ABS. On May 2015, the ISJ established “ABS Team in ISJ”. The team is comprised of six member researchers studying taxonomy, molecular phylogeny or ecology. An action policy of the ABS Team in ISJ is described as follows: 1) response to questions or questionnaires on ABS from other associations/agencies to ISJ, 2) familiarizing members and staffs with information about ABS, 3) making a basic principle for complying with ABS regulations if needed.

The team members make consensus that

it should develop a leniency system for innocent in compliance with ABS in scientific studies in the transition phase of the NP. We consider that it is premature judgement to check presence or absence of PIC in applications in order to reclaim grants-in-aid for scientific research and reject submission of papers to scientific journals when innocent in compliance of ABS by some researchers is found out.

Question and Answer

Question 1:

As to access to Vietnam fishes, we wanted to go sampling in Vietnam and we made an ABS submission with a Vietnam collaborator. But the Vietnam authority did not respond it at all. I wonder whether our collaborator in Vietnam is an appropriate person to conclude MATs or not. How did you get such kind of information?

Answer 1:

We had some personal connections to Vietnam researchers. It is very important to have good information so that connection methods to the right competent authority, a focal point or at least the department in charge can be identified. If you live in Vietnam, you may be able to make a phone call and

check them. If not, the local research collaborator in Vietnam gives us identification of the authority. We send necessary documents to the counterparty, but it does not mention whether this is the right place or not. It is a kind of tight rope situation. If something goes wrong under submission and review process, national focal point may contact us if we are reaching the right place.

Comment 1:

In Asia, to identify the right contact is very difficult because situation is different country by country. No matter how many websites you visited there is no information that is what a collaborator mentions. We hope that the ABS Task Force Team in Japan and other supporting person may provide some kind of right information. We hope that some mechanism should be in place so that we can easily identify the right counterparty. The ABS Task Force Team in Japan is preparing a quick reference chart which shows permit procedures in providing countries.

Question 2:

In the past, we wanted to study certain type of fish, and we got some samples from a tropical aquaculture vendor. Is this access violation of ABS regulations? And what kind of contract we should

make?

Answer 2:

If you follow ABS regulations very strictly, tropical fishes usually supplied for leisure are not commodity for research even though the species are distributed domestically. But the word 'commodity' is not clearly defined. I faced the same situation. I had anatomical study and I tried to publish an African originated fish,

but I thought that it might be violation of ABS regulations in certain African countries, so I stopped the study. When I could luckily identify a country of origin for that fish, and might notify the country that I had done this study, it would be good for me if I could have post MAT and post PIC. But I believed that I might have no response from whomever I sent a request so that my publication would be suspended forever. This is where we are now.

Case 4: Principle of ABS on Genetic Resources from DV *Chikyu* -Heading towards Implementation of the Nagoya Protocol

Presenter: Dr. Nan Xiao, Kochi Institute for Core Sample Research, Japan Agency for Marine Earth Science and Technology (JAMSTEC)

The International Ocean Discovery Program (IODP) and DV Chikyu

The International Ocean Discovery Program (IODP) is an international marine research collaboration that explores Earth's history and dynamics using ocean-going research platforms to recover data recorded in seafloor sediments and rocks and to monitor subsea floor environments. One of the research platforms is the Drilling Vessel (DV) *Chikyu*, which was built in 2005 and is equipped with the modern riser drilling system. The DV *Chikyu* holds the deepest scientific drilling record in the world.

The IODP consist of four major science themes such as; climate and ocean change, biosphere frontiers, earth connections and earth in motion. A major theme of biosphere frontiers aims to evaluate biodiversity of life in the deep biosphere and the environmental forcing

of evolution of the deep life. Major scientific questions are the origin, composition and the global significance of subsea floor communities, what are the limits life in the subsea floor, and how sensitive are ecosystems and biodiversity to environmental change.

There are three repositories of the IODP to store drilling core samples which are in Kochi, Japan, Texas, U.S.A., and Bremen, Germany. In the Kochi Core Center, we conduct curation of deep biosphere samples as called DeepBIOS. Samples collected so far for the past ten years by the DV *Chikyu* are all from the territorial waters of Japan. The samples are basically “drilling core”, which are difficult to be identified as biological organisms. As an international scientific research program, genetic resources isolated from the DV *Chikyu* are to be distributed to scientists from the member countries under IODP policy and management. Deep biosphere research is still in the phase of “discovery”.

ABS on Samples Collected by the DV Chikyu under the IODP

Several problems exist in ABS on genetic resources in the IODP. Japan has not established any regulations on ABS based on the Convention on Biological Diversity. Also no rules of the IODP have been established for utilization of

genetic resources. The IODP administrators are lack of knowledge or recognition of the Nagoya Protocol or ABS regulations. Under this circumstance, building rules of ABS and also keep it consistent with IODP sample distribution policy became greatly important. Kochi Core Center has therefore stopped providing deep biosphere samples to foreign microbiologists since the Nagoya Protocol had been entered into force.

We have decided to make bottom-up efforts to develop our own sample distribution policy. First, we have discussed situation surrounding core samples of the DV *Chikyu* with staffs of the JAMSTEC and other IODP administrators. Second, we have initiated to educate scientists inside the Kochi Core Center about ABS principles. Third, we have consulted with the ABS Task Force Team for Academia in Japan and were suggested to have our own principles for access and benefit-sharing. We were suggested to look through the measures of the Micro B3 project, the Kew Garden's policy and the Pharma Sea project as references.

Draft Guidance

We considered possible measures of ABS for the genetic resources collected by DV *Chikyu's* and stored in the Kochi Core

Center (KCC). We first attempted to create a draft of guidance about rules of ABS to subsea floor genetic resources from the DV *Chikyu*. Current draft of guidance describes property rights, acquisition of genetic resources, utilization of genetic resources, supply genetic resources to third parties for their utilization, use of written agreements, benefit-sharing, curation and data management, institutional policy and staff training. As to PIC, the Japanese focal point has suggested that no PIC is required when providing Japanese genetic resources to outside Japan. And when it is required from other countries, the Center for Deep Earth Exploration in the JAMSTEC will seek it.

Draft Standard MATs

As to MATs, the JAMSTEC has made MATs for providing Japanese genetic resources for IODP expeditions (Type 1) and for non IODP expeditions (Type 2). New MATs will be required when DV *Chikyu* obtains genetic resources from other countries. MTAs between the JAMSTEC and third party scientists will be necessarily alternated as IODP expeditions (Type 3) and non IODP expeditions (Type 4). A standard MAT contains definitions of terms, access to genetic resources, utilization of the genetic resources, transfer of genetic resources to the third parties,

dissemination of knowledge, recording and reporting, sharing of knowledge, scientific collaboration with the provider, benefit-sharing in case of utilization for proprietary purposes, intellectual property rights, other laws to be respected, responsibilities, warranties, duration of the agreement, termination of the agreement, applicable law and dispute settlement.

We presented several important points of our current measures. Property rights of genetic resources acquiring in the area under Japanese jurisdiction by DV *Chikyu* should belong to the JAMSTEC. KCC stores and manages the core samples curation of DV *Chikyu* as implementing offices under the IODP.

The main benefit-sharing will be scientific results considering the nature of the IODP. Although the policy of the Center for Deep Earth Exploration of the JAMSTEC and KCC does allow the utilization of genetic resources for application of commercial use, benefit-sharing in such case should be further negotiated. The policy does not allow third party recipients to apply for intellectual property rights. Genetic resources will be identified by both GPS and drilling depth information. KCC will keep records of genetic resources and keep tracking them after transfer to the recipients. The JAMSTEC will organize an oversight committee to supervise ABS

activities of genetic resources obtained by DV *Chikyu*.

In sum, documents for ABS for genetic resources obtained by DV *Chikyu* are almost ready. We are checking details and waiting for internal approval of the JAMSTEC. Since IODP expedition of DV *Chikyu* has been scheduled in next February, we will implement the procedure during the next expedition. This is the first implementing ABS measure in the IODP and JAMSTEC, and will be a role model for other projects.

Question and Answer

Comment 1:

I think that ABS for scientific utilization should be differentiated from that for commercial utilization. IODP's core sample utilization provides a very good example of managing genetic resources for scientific utilization. All of the genetic information accumulated in your repository can be provided to outside researchers where management of genetic resources can be done very well. It is very important for you to make a good template here and provide a basis for the handling of genetic resources. You are at a very good starting point to develop a system that will not create a headache for researchers and scientists.

The legal situation in Japan is very simple at the moment and we cannot violate a non-existing law. As long as Japan does not adopt national access legislation, we are basically free to use the genetic resources that are present in Japan.

This might change if a future ABS law or only access law in Japan would have some sort of retroactivity by defining how far we go back either to the NP or to the CBD. That would also have consequences for samples that would be taken now or even in the past, or if the interpretation of the scope of the type of access resulted in some sort of retroactivity. That is the only situation that might create future problems in terms of lawful access to materials in the collections. But any materials stored at this moment can be freely used.

But as a person to make the system, it would never be perfect, but the point to make a system is to do everything we can to make it safe. As mentioned, there could be a risk after a while when Japan has ratified the NP. I feel that there is a risk for the samples when we will go back to the samples which are taken without any legal things. So to make an agreement may be the thing we can do for

now as a person who is making the system. It is a basic agreement that scientists can accept and we actually do not restrict a lot of activities.

It is very good and smart that the KCC is putting in this effort to have a system in place, even though it is not strictly required under a non-existent Japanese law, especially since you are planning to go to other countries' EEZs where there might be a national obligation under ABS regulations.

Question 1:

Are the procedures that KCC is putting in place taken up by the other IODP partners? And further to that, has KCC planned to expand the idea and principles to other International Ocean monitoring and modeling programs including the Census of Marine Life?

Answer 1:

At least from my knowledge, there is no system in place in IODP partners such as the ICDP (International Continental Drilling Program). The IODP does not have any system of ABS measures. So, KCC's approach is the first.

Case 5: Marine Scientific Researches

*Presenter: Dr. Atsushi Tsuda,
Atmosphere and Ocean Research
Institute, University of Tokyo*

*The Atmosphere and Ocean Research
Institute and the RV Hakuho Maru*

The Atmosphere and Ocean Research Institute (AORI) uses the RV *Hakuho Maru* and the RV *Shinsei Maru* for ocean research activities. Research cruises are coordinated as follows: 1) Announcement of application by every three years cycle, 2) Symposium on cruise proposals, 3) Evaluation by a collaboration committee, 4) Cruise planning, 5) Approval of the planning by the committee, 6) Notification to proponents, and 7) Cruise coordination by the JAMSTEC and the AORI.

RV *Hakuho Maru* cruises in 2014 were conducted in the High Sea and the EEZs of Northwest and South Pacific Ocean, Bering Sea, and Arctic Ocean for purposes of biogeochemical processes and ecosystem dynamics. Concerns on marine scientific research (MSR) from experience of RV *Hakuho Maru* cruise missions are summarized as follows: 1) clearance of marine scientific research in the EEZ, 2) ABS by utilization of marine genetic resources in the EEZs, 3)

biodiversity beyond national jurisdiction (BBNJ), and 4) mining sites.

*MSR Clearance in the Exclusive
Economic Zone (EEZ)*

Processes of MSR clearance are similar to those of PIC in the CBD but must be submitted through the Japanese government offices. An application for permit with a final member list must be sent to the Ministry of Education, Culture, Sports, Science and Technology (MEXST). The MEXST then requests to the Ministry of Foreign Affairs. A Japanese Embassy submits to an adverse party 6 month advance to an actual activity under the UNCLOS rules. Relevant organizations of the adverse party may examine and issue permission.

MSR clearance procedures are becoming to be tightened and more complex because sea environment of providing countries requests environmental evaluation and lists of equipment on submission. Also increase of interests on ocean resources such as biological resources poses additional submission under domestic regulations. Other changes for MSR clearance are requests such as embarkation of officers with expense included and of special researches of providing country.

Marine Biological Diversity in the Area

beyond National Jurisdiction (BBNJ)

Since no recognition and discussion has been made regarding marine biological diversity in negotiation process of the UNCLOS, no specific clauses regarding BBNJ are included in the UNCLOS. BBNJ is therefore not clear position in the international law.

Five countries including Japan, U.S.A., France, Russia and China possess manned research submersibles able to dive under 4,000 meter below sea level in 2012. And United Kingdom, Germany and Korea aggressively conduct marine survey. Current situation indicates that limited countries can access to BBNJ. This causes that a first-come-first-served rule under the principle of freedom in the high sea is criticized by other countries. Potential market of benefits of BBNJ utilization is considered huge and versatile. Current sales volume of medicinal drugs originated from marine biological resources is about 2.4 billion USD. Patents from marine environments from 1991 to 2009 are estimated to exceed 677. Other countries eagerly look for opportunities to engage such BBNJ utilization and sharing of benefits.

International negotiations on BBNJ are conducted in UNCLOS. A package of the negotiations toward to develop a new

international regime includes BBNJ including ABS. In Europe, the PharmaSea project held a meeting discussing BBNJ and as a conclusion, it recommended to establish a code of conduct regarding sampling of BBNJ.

My Opinions

The Ocean is changing very quickly by anthropogenic activities including global warming, ocean acidification, coast line modification and pollutions and we have to monitor and conserve the environment and biota in the ocean. But, countries to conduct scientific researches in the Pacific Rim region are limited. We should open opportunities to more countries to participate ocean discovery program. To do so, international regimes should not restrict scientific researches in the ocean, but should enhance them for welfare of mankind. It is not because of the selfish reason, but now it is our mission to help research activities. In the diplomatic circumstance, I think we go forward and voice our opinions as much as possible through every channel and procedure to the negotiation forum.

Question and Answer

Question 1:

The sea has become a target of many

pharmaceutical researchers. The sea is a source for products for human use. If we are to be profit-oriented, there would be so many obstacles for researchers. It should be understood by developing countries that the education is one of fundamental benefits for humanity as a whole simply instead of focusing on some future benefits for their countries.

I think that laws and regulations should consider importance of such educational objectives as well. Japan should take the leadership in promoting this point and Southeast Asian nations should be particularly encouraged to focus more on education benefits because direction toward profitability would become an obstacle for human resource development in such countries.

Answer 1

I agree with educational objectives. When we made an application in Kiribati and Federation of Micronesia, we needed to develop relations with the counterparts in these countries, and then created a plan of faculty development and

capacity building programs. Such educational contribution should be made by us, but there are three problems. First of all, we can obtain some funding for cruising, but not for capacity building and faculty development purposes. We are really constrained with money for such purposes. Secondly, even if we are able to find counterparts in these countries, it is difficult to find appropriate people in such island nations, who should be planktologists or any other core specialists. This is an extremely difficult issue for us. In such small island nations, whom should we contact and what kind of relationships should we make to achieve educational purposes for the future? Thirdly, how can we intertwine all together including educational objectives in the strategy or planning with different time span? I think individual scientist cannot make a plan including education under the condition of limited money resources. If I was told to do this, we could have 100 million yen every year for 10 years.

2. Legal Considerations

Access and Benefit-sharing in Marine Genetic Resources (MGR): Lessons Learned in Europe

Presenter: Dr. Thomas Vanagt, eCoast and ABS-int

The PharmaSea Project

The PharmaSea project is a European research project funded under the Seventh Framework Programme, which is the largest research funding program in the world. The PharmaSea project has 24 partners within EU and outside EU. There are partners from China, Chile, South Africa, New Zealand and Costa Rica. It is a very large project in terms of budget and we have a budget of nearly 14 million euro for 4 years of research. We started in October 2012, and the project will end in March 2017.

The philosophy behind the PharmaSea project is that if you go to extreme marine environments, it is very likely that we will find novel biological materials that no one has ever looked at. This means that it is very likely that we will find new chemical compounds that no one has ever seen. Hopefully, these chemical compounds will show some biological activities that we do not know of and these activities will lead to valuable

product. PharmaSea concentrates on anti-epileptics, anti-cancer and anti-antibiotics.

A biodiversity pipeline of the PharmaSea project consists of three categories, 1) material from existing collections obtaining from within the consortium, 2) material collecting from marine environments, and 3) new materials collecting from extreme marine environments called hot and deep habitats. We put them into the pipeline and aim to find two valuable drug leads by the end of the project.

The second main goal of the PharmaSea project is that we look at the different barriers that come along this pipeline and try to help lower these barriers for marine natural product research. The first barrier is the fact that sampling is not easy in the marine environment, especially if we go to more extreme environments. The second barrier is to do with the legal access, where the work on ABS in the PharmaSea project is coming into play. In any biodiversity process, it is necessary to try to narrow what goes into the pipeline. Where the risk related to the NP is present at the beginning of the pipeline, the financial risks in the pipeline are in the second half, when the major costs are incurred.

This legal access to samples is therefore very important to the project. We have a dedicated work package in the project which eCOAST is leading. This legal access to samples is therefore very important to the project. We have a dedicated work package in the project which eCOAST is leading.

Policy and Management of ABS in the PharmaSea project

The Work Package 6 of the PharmaSea project deals with legal aspects and policy of marine biodiscovery. We are trying to stand in between the users, both academic and commercial users, of marine genetic resources and the people that are making policy. One of the reasons why we do this is because we see that there is a quite big mismatch between these two groups. It is very difficult for them to talk to them and the other way around. The other reason is lack of information stream in both directions. So many scientists are now unhappy with the NP and with some specific aspects of the NP. These are two different worlds that have difficulties to communicate. That is one of the things we are trying to do in the PharmaSea project, and actually that is also one of the things that the ABS Task Force Team is doing in Japan. We are helping to have information flow in two directions.

The Work Package 6 of PharmaSea project aims: 1) to clarify marine genetic resources users of their obligations under the CBD, the NP, the EU Regulation 511/2014 and UNCLOS, 2) to raise awareness amongst marine genetic resources users of these obligations, 3) to develop tools to support compliance (MGR User Toolkit), 4) to inform policy makers and legal experts of specificities of marine genetic resources and practices of marine genetic resources users.

It is very important that we are aware of what we have to do if we want to have a good compliance to the NP. A capacity building amongst users is actually crucial to get to a good compliance to the NP. Dissemination and awareness raising is very important. If scientists don't know the regulations, they don't know what they need to do. We have to translate the regulations into clear guidelines and model agreements such as material transfer agreement. We consider unique biological characteristics of marine genetic resources and clarify the legal and policy framework relevant to sampling and utilizing marine genetic resources from within or beyond national jurisdiction, and sourced either *in situ* or from *ex situ* collections or even in-silico databases. We do a stakeholder consultation with users on the level of awareness on access and benefit sharing.

We get a good response which gives us a really good insight in what are the actual problems that scientists see.

Consultation gives us enough information to make sure that we go back to some basis of ABS.

To identify bottlenecks in the marine biodiscovery pipeline is relevant to legal/policy frameworks and to propose pragmatic solutions to address them. Perspective and expertise of marine genetic resources practitioners may contribute to discussions about regimes which may impact research and development on marine genetic resources.

We present at several meetings where the policy people are and where they actually listen to the comments we are making on what is working, what is not going to work. We are really trying to be present at places where policymakers come together and where often decisions are made on what direction we are going to take as different states that negotiate these protocols.

Practices of Access and Benefit-sharing in the PharmaSea Project

In the PharmaSea project, we are actually collecting samples, and shipping samples all over the world. We both work on existing collections and on new samples. They are shipped from inside the EU to outside the EU. We are

collecting samples in countries that do have access legislation and countries that do not have access legislation. The PharmaSea Project is non-commercial work at the beginning but is clear commercial work and there is also a lot of third-party transfer. The PharmaSea project is therefore a very complicated example for considering ABS. We really have to track every movement of samples very carefully and have to make a lot of agreements not only in terms of access, PIC and MAT, but also in terms of material transfer between academic and commercial partners.

What we have learned in this very complicated context is that even within this project that has a dedicated work package on ABS, it is extremely difficult to motivate the scientists on board to provide the information on where they are sampling, when they are going to sample, who they are going to send the samples to, and whether they have a material transfer agreement or not. It will take some more years before it will become common practice in the scientific community to take ABS seriously as one of the things scientists just do as part of their work.

Marine Genetic Resources User Toolkit

The PharmaSea Marine Genetic Resources User Toolkit will support the

lawful and sustainable use of MGRs within European marine biotechnology. The user toolkit will be a portal website that will contain all the necessary information that we need to have as a user of marine genetic resources and to make sure that we can comply with all the legal obligations, both under the UNCLOS and under the NP.

Scientists who are familiar with the potential challenges of collecting samples of marine genetic resources in the marine environment, are often less aware of the legal and policy frameworks governing access to marine genetic resources. The applicable regimes governing sampling and utilization of marine genetic resources vary depending on where marine environment samples are taken or for what purpose they will be used. Certain obligations also extend to accessing samples from *ex situ* collections, depending on the applicable laws in the State from whose jurisdiction the samples were originally sourced.

Also we are developing a best practice under the EU regulation. Even for users outside the EU, it will be a very valuable document because we have basically done best possible efforts to comply with the NP if we follow this document.

We are developing an online user toolkit which will be open to other users outside

the PharmaSea project under a marine biodiversity portal www.marinegeneticresources.org in the Data Centre of VLIZ Flanders Marine Institute. What will be very valuable is basically a flowchart that will guide you at different steps of the process from writing a grant to commercializing a product. We are still developing this flowchart which should be ready by the end of next year. We also try to have a generic MTA that could be used for any type of shipment of samples. This MTA only works for third-party transfer. Third-party transfer is very tricky to many provider countries. Third party-transfer is one of the basic things that we were doing in the PharmaSea project because materials will go through the whole pipeline, which means that materials have to go through several partners in the project.

Some observations about marine genetic resources and ABS are that actually marine scientists have already done a lot of basic things necessary for ABS and tracking of information. Marine scientists are already best in class amongst users of genetic resources in terms of the basic things we have to do to comply with ABS. However, it becomes more complex that the UNCLOS has the MSR provisions. This is just a permit to go to a certain place and take a sample and this permit does not say what you

can do with a sample. Under the UNCLOS, MSR and ABS are not related. You might have to have both, but it is not always the case.

Issues of the area beyond national jurisdiction and related transboundary issues in the marine environment make it more complicated because more species travel between different places.

Compliance in the EU

The EU's answer to compliance to the NP is to have a system in place on monitoring compliance of scientists with the NP.

The EU regulation is based on due diligence declaration system. As a user, there are two points in the R&D process where we have to provide information to a national competent authority on how we complied with ABS rules. The first one is on receiving a research funding, which is something really for the basic scientists such as university and institute scientists. The second one is at the end of the R&D process, or at the end of utilization or when the material leaves the EU. Important is that the due diligence system is an obligation of conduct. At this moment, several issues, for instance relating to scope, are still being discussed at EU level.

Considerations about Biodiversity Beyond National Jurisdiction (BBNJ)

Discussions on regulating access to marine genetic resources, including BBNJ are going on in a working group of the United Nations (UN). In ABNJ, there is no regime at this moment because there is no provider. For the Nagoya Protocol, you have to have a provider country. There is no provider in the High Sea and in the Area, so there is no regime under the UNCLOS.

But there is now a mandate given by the UN to the UNCLOS to negotiate for a regime for access to genetic resources from areas beyond national jurisdiction. This process is starting next year. This meeting is very timely. Researchers come together to discuss about what is important for BBNJ researches we do and how we transfer this information to the people that are going to negotiate this new implementing agreement at the UNCLOS.

There are several important issues concerning access and benefit sharing about the BBNJ in the UNCLOS. Issues such as the High Sea, the Area, and the Extended Continental Shelves, and status of the Common Heritage of Mankind must be solved and agreed. As a governing mechanism, there are several options are discussed. By using the

CBD Clearing House mechanism, establishment of a new ABS clearing-house mechanism for ABNJ is considered. And an option is to establish an international organisation with a mandate to grant and monitor accesses.

Benefit sharing mechanisms must be multilateral compared to bilateral for the NP. In many cases most important benefits from use of BBNJ are non-monetary. Non-monetary benefits may include: 1) scientific exchanges/training, 2) technology transfer, 3) capacity building and infrastructure development, 4) enhanced reputation, 5) increased number/quality of scientific publications, 6) biodiversity conservation, and 7) valuable regional resources developed such as knowledge, samples, and data. A potential regime for BBNJ should learn from the mistakes of the NP. It should be practical and take into account the future of science. The best examples from existing answers include the EU regulation in terms of check points and Brazilian access law in terms of benefit sharing.

To create a multilateral/pool system based on the public domain approach may facilitate international access to scientific research on BBNJ as well as associated data. As to fair and equitable sharing of non-monetary benefits,

samples of marine genetic resources collected in ABNJ as well as associated data in the public domain should be as available as soon as possible, however we have to consider to have an embargo period. Sharing further non-monetary benefits by facilitating international collaboration, technology transfer and capacity-building should be available. To do this regime, samples and related data should be put in public domain. Sharing through international networks of biorepositories and international networks of databases may create common pools.

As to benefit sharing, pre-set monetary benefit sharing terms is considerable, conferring with the new Brazilian access law which includes percentage capped per sector. Payment goes into a global fund governed directly by the Division for Ocean Affairs of the UNCLOS (DOALOS) and is used for conservation. Milestone payment system is introduced to coincide with R&D steps. An issue is who deals with sanctions in case of non-compliance. Similar national obligations for monitoring to those under the NP may be established. One principle for BBNJ is that it is not situation of one provider and one user, and instead of a bilateral approach like in the NP. We are moving towards a multilateral approach where one user is going to negotiate with basically a whole set of providers, namely

all the parties to the UNCLOS. There are a number of questions for building up a package for ABNJ, such as who should govern it, who should have benefits, and what about status of the common heritage for mankind. It seems confusing that organisms in the seabed and in the water column are governed separately under the UNCLOS. The extended continental shelves are also a problem.

It is important that scientists should be on board in negotiation processes at the UNCLOS and that we do not repeat the same mistakes of the NP. This is where scientists have to provide the information of what are the mistakes, and what are the illogical things in the NP and do not make the same mistakes for the ABNJ Implementing Agreement.

Scientists Involvement in Emerging Benefit-sharing Issues

The major flaws in the NP are that it is not taking into account the future science. It is not even taking into account the present science too. Since science is moving very quickly, any types of agreements have to be flexible enough so that they are still applicable when the science goes forward in the future. The smart thing about the new Brazilian law in benefit-sharing is a sector approach and capping system for the maximum

percentage when we commercialize a project and are going to pay. When a scientist goes and negotiates MAT in a country in an early process, he/she has to negotiate monetary benefit sharing terms. But this scientist is often not aware of what is an acceptable percentage and will agree on 30% monetary benefit-sharing on revenue. This is totally ridiculous. The smart thing about the Brazilian legislation is that we know beforehand monetary benefit-sharing cannot exceed more than a percentage that was accepted by the industry during the negotiation of the draft Brazilian access law. Since negotiators and diplomats have never heard about this, scientists have to tell them this again and try to be involved.

Scope Issues Related to Academic Research

There are still a lot of unresolved issues in terms of definitions and scopes in the NP. It is very crucial whether genetic information is an access to material or not in the material scope. This is an issue of synthetic biology. If genetic information is within the scope of the NP, then it will be discussed and solved only within the NP. Other issues in the scope are what were *ex situ* materials and how to deal with retroactivity. Transboundary issues are huge, especially with marine microorganisms

that have sometimes a cosmopolitan distribution. As for the implementing agreement under the UNCLOS, it is very difficult to manage expectations in terms of potential monetary benefits for especially developing countries since there is a really mismatch between potential monetary benefits and actual ones.

Question and Answer

Question 1:

Are fatty acids from fish included in the Nagoya Protocol?

Answer 1:

This is one of the discussions on material scope of the NP. But whether something like fatty acids is within or outside of scope has not been sufficiently resolved. If there is a clear link to the genetic resource, it is within scope. Fatty acids are within scope even if they are taken without having the host organism, but this answer is still debatable.

Question 2:

Institutions like the JAMSTEC have advantages of taking samples of marine genetic resources by using submarines or big ships. Do you have any advice on such institution like the JAMSTEC when

it wants to make any measures on ABS?

Answer 2:

It is difficult, as an institution like the JAMSTEC, to make sure that everything is ABS compliant. Under the marine scientific research provisions under the UNCLOS, research permit is done at a cruise level, and not at a research project level. This research permit (MSR) under the UNCLOS is done as an institute and goes through governments. It is not easy but there is at least a process for that. However, for ABS under the Nagoya Protocol, it depends on where to go but still manageable as an institute. As discussed, utilization of samples is a crucial part of PIC and MAT. The JAMSTEC is collecting samples for a repository and then hopefully researchers will come to the repository and do some research on these samples. The JAMSTEC can make sure that it has right paper works and negotiate some generic PIC and MAT for JAMSTEC samples. This is likely to be limited in what the JAMSTEC can do with it because the provider country will be worried to give it a broad permit if it cannot tell them this is exactly what is going to happen with the samples. To a certain extent, the JAMSTEC can do PIC and MAT paperwork, and this is definitely helpful for your users who will come and do science on your samples, but

it cannot have all possible users in your documentation.

Question 3:

You mean that the institution such as the JAMSTEC needs to make flexible contracts expecting that there will be any changes happening in the future.

Answer 3:

The other thing what is important is that we inform users of what they can do and cannot do. This is why a MTA is so important since it clearly states what to do and also not to do because a MTA basically means an agreement on use. As a sampling institute and as a collection, the JAMSTEC must have an MTA with researchers who want to use your samples and must state clearly what researchers can do with them. If they want to do different utilization that is not described in the PIC and MAT which you negotiated with the provider country, it is clear that users will have to go back to the provider country and renegotiate about a new utilization.

ABS of Marine Genetic Resources under UNCLOS and CBD/NP

Presenter: Dr. Taro Saishu, National University of Fisheries

Relevant International Legal Frameworks

ABS of marine genetic resources can be governed under the United Nations Convention on the Law of the Sea (UNCLOS) as well as the Convention on Biological Diversity (CBD). The UNCLOS itself is very comprehensive and providing the norms for the laws of the sea. The UNCLOS is the legal framework for the oceans and navigation to the site, access, and marine scientific research. Access to marine genetic resources is particularly relevant amongst UNCLOS factors.

The CBD and its Nagoya Protocol (NP) are legal frameworks for the genetic resources. It essentially deals with conservation, sustainable use of biological diversity and benefit-sharing. It also implements consistent with right and duties under the UNCLOS. The NP is an international framework for ABS of genetic resources. The concept of the biological diversity relates to the organisms, the species and the genes. We are going to deal with marine genetic

resources and benefit-sharing of use of such resources. The marine environmental protection is provided for under the UNCLOS. We must comply with the relevant provisions of the UNCLOS where to use sustainably the marine genetic resources.

We need to distinguish the maritime zones under national jurisdictions and areas beyond national jurisdiction. In the zones under national jurisdiction, national ABS legislation under the CBD is applied. About the areas beyond national jurisdiction (ABNJ), which is beyond areas of the coastal nations' jurisdiction, presently there is under free access or Common Heritage of Mankind (CHM) to genetic resources.

Implementation agreement is under discussion of the drafting and it would be handled as CHM. If such a framework is established under the UN, the ABS of genetic resources within the national jurisdiction is regulated under the bilateralism, while that of the areas beyond national jurisdiction would be regulated under the multilateralism.

ABS of Marine Genetic Resources under the National Jurisdiction

Industrial use of marine genetic resources is currently not large and applications for the intellectual property protection of marine genetic resources

have been found mainly in the exclusive economic zones (EEZs). The national maritime zones are therefore important which consists of territorial waters, EEZs and continental shelves.

Sovereign rights over the natural resources are provided for the EEZs in the Article 56 (1) and for the Continental Shelf in the Article 77 (1) of the UNCLOS. According to the Article 56 of the UNCLOS, living and non-living resources of the EEZs are under the sovereign rights of the coastal nations when it comes to prospecting the exploration and exploiting.

MGRs in AUNJ are also regulated in the Article 4 (a) in the CBD. The Article 15 of the CBD is applicable to marine genetic resources in the EEZs as it refers to genetic resources subject to national sovereignty. Since the state sovereign rights are provided for, marine genetic resources are also under the national jurisdiction. In this case, the ABS laws of the provider countries are applied. If national ABS regulations are applied, then prior informed consent, PIC, and mutually agreed terms, MATs, are required.

Access and Benefit-sharing of Marine Genetic Resources (MGRs) in the Areas beyond the National Jurisdictions (ABNJ)

There has been virtually no example of the industrial application of MGRs in the ABNJ. Since two-thirds of the world oceans are under the ABNJ, ABS issues could emerge when development of science and technology reaches to the ABNJ in the future.

The CBD does not provide specific rules for ABS in the ABNJ (Article 4(a)). Under the UNCLOS, a term “genetic resources” is not used at all in any provisions. Since the UNCLOS text itself was drafted in the 1980s, such concept was not existent in the process of drafting of the law. The Part XI and Part XIII of the UNCLOS are considered to be relevant. The Part XI concerns the Area or the deep seabed, but these provisions are very clear. The Article 133(a) gives definitions that “resources” means the mining resources and it means that genetic resources are naturally explicitly eliminated. The Part VII provides provisions for conservation and management of biological resources in the High Seas. In the Article 118 there was some text for duty to cooperate in management of living resources but no ABS regime for marine genetic resources. Basically, this “living resources” means

fishing resources for consumption and we cannot include marine genetic resources in the fishing resources. The Part XIII provides for benefit-sharing related to marine scientific research in pelagic zone. The Article 244.1 deals with information and knowledge from research programs and the Article 244.2 data and knowledge transfer. The Article 242 describes international cooperation in research.

The hot issues come from discussions regarding to MSR, information and knowledge from research programs and its transfer and the international cooperation. For example, it is argued how much extent we disclose data. This discussion is crucial for science but sensitive to consider ABS. An issue in the Part III is whether MSR contains “bioprospecting” of MGRs or not. There is no clear consensus. In the 1980s, MGRs were outside the scope of discussion. The Part XI provides benefit-sharing related to MSR in the Area. Outcomes of marine scientific research in the Area should be disseminated because they are benefits of Mankind as a whole (Article 143.1).

Ongoing Discussions about Marine Genetic Resources in the Areas beyond the National Jurisdictions

A main issue in the ABNJ is whether MGRs in the Area are the CHM or not.

The UN has been discussing this issue for long time. The Group of 77 developing countries plus China provide an opinion that MGRs are within the CHM. They describe that there should be a rule to clarify this point because it is common asset. Japan, US, and France for the EU, are more or less neutral but those countries express against that position and clearly oppose to the opinion of developing countries. Iceland is also against because they are probably thinking of their fishing rights in their territorial water.

The UN should address the issues. Negotiations are still going on in the General Assembly which is assisted by the Informal Consultative Process on Oceans and the Law of the Sea from 2000. Since 2006, discussions regarding biodiversity and sustainable use are held in the Ad-hoc Open-ended Informal Working Group. It should be noted that international opinions are formulated and a policy will be soon developed at the General Assembly of the UN.

The Ad Hoc Open-ended Informal Working Group has studied issues relating to the conservation and sustainable use of marine biological diversity beyond areas of national jurisdiction. Discussing points are 1) governance, 2) conservation and management tools including area-based

management and environmental impact assessments, 3) marine genetic resources, 4) capacity-building and transfer of marine technology. It is notable that, countries possessing deep-sea explorer probes, remotely operated vehicles or submersibles are only Japan, U.S.A., France, China, and Russia. Five countries among 193 countries under the UN can conduct MGR in ABNJ but others can make their opinions. This means that the majority is those who do not have technologies but are the main drivers to form opinions or consensus.

Some conclusions are summarized. A decision on launching official negotiations for a multilateral agreement regarding to legal certainty of doing research and business in relation to marine genetic resources from ABNJ under the UNCLOS was made at 69th session of the United Nations General Assembly in 2015. In June 2015, the UN Resolution 69/292 provides legally binding treaty for the conservation of marine biodiversity on the High Sea. This Resolution includes marine protected area to be established and environmental impact assessment and marine genetic resources are included. Marine genetic resources are obviously associated with ABS.

Opinions about Marine Genetic Resources in the Areas beyond the

National Jurisdictions

Considering these situations, it is probably going to be disputable in negotiations about ABS on MGRs. Main issues are 1) who issues access permit, 2) what types of benefits exist, monetary and non-monetary benefits, and 3) who and how to decide benefit-sharing. As to benefit-sharing, it seems very difficult and will not be resolved until the very end because of protection of intellectual property. Especially for deep-sea exploitation, large amounts of initial investment are necessary. This condition eventually leads to that companies, enterprises, or countries with good fund and budget can only do such exploitation and that much confidential information would accumulate. This makes it difficult to reach consensus about benefit-sharing of deep-sea exploitation. Several approaches to solve the issues have been and will be taken in the UNCLOS forum since the UNCLOS is the guiding principle. One notable approach is to have a possible revision of the UNCLOS provisions. A provision of the mandate of the International Seabed Authority (ISA) may be expanded. The definition of the term “resources” under Article 133 of the UNCLOS needs to be changed. Genetic resources, bio-resources, MSR and commercial researches need to be well understood.

Relationship between the UNCLOS and the CBD should be well considered. The CBD is not excluding marine resources, and provides some applicable scope for MGRs in AUNJ. The Article 4(b) of the CBD provides a jurisdictional scope and includes the AUNJ. The Article 15 of the CBD does not expressly exclude MGRs in the ABNJ, but refers to genetic resources subject to national sovereignty. This means that flag state principle may be applicable as a national jurisdiction. Since the High Seas can be researched by ships, flag state principle would be probably a guiding principle. If the vessel of a country conducts some activities, then this principle will be possibly applied. Therefore, national jurisdiction can be applied. If that is the case, the CBD may be applicable.

A next question is whether the NP is irrelevant or not to deal with MGRs in the ABNJ. The NP introduces the idea of global multilateral benefit-sharing mechanism in the Article 10. The reason why we have this kind of discussion is based on that prior informed consent should be provided but if that is not the case or if it is impossible, benefit-sharing by the use should be based on the multilateral mechanism. It is obviously impossible to get prior informed consent in the deep sea exploitation. The Article 10 provision of

the CBD may provide for development of specialized international ABS instruments, such as an ABS regime for MGRs in the ABNJ. Currently after the NP, so-called article 10 experts meetings are going on in the CBD forum as intergovernmental discussions. An important part of the article 10 discussion is who and how to manage the mechanism.

Question and Answer

Question 1:

A question is related to the Article 4 and the Article 15 of the CBD. The Article 4 provides a jurisdiction scope of the CBD and the Article 15 provides zones under the national jurisdiction. Does this mean that ABS is limited to the area under the national jurisdiction?

Answer 1:

The Article 4(a) is preponderance. This article should be applied first and foremost. The Article 4(b) is totally irrelevant because the national jurisdiction could be claimed under the Article 4(a) according to the Article 4(b) provision. For example, the ABNJ could be used for some drilling and some resources could be found by Japanese operators except for chartering vessels. Then, by introducing the principle of the

flag state, Japan could claim for the rights to such resources under the ABNJ or the principle of ABS. It seems legally possible.

But according to the Article 15 of the CBD, this is only limited to the areas under the national jurisdiction. Discussion is different from the arguments under the flag state principle. Therefore, these two must not be mixed

up. For example, the Article 22 (1) of the CBD states that environmental laws and regulations must not be violated and the Article 22 (2) of the CBD must be implemented with respect to the marine environment consistently with the rights and obligations of the States under the UNCLOS. This article seems more relevant in that respect.

3. Panel Discussion

3.1 Introduction

The potential value of genetic resources is being featured, especially in the developing countries. Protection of the marine environment is also an important aspect. Trends of marine scientific researches focus on deep sea scientific researches, and value of marine genetic resources is emerging in scientific community. The developing countries have been expressing interests and creating public opinions about possibilities for participating genetic resources research at the UN and other fora.

In this panel discussion, we first focused on scientific research activities, mainly within the EEZs, continental shelves or the territorial waters since these were the main part of the presentations today. Scope and regime of ABS in the relation to marine scientific research need to be understood since these two trends move in different directions. Scientists have to consider utilization of marine genetic resources depends on commercial or non-commercial purposes.

We then moved to discuss issues surrounding institutional

implementation of the NP. Since marine scientists are moving toward Nagoya Protocol era, we focused on developing practices of codes of conduct and guidelines for marine science researches in institutions especially in Japan.

3.2 Benefit-sharing from Marine Scientific Research in AUNJ and ABNJ

It is well recognized that vast majority of marine information is non-commercial. It may depend on the use, but we should focus on benefits that information can provide to humanity. When we compare marine with outer space, we may understand the reason why. It is only the developed countries possessing large telescopes, rockets and space stations that can do exploration in outer space and they provide benefits to the world. If people start fighting over IPRs in space, the scientific realm will fall into chaos. There is an implicit agreement that outer space is a shared resource for everyone. The developed countries will issue the big data, but it is best not to make an issue about the rights for that. As for commercial use of knowledge of marine science, it might be applicable to pharmaceuticals or foods or cosmetics.

The commercial application should be limited to first certain industries. That kind of knowledge is a common asset for all of humanity. Some people in developing countries might complain that they did not have education so they were not able to develop that but they should have a right to use benefits from that. I therefore think that it may be difficult to divide between commercial and non-commercial. We should clearly divide the debate between commercial and non-commercial knowledge. Otherwise, we might end up delaying important discoveries 10 or 20 years into the future, if we do not draw a clear line there.

In terms of commercial versus non-commercial, it clearly states in the Nagoya Protocol that both are within scope for that a country can decide to facilitate access for non-commercial research. The EU regulation for compliance does not make a difference between commercial and non-commercial. It therefore makes sense that we do not want to make this distinction because it is very hard. If there would be a very clear distinction between commercial and non-commercial research, we would not have a debate about this term for last 10 years. I think that there is no clear line, and it would make much more sense. This is actually mostly relevant in terms of negotiating ABS conditions.

Negotiations with provider country will make a distinction between the future applications of the results and intended ongoing researches. It is easy to define what is a potential commercial use rather than what is commercial research. I think the intended use of outcomes of the current utilization is probably a better starting point to make a distinction between where you should facilitate access and where not. This is quite important to note that even non-monetary benefits can be very expensive. It is just a different kind of benefit sharing, but it is often forgotten that non-monetary benefits can be very costly.

I think one of the difficult discussions is to distinguish commercial and non-commercial research. It is also difficult that commercial use should be permitted or limited. But as was mentioned in the presentation, deep biosphere research in IODP is in discovery phase, and it is sometimes really difficult to find some specific applications. We do not worry about this situation too much. But I understand that we need further improvement in the definition and that this is a reason how we are developing our draft guidance for compliance. I wonder how the PharmaSea project or other marine research projects are to be extended in future, and as an output, what would come out as the results.

I tend to lean towards the emphasis on scientific research. The NMNS have only been involved in pure academic research, even though some of our results may be commercially applicable. We think that ABS may be involved in such possible case and therefore add some wording about commercialization in our policy statement.

I understand why we want to differentiate benefit-sharing terms when end results of R&D are commercial products. I really do not see any reason why a genetic resource could not result in a commercial product and we would restrict your research only in

non-commercial research. I can understand why we would have different conditions by saying this is allowed and this is not allowed.

An important element in ABS legislation, and this is to ensure the sustainability of the project in terms of not compromising biodiversity, i.e. to identify whether you are going to damage the environment or not. This concern is common to both pure science and the commercialization pathway. We need to apply for an Access permit if we want to do even pure research. Marine scientific research under the UNCLOS could be put in between pure science and commercialization. This may fulfill the concept or the philosophy that we are creating a platform for the future. As new techniques and technologies are developed, scientists can re-explore genetic resources again and again utilizing new tools or investigating new outcomes. Hence it is important to ensure sustainability in all research especially that conducted around rare resources (such as deep sea venting systems) thereby by guaranteeing as much as possible generational opportunity.

This comment may be closely related to contribution to the benefit of humanity. When we are using and developing genetic resources, we are not necessarily

starting out either with some commercial exploitation in mind or limiting it to pure scientific research. Somethings which might be developed for non-commercial uses can eventually lead to other uses which might be commercial. It may be necessary to establish new PIC and MAT if knowledge is going to be used for commercial purposes. I think that connection between commercial and non-commercial situations is to have guidelines and codes of conduct for ABS voluntarily in each research institution.

3.3 Involvement of First-class Scientists

Many scientists in Japan participate in a project if it is non-commercial, but when the project is commercial, much less are in the project. But when we look at overseas project, whether it is a commercial project or not, there are many ways that scientists can get involved. A question is why it is difficult to get involvement of first-class scientists. How can you engage or involve scientists in very positive manner?

In both Australia and New Zealand, there is a contestable process, to gain access to ship time since the governing bodies of those vessels or any large research program, including Antarctic research, want to maximize the investment in that facility. It is a mechanism by which it guarantees the best scientists through a

competitive process. Since there is also recognition that emergent scientists and young people need an opportunity to start, there is a space made for them. It is interesting that most of the research voyages are around environmental research in both Australia and New Zealand and researchers who are coming on board to look at genetic resources for some biotechnology application are often in the minority. This reflects some of the priorities of the government funding for science in those two countries.

In Europe we have a very similar system to those of Australia and New Zealand, where application for research funding and ship time is very competitive. And through the peer-review system, the best possible projects are awarded the funding in most cases and therefore the best scientists are working on the selected projects. The peer-review system works not only for publications but also for research funding. It however has its limitations, but unbiased reviewers in a panel make their effects to choose good projects and first-class scientists.

I have noticed that the level of international collaboration particularly in New Zealand has been reduced. International partners certainly invite New Zealand scientists on their vessels and for research trips, but the mechanisms by which New Zealand can

support invitations of international researchers to New Zealand appear to be very much reduced in recent years through funding cuts. This is a tragedy because we could benefit enormously from international partnerships based in New Zealand and in Australia.

Researchers in Japan show less interest in a commercial research. We see exactly the opposite in Europe. It is actually almost impossible to get funding for a research project that does not contain some sort of a chapter on what is the future application of research. Even if we would want to do non-commercial and pure fundamental research, we are forced to sometimes totally make up a potential application of your research.

I understand that economic reward needs to be considered for involvement of first-class scientists. A grant proposal for the Ministry of Education, Culture, Sports, Science and Technology in Japan (MEXT) is required to mention ramifications or secondary effects of research. This MEXT grant is really the fundamental fund to contribute to the bottom-up or basis of sciences in Japan. Even for such a grant proposal of basic scientific research, we need to mention how it is applicable in the real world. We can only provide our vessels for joint research and researchers can participate only if he/she is working at universities or

national institutes. There used to be a very strong wall in Japan between academic and enterprise-based research. Even though the wall is getting thinner and weaker, we still see that wall in terms of the traditional system. This is the culture we grew up in. Pure research and basic science should be funded because these make contribution to asset of humankind or heritage.

3.4 Development of Institutional Codes of Conduct and Guidelines

At the NMNS, we have been approaching development of codes of conduct and guidelines from the aspect of taxonomic activities and have already developed the ABS policy in this regard. But since there is no national implementation of the Nagoya Protocol in Japan, we are not able to develop detailed guidelines. A designated group drafting the policy uses their own knowledge and experience to develop the policy. But we are not able to flush it out into a full-fledged guideline without knowing governmental user policy about ABS.

In JAMSTEC, we have considered requirements for users of genetic resources from a viewpoint of the CBD. We are voluntarily developing and providing a framework for user requirements. I talked about utilization of the samples taken by the DV *Chikyu*

as an international project, which obtain very unique and valuable samples from the Japanese territorial waters. I also mentioned rules for providing the samples from the Japanese territorial waters. Since Japan does not have any law as for providers of genetic resources, KCC has been considering our own rules to supply genetic resources collected within the Japanese territorial waters. JAMSTEC's researchers in the field feel that bottom-up efforts are important in this regard. I however think that bottom-up efforts have limitations and we also need a balance with top-down approach as well.

Japan does not have any laws in terms of provider of genetic resources. Different organizations are making own guidelines that deserve our respect. In terms of development of science and technology, it is best that all countries can use knowledge as much as possible. I wonder what is an effect of having own guidelines to improve sharing of knowledge as much as possible.

Guidelines that we are developing are not for providing materials and knowledge to outside, but for use of overseas genetic resources and for ensuring that we will comply with ABS laws of the provider countries. However, there is no legal framework for this concept in Japan. I am not saying that we want to restrict to

provide Japanese genetic resources to overseas, but that our institute must follow ABS laws of provider countries when we use their genetic resources. If the NMNS want to get overseas genetic resources and then provide them to a third party, we will need to follow providing country regulations. I think our guideline says it is best as a provider measure to have a material transfer agreement for Japanese genetic resources.

Dr. Xiao spoke about JAMSTEC guidelines. JAMSTEC are currently not providing own samples to outside researchers because there is no domestic law in Japan. I would like to know the reason why the JAMSTEC is restricting to provide own samples.

One of the reasons we are restricting to provide samples is because Japan does not have any ABS laws. Also, JAMSTEC has not defined its rules as a provider of genetic resources. In the IODP, we are obligated to provide samples, but prior to the Nagoya Protocol coming into force, we were able to provide samples based on the IODP rules. But after the Nagoya Protocol came into force, we had to think about stakeholder relations in the project. We need to develop an internal rule about ABS and practices how to apply such rule to provisional samples. Our intention is

not to restrict supply of our materials, but to share benefits from samples that are extremely valuable. We are considering more about non-monetary benefits than monetary ones. For this purpose, we want to develop our own MAT or MTA for just recognition of the special scientific value of samples.

I would like to add a comment on MAT discussions. If anyone is asking materials of another country to a Japanese institute, the institute cannot add another MAT to these materials because the materials are Thai genetic resources. If you want to make another contract, you are not falling under this international legislative framework anymore and in the private contract law. This is a completely different ballgame. You are not in the position to add conditions, mutually agreed terms conditions if you are an intermediate provider in this case as an ex situ provider of oversea materials.

Some of the future path should be clarified in order to have minimum standard or we should limit ourselves to bilateral relations. Minimum standards are necessary at least, but it really depends on which country we work with because countries have different laws and regulations. We have to go through and to share accumulated experiences. This is a very typical example. An overseas

student has brought microorganisms from his country to Japan for some doctorate researches in a university. The student had brought microorganisms with a prior informed consent with limited conditions. A teacher knows the ABS regulation of the country and understands the permit is only given on the condition that the student would use the microorganisms for his own doctoral research, and he needs to discard the microorganism upon the graduation. After the student comes back home but he leaves microorganisms, derivatives and some data instead of discarding. An issue is that the teacher is able to use these materials and data for further research activities. The former student's research results are not allowed to be used by other researchers. He has very good results, but the results are not allowed to be used for publication and not used for further activities including commercial utilization. This is very impractical situation and must be addressed in some way.

3.5 Japanese Implementation Measures

Several panels are discussing a provider measure of Japan. As our working group has been discussing, I think that a provider measure seems difficult for Japan to formulate legislation under the NP and to monitor Japanese users. The basic concept of the CBD is that genetic

resources must be distributed in an appropriate manner and benefits must be shared fairly and equitably between providers and users.

In areas other than the designated and protected areas, foreign researchers would access freely wherever in Japan to collect and take genetic resources out of Japan. The free access for researchers is ideal and depends on the goodwill.

Legally binding is very problematic for our stakeholder group because we do not know how much impacts from influence, interference or intervention of Japanese government would become our burdens on paperwork of researchers even though we are very hard to comply with the procedures of provider countries. Even though we need domestic laws which stipulate strictly monitoring measures, such regulations must include concerns of the Japanese researchers. It is necessary to make a transparent process of discussing and drafting such laws and measures in Japan in order to hear the concerns of researchers. .

Even though some access restriction exists for designated area, national ABS legislation does not exist in Japan. But it totally depends on the sovereign right of a country to decide whether they want to have them or not. If Japan chooses not to have an access law, consequence is that everyone in the world can come and

take rare and precious genetic resources out to overseas and can do whatever they want with them. And then they do not come back to Japan and do not share any benefits with Japan even if they make billions of money from their uses of Japanese genetic resources such as very important drugs and key genes. Japan does not have any claims on it. That is basically what it is. This is the choice of a country to not regulate access of genetic resources. The NP provides that the Japanese users will comply with whatever regulations the provider country sets. If Japanese researchers get material from Thailand without any permit and conduct a research, Thailand does not have any power to bring Japanese researchers to a Thailand court. Thailand cannot punish Japanese researchers when in Japan. Now it changes. The NP provides that Japan must have a system in place that Japan can punish Japanese who is violating a law of another country when Japan is a party to the NP. This is basic difference between access legislation and user compliance legislation under the NP. It is slightly more complicated than this, but this is the basic distinction. If Japan can choose not to regulate access to Japanese genetic resources but be a party to the NP, Japanese users have to comply with whatever is access legislation of another country and can otherwise be punished in Japan if they violate a

foreign law. That is the basic principle.

According to the CBD, there are two lines of legislations necessary, one for provider measures, and the other for user measures. Japanese government is now discussing only user measures in order to ratify the NP. User measures in Japan must follow the basic principle of the NP. There have been many opinions about user measures for genetic resources obtained from Japan. For example, someone wants Japanese user measures such as an IRCC as an evidence of no-biopiracy later. This comes from primary concerns of the industry as users' point of view. I think provider measures in Japan are necessary. In many cases the path that we have to go through is not clear and not transparent in processes of the decision making in Japan. This issue could be addressed through the capacity building programs in order to help the partner countries to formulate the provider measures.

3.6 *Comprehensive Procedure*

We understand that ABS is a part of researchers' daily works in future. But depending on organizational or national projects, I propose that we should have comprehensive framework agreements with providing countries prior to individual projects. Then individual researchers can conduct own research

activities under such a framework.

That is actually a very good and interesting idea. It means a sort of master agreement where the major elements of interaction with a partner country worked out beforehand and then specific projects can be designated on a case-by-case basis as they come up to fast-track agreement. It seems a huge advantage to identify the major concepts and agreements of what is intent of the workers, both now and into the future, and what is financial impact of the project.

In theory, every access is an individual case that would require an individual negotiation if that is what the national access law of the provider country states. But the idea of having some sort of framework contract with a certain country would make life easier if you want to go back on a regular basis. Not only a user or collector but also a provider country can reduce paper burden to make an application and an agreement. It is exactly the same paper burden for the provider countries too. It would be a brilliant concept to have framework contracts. I am sure it will be copied by other countries as well to reduce paperwork but still it should be within the law.

4. Conclusion

In this workshop, we discussed access and use of marine genetic resources under the legal framework, mainly from a viewpoint of ocean science. The main topics were to implement the CBD and the NP on marine science and fisheries research and to understand the legal framework of marine biological diversity in the ABNJ under the UNCLOS.

Even though several cases indicate implementation activities of the NP including development of principles and guidelines with tools, marine science researchers are still confused about the legislative system. To comply with the regulations in marine biodiversity research, scientists must understand two conventions and also consider two sea areas: areas under national jurisdiction (AUNJ) and ABNJ. Since access and utilization of marine biological materials in the ABNJ are not well discussed among the Parties of the UNCLOS, oceanographic scientists dealing with biodiversity in the ABNJ show strong intentions to understand the future prospects of this issue.

Development of institutional codes of conduct and guidelines was discussed

deeply. Several research institutes in Japan have attempted to develop their own ABS policy, as well as codes of conduct and guidelines to adopt the NP. These attempts may be good stimulations for other institutions considering their own systems. Dedicated groups with knowledge and experience within the institutions have made bottom-up efforts for such development. However, they consider that it is quite difficult to go into detailed systems and development of working tools with a bottom-up approach because the Japanese Government has not yet shown its policy and details of implementation of the NP as domestic regulation.

Pure research and basic science should be continuously funded because they contribute to assets of common heritage of mankind. Many Japanese marine scientists tend to participate in non-commercial but not commercial projects since they have less interest in commercial research. Little involvement of first-class scientists has become one issue for further advances in marine scientific research. In comparison, New Zealand, Australia and Europe have introduced a contestable process that it guarantees the best

scientists. Applications for research funding and for ship time are very competitive and, through the peer-review system, these result in awarding of the best possible projects and scientists. The peer-review system works not only for publications but also for research funding. It is almost impossible in Europe to get funding for a non-commercial research project that does not contain future applications.

Japanese scientists ponder whether the commercial use of marine scientific research should be permitted or restricted. Marine scientific research could be positioned between pure science and commercialization, and there is no reason that it should be restricted to only non-commercial research. When new techniques and technologies are developed, the stored genetic resources can be repeatedly explored for different non-commercial and commercial purposes. When using and developing marine genetic resources, it is not necessary to restart with some commercial exploitation from the beginning or to be limited to pure scientific research. Outcomes for non-commercial uses might eventually be directed to commercial development.

However, it might be necessary to establish new permits and agreements if non-commercial knowledge of marine scientific research is to be used for commercial purposes. This means that the connection from non-commercial to commercial situations will require guidelines and codes of conduct for ABS.

Two ideas to reduce the burden of getting permits and making agreements were proposed. One was that a core center specialized for getting permission from providing countries and making contracts could be dedicated. This center may be set up under government control or voluntary basis, and also act for multiple research areas. The second was to establish a comprehensive framework agreement or a master contract that might work between a research organization and a providing country in advance. The major elements of contracts with providing countries could be established well in advance. Then specific matters of each project could be designated on a case-by-case basis as fast-track agreements. This should reduce the paper burden not only for users but also for providing countries.

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Dr. Atsushi Tsuda, Atmosphere and Ocean Research Institute, University of Tokyo

Dr. Thomas Vanagt, eCoast and ABS-int

Dr. Taro Saishu, National University of Fisheries

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Hajimu Morioka, Ph.D.

ABS Task Force Team

Intellectual Property Unit

National Institute of Genetics

105 1F Yaesu Daibiru, 1-1-1 Kyobashi, Chuo-ku, Tokyo 104-0031, Japan

TEL: +81-3-5542-1931,

FAX:+81-3-3542-1932

E-mail: hmorioka@nig.ac.jp

URL:<http://abs-academia.jp/> , <http://idenshigen.jp/>