European Marine Biological Resource Centre Biobank (EBB)

WP 6 ABS compliance for innovative uses of Marine Biological Resources
Action 2

D6.2 Report on the Use cases

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Disclaimer

The following report compiles outcomes collected while implementing ABS regulations within the project. It is solely intended to inform on the experience gained through "doing" and to help in the drafting of the two guidance documents delivered by the EBB project:

- *D3.4: Seek, Keep and Transfer - the Step-by-Step Guide to ABS compliance when utilizing marine genetic resources*
- *D5.1: the guide to ABS compliance. Recommendations to marine biological resources collections' and users' institutions*

The content herein mostly refers to the Guidance document C(2020)8759 on the scope of application and core obligations of Regulation (EU) No 511/2014 (EU ABS Regulation) published in December 2020 by the European Commission to help users with the ABS compliance measures adopted within the European Union. The guidance document was issued after the adoption of D3.4 and D5.1 and will be taken into account in their subsequent versions.

Conclusions and opinions expressed in this report replace and / or supersede neither the abovementioned EBB guidance documents, nor official national ABS legislation and guidance documents.

Introduction

The Nagoya Protocol on Access and Benefit Sharing (ABS) is the global mechanism to regulate the access and utilization of genetic resources, including marine genetic resources. The agreement entered into force on October 12, 2014, as a supplementary agreement to the 1992 Convention on Biological Diversity (CBD). In April 2021, 128 countries plus the EU are parties to the Protocol (129 parties). The NP organises an international mechanism called ABS, based on the sovereignty rights of countries over their genetic resources and the fair and equitable share of benefits for their utilization, in force since the CBD. The volume of national implementing rules continues to proliferate, and this requires continuous screening of the national regulatory landscape globally. In Europe, and as of January 2021, the genetic resources providing states with approved National ABS regulations imposing obligations of previous informed consent on access (PIC) and mutual agreed terms (MAT) of utilization of such resources are Bulgaria, Croatia, France, Malta, Portugal (only for Açores Islands) and Spain. Most other European countries have decided to grant free access to their genetic resources, others have still not transferred international rules into national regulations.

Utilization of marine genetic resources from National waters requires providing proof that sampling and utilization of resources has been done in accordance with National ABS regulations in place. In countries with approved National ABS regulations, this is a matter of applying for the necessary permits and keeping note of the permit id/code. In countries where *no* actions have been taken to regulate access to national genetic resources, proof of such circumstance has to be provided, i.e. it is still necessary to prove that you were duly diligent in seeking to conform to the national regulations.

National Focal Points need to be contacted before doing any sampling.

We propose to follow six steps that appear in the step by step guide produced within the EBB project in relation to seeking, keeping and transferring information and ABS documents and permits (https://www.embrc.eu/sites/default/files/publications/A-step-by-step-guide-to-ABS-compliance-when-utilizing-marine-genetic-resources.pdf).
Regarding the process of seeking information and complying with ABS regulations to access genetic resources, four are the important steps that will be dealt with in the present document.

STEP 1. Where do the resources used for my Project come from?

STEP 2. Is my Project impacted by ABS?

STEP 3. If so, where do I find information about ABS? Visit the ABS clearing house (https://absch.cbd.int) to search for information on the National ABS landscape (legislation, administration and policy issues, contact points…) for the country where the sampling will occur.

STEP 4. If required, how do I negotiate ABS permits?

In the present document we present different scenarios or case studies in which these steps have been followed to show the possible constraints, problems and present easy to follow solutions. The lessons learned were applied to improve the EBB best practice guidelines on ABS produced for ex-situ and in-situ genetic resource provision from Atlantic area EMBRC collections and Biobanks (D5.1. Handbook on implementation of EBB Best Practices and Sample Identification System) and to produce a Step by Step guide towards ABS compliance (D3.4. EBB Best Practice Guidelines on Accessing MBRs for commercial research in compliance with ABS Regulations).

Originally, the intention was to apply this approach to industrial or commercial use cases, beta testing real genetic resources access needs from the marine biotechnological companies in Europe. In doing so we have experienced two main constraints. For instance, Spain approved its ABS regulations in 2017 and, since then, only 90 (as of the 7th of January 2021) Internationally Recognized Certificates of Compliance (IRCC) have been issued and are available at the ABS clearing house, and only one issued on December 2020 is for commercial utilization. Of the 373 IRCCs (January 2021) issued by the French authorities only one (issued on the 31st of December 2020) has got a MAT for commercial purposes as stated in the ABS clearing house. Therefore, there is virtually no apparent "commercial" activity. This is not completely true. There have been IRCCs issued for companies but for initial research and development. This means that the companies are actors in the same arena and under the same circumstances as academic researchers doing basic research until the final product development stage. On the other hand, MAT negotiations for product commercialization are subject to confidentiality issues that companies are not willing to share with third parties.

In this context, we decided that case studies for non-commercial use, as it is the case in most of the academically driven research, can provide sufficient learning outcomes also to inform industry, as well as being informative for the academic scientific community quite normally living backwards to surrounding regulations and legislation limiting their research activities.

In the next sections we will be presenting 16 case studies for non-commercial use, selected amongst the more than 30 that EBB followed and supported. These cases illustrate a number of difficulties and questions regarding the applicability or not of the Nagoya Protocol for different research contexts and applications and how they were solved. Considering all those case studies globally, the document offers a last section that summarizes the main lessons learnt and some suggestions for the consideration of the ABS authorities, to alleviate and ease the administrative burden that ABS legal framework imposes.

This has been a living document that has been extended with use cases as they have been appearing and have been dealt with during the life of the project.

Case 1: Access to marine genetic resources for pollution biomonitoring using molecular tools (Spain).

Introduction

Environmental monitoring using marine organisms as passive samplers or pollution sentinel species is something common since the 1960s, and mostly in an academic and scientific context, with the incorporation of the mussel-watch program in USA. The mussel-watch was introduced for the evaluation of the bioavailability of pollutants in marine bivalves, notably using marine mussels of the *Mytilus* group where concentrations of chemicals were measured. This evolved into the biomarker approach in which biological endpoints, at the biochemical, cell- or tissue-level, were measured in sentinel organisms as early signals to recognize health effects arising from chemical exposure. In the last years, molecular approaches have gained importance, and the biomarker approach has been slowly incorporated into academic research or in national pollution biomonitoring programs around the European water framework directive and the European Marine Strategy Framework directive. All these approaches use marine genetic resources (notably marine bivalves or fish) accessed periodically in sites of interest (due to chronic exposure to pollutants) or in sites receiving acute inputs of pollutants accidentally (oil spills…).

Case 1.1: Molecular tools to assess marine environmental health in a pollution biomonitoring context.

Background

In the last years, molecular approaches applied on sentinel organisms have acquired special relevance in pollution biomonitoring. Molecular biomarkers are considered early warning tools that can be applied in organisms strategically placed in their ecosystems and accessed periodically in sites of interest. For instance, hepatic vitellogenin gene expression is widely applied in sentinel fish to assess environmental exposure to xenoestrogens. Alternatively, ELISA tests are used to analyse viltellogenin protein levels in plasma of male fish. Another widely used molecular biomarker is metallothionein gene upregulation under exposure to metal exposure, both in tissues of invertebrate and vertebrate sentinel organisms.

The access to these genetic resources (sentinel organisms) in the framework of the ABS regulations could impose some constraints such as:

- The need for periodic and yearly sampling campaigns where an umbrella kind of PIC (Prior Informed Consent) and MAT (Mutually Agreed Terms) would be desirable (instead of requesting for permits at each sampling).

- The need for rapid sampling response in the context of accidental spills where delays in obtaining PIC and MAT can be a constraint.

The Spanish national contact point was interrogated on those two aspects.

Question:

Does the access to pollution sentinel organisms where molecular approaches are to be applied for the assessment of environmental health require asking for permits in the light of the Spanish regulations on ABS?

Answer from Spanish Nagoya mailbox:

-The use of indicator species in a biomonitoring context is not considered use of genetic resources and it is OUT OF SCOPE, if accepted and already validated methods are applied on them.

-The use of indicator species for the development or identification of new characteristics of the biochemical or genetic composition is considered use of genetic resources and IT IS WITHIN SCOPE.

Case 1.2: Development of a new molecular biomarker to assess marine environmental health in pollution sentinel organisms.

Background

Mussels of the *Mytilus* group are the most widely used marine sentinel species due to their ability to filter water both in coastal and in estuarine areas. This filtering ability results in accumulation of chemicals, sometimes well above the concentrations present in the water column, and providing the possibility to integrate in time the history of different exposure periods. Many biochemical and molecular biomarkers are used to analyze the health status of mussels: levels of antioxidant enzymes, production of oxyradicals, transcriptional regulation of metallothioneins or heat shock proteins among others.

Mussels are broadcast spawners, and this imposes some constraints into their gametes and the newly formed embryos. Fertilization on the other hand results in production of oxyradicals against which the embryo needs protection, ideally provided maternally through the oocyte. The sea urchin oocytes were described in the 1980s to produce big amounts of a mecaptohistidine molecule called ovothiol. This potent antioxidant molecule with high reactivity against H_2O_2 is produced by two enzymes, ovothiol synthase taking care of the first and the third and last step in ovothiol production. Ovothiol levels and ovothiol synthase upregulation could constitute useful biomarkers of stress (oxidative stress) in pollution sentinel mussels.

Questions:

-Is the identification and sequencing of ovothiol synthase in mussels under the scope of ABS regulations?

-Is the identification and quantification of ovothiol in mussel tissues under the scope of ABS regulations?

-Is the utilization of ovothiol and ovothiol synthase, as biomarkers of stress, under the scope of ABS regulations?

YES, IT IS IN SCOPE

Procedure of application

In Spain there is a portal to apply for ABS permits to the Spanish Ministry responsible (Ministry for Ecological Transition; MITECO).

Online application is available for Spanish nationals, holding an electronic identity card. There are two application formats, one for applications only for scientific purposes another one for commercial purposes.

Foreigners can download formats for application, and submit through their Spanish Embassies. Alternatively, they can submit in paper by snail mail and catalyze the process contacting the Nagoya mailbox by e-mail. There is an electronic procedure under construction for EU citizens.

Data required:

-Applicant

-Particular, Company, Public Institution, NGO.

-Name of responsible (remember that to ask in name of institution you would need electronic signature of legal representative).

-Data on institution.

-Information for non-commercial research:

-Title and or reference of project.

-Short description of utilization (purpose, justification and objectives).

-Program of utilization (dates, techniques).

-Participants in project.

-Expected outcomes and benefits.

- Information related with the access to genetic resources
  - -Scientific name of species to be collected.
  - -Type of sample (individual, colony, tissue…).
  - -Place of collection (LONGITUDE and LATITUDE).
  - -Method of collection.
  - -Planed dates of collection.
  - -Is material to be deposited in a collection? If yes, indicate which one

-Information on confidentiality of any of the fields

-Signed declaration by user

If no questions would arise through the process, the Spanish competent authority needs a period of two months to issue permits.

Competent authorities to award PIC and MAT are many (regional and national authorities), but the ministry centralizes application and reply to the application. After this time PIC and MAT are received and International Certificate of Compliance (IRCC) issued by the ABS clearing house (ABSCH).

Particular case:

Request was done at the personal level, as institutional request which should be ideal, is not considered in general by Universities and research institutions.

Permit was requested to access genetic resources stored in a Biospecimen Bank, and that were accessed in the field in two points during 6 months and after 2014 without PIC and MAT, but with previous sampling permit by regional competent authorities in the light of Case 1.1.

Initial request received immediate reply asking for LONGITUDE and LATITUDE information to be provided (this is important information in Spain to decide on National competent authorities).

PIC and MAT

EUSKO JAURLARITZA GOBIERNO VASCO

Autorización de acceso a los recursos genéticos de la Comunidad Autónoma del País Vasco procedentes de taxones silvestres cuando su utilización sea con fines de investigación no comercial

Autoridad competente de acceso

Dirección de Patrimonio Natural y Cambio Climático del Departamento de Medio Ambiente, Planificación Territorial y Vivienda del Gobierno Vasco

Órgano que presta el Consentimiento Previo Informado y establece las Condiciones Mutuamente Acordadas

Dirección de Patrimonio Natural y Cambio Climático del Departamento de Medio Ambiente, Planificación Territorial y Vivienda del Gobierno Vasco

Número de referencia de la autorización

PN-2019_001

Fecha en que se otorga la autorización

11 de octubre de 2019

Fecha de expiración de la autorización

11 de julio de 2020

Datos de la persona usuaria interesada a la que se concede la autorización

a) Nombre y apellidos
XABIER LECUBE ITURRIOZ

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b) D.N.I./N.I.F., pasaporte o documento equivalente en caso de extranjeros
30525809M

c) Dirección completa (Calle, nº, Ciudad, CP, País)
UNIVERSIDAD DEL PAÍS VASCO/EUSKAL HERRIKO UNIBERTSITATEA UPV/EHU
Barrio Sarriena s/n, Leioa (Bizkaia) 48940 ESPAÑA

d) Teléfono, fax

e) Correo electrónico
xabier.lecube@ehu.es

La presente autorización de acceso se otorga como muestra del Consentimiento Previo Informado y de haber convenido las Condiciones Mutuamente Acordadas para la utilización con fines de investigación no comercial de los recursos genéticos especificados a continuación para llevar a cabo una investigación:

a) Tipo de investigación

Determinación de la concentración ovotiol en tejidos del mejillón *Mytilus galloprovincialis*.

b) Finalidad de la investigación

Se pretende identificar y secuenciar una porción de la secuencia del dominio codificante del gen de la ovotiol sintasa (ovo-A) en gónadas del mejillón *Mytilus galloprovincialis*. Una vez obtenida la información de la secuencia de ovo-A, se analizarían los patrones de transcripción génica a lo largo de todo el ciclo gametogénico en las gónadas de mejillones de dos estuarios que presentan diferente carga contaminante como son Plentzia y Arriluze (posteriormente se indican las posiciones GPS de los puntos). Si los niveles de ovotiol en los dos grupos de mejillones fuesen diferentes, estos podrían ser utilizados como biomarcador de exposición a contaminantes y de estrés oxidativo en programas de seguimiento para determinar el estado de salud ambiental de los ecosistemas estuarinos.

Recursos genéticos cubiertos por la autorización y descripción

Tejido blando de ejemplares de mejillón *Mytilus galloprovincialis* recolectados en los puntos de Arriluze (Getxo, Bizkaia; 43º 20' 20,53" N, 3º 0' 46,15" W) y Plentzia (Plentzia, Bizkaia; 43º 24' 32,35" N, 2º 56' 50,32" W) mensualmente entre agosto de 2017 y marzo de 2018, actualmente disponibles en el Banco de especímenes medioambientales de la Bahía de Bizkaia (BBEBB), situado en la estación Marina de Plentzia (PIE-UPV/EHU) (Bizkaia).

Las muestras se recogerán de la citada colección, donde están almacenados y archivados una extensa colección de mejillones congelados y también fijados con fines histológicos, que son muestreados para realizar estudios de seguimiento para determinar la salud ambiental de los ecosistemas marinos/estuarinos.

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Utilización para la cual se concede la autorización y limitaciones

Fines de INVESTIGACIÓN NO COMERCIAL. Cuando en el transcurso de la investigación devenga una posible utilización con fin comercial, se deberá solicitar una nueva solicitud de utilización con fines comerciales. Indicar siempre el origen del recurso genético utilizado como español.

Condiciones para transferir el recurso genético a terceros

No facilitar el recurso genético a ninguna persona no autorizada y, en todo caso, la transmisión del recurso genético a terceros se realizará en las mismas condiciones que las impuestas en esta autorización y de acuerdo con la Declaración Responsable realizada por el usuario interesado.

Información a la autoridad competente

Se deberá informar por escrito a esta Dirección de Patrimonio Natural y Cambio Climático de los resultados finales de la investigación.

Lugar y fecha
Vitoria-Gasteiz, 11 de octubre de 2019

NATURA ONDARE ETA KLIMA ALDAKETAKO ZUZENDARIA
DIRECTOR DE PATRIMONIO NATURAL Y CAMBIO CLIMÁTICO

AITOR ZULUETA TELLERIA

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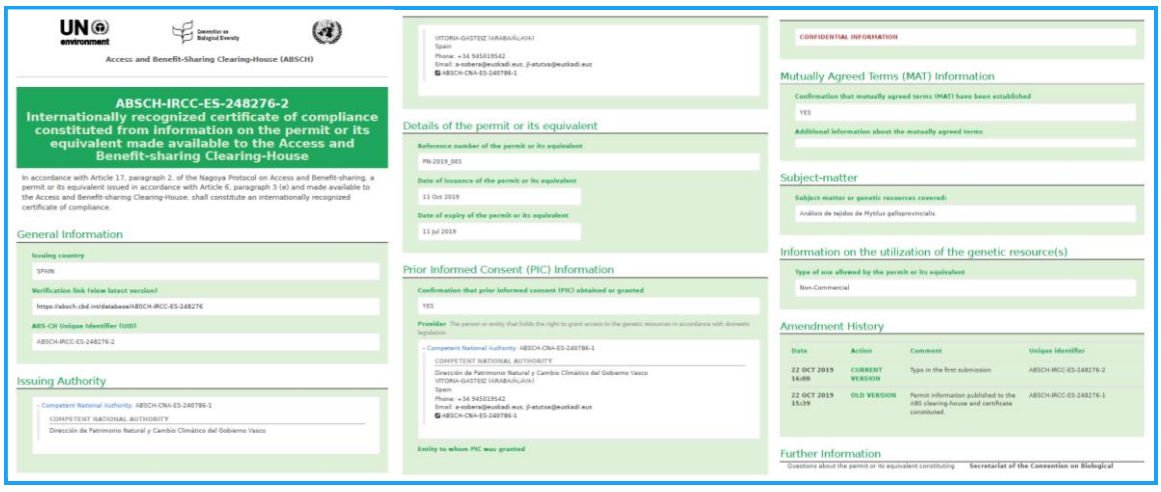
Figure 1. PIC and MAT for the access to marine genetic resources *Mytilus galloprovincialis* in Biological Biospecimen Bank of the Plentzia Marine Station to sequence one gene and identify production of ovothiol.

IRCC



Access and Benefit-Sharing Clearing-House (ABSCH)

ABSCH-IRCC-ES-248276-2
Internationally recognized certificate of compliance constituted from information on the permit or its equivalent made available to the Access and Benefit-sharing Clearing-House

In accordance with Article 17, paragraph 2, of the Nagoya Protocol on Access and Benefit-sharing, a permit or its equivalent issued in accordance with Article 6, paragraph 3 (e) and made available to the Access and Benefit-sharing Clearing-House, shall constitute an internationally recognized certificate of compliance.

General Information

Issuing country: SPAIN

Verification link (view latest version): https://absch.cbd.int/database/ABSCH-IRCC-ES-248276

ABS-CH Unique Identifier (UID): ABSCH-IRCC-ES-248276-2

Issuing Authority

- Competent National Authority: ABSCH-CNA-ES-240786-1
COMPETENT NATIONAL AUTHORITY
Dirección de Patrimonio Natural y Cambio Climático del Gobierno Vasco

VITORIA-GASTEIZ (ARABA/ÁLAVA)
Spain
Phone: +34 945019542
Email: a-sobera@euskadi.eus, jl-aturus@euskadi.eus
ABSCH-CNA-ES-240786-1

Details of the permit or its equivalent

Reference number of the permit or its equivalent: PN-2019_001

Date of issuance of the permit or its equivalent: 11 Oct 2019

Date of expiry of the permit or its equivalent: 11 Jul 2019

Prior Informed Consent (PIC) Information

Confirmation that prior informed consent (PIC) obtained or granted: YES

Provider: The person or entity that holds the right to grant access to the genetic resources in accordance with domestic legislation

- Competent National Authority: ABSCH-CNA-ES-240786-1
COMPETENT NATIONAL AUTHORITY
Dirección de Patrimonio Natural y Cambio Climático del Gobierno Vasco
VITORIA-GASTEIZ (ARABA/ÁLAVA)
Spain
Phone: +34 945019542
Email: a-sobera@euskadi.eus, jl-aturus@euskadi.eus
ABSCH-CNA-ES-240786-1

Entity to whom PIC was granted

CONFIDENTIAL INFORMATION

Mutually Agreed Terms (MAT) Information

Confirmation that mutually agreed terms (MAT) have been established: YES

Additional information about the mutually agreed terms

Subject-matter

Subject-matter or genetic resources covered: Análisis de tejidos de Mytilus galloprovincialis.

Information on the utilization of the genetic resource(s)

Type of use allowed by the permit or its equivalent: Non-Commercial

Amendment History

Date	Action	Comment	Unique Identifier
22 OCT 2019 16:08	CURRENT VERSION	Typo in the first submission	ABSCH-IRCC-ES-248276-2
22 OCT 2019 15:39	OLD VERSION	Permit information published to the ABS clearing-house and certificate constituted.	ABSCH-IRCC-ES-248276-1

Further Information

Questions about the permit or its equivalent constituting: Secretariat of the Convention on Biological

Figure 2. IRCC on the utilization of *Mytilus galloprovincialis* for the identification and quantification of a molecule that could be used as molecular biomarker of exposure to pro-oxidant chemicals.

Case 2: Project "SCUBA CANCERS: Finding the genetic causes of clonally transmissible cancers under the sea"

(Denmark, France, Germany, Morocco, The Netherlands, Norway, Portugal, Spain and United Kingdom)

Introduction

The cancers that are clonally transmissible are cell lineages of somatic cells that are transmissible between individuals by the transfer of live cancer cells. There are only three types of clonally transmittable cancers found in nature. Among them, one type is close to leukaemia found in marine bivalves that is called hemic or disseminated neoplasia (DN). DN in bivalves, and especially in the cockle *Cerastoderma edule,* offers a unique opportunity in relation to other clonally transmissible cancers, for the discovery of genetic mechanisms of transmission of cancer, because (1) DN in cockles has a polyphyletic origin, which allows to identify the genes that mutate between different and non-related linages of HN in bivalves; (2) DN is an *in vivo* and *in vitro* reliable model for the discovery and validation of the genes responsible by genetic engineering; (3) DN in bivalves is an unlimited source of biological resources for the study and experimentation of the origin and evolution of clonally transmissible cancers, due to the wide distribution of cockles populations and other bivalve species in which a high prevalence of DN (>20%) is observed along the Atlantic cost of Europe. Using the DN in bivalve as model of cancer clonally transmissible, the project Scuba Cancers aims to identify the genomic alterations and mutational processes that drive transmissible cancers in the cockle *Cerastoderma edule* to depart from their hosts and evolve as parasitic clonal lineages in the marine environment. It will allow shedding light in the universal processes of metastasis in cancers.

Background

The project will be developed between 2017 and 2021 (both included). First, the clonal structure of transmissible cancers in bivalves will be characterized by phylogenetic approaches. Then, Next Generation Sequencing (NGS) analysis techniques will be used to characterize somatic alterations associated to the different clonal lineages of DN for unraveling the mutational processes that are responsible for transmissible marine cancers, and for identifying the putative genes responsible for the transmission of cancers, which will be lastly validated by techniques the genetic edition. During 2017-2018 samples of *Cerastoderma edule* were collected in different European countries (Denmark, France, Germany, Norway, Portugal, Spain, The Netherlands and United Kingdom) and Morocco.

Question:

Is it required a permit (PIC and MAT) to access the genetic resources in all the countries where samples will be collected for this project?

Answer:

Emails to the National Focal Point (NFP) of these countries were sent by the end of August 2016 to know if a permit to access genetic resources was required for each country. The NFP contacts of Denmark, Germany, Norway, Portugal, The Netherlands, United Kingdom and Morocco replied that no access regulations were in place in their respective countries, and therefore there was not need of requesting a permit to access the genetic resources (Table 1). Some countries provide links to webs dealing with ABS regulations in their countries in the ABS clearing house (Table 1). Their replies where archived to keep as a proof of due diligence.

Table 1. Contacts to the National Focal Points (NFP) and their replies and national websites with ABS information.

Country	Contact to NFP	Reply from NFP	National websites
Denmark	E-mail 29/08/2016	No access regulation (reply 07/02/2017)	Link web
France	E-mail 29/08/2016	PIC/MAT (14/02/2019), IRCC 247147-1	Link web
Germany	E-mail 29/08/2016	No access regulation (reply 29/08/2016)	Link web
Morocco	E-mail 29/08/2016	No access regulation (reply 29/08/2016)	Link web
Norway	E-mail 29/08/2016	No access regulation (reply 29/08/2016)	
Portugal	E-mail 29/08/2016	No access regulation (reply 29/08/2016)	
Spain	E-mail 31/08/2016	No need to request PIC until by law entered into force (reply 02/09/2016). PIC/MAT, for samples collected between March 2017 - March 2018. ESNC15 (06/07/2018). **Amendment to ESNC15 to include Sanger (24/04/2019)**	Link web
The Netherlands	E-mail 29/08/2016	No access regulation (reply 29/08/2016), redirected to the website www.absfocalpoint.nl	Link web
United Kingdom	E-mail 29/08/2016	No access regulation (reply 29/08/2016)	Link web

France has regulated the access to its genetic resources and the research conducted in this project is considered in scope of the access regulations. A *Cerfa* form was completed and sent in January 2019 (Figure 3).

The *Cerfa* form contains the following information that must be provided:

-Contact details of the physical person or institution that submit the request.

-Description and objective of the activities that are foreseen during the research.

-Taxon of the organisms that will be collected and place of sampling, which should include the name of the French department, or name of the culture collection or biobank.

-Sampling techniques to collect the genetic resources.

-Timeframe for the collection of samples.

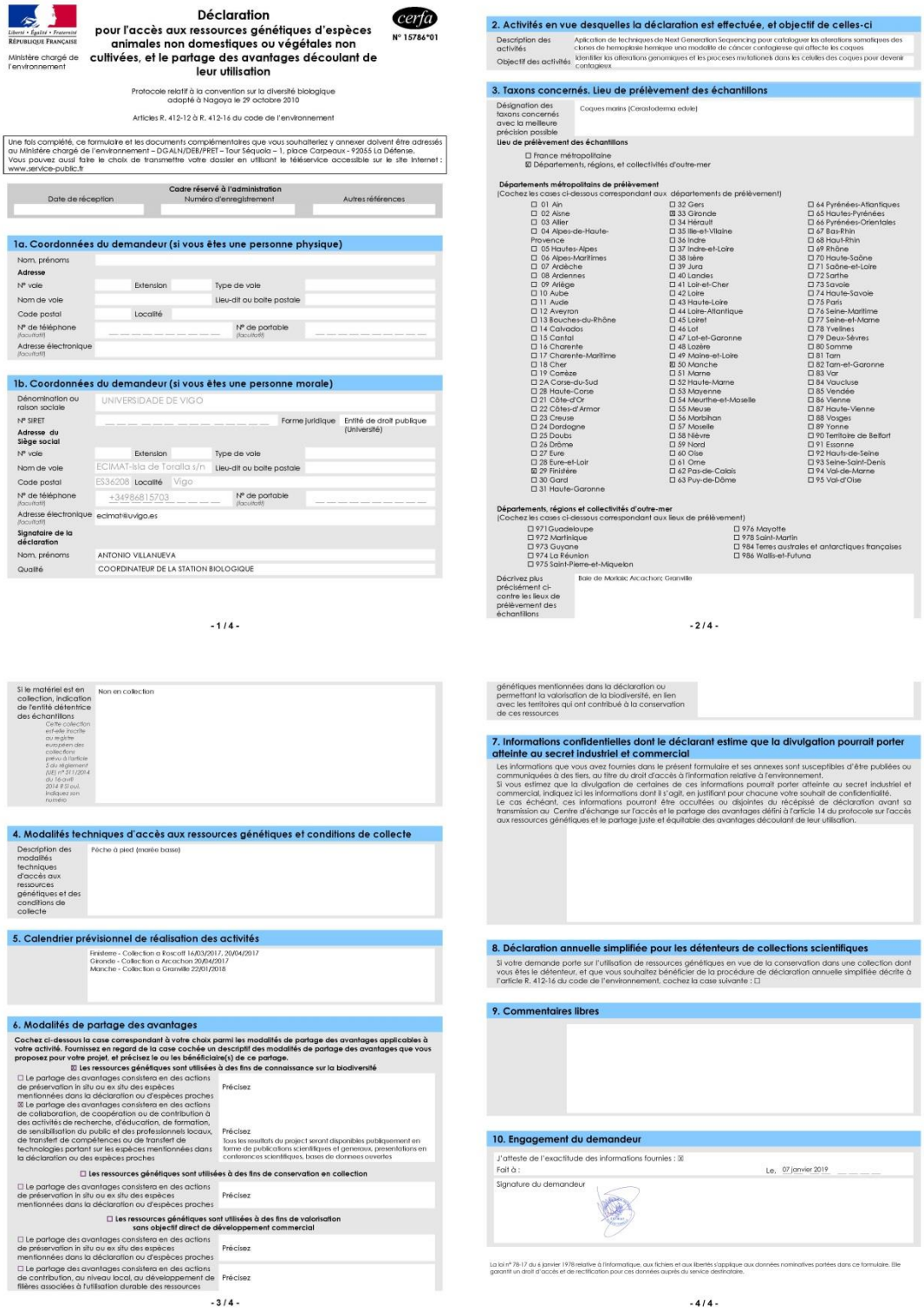
-Types of benefit sharing that are foreseen. The user can choose between several options and should explain its choice. The different options are: (1) The genetic resources will be utilized to increase the knowledge about biodiversity; (2) The genetic resources will used to be deposited on a culture collection; (3) The genetic resources will used utilized for a valorisation with a direct objective of commercial development.

-Any confidential information.

-Scientific collections has the possibility of making an annual declaration simplified as is described in the article R. 412-16 of the environmental code marking this field.

-Free comments.

-Date and signature of the request.



Déclaration pour l'accès aux ressources génétiques d'espèces animales non domestiques ou végétales non cultivées, et le partage des avantages découlant de leur utilisation

cerfa N° 15786*01

Liberté • Égalité • Fraternité
RÉPUBLIQUE FRANÇAISE
Ministère chargé de l'environnement

Protocole relatif à la convention sur la diversité biologique adopté à Nagoya le 29 octobre 2010

Articles R. 412-12 à R. 412-16 du code de l'environnement

Une fois complété, ce formulaire et les documents complémentaires que vous souhaiteriez y annexer doivent être adressés au Ministère chargé de l'environnement – DGALN/DEB/PRET – Tour Séquoïa – 1, place Carpeaux - 92055 La Défense.
Vous pouvez aussi faire le choix de transmettre votre dossier en utilisant le téléservice accessible sur le site Internet : www.service-public.fr

Cadre réservé à l'administration
Date de réception | Numéro d'enregistrement | Autres références

1a. Coordonnées du demandeur (si vous êtes une personne physique)

Nom, prénoms
Adresse
N° voie | Extension | Type de voie
Nom de voie | Lieu-dit ou boîte postale
Code postal | Localité
N° de téléphone (facultatif) | N° de portable (facultatif)
Adresse électronique (facultatif)

1b. Coordonnées du demandeur (si vous êtes une personne morale)

Dénomination ou raison sociale: UNIVERSIDADE DE VIGO
N° SIRET | Forme juridique: Entité de droit publique (Université)
Adresse du Siège social
N° voie | Extension | Type de voie
Nom de voie: ECIMAT-Isla de Toralla s/n | Lieu-dit ou boîte postale
Code postal: ES36208 | Localité: Vigo
N° de téléphone (facultatif): +34986815703 | N° de portable (facultatif)
Adresse électronique (facultatif): ecimat@uvigo.es
Signataire de la déclaration
Nom, prénoms: ANTONIO VILLANUEVA
Qualité: COORDINATEUR DE LA STATION BIOLOGIQUE

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2. Activités en vue desquelles la déclaration est effectuée, et objectif de celles-ci

Description des activités: Aplication de techniques de Next Generation Sequencing pour cataloguer les alterations somatiques des clones de hemopoiese hemiqee ena modalite de cáncer contagiense qui affecte les coques
Objectif des activités: Identifier les alterations genomiques et les proceses mutationels dans les cèlules des coques pour devenir contagieux

3. Taxons concernés. Lieu de prélèvement des échantillons

Désignation des taxons concernés avec la meilleure précision possible: Coques marins (Cerastoderma edule)

Lieu de prélèvement des échantillons

☐ France métropolitaine
☒ Départements, régions, et collectivités d'outre-mer

Départements métropolitains de prélèvement
(Cochez les cases ci-dessous correspondant aux départements de prélèvement)

☐ 01 Ain	☐ 32 Gers	☐ 64 Pyrénées-Atlantiques
☐ 02 Aisne	☒ 33 Gironde	☐ 65 Hautes-Pyrénées
☐ 03 Allier	☐ 34 Hérault	☐ 66 Pyrénées-Orientales
☐ 04 Alpes-de-Haute-Provence	☐ 35 Ille-et-Vilaine	☐ 67 Bas-Rhin
☐ 05 Hautes-Alpes	☐ 36 Indre	☐ 68 Haut-Rhin
☐ 06 Alpes-Maritimes	☐ 37 Indre-et-Loire	☐ 69 Rhône
☐ 07 Ardèche	☐ 38 Isère	☐ 70 Haute-Saône
☐ 08 Ardennes	☐ 39 Jura	☐ 71 Saône-et-Loire
☐ 09 Ariège	☐ 40 Landes	☐ 72 Sarthe
☐ 10 Aube	☐ 41 Loir-et-Cher	☐ 73 Savoie
☐ 11 Aude	☐ 42 Loire	☐ 74 Haute-Savoie
☐ 12 Aveyron	☐ 43 Haute-Loire	☐ 75 Paris
☐ 13 Bouches-du-Rhône	☐ 44 Loire-Atlantique	☐ 76 Seine-Maritime
☐ 14 Calvados	☐ 45 Loiret	☐ 77 Seine-et-Marne
☐ 15 Cantal	☐ 46 Lot	☐ 78 Yvelines
☐ 16 Charente	☐ 47 Lot-et-Garonne	☐ 79 Deux-Sèvres
☐ 17 Charente-Maritime	☐ 48 Lozère	☐ 80 Somme
☐ 18 Cher	☐ 49 Maine-et-Loire	☐ 81 Tarn
☐ 19 Corrèze	☒ 50 Manche	☐ 82 Tarn-et-Garonne
☐ 2A Corse-du-Sud	☐ 51 Marne	☐ 83 Var
☐ 28 Haute-Corse	☐ 52 Haute-Marne	☐ 84 Vaucluse
☐ 21 Côte-d'Or	☐ 53 Mayenne	☐ 85 Vendée
☐ 22 Côtes-d'Armor	☐ 54 Meurthe-et-Moselle	☐ 86 Vienne
☐ 23 Creuse	☐ 55 Meuse	☐ 87 Haute-Vienne
☐ 24 Dordogne	☐ 56 Morbihan	☐ 88 Vosges
☐ 25 Doubs	☐ 57 Moselle	☐ 89 Yonne
☐ 26 Drôme	☐ 58 Nièvre	☐ 90 Territoire de Belfort
☐ 27 Eure	☐ 59 Nord	☐ 91 Essonne
☐ 28 Eure-et-Loir	☐ 60 Oise	☐ 92 Hauts-de-Seine
☒ 29 Finistère	☐ 61 Orne	☐ 93 Seine-Saint-Denis
☐ 30 Gard	☐ 62 Pas-de-Calais	☐ 94 Val-de-Marne
☐ 31 Haute-Garonne	☐ 63 Puy-de-Dôme	☐ 95 Val-d'Oise

Départements, régions et collectivités d'outre-mer
(Cochez les cases ci-dessous correspondant aux lieux de prélèvement)

☐ 971 Guadeloupe	☐ 976 Mayotte
☐ 972 Martinique	☐ 978 Saint-Martin
☐ 973 Guyane	☐ 984 Terres australes et antarctiques françaises
☐ 974 La Réunion	☐ 986 Wallis-et-Futuna
☐ 975 Saint-Pierre-et-Miquelon	

Décrivez plus précisément ci-contre les lieux de prélèvement des échantillons: Baie de Morlaix; Arcachon; Granville

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Si le matériel est en collection, indication de l'entité détentrice des échantillons: Non en collection
Cette collection est-elle inscrite au registre européen des collections prévu à l'article 5 du règlement (UE) n° 511/2014 du 16 avril 2014 ? Si oui, indiquez son numéro :

4. Modalités techniques d'accès aux ressources génétiques et conditions de collecte

Description des modalités techniques d'accès aux ressources génétiques et des conditions de collecte: Pêche à pied (marée basse)

5. Calendrier prévisionnel de réalisation des activités

Finistere - Collection a Roscoff 16/03/2017, 20/04/2017
Gironde - Collection a Arcachon 20/04/2017
Manche - Collection a Granville 22/01/2018

6. Modalités de partage des avantages

Cochez ci-dessous la case correspondant à votre choix parmi les modalités de partage des avantages applicables à votre activité. Fournissez en regard de la case cochée un descriptif des modalités de partage des avantages que vous proposez pour votre projet, et précisez le ou les bénéficiaire(s) de ce partage.

☒ **Les ressources génétiques sont utilisées à des fins de connaissance sur la biodiversité**

☐ Le partage des avantages consistera en des actions de préservation in situ ou ex situ des espèces mentionnées dans la déclaration ou d'espèces proches — Précisez
☒ Le partage des avantages consistera en des actions de collaboration, de coopération ou de contribution à des activités de recherche, d'éducation, de formation, de sensibilisation du public et des professionnels locaux, de transfert de compétences ou de transfert de technologies portant sur les espèces mentionnées dans la déclaration ou des espèces proches — Précisez: Tous les resultats du project seront disponibles publiquement en forme de publications scientifiques et generaux, presentations en conferences scientifiques, bases de donnees ouvertes

☐ **Les ressources génétiques sont utilisées à des fins de conservation en collection**

☐ Le partage des avantages consistera en des actions de préservation in situ ou ex situ des espèces mentionnées dans la déclaration ou d'espèces proches — Précisez

☐ **Les ressources génétiques sont utilisées à des fins de valorisation sans objectif direct de développement commercial**

☐ Le partage des avantages consistera en des actions de préservation in situ ou ex situ des espèces mentionnées dans la déclaration ou d'espèces proches — Précisez
☐ Le partage des avantages consistera en des actions de contribution, au niveau local, au développement de filières associées à l'utilisation durable des ressources — Précisez

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génétiques mentionnées dans la déclaration ou permettant la valorisation de la biodiversité, en lien avec les territoires qui ont contribué à la conservation de ces ressources

7. Informations confidentielles dont le déclarant estime que la divulgation pourrait porter atteinte au secret industriel et commercial

Les informations que vous avez fournies dans le présent formulaire et ses annexes sont susceptibles d'être publiées ou communiquées à des tiers, au titre du droit d'accès à l'information relative à l'environnement.
Si vous estimez que la divulgation de certaines de ces informations pourrait porter atteinte au secret industriel et commercial, indiquez ici les informations dont il s'agit, en justifiant pour chacune votre souhait de confidentialité.
Le cas échéant, ces informations pourront être occultées ou disjointes du récépissé de déclaration avant sa transmission au Centre d'échange sur l'accès et le partage des avantages défini à l'article 14 du protocole sur l'accès aux ressources génétiques et le partage juste et équitable des avantages découlant de leur utilisation.

8. Déclaration annuelle simplifiée pour les détenteurs de collections scientifiques

Si votre demande porte sur l'utilisation de ressources génétiques en vue de la conservation dans une collection dont vous êtes le détenteur, et que vous souhaitez bénéficier de la procédure de déclaration annuelle simplifiée décrite à l'article R. 412-16 du code de l'environnement, cochez la case suivante : ☐

9. Commentaires libres

10. Engagement du demandeur

J'atteste de l'exactitude des informations fournies : ☒
Fait à : | Le, 07 janvier 2019
Signature du demandeur

La loi n° 78-17 du 6 janvier 1978 relative à l'informatique, aux fichiers et aux libertés s'applique aux données nominatives portées dans ce formulaire. Elle garantit un droit d'accès et de rectification pour ces données auprès du service destinataire.

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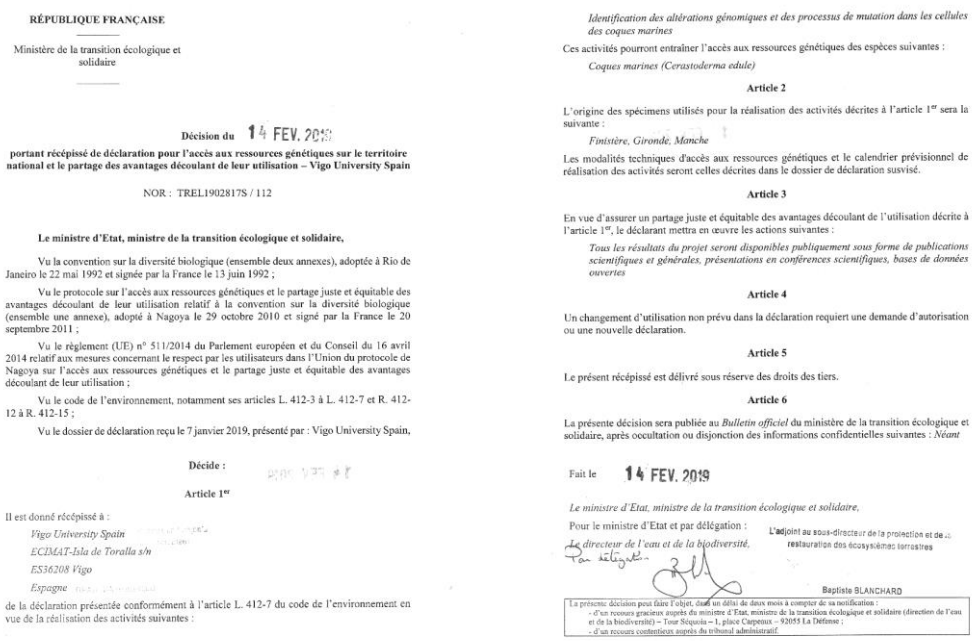
Figure 3. Completed *Cerfa* form to request the authorization to access the French genetic resources.

On the 14th February 2019 an authorization to access the French cockles was granted (Figure 4) and an IRCC (ABSCH-IRCC-FR-247147-1) was uploaded to the ABS clearing house.



RÉPUBLIQUE FRANÇAISE

Ministère de la transition écologique et solidaire

Décision du 14 FEV. 2019

portant récépissé de déclaration pour l'accès aux ressources génétiques sur le territoire national et le partage des avantages découlant de leur utilisation – Vigo University Spain

NOR : TREL1902817S / 112

Le ministre d'Etat, ministre de la transition écologique et solidaire,

Vu la convention sur la diversité biologique (ensemble deux annexes), adoptée à Rio de Janeiro le 22 mai 1992 et signée par la France le 13 juin 1992 ;

Vu le protocole sur l'accès aux ressources génétiques et le partage juste et équitable des avantages découlant de leur utilisation relatif à la convention sur la diversité biologique (ensemble une annexe), adopté à Nagoya le 29 octobre 2010 et signé par la France le 20 septembre 2011 ;

Vu le règlement (UE) n° 511/2014 du Parlement européen et du Conseil du 16 avril 2014 relatif aux mesures concernant le respect par les utilisateurs dans l'Union du protocole de Nagoya sur l'accès aux ressources génétiques et le partage juste et équitable des avantages découlant de leur utilisation ;

Vu le code de l'environnement, notamment ses articles L. 412-3 à L. 412-7 et R. 412-12 à R. 412-15 ;

Vu le dossier de déclaration reçu le 7 janvier 2019, présenté par : Vigo University Spain,

Décide :

Article 1er

Il est donné récépissé à :

Vigo University Spain
ECIMAT-Isla de Toralla s/n
ES36208 Vigo
Espagne

de la déclaration présentée conformément à l'article L. 412-7 du code de l'environnement en vue de la réalisation des activités suivantes :

Identification des altérations génomiques et des processus de mutation dans les cellules des coques marines

Ces activités pourront entraîner l'accès aux ressources génétiques des espèces suivantes :

Coques marines (Cerastoderma edule)

Article 2

L'origine des spécimens utilisés pour la réalisation des activités décrites à l'article 1er sera la suivante :

Finistère, Gironde, Manche

Les modalités techniques d'accès aux ressources génétiques et le calendrier prévisionnel de réalisation des activités seront celles décrites dans le dossier de déclaration susvisé.

Article 3

En vue d'assurer un partage juste et équitable des avantages découlant de l'utilisation décrite à l'article 1er, le déclarant mettra en œuvre les actions suivantes :

Tous les résultats du projet seront disponibles publiquement sous forme de publications scientifiques et générales, présentations en conférences scientifiques, bases de données ouvertes

Article 4

Un changement d'utilisation non prévu dans la déclaration requiert une demande d'autorisation ou une nouvelle déclaration.

Article 5

Le présent récépissé est délivré sous réserve des droits des tiers.

Article 6

La présente décision sera publiée au *Bulletin officiel* du ministère de la transition écologique et solidaire, après occultation ou disjonction des informations confidentielles suivantes : *Néant*

Fait le 14 FEV. 2019

Le ministre d'Etat, ministre de la transition écologique et solidaire,

Pour le ministre d'Etat et par délégation :

Le directeur de l'eau et de la biodiversité,

L'adjoint au sous-directeur de la protection et de la restauration des écosystèmes terrestres

Baptiste BLANCHARD

La présente décision peut faire l'objet, dans un délai de deux mois à compter de sa notification :
- d'un recours gracieux auprès du ministre d'Etat, ministre de la transition écologique et solidaire (direction de l'eau et de la biodiversité) – Tour Séquoia – 1, place Carpeaux – 92055 La Défense ;
- d'un recours contentieux auprès du tribunal administratif.

Figure 4. Authorisation granted to University of Vigo to access the French genetic resources (project Scuba cancers).

In the case of Spain, the reply obtained in September 2016 was that genetic resources obtained before the 15th of March 2017 (date when the Spanish Royal Decree 124/2017 entered into force) do not need to request an authorization. Since *Cerastoderma edule* and *Venus verrucosa* samples were collected between March 2017 and 2018 it was necessary to request an authorization. An authorization (ESNC15) was obtained on the 6th of July 2018, which corresponded to the IRCC (ABSCH-IRCC-ES-240493-1). Cockles' samples were sent for genetic analyses to Sanger Institute (United Kingdom). The Ethical committee of Sanger institute requested all ABS permits and due diligence documents. It is a request by the Sanger Institute to be included in the ABS authorization in order to analyze the samples as that they would be utilizing the genetic resources and this was not covered by the first authorization. This represents an additional checkpoint to those included in the EU regulation and Spanish ABS regulation. An amendment to the Spanish authorization ESNC15 to include Sanger Institute was requested and granted on the 24th April 2019.

Case 3. Project COCKLES "Cooperation for the recovery of cockle fisheries and their environmental services in the Atlantic Area" (Denmark, France, Germany, Ireland, The Netherlands, Norway, Portugal, Spain and United Kingdom)

Introduction

The activities planned in COCKLES project are aimed to restore cockle production and the services it provides by developing resistant strains, improving protocols for aquaculture and for recovering natural stocks, optimizing resource management and upskilling stakeholders, which will aid recovering resources, increase the understanding of ecosystem services and contribute to the good environmental status and boost coastal economies of AA.

In order to achieve the objectives, samples along the Atlantic Area have been collected with the following purposes:

- Investigate the current status of cockle distribution, abundance, population dynamics and reproductive health.

- Study the temporal and geographic genetic structure of cockles.

- Undertake an exhaustive screening of pathogens affecting cockles.

- Address the efficiency of the response of cockles to stress, with emphasis in pathogens and climate change, involving two key components in resistance to stress, characterization of the cockle immune ability and the quality of the cockle microbiota.

- Study the distribution of bivalve non-indigenous species, assessing the risk involved by non-indigenous species as competitors or carriers of pathogens.

- Evaluate possible feeding niche overlap among intertidal suspension feeding benthic species and to understand if these species deal with competition for food. To do this primary producers and intertidal consumers need to be sampled. On these samples stable isotope analyses are performed to identify the food sources of the suspension feeding benthic species.

- Identify protein markers and candidate genes and genetic markers of resistance to marteiliosis in cockles.

- Quantify the role of cockles as an engineering species and expected effects of cockles on biodiversity and ecosystem functioning services.

Background

Cockles (*Cerastoderma edule*), other marine bivalve species, macroalgae and sediment samples were collected at different locations between 2017 and 2019. Samples were collected in France, Germany, Ireland, Norway, Portugal, Spain, The Netherlands and United Kingdom. Not all the samples collected in the different countries were to be used to carry out the same analysis or tackle the same objectives.

Question:

Does the project need to request an authorization to utilize the genetic resources collected in all these countries?

Answer:

Only Spain and France regulate access to their genetic resources. In the case of Portugal, only Açores region, regulates access to their genetic resources. Even if we have contacted all the NFP, most of the countries where samples were collected do not regulate access.

Question:

Are the same type of analysis considered in scope in Spain and France?

Answer:

There are exceptions and variations intrinsic to national regulations.

Population genetics studies are considered taxonomic studies under Spanish regulation, and they are OUT OF SCOPE (it is an exception). However, in France taxonomic studies are IN SCOPE.

In Spain, the access for utilisation for fishery resources is regulated under the Law 3/2001 on the state of maritime fisheries which falls OUT OF THE SCOPE of the Royal Decree 124/2017 on access to the genetic resources from wild taxa and control of utilisation. Therefore, access for utilisation of genetic resources from fishery resources does not require an access authorisation under Royal Decree 124/2017 when the aim of the research pursues fisheries or aquaculture purposes. However, if the utilisation of such genetic resources is aimed at a final different objective other than fisheries and aquaculture, the provisions of the Royal Decree 124/2017 would apply (IN SCOPE) and an access authorisation would indeed be required.

The access authorisation in Spain can be requested by the coordinator of a project, for all the activities that fall in scope of the Royal Decree 124/2017 and it should include all the institutions participating in the research.

Case 4. Utilization of microorganisms from mainland France

In France, the request for access to microorganisms as genetic resources has an exception included in a recent French law n° 2019-486 (article 129) that has established a three-year experimental/simplification period, which excludes microorganisms of mainland France from the scope of the national ABS regulation (it does not concern French overseas territories). It means that, for a period of 3 experimental years, no PIC and MAT are required (although ABS obligations remain, see later) for the utilization of those microorganisms from mainland France. Pursuant to this article, a decree (Décret n° 2019-916 of 30/08/19) has been published (https://www.ecologique-solidaire.gouv.fr/sites/default/files/Access_and_sharing_the_benefits_arising_from_the_utilisation_of_genetic_resources_and_their_associated_traditional_knowledge_ABS.pdf); it gives details about certain information that the users will have to provide annually to the Ministry. In practice it is it is a 3-year experimental exclusion from the general track and trace framework; in reality, there is no exclusion from ABS and it is a simplified track and trace mechanism whereby the declaration occurs after the use. The information gathered serves as a basis for the evaluation of the experiment by the Ministry (which is mandatory), and to decide on what action to take permanently after these 3 years.

So, utilization of microorganisms, including prokariotic of eukaryotic organisms form metropolitan France is IN SCOPE but simplified for a period of 3 experimental years to avoid complicated negotiations. This has important implications for French holdings of culture collections, although they need to be aware that utilization is subject to an annual declaration from the users. In such declaration, it is necessary to provide information on the use of the genetic resource, which is virtually identical to a declaration for basic research (i.e. PIC / MAT), safe that it is produced after the utilisation and once a year, or to a scientific collection that may obtain a unique PIC/MAT for the duration of a project.

BUT

A lot of the research in marine waters involves bio-exploration and results in discovery of new species of microorganisms. When publishing information of a new species it is compulsory to deposit the newly identified strain in two independent and recognised

culture collections. The Leibniz Institute DSMZ-German Collection of Microorganisms and Cell Cultures (which is an ABS registered culture collection), could reject deposits based in the exception mentioned above and without a guarantee that the resource could be transferred to subsequent users without an ABS compliance check. This is against DSMZ´s open access policy.

Case 5. High added-value industrial opportunities for microalgae in the Atlantic Area (EnhanceMicroAlgae) (France, Spain, Unite Kingdom and USA)

Introduction

Microalgae production for high added value compounds is identified as a business sector with high growth potential in the coming decades, especially in the Atlantic Area. Barriers to improve an industrial use are dominated by a lack of technology expertise. EnhanceMicroalgae project will facilitate information transfer between a panel of experts and companies specializing in different areas (nutrients, cosmetics, pharmaceuticals, feed, energy, etc.) thus encouraging business cooperation among the different countries. The main objective is to contribute to the competitiveness of microalgal-based industries in the Atlantic Area.

Background

Microalgae account for the basis of the food chain in aquatic ecosystems and they are ubiquitously distributed throughout the biosphere. This wide span of ecosystems contributes to the myriad of chemical compounds that they are able to synthesize, thus accounting for their unique potential in blue biotechnology. In aquaculture, bacterial infections are nowadays considered as the main responsible for serious mass mortalities and considerable economic losses and antibiotics have been largely used in intensive farming, however, the risk of transferring resistance to humans bacteria have led to a great concern for public health about the misuse of antibiotics. The antimicrobial activity of microalgae has been largely studied and it has been attributed to compounds belonging to several chemical classes – including indoles, terpenes, acetogenins, phenols, fatty acids and volatile halogenated hydrocarbons. Twelve species of microalgae (*Tetraselmis chuii*, *Chaetoceros calcitrans*, *C. salsugineus*, *Nannochloropsis gaditana*, *Pavlova gyrans*, *Conticriba weissfloggi*, *Rhodomonas lens*, *R. otrorose, Isochrysis galbana, Tisochrysis lutea, Thalassiosira pseudonana* and *Phaeodactylum tricornutum*) were cultivated (Table 2). Some of them were processed and used as feed for bivalve culture. Among them, *T. chuii, C. calcitrans, C. salsugineus, N. gaditana, P. gyrans, C. weissfloggi, R. lens* and *I. galbana*, have been studied to check the antimicrobial activity against *Vibrio anguillarum* CECT 522 and *Aeromonas*

salmonicida subsp. *salmonicida* CECT 894. Also, amino acid and fatty acid composition of these species have been analyzed to study the correlation among these two parameters and antimicrobial activity results.

Table 2. Microalgal strains, strain supplier, sampling date and country of origin.

	Strain supplier	Strain	Sample Id	Sampling date	Country of sampling
Chaetoceros calcitrans	AQUALGAE	No traceability			
Chaetoceros cf. salsugineus	Universidad Pais Vasco			17/03/2015	Spain
Conticriba weissfloggi	ECIMAT	CCMP1336	ECC011	2008	USA
Isochrysis galbana	ECIMAT	CCAP927/1	ECC023	5/2009	UK
Nannochloropsis gaditana	AQUALGAE	CCMP527		1952	USA
Pavlova gyrans	Universidad Pais Vasco	HP10EHU		05/08/2003	Spain
Rhodomonas lens	ECIMAT		ECC030	2012	
Tetraselmis chuii	AQUALGAE	CCAP 8/6		1959	UK
Thalassiosira pseudonana	Universidad Pais Vasco	Bc6EHU	KP201658	31/05/2012	Spain
Phaeodactylum tricornutum Bohlin	CCAP	1055/1	CCAP 1055/1	2003	UK
Tisochrysis lutea	CCAP	927/14	CCAP 927/14	1977	French Polynesia
Rhodomonas atrorose	CCAP	978/6B	CCAP 978/6B	1989	UK

Question:

Do we need to request an access authorisation for the microalgae used as feed for bivalves?

Answer:

No, we do not need to request an authorisation because microalgae production for its use as food for bivalves in OUT OF THE SCOPE of the ABS regulations and it does not fall into the definition of utilisation of genetic resources.

Question:

Do we need to request an access authorization for all the strains used for the biochemical composition and antimicrobial activity study?

Answer:

It depends on the sampling date and country of origin. For those strains coming from an ex-situ collection that were sampled in United Kingdom or USA (*T. chuii, N. gaditana, C. weissfloggi,* and *I. galbana*) it is not necessary to request an access authorisation (PIC and MAT) because USA is not a party of Nagoya protocol and USA does not have any access regulations in place. The United Kingdom has not access regulation for its genetic resources (https://www.gov.uk/guidance/abs). In addition to that, these strains were sampled before the implementation of the Nagoya protocol.

It is recommended avoiding the utilization of *C. calcitrans* and *R. lens* to investigate its genetic and biochemical composition because there is not any traceability about its origin or sampling date, and thus the need of requesting PIC/MAT is unknown.

Since *P. gyrans, Thalassiosira pseudonana* and *Chaetoceros cf. salsugineus* were originally sampled in Ría de Bilbao (Spain) and they were provided to a third entity (ANFACO-CECOPESCA) by a Spanish culture collection (microalgal collection of University of the Basque Country) it is required to request an authorization of access to utilization of genetic resources. A Spanish genetic resource found in a Spanish ex-situ collection or under the disposal of a company, institution or research center or any individual or legal entity, collected and deposited or stored therein prior to the entry in force, on 15th March 2017, of Royal Decree 124/2017 and which is accessed by a third user for its utilization after that date on 15th March 2017, is within the scope of the aforementioned Royal Decree and the user must request the access authorization even if the genetic resource had been stored in the culture collection before the date of entry into force of the Royal Decree 124/2017. The authorisation was requested retrospectively and the Basque Country competent authorities granted the permit (OP-2020_078) on the 11th August 2020 and the IRCC (ABSCH-IRCC-ES-252030-1).

Case 6. Marine Genomic Observatories (ASSEMBLE Plus)

Background

A Marine Genomic Observatory is a marine ecosystem and/or site subject to long-term scientific research, including (but not limited to) the sustained study of genomic biodiversity from single-celled microbes to multicellular organisms. In the European H2020 project ASSEMBLE Plus, there is a Genomics Observatories joint research activity, coordinating genomics observations of planktonic and benthic communities are performed and optimised. Building on the long-term investment, infrastructure, expertise, and traditions of more than 20 ASSEMBLE Plus marine stations, ASSEMBLE Plus aims to produce a roadmap for European marine genomic observatories, to

optimise methodologies and outputs ensuring the longevity and sustainability of the observatories under the umbrella of a European Research Infrastructure, EMBRC-ERIC. Two activities are carried out in the genomic observatories of ASSEMBLE Plus, the Ocean Sampling Day (OSD) and the deployment of Autonomous Reef Monitoring Structures (ARMS).

OSD is a world-wide sampling programme. One day every year hundreds of scientists and citizens collect water samples from the ocean in a coordinated and controlled manner. These samples are sequenced at HCMR in Greece, where they extract the DNA present in the water and filtered onto special filters. Each yearly OSD dataset can tell us the composition of the ocean as sampled from hundreds of sites across the world. Taken together with the in-situ measurements of the physical (temperature, etc) and chemical (salinity, etc.) conditions, the OSD data over the years can tell us how climate change is affecting life in the oceans. OSD in 2018 and 2019 delivered high-quality genomic DNA from 65 marine stations, which are being amplicon sequenced and will soon be jointly submitted to shotgun metagenomics sequencing.

The ARMS are units made up of eight connected and stacked plates and developed originally by the Smithsonian Institute. A unit is placed on the sea floor, and over a period of time it gets colonized by the fauna and flora in the hard substrate benthos. Because of their three-dimensional structure, mimicking the complexity of hard bottom marine substrates, they attract encrusting species (corals, algae, etc.) and motile organisms (crustaceans, molluscs, polychaetes, etc.). The key innovation of the ARMS is their ability to sample marine communities over precisely the same area and in the same manner providing a standardized and quantifiable measure of biodiversity over time and across locations. ARMS units have been deployed in 19 sampling areas at ASSEMBLE Plus sites, with the ARMS-MBON program, in European coastal waters and Antarctica, in triplicates whenever possible. Once recovered from the sea bottom, each ARMS plate is treated separately (high-resolution photographs are taken, and DNA metabarcoding of eukaryotic communities are produced). ARMS can be used to answer a broad range of questions including long-term ecological research, monitoring of endangered/invasive species and biodiversity inventories (LTER).

Question:

How to apply for permission to access to samples in your country (if signatory of Nagoya or member of the EU) in the light of the Nagoya linked national regulations and in the context of the OSD and ARMS activities?

Answer:

Ideally, researchers should be aware of the Access and Benefit Sharing Regulations in their country. Researchers need to ask in their country and prove to the ASSEMBLE Plus consortium that they are accessing the samples legally.

Users must ask their Nagoya National Focal Point. In order to do that, go to the ABS clearing house (https://absch.cbd.int) and search for user's country. Users will find an ABS National Focal Point with contact information. Users must write asking about OSD or ARMS. Phone calls are not valid because users need to prove contact. Some countries have national websites in relation to Nagoya and ABS, where users could find if they have a Nagoya mailbox.

Users should receive an answer that will range from:

1) Access to national genetic resources is free under our national regulations NO ACCESS REGULATION;

2) Access to national genetic resources for taxonomic purposes is OUT OF SCOPE (that is the case in Spain).

In the Spanish regulation, Royal Decree 124/2017, access authorization is not necessary when users access to Spanish genetic resources for *exclusively taxonomic purposes*, according to the definition of 'exclusively taxonomic purposes' in article 2.3 of the Royal Decree 124/2017. These genetic resources may only be transferred to subsequent users under the same terms they were accessed, that is with exclusively taxonomic purposes. Otherwise, an access authorization is required. *Exclusively taxonomic purposes* (definition in Art. 2.3. Spanish ABS Royal Decree): Application of principles and methods for identification, delimitation and classification of living beings, which requires the study of their phylogenetic relationships as well as the evolutionary and ecological processes that have generated biodiversity using morphological, physiological, genetics, behavioural and environmental data.

These e-mails saying that you project is OUT OF SCOPE constitute the user's proof of due diligence (these e-mails must be sent along with your samples and logsheets).

In France, PIC and MAT is required for OSD and ARMS. The PIC and MAT are the permits and are linked to an International Certificate of Compliance (IRCC). The IRCC should be send along with OSD/ARMS samples and logsheets.

3) IF ANSWER IS NOT RECEIVED

-Users must provide proof that they have asked (e-mails).

-If it is the case, provide link to the documentation indicating that access to national genetic resources is free in users' country, but still provide proof of the e-mails in which you ask for information.

Case 7. Anti-fouling defence dynamics of a foundation seaweed from high and low latitude populations (AFODS) (Finland and Spain)

Background

AFODS is a transnational access project of the European project H2020 Assemble Plus. Biofilms, composed mainly of bacteria, are paramount in the marine environment colonizing both non-living and living surfaces like macroalgae. Bacterial colonization followed by an unhindered settlement and growth of macrofoulers bring along multifold consequences (mostly detrimental) for the algal host: fouled algae may be more susceptible to drag and shading, attract or repel potential grazers; encounter decreased flexibility, mechanical damage, impeded transepidermal exchange, altered smell, color and texture with multiple consequences. Given the disadvantages of small to heavy scale fouling, a control over the fouling process is expected and has been postulated to be the driving force behind the evolution of antifouling defenses – a critical trait maintaining overall fitness of an algal host. Algal chemical defenses inhibiting the settlement and growth of bacterial foulers represent the first line of defense against epibiosis. As control mechanisms, physical (e.g. surface topography) and/ or chemical strategies may be employed by macroalgae; among which existence of chemical strategies seems to be very common. The aim of AFODS is to investigate (i) whether the anti-fouling defense of a foundation macroalga can vary among high (Finland) and low latitude (Spain) populations and (ii) whether the defense strength among low and high latitudinal populations can vary according to season. For macroalgal populations growing along the European thermal gradient, a better understanding of interspecific variability of chemical defense to biotic and abiotic factors has not only important implications for the ecology and evolution of antifouling defense in macroalgae but also in predicting response of chemically mediated interactions under climate change.

Question:

Does this project need to request authorization for the access to genetic resources in Finland and Spain?

Answer:

The use of Finnish genetic resources is free for users from both Finland and abroad, and no Prior Informed Consent from the authorities is required for their acquisition (see https://www.biodiversity.fi/geneticresources/guidelines/genetic-resources-in-finland).

In the case of the samples of *Fucus* collected in Spain it was required to request and access authorization at the electronic platform of the Spanish CNA (link MITECO) because the research on the biochemical composition of the macroalgae samples and its effect on the microbial communities found in the surface of *Fucus* is under the scope of the Spanish regulations. An access authorization was requested on the 26th June 2019. The CNA requested complementary information regarding the GPS coordinates of the sampling and an amendment of the request was submitted on the 24th July 2019. The authorization (PIC and MAT) was granted on the 23rd September 2019 (reference ESNC43) and the IRCC was uploaded to the ABS clearing house and sent to the user (ABSCH-IRCC-ES-247984-1).

Case 8. Evolution of ascidians under ocean warming and ocean acidification (Spain)

Background

Atmospheric carbon dioxide levels have reached unprecedented levels of ~400 ppm and are expected to increase up to 730-1020 ppm, by 2100. Concomitantly, ocean CO_2 uptake has increased and as a result, ocean surface pH is projected to decrease 0.13-0.42 pH units, by the end of the 21st century. These future changes in ocean's chemistry are expected to pose severe impairments to marine biota by directly affecting physiological related processes and over processes to which growth/reproduction depend upon. Moreover, increasing greenhouse effect has significantly contributed to global warming and subsequently ocean warming (OW). As a result, sea surface temperature is expected to increase by 0.71-2.73°C, by 2090. Under these future environmental conditions, marine species possess a limited capacity to maintain their performance and limited options to survive. Therefore, it is imperative to address the synergistic, cumulative or even antagonistic effects of climate change drivers/stressors, under a broader point of view, i.e. involving species ontogenic responses under a multigenerational perspective in opposition to single species/life stage, single-stressor and short-term experimental trials. This case study aims to experimentally describe *Ciona robusta* potential for adaptive evolution, under OW and OA conditions, within a multigenerational perspective and to develop a conceptual model of organism adaptation to marine climate change. *C. robusta* samples were collected by ECIMAT-UVIGO during 2019 in order to tackle the following research goals: i) setting up a *C. robusta* ancestral population; ii) *C. robusta* laboratory acclimation; iii) establish selection treatments (control, OA, OW and OA/OW scenarios); iv) multigenerational *C. robusta* development; v) perform critical testing for adaptation. Further stages comprised the determination of developmental/reproductive endpoints; the assessment of physiological endpoints; the assessment of gene expression levels and genetic signatures of selection; the determination of neurophysiological endpoints to end with data analysis and results.

Question:

Do all these research activities require an access authorization in Spain?

Answer:

No, some of the activities may be out of scope of the Spanish Royal Decree 124/2017. Some of the goals fall into the exception of taxonomic activities. However, others such as the assessment of gene expression levels and genetic signatures of selection in response to the effect of global climate change are IN SCOPE of the Royal Decree 124/2017. An access authorization was requested on the 27th June 2019. The CNA requested complementary information regarding the GPS coordinates of the sampling and an amendment of the request was submitted on the 27th July 2019. The authorization (PIC and MAT) was granted on the 23rd September 2019 (reference ESNC44) and the IRCC was uploaded to the ABS clearing house and sent to the user (ABSCH-IRCC-ES-247989-1).

Case 9. Negotiation of PIC and MAT a posteriori: Utilization of samples from stranded mammals stored in Biobanks (Spain).

Stranded mammals are monitored by different academic organizations and/or NGOs with the aim to analyse evolution over time and ultimately to analyse the reasons that lead these animals to death. Necropsies can give information about the cause behind these casualties although in many cases the reasons may remain elusive. Tissue biobanking is a (cryogenization and lyophilisation of tissues, histological processing) is a good alternative to allow downstream research of causes and drivers of such strandings. The Biscay Bay Environmental Biospecimen Bank of the Plentzia Marine Station has an agreement with a local NGO (AMBAR) that carries out monitoring of stranded mammals in the Basque coastline. Through this agreement, all recovered corpses are necropsied in the Plentzia Marine Station and tissues stored in the Biobank. Such tissues are available for genetic, genomic, biochemical, histological and chemical analysis. For some species, this is valuable reference material not only environmentally but also phylogenetically to understand the molecular evolution of mammals. Of course, stranding of a marine organism cannot be anticipated so access (PIC) cannot be anticipated. In this circumstance, the samples are collected without the permissions or they are lost. In the case of the Basque Autonomous Region sampling of marine mammals is delegated and authorized by the regional government to a NGO (AMBAR) to analyse the possible causes of death. Then, by an agreement with PiE-UPV/EHU such samples are stored in the Biscay Bay Environmental Biospecimen Bank

Question:

Can a framework PIC and MAT be negotiated for research purposes on the whole collection of marine mammals in the collection.

Answer:

PIC and MAT are necessary for genetic material utilization if the samples come from Spanish jurisdictional waters and belong to wild taxa. Storage in the Biobank is not considered utilization under the Spanish ABS regulations, so the date of access to these genetic resources in the Biobank marks the need to negotiate PIC and MAT. The Spanish authorities do not issue "umbrella" PICs and MATs and the permits have to be awarded in the case by case situation being important, the identification of the user and the specific utilization of the genetic resource that cannot be anticipated in a generic a priori permission. Any user willing to utilize the samples will have to obtain prior to access the corresponding CITES permits, being marine mammals protected species.

Case 10. Utilization of genetic resources accessed as commodities in the market (Spain)

Background:

Biological resources (fish, shellfish, algae) accessed as commodities from extractive fisheries or from aquaculture facilities made available in the markets for human or live-stock consumption are considered OUT OF SCOPE under ABS regulations. In many circumstances, researchers access to their study biological resources made available as commodities in the market to utilize them as genetic resources.

Question:

Access to Spanish wild taxa in the commercial market for utilization as genetic resources requires PIC and MAT?

Answer:

This issue has been object of three questions to the Spanish national contact point, in regard to fish and molluscs acquired in supermarkets. The first two answers pointed out that this question required juridical consultation by the Spanish Ministry of Ecological Transition to the State Council of Spain to understand the implications under the Spanish ABS regulations.

Finally, a response was received on the 15th of June of 2020 specifying that the ABS regulations in the Royal Decree 124/2017, of February 24, and its indications on access

are applicable also to Spanish wild taxa purchased in the market and utilized as genetic resources. IT IS IN SCOPE.

The EU has recently published a Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 that among other addresses this point that was not clear before (https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021XC0112(02)&from=EN).

Case 11. Screening of fungal biodiversity and isolation of metal sequestering species from marine sediments (Spain)

Background:

Electronic waste (e-waste) in general comprises of old end-of-life computers, audio and video products, refrigerators, freezers, mobile phones etc. In the European Union, total amount of e-waste generation ranges from 5-7 million tons per annum or about 14-15 kg per capita and is expected to grow at the rate of 3-5% per year. The physical composition of e-waste is very diverse and contains over 1000 different substances. Heavy metals form a significant part of inorganic fraction accounting for 20-50%. Whether hazardous or precious, heavy metals are non-renewable and finite resource and therefore eventually become very valuable. It is, therefore an urgent need to manage e-waste in a formal, systematic and eco-friendly manner by way of removing/recycling the precious metals from waste streams. The advantages of biosorption are: (i) non-living biomass are not subject to toxicity limitations; (ii) costly nutrients and aseptic conditions are not required for the cultivation of biomass; (iii) the process is very rapid; (iv) waste from fermentation industry and nature could be cheap source of biomass; (v) biosorption could be operated at wider range of pH, temperature and target compound concentration; (vi) established theories, conventions and formulae could be applied to the adsorbent. The possible contribution of biotechnology as a clean/sustainable alternative can be a solution applying bioremediation methods for the rehabilitation of highly polluted marine sites using bacteria and fungi. It is proposed that marine fungi from polluted coastal areas that can grow and incorporate heavy metals from e-waste, can be used for easy waste recovery from the biomass. Preliminary results have demonstrated the capability of some fungi strains isolated from Bagnoli coast (Naples, Italy) which is a highly polluted area post industrialization, to grow and colonize e-waste fragments in vitro.

The proposal was to isolate fungi species with capacity to accumulate metals from the metal polluted estuaries of the Bilbao estuary. This research was proposed by Italian researchers to conduct research in the environment and in the laboratory (including laboratory exposure experiments and uptake chemical analysis) in Spain. In this case, the Italian group is the user group and the Spanish team is only providing service.

Questions:

Can be PIC obtained for access to an environmental sample without indicating specific taxon/taxa?

The analysis of metal bioaccumulation capacity in fungi is considered utilization of genetic resources?

Answer:

-Project is considered IN SCOPE (screening of marine sediments, selection of bioaccumulating strains and analysis of metal bioaccumulation characteristics in isolated strains considered utilization) and PIC and MAT need to be negotiated.

-Specifying the taxon/taxa was not necessary

Procedure:

-Online petition to the Spanish National Focal Point is available for Spanish citizens.

-The request was done from the service providing organization (PiE-UPV/EHU) taking advantage of the online request platform for National.

-Users and their institution were incorporated as part of the research team.

-Specific methodology to be applied and sampling GPS location information needs to be provided.

-Exact resource access period needs to be stablished.

-There was no need to specify exact taxa or taxon to be utilised as it is a screening project. It was specified that fungi were going to be assessed and there was a need to specify whether they were microscopic fungi.

Main constraint found:

-Lack of information and request forms in any other language than Spanish.

-The impossibility for non-Spanish to complete the request on-line as electronic national identity is compulsory,

The necessary PIC and MAT for non-commercial use were obtained and the IRCC was obtained ABSCH-IRCC-246278-1.

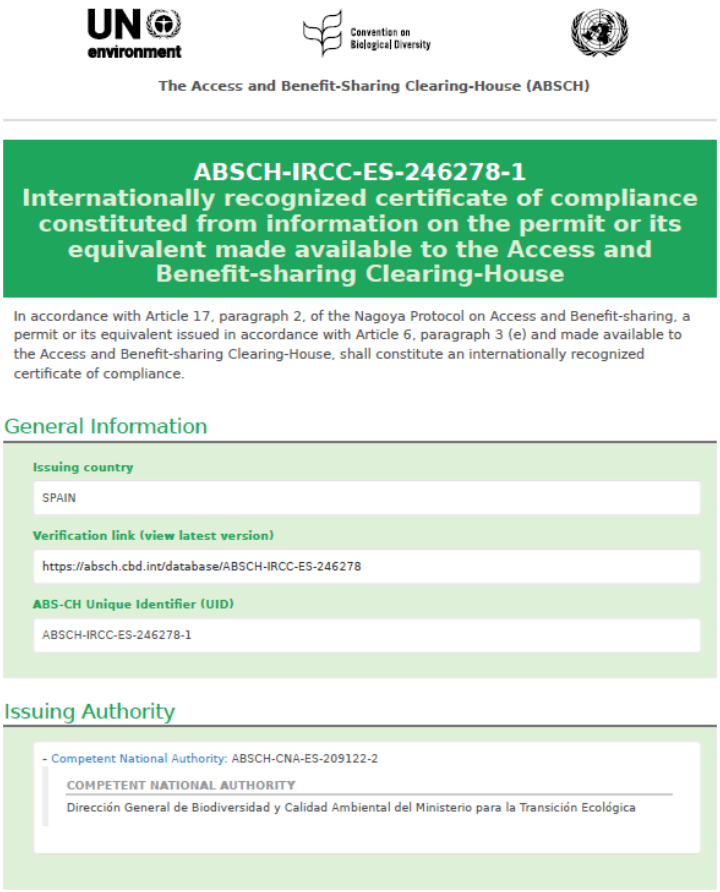

UN environment
Convention on Biological Diversity
The Access and Benefit-Sharing Clearing-House (ABSCH)
ABSCH-IRCC-ES-246278-1
Internationally recognized certificate of compliance constituted from information on the permit or its equivalent made available to the Access and Benefit-sharing Clearing-House
In accordance with Article 17, paragraph 2, of the Nagoya Protocol on Access and Benefit-sharing, a permit or its equivalent issued in accordance with Article 6, paragraph 3 (e) and made available to the Access and Benefit-sharing Clearing-House, shall constitute an internationally recognized certificate of compliance.
General Information
Issuing country
SPAIN
Verification link (view latest version)
https://absch.cbd.int/database/ABSCH-IRCC-ES-246278
ABS-CH Unique Identifier (UID)
ABSCH-IRCC-ES-246278-1
Issuing Authority
- Competent National Authority: ABSCH-CNA-ES-209122-2
COMPETENT NATIONAL AUTHORITY
Dirección General de Biodiversidad y Calidad Ambiental del Ministerio para la Transición Ecológica

Figure 5. IRCC on the screening of microscopic fungi species from marine sediments inside an estuary. No specific taxa were indicated.

Case 12. Pink sea fan population structure in the Cantabrian sea and in the Biscay Bay through genotyping (Spain)

Background

A group or researchers form the UK is conducted molecular studies of variation and connectivity in the pink sea fan (*Eunicella verrucosa*) European populations and were willing to obtain some samples from around the Biscay Bay around the Basque Country and/or Cantabria and Galicia. Sampling requires collection of small clip (around 5 cm) from each living sea fan for DNA extraction and genotyping.

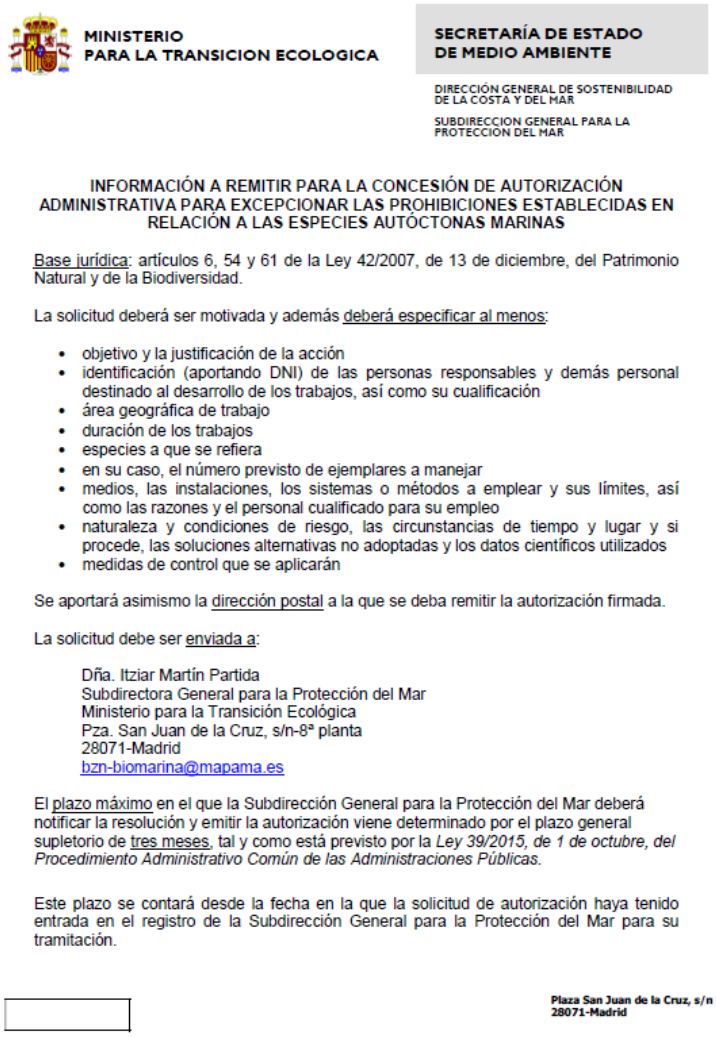
Question:

Does molecular genotyping suppose utilization of genetic resources under the Spanish ABS regulations?

Answer:

Even if molecular approaches are applied analysing the gene sequence of a given species if they are used for genotyping or phylogenetic studies they are understood as taxonomic research and therefore are OUT OF SCOPE.

However, access to Spanish biological resources requires permission to collect marine autochthonous species under communication of information on location, sampling team, duration of sampling, aim of study etc., very similar to those required to negotiate PIC.



MINISTERIO
PARA LA TRANSICION ECOLOGICA

SECRETARÍA DE ESTADO
DE MEDIO AMBIENTE

DIRECCIÓN GENERAL DE SOSTENIBILIDAD DE LA COSTA Y DEL MAR

SUBDIRECCION GENERAL PARA LA PROTECCION DEL MAR

INFORMACIÓN A REMITIR PARA LA CONCESIÓN DE AUTORIZACIÓN ADMINISTRATIVA PARA EXCEPCIONAR LAS PROHIBICIONES ESTABLECIDAS EN RELACIÓN A LAS ESPECIES AUTÓCTONAS MARINAS

Base jurídica: artículos 6, 54 y 61 de la Ley 42/2007, de 13 de diciembre, del Patrimonio Natural y de la Biodiversidad.

La solicitud deberá ser motivada y además deberá especificar al menos:

- objetivo y la justificación de la acción
- identificación (aportando DNI) de las personas responsables y demás personal destinado al desarrollo de los trabajos, así como su cualificación
- área geográfica de trabajo
- duración de los trabajos
- especies a que se refiera
- en su caso, el número previsto de ejemplares a manejar
- medios, las instalaciones, los sistemas o métodos a emplear y sus límites, así como las razones y el personal cualificado para su empleo
- naturaleza y condiciones de riesgo, las circunstancias de tiempo y lugar y si procede, las soluciones alternativas no adoptadas y los datos científicos utilizados
- medidas de control que se aplicarán

Se aportará asimismo la dirección postal a la que se deba remitir la autorización firmada.

La solicitud debe ser enviada a:

Dña. Itziar Martín Partida
Subdirectora General para la Protección del Mar
Ministerio para la Transición Ecológica
Pza. San Juan de la Cruz, s/n-8ª planta
28071-Madrid
bzn-biomarina@mapama.es

El plazo máximo en el que la Subdirección General para la Protección del Mar deberá notificar la resolución y emitir la autorización viene determinado por el plazo general supletorio de tres meses, tal y como está previsto por la *Ley 39/2015, de 1 de octubre, del Procedimiento Administrativo Común de las Administraciones Públicas.*

Este plazo se contará desde la fecha en la que la solicitud de autorización haya tenido entrada en el registro de la Subdirección General para la Protección del Mar para su tramitación.

Plaza San Juan de la Cruz, s/n
28071-Madrid

Figure 6. Spanish Government document where all the required data for the sampling of an autochthonous species are indicated.

Case 13. Retrospectivity and nationality of culture collections. Ex-situ access to Spanish genetic resources kept in culture collections in two countries and isolated previous to Spanish ABS regulations (Spain)

Background

Emiliana huxleyi is a ubiquitous unicellular algal species that shows extensive genomic variability around its wide ambit of distribution. In this sense, different strains collected in different latitudes, years of periods of year can display very different capacity for the production of certain metabolites. The aim is to isolate and analyse the capacity to produce fucoxanthines with anticancer and antioxidant capacity in strains from two different Spanish localities (Canary Islands and in the Abra of the Bilbao estuary) and stored in two culture collections (Basque Algal Culture in Spain condition and Roscoff Culture Collection in France).

One of the strains was isolated in the Abra of Bilbao in 2002, prior to the ABS regulations in Spain and Spanish ratification of the Nagoya protocol and is since then deposited in the Basque Microalgae Culture Collection. Another strain was isolated form waters in the Canary Islands in 2010, also before the approval of the Spanish ABS regulations but deposited in a French collection.

Questions:

Genetic resources were accessed in the field previous to Spanish ABS regulation, does retrospectivity apply here? Is the access date marked by the day of access to the resources for utilization from the ex-situ collection?

Do the same rules apply for Spanish and non-Spanish culture collections?

Answer:

1.- Any Spanish genetic resource IN A SPANISH ex situ collection and collected before Royal Decree 124/2017 of February 24, could be utilized for own purposes without any need of access authorisation. OUT OF SCOPE.

2.- Any Spanish genetic resource IN A SPANISH ex situ collection and collected before Royal Decree 124/2017 of February 24, to be transferred and utilized outside the institution holding the ex situ collection will require to obtain permission. IN SCOPE.

3.- Spanish genetic resource in an ex situ collection OUTSIDE SPAIN and collected before Royal Decree 124/2017 of February 24, could be utilised for own purposes without any need of access authorisation. OUT OF SCOPE.

4.- Any Spanish genetic resource in an ex situ collection OUTSIDE SPAIN and collected before Royal Decree 124/2017 of February 24, to be transferred and utilized outside the institution holding the ex situ collection will require to obtain permission. OUT OF SCOPE.

Spanish collections are clearly under more constrains than non-Spanish ones in this case with important implications on the need for retrospective compliance.

Case 14. Screening of algal strains with anti-pathogenic activity in the Basque Microalgae Culture Collection (Spain)

Background

The Fundación-Medina, public private partnership leader in the search of pharmaceuticals of microbial origin. In a research project with the Universities of the Basque Country and Almeria they want to select microalgae with bioactive properties against a panel of pathogens. The algae to be screened and with potentially new bioactive compounds belong to existing collection, the Basque Microalgae Culture collection. Positive strains will be analysed based on NMR metabolome and biochemical composition preliminary evaluation of potential relationships between bioactivities and metabolome will be stablished.

The OSMAC strategy will then be applied to stimulate the synthesis of metabolites with associated bioactivity. This will be followed by a fractionation and structural determination of bioactive compounds. Best extraction, pre-fractionation and dereplication procedures will be stablished. Then, the purification of bioactive compounds will be accomplished with different solvents and chromatography fillers following a process guided by bioactivity check outs through bioassays accompanied by structural elucidation of bioactive compounds.

The projects aims to run a pilot proof of concept that will include a scaling up process for biomass production, harvesting, extraction of metabolites of interest and bioactivity screening. The change of scale and type of illumination (solar or led) fluid dynamic conditions and configuration of the photobioreactor in crop yield and in the levels of metabolites of interest produced will be evaluated. Metabolomic analysis of harvested biomass will be performed to determine NMR-based biomarkers associated with the effect of scale and abiotic factors on the cellular biosynthetic machinery. The goal is to obtain the stable supply of bioactive compounds from at least two algal strains.

Regarding the cultures the intention is to analyse around 200 strains from different groups of microalgae and cyanobacteria in collection with the Basque Microalgae Culture Collection (www.ehu.es/bmcc), many of them without identification at the species level, included in the following divisions: Haptophyta, Bacillariophyta, Dinophyta, Chlorophyta, Chrysophyta, Ochrophyta.

Question:

How should this kind of project be dealt with to work with Spanish genetic resources in a Spanish culture collection? The origin of the strains is varied geographically (regional administration within Spain) and time of sampling (anterior to the adoption of Spanish ABS regulations and present times).

Answer:

1.- Any Spanish genetic resource IN A SPANISH ex situ collection and collected before or after Royal Decree 124/2017 of February 24, to be transferred and utilized outside the institution holding the ex situ collection will require to obtain permission. IN SCOPE.

2.- If the exact strains in the culture collection that are going to be utilized cannot be specified, and if potentially any of the strains in collection could be utilized, then a catalogue of the collection should be provided during the application. If an online catalogue or search portal is available the web address of the portal should be provided. In case of this not being available the list of strains in the collection should be provided. In all cases, site of collection, person(s) who sampled and date of sampling needs to be provided.

3.- The Ministry acknowledges that external users are accessing an ex situ collection placed in an Institution in the Basque autonomous region and may consider the possibility of granting access to strains collected and stored without ABS permission, before and after the adoption of the Spanish regulation, and in different regional jurisdictions, as a single access permit to be dealt by the national competent authority in the Basque autonomous region.

A similar access permission is being dealt with but with a Spanish pharmaceutical company that does not wish its name included in this document.

Case 15. Screening of coastal environmental samples for Biocontrol: Spain vs France.

Background

The French company "Immunerise", specialized in bioprospection and screening of bioactive substances and organisms applicable in biocontrol in land crops (vineyards) presented a PIC and MAT request to the French ABS national authorities. The needed documentation was obtained and an IRCC issued under number ABSCH-IRCC-FR-247228-1 for non-commercial use. The CERFA application presented requested access to genetic resources (no-taxon specified) in coastal waters of 26 of the 95 Departments in which the metropolitan France is divided and to its 9 overseas territories.

Question:

How should this kind of permit be dealt in Spain, where the competence is divided between the Spanish state administration and the regional governments (20 national competent authorities)?

Should each access to each of the territories within the scope of each competent authority be dealt in separate?

Answer:

There is no possibility to grant a general ABS permit to access genetic resources in Spain (in its whole as a country) without delimiting exact location of sampling. In Spain there is one single ABS national focal point but 20 ABS national competent authorities linked to the regional (autonomous region or city in the case of Ceuta and Melilla) administration in charge. The Spanish Ministry of Ecological Transition is the central point receiving requests, which then are distributed to relevant authorities.

Permits can be issued for projects spanning different jurisdictions but gross geographical scope has to be provided delimiting the range of authorities involved. This is more complicated in the marine environment in connection to the intertidal zone, as in some circumstance is not the regional authority that is responsible but the central government one (harbour areas). Other administrations may apply in case of involving access to protected areas.

It must be remembered that ABS permits do not grant sampling permits, which need to be arranged independently with the administration in charge.

Case 16. Phylogenetic analysis of porifera from Brazil.

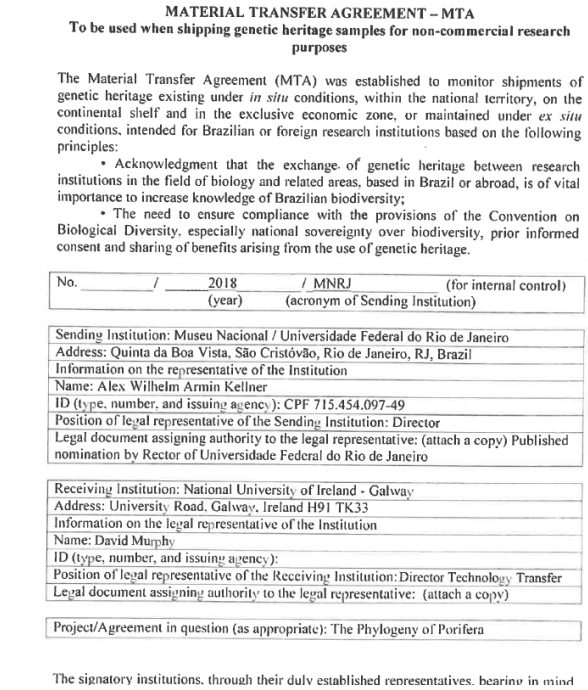
Background

Brazil is not party to the Nagoya protocol although it has initiated action to do so as in September 2020. In any case, it has got very stringent laws on access and benefit sharing of national genetic resources. Brazil has got a Biodiversity law, with a standard Material Transfer Agreement (MTA) form to be filled as regulatory or administrative measure. The purpose of the (MTA) is the shipment of genetic heritage samples identified in the Shipment Invoice(s) pursuant to the art. 12, IV, of Law no. 13.123, of 2015 and will integrate the shipment registration at National System for the Management of Genetic Heritage and Associated Traditional Knowledge - SisGen. Through the MTA the recipient of genetic resources needs to acknowledges that he / she shall:

- Partner with a national Brazilian scientific and technological research institution to perform research or technological development from the genetic heritage sample(s), or associated traditional knowledge, if the recipient is a foreign legal entity;

- Notify through sisgen.gov.br, and share benefits, in case of commercial exploitation of finished product or reproductive material developed from the samples subject to the Shipment Invoice(s) attached to the MTA;
- Obtain the Prior Informed Consent (PIC) from the provider of the traditional local or Creole varieties or locally adapted or Creole breeds, to perform research or technological development, if the samples are not used in agricultural activities; and
- Obtain the Prior Informed Consent (PIC) from the provider in the case of research or technological development related to traditional knowledge associated with the samples subject to the Shipment Invoice(s) attached to the MTA.

The University of Galway (NUIG) was interested in conducting non-commercial phylogenetic analyses of Porifera from Brazil, and for that UG partnered with the National Museum, Federal University of Rio de Janeiro.



MATERIAL TRANSFER AGREEMENT – MTA
To be used when shipping genetic heritage samples for non-commercial research purposes

The Material Transfer Agreement (MTA) was established to monitor shipments of genetic heritage existing under *in situ* conditions, within the national territory, on the continental shelf and in the exclusive economic zone, or maintained under *ex situ* conditions, intended for Brazilian or foreign research institutions based on the following principles:

• Acknowledgment that the exchange of genetic heritage between research institutions in the field of biology and related areas, based in Brazil or abroad, is of vital importance to increase knowledge of Brazilian biodiversity;

• The need to ensure compliance with the provisions of the Convention on Biological Diversity, especially national sovereignty over biodiversity, prior informed consent and sharing of benefits arising from the use of genetic heritage.

No. _____ / _____2018_____ / MNRJ _____ (for internal control) (year) (acronym of Sending Institution)
Sending Institution: Museu Nacional / Universidade Federal do Rio de Janeiro
Address: Quinta da Boa Vista, São Cristóvão, Rio de Janeiro, RJ, Brazil
Information on the representative of the Institution
Name: Alex Wilhelm Armin Kellner
ID (type, number, and issuing agency): CPF 715.454.097-49
Position of legal representative of the Sending Institution: Director
Legal document assigning authority to the legal representative: (attach a copy) Published nomination by Rector of Universidade Federal do Rio de Janeiro

Receiving Institution: National University of Ireland - Galway
Address: University Road, Galway, Ireland H91 TK33
Information on the legal representative of the Institution
Name: David Murphy
ID (type, number, and issuing agency):
Position of legal representative of the Receiving Institution: Director Technology Transfer
Legal document assigning authority to the legal representative: (attach a copy)

Project/Agreement in question (as appropriate): The Phylogeny of Porifera

The signatory institutions, through their duly established representatives, bearing in mind

Figure 7. Brazilian Material Transfer Agreement form where all the data for the sample transfer must be indicated.

Lessons learned: conclusions.

The use cases studied during the EBB project have provided learning lessons that have been incorporated into an EBB deliverable "D6.4 Report on application and EBBs contribution to Best Practice Guidelines". The lessons learned for a possible user can

be summarised in six steps (step by step guide of EBB) that need to be taken (https://www.embrc.eu/sites/default/files/publications/A-step-by-step-guide-to-ABS-compliance-when-utilizing-marine-genetic-resources.pdf):

1.- Where do the resources used for my Project come from?

2.- Is my Project impacted by ABS?

3.- If so, where do I find information about ABS?

4.- If required, how do I negotiate ABS permits?

5.- How do I demonstrate ABS compliance?

6.- How do I manage ABS documentation

Remember always to:

-Check for the information available in the ABSCH for the country providing your genetic resources.

-Regulations and definitions of different aspects (from the definition of genetic resource to the definition of utilization) vary from country to country.

-Get in touch with the pertinent national Nagoya focal point well in advance in your project.

-National Nagoya focal point when accessible are there to help you.

-Complying with Nagoya involves additional time and costs for researches.

-Compliance with ABS regulations requires planning your experiments early enough.

-Explain your research purpose and protocols.

-Language could be a barrier.

-Collaboration with researchers in providing country could be helpful.

-Track all your communications, also those that do not receive any response.

-If possible obtain your resources from a culture collection with ABS protocols in place.

-You will have to proof your due diligence at different check points during your normal research activity depending on the providing country.