Conditions for the Transfer of Strains from the CCVIEO Collection

The VGOHAB group reserves the right to distribute strains based on the intended use by the applicant. To request strains, applicants must complete the form available on the website, clearly specifying the intended purposes for the strains. This information must include:

- 1. The person or research/technological team that will conduct the activities with the requested strains.
- 2. The type of study or tests to be conducted, explaining the research project, technological initiative, or other program under which the activities are framed.
- 3. A detailed explanation of the study or tests to be performed with the strains.
- 4. Information on whether any commercial use will result from the use of the strains. In such cases, the isolation and production of compounds derived from a CCVIEO strain, in its original form or using genetic manipulation techniques, is not permitted without a negotiated agreement between the user and the Spanish Institute of Oceanography.

The distribution of strains will not entail financial compensation if carried out within the framework of collaborations in research or technological projects or any other type of collaborative programs, including publications. In other cases, the group reserves the right to request a financial contribution, which will be communicated once the request is received.

The VGOHAB research group performs taxonomic identification of the cultures, though this does not certify the accuracy of such identification (at the species level) in all cases. In case of doubt, the user must confirm this taxonomic information through their own analyses and, in the event of discrepancies, notify VGOHAB.

The applicant is responsible for ensuring that the live material provided by CCVIEO is handled safely and by sufficiently trained personnel. This is particularly important in the case of toxic species.

The user must cite the CCVIEO strain code in all publications and patents derived from the material. VGOHAB requests and appreciates this information.

Convention on Biological Diversity and Nagoya Protocol

The fair and equitable sharing of the benefits arising from the utilization of genetic resources is one of the three objectives of the Convention on Biological Diversity (CBD). The CBD recognized the sovereignty of countries over their genetic resources, thus making access to these resources subject to the national regulations of each country. The Nagoya Protocol (NP) came into force on October 12, 2014, and develops the third objective of the CBD, which is to provide guidance on access to genetic resources and the fair and equitable sharing of benefits arising from their utilization (ABS, Access and Benefit Sharing).

This Protocol aims to strengthen compliance with national access regulations of the provider countries of genetic resources by requiring the implementation of compliance and monitoring measures in third countries where these genetic resources are utilized.

Thus, the signatory countries of the Protocol commit to ensuring that genetic resources used within their jurisdiction are accessed in accordance with the national framework of the country where the resource originated, thereby committing to combat biopiracy.

To this end, they must establish checkpoints within their jurisdiction where users of genetic resources must present information on the legal access to these resources, primarily through the international certificate of compliance. Much of the legislation on this matter, as well as the contact details of the responsible authorities in each signatory country, can be consulted on the ABS Clearing-House website.

In the case of Spain, access to Spanish genetic resources is regulated by Law 33/2015 on Natural Heritage and Biodiversity and RD 124/2017, which regulates access to genetic resources from wild taxa and the sharing of benefits arising from their utilization. The access permit is requested through the electronic headquarters of the MITECO.

Regarding the control mechanisms provided in the Nagoya Protocol, the measures for the entire European Union are contained in Regulation (EU) No 511/2014, which came into force along with the NP on October 12, 2014, and establishes the compliance measures for users regarding access to genetic resources and the fair and equitable sharing of benefits arising from their utilization in the European Union.

This means that when genetic resources are used, in accordance with the definition included in Royal Decree 124/2017, prior authorization for access must be requested before utilizing them, and subsequently, depending on the user's situation (research funding recipient; final product development stage; patent application), the due diligence declaration form must be submitted.

It is the responsibility of the user of biological resources supplied by the scientific-technical service for the sale of microalgae strains (CCVIEO collection, Vigo Oceanographic Center, IEO-CSIC) to ensure that their use complies with the ABS legislation and utilization control of the country of origin of the genetic resource.

Information for submitting the due diligence declaration form can be found on the Ministry's website.

How does Spanish access regulation apply to resources in the CCVIEO collection?

Genetic resources of Spanish origin in the collection, collected and deposited therein before the entry into force of Royal Decree 124/2017, of February 24, and accessed by a third party for utilization after March 15, 2017, are within the scope of the aforementioned Royal Decree. Therefore, the user/institution/company accessing a Spanish genetic resource from CCVIEO for utilization after March 15, 2017, even if it was established before that date, must request administrative access authorization in accordance with Royal Decree 124/2017, of February 24.

It is important to note that access authorization for genetic resources under this regulation is only necessary if there is an intention to utilize these genetic resources. Utilization of genetic resources is defined as "conducting research and development activities on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology, as stipulated in Article 2 of the Convention on Biological Diversity." (Article 2 of RD 124/2017, of February 24).

The application for access authorization to genetic resources can be made through the MITECO electronic headquarters. There are two procedures for requesting access authorization to Spanish genetic resources from wild taxa, depending on whether their utilization is for commercial or non-commercial purposes. In both cases, the application form can be downloaded from the following website: MITECO Access to Genetic Resources.

For resources from third countries, it is recommended to access this link (ABS Clearing House: <u>ABS Clearing-House</u>) where the information of each country, whether they are signatories of the Nagoya Protocol, their national legislation (whether or not they are signatories of the Protocol), and their corresponding National Focal Points can be found.

Useful Resources:

- Real Decreto 124/2017, do 24 de febreiro, relativo al acceso a los recursos genéticos procedentes de taxones silvestres y al control de la utilización.
- Preguntas y respuestas en relación con la aplicación del Real Decreto 124/2017, de 24 de febrero, relativo al acceso a los recursos genéticos procedentes de taxones silvestres y al control de la utilización.
- Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16
 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union
- Texto del Protocolo de Nagoya