



The mission of IP is to advance knowledge on prevention and treatment of diseases, primarily infectious diseases, through public health research, education and training, and the development of research applications. The CRBIP is the custodian of microbial collections and distributes microbial strains or their derivatives (e.g. nucleic acids), i.e. microbial genetic resources within the meaning of the Convention of Biological Diversity (CBD), to users for specific research, teaching, or quality control purposes. Most of these strains have been deposited at CRBIP by depositors from around the world over a period spanning more than 75 years. The CRBIP biobanking activities, framed by an ISO 9001:2015 certification, focus on acquisition, preservation and distribution and do not constitute “utilization” in the sense of the NP. Moreover, no intended end use is ever specified by the depositor at the time of the deposit. Therefore, the role of the CRBIP is that of an intermediary who can only inform the end user about the origin and obligations related to the utilization that the user will make.

It is in this sense that the CRBIP takes all measures to support compliance with Regulation (EU) 511/2014, also considering Implementing Regulation (EU) 2015/1866. Consequently, the NP related obligations always remain with the User to whom the CRBIP distributes a microbial genetic resource.

The CRBIP has made best efforts by contacting the focal points of all countries of origin (provenance) of the historical strains of which CRBIP is the custodian. The CRBIP considers best efforts have been deployed when we have tried to obtain an answer whether there were any ABS laws or procedures in place in the country of origin, and the date of their entry into force, from a National Focal Point at three independent attempts, with at least one month interval between two attempts. Even when all three attempts have remained without answer, we continue trying, by re-contacting the relevant focal points once a year with this question.

We consider that there are no known Nagoya Protocol restrictions when the genetic resource has been collected outside the scope of the Nagoya Protocol (from a time perspective or because the country is not a Nagoya Protocol Party) or when there are no documents available because the country has not imposed ABS restrictions, we have not found any other applicable ABS restrictions on the CBD ABS Clearing House portal, and the Focal Point has not answered our requests.

In parallel, the CRBIP has made an extensive review of applicable national regulations of all countries of provenance of microbial genetic resources or which it is the custodian, and communicates all relevant information to the subsequent “user” upon distribution of a strain. Once a year, the CRBIP checks the CBD ABS Clearing House portal and updates its communication documents based on any updates that may have been added on the portal, and bearing a visible date.

For all deposits of strains since the entry into force of the NP, the CRBIP has been requiring verification of NP compliance from the depositor.



We consider a utilization of a microbial genetic resource to be in the scope of NP when ALL the relevant criteria of the Regulation (EU) 511/2014 are met, according to the Guidance document on its implementation:

- Material scope (article 2.3)
- Temporal scope (article 2.2)
- Geographic scope 1 (article 2.1)
- Geographic scope 2 (article 2.5)
- Personal scope (article 2.4)
- Activity scope ("utilization" = R&D)

In alignment with Regulation (EU) 511/2014, the CRBIP considers biological materials of human origin, such as blood, urine, saliva or stool, to be out of the scope of the NP. Therefore, we consider microbial molecules, such as proteins or metabolites that may be found in such primary human specimens to be out of the scope of the NP. Human antibodies are also considered out of the NP scope, even when they are specific against a microbial strain. Only microbial strains that have been isolated from a primary source, including human specimens, fall within the scope of the NP when they are "utilized" as defined by the NP. Accordingly, we consider that use of strains for purposes of internal quality control or External Quality Assurance programs do not constitute "utilization" in the sense of the NP. Likewise, the use of microbial genetic resources solely for taxonomy purposes does not constitute "utilization".

References:

A. Sirakaya. Balanced options for access and benefit sharing: stakeholder insights on provider country regulation. *Frontiers in plant science* 2019;10:1175.

Report from the Commission to the European parliament and the Council, <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52019DC0013>

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, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0511&qid=1768201860260>

Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices, https://eur-lex.europa.eu/eli/reg_impl/2015/1866/oj/eng

Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52016XC0827%2801%29&qid=1768202017830>