MAN.01 - Brazilian Genetic Heritage Act and its impact on Bio-Manguinhos' scientific publications

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Introduction: The Brazilian Genetic Heritage Act (13.123) was enforced on November 2015. It seeks to protect and to encourage the sustainable use of Brazilian biodiversity. The Act defines Genetic Heritage (GH) as information on the genetic origin of vegetal, animal and microbial species, or species of other nature, and on the substances derived from the metabolism of those living beings. Therefore, the Act encompasses every scientific activity utilizing viruses/ bacteria/fungi which have been collected from Brazilian individuals or endogenous animals; Brazilian genetic sequences from GenBank*; *in silico* research of endogenous viruses/bacteria/fungi; microorganisms engineered with endogenous genetic sequences; antibodies produced by endogenous animals, domesticated species and spontaneous populations found in Brazilian territory. Among the legal demands there is a mandatory registration in the National System for the Management of Genetic Heritage and Associated Traditional Knowledge (SisGen) prior to the disclosure of either final or parcial results of researches using endogenous GH.

Objective: To evaluate the impact of the Brazilian Genetic Heritage Act on Bio-Manguinhos' scientific publications. Therefore, this abstract addresses the role of Bio-Manguinhos through its Office of Technology Transfer (NIT-Bio) on the regularization/registration of dissertations from the Professional Master Course in Immunobiological Technology (MPTI) and abstracts from the Annual Scientific and Technological Seminar (SACT) whenever they address genetic heritage.

Methodology: In this evaluation, the dissertations submitted to the MPTI (2003 through 2015) as well as the abstracts submitted to the SACT (2013 through 2018) were verified by NIT-Bio in order to identify the access to genetic heritage. Each dissertation/abstract was read, performing a case-by-case evaluation. When doubts have arisen, they were forwarded to Fiocruz's Genetic Heritage Work Group to solution. The authors of the selected dissertations/abstracts were informed by e-mail and were guided to proceed the regularization (for GH access initiated before November 17th, 2015) or the registration (for GH access initiated after November 17th, 2015) on SisGen, with NIT-Bio guidance.

Results: Within the selected periods, 32 dissertations out of a 121 from MPTI had accessed the Brazilian GH (26%). Out of the 418 abstracts from SACT, 289 were elaborated by Bio-Manguinhos employees, amongst them, only 93 have accessed the Brazilian GH (32%). As a result, 23 registrations and 16 regularizations entered the SisGen. It should be noted that registrations and regularizations had more than one dissertation or abstract.

<u>Conclusion</u>: The access to the Brazilian Genetic Heritage occurred in 26% of the dissertations submitted to MPTI and in 32% of the abstracts submitted to SACT, indicating that the Brazilian Genetic Heritage Act impacts on. Therefore, researchers should follow the institutional guidance regarding scientific publications involving Brazilian GH in order to avoid the sanctions enforced by the Act.

Keywords: Genetic Heritage; Scientific publications; Bio-Manguinhos

