

BRAZIL



The Brazilian PTO published, in its Official Bulletin No.2604, dated 1 December 2020, a review of the Guidelines for the Examination of biotechnology patent applications.

The purpose of this new version is to update and detail the current Biotechnology Guidelines. The Brazilian Guidelines setting out the understanding of the BRPTO on Biotechnology Inventions were firstly published on 12 March 2015, using Rule 144/2015. However, after a public consultation carried in 2019, the Brazilian PTO has reviewed said Guidelines, resulting in this updated version. The new Guidelines have come into force on 1 December, 2020.

The main relevant modifications refer to the following:

Degenerate sequences

Degenerate nucleotide sequences may be accepted provided that they generate the same protein. Presentation of each of the possibilities of nucleotide sequences is not required. It should be noted that DNA or RNA must be defined by its nucleotide sequence and a protein by its amino acid sequence to clearly define the subject matter of protection.

Genetic use restriction technologies

A new section has been added to the Guidelines to encompass genetic use restriction technologies. Aligned with the Brazilian Biosafety Law No. 11.105 the rules establish that the patenting of these technologies shall be prohibited.

The use, commercialization, registration, patenting, and or licensing of genetic use restriction technologies shall be prohibited.



According to Article 6 of the Brazilian Biosafety Law No. 11.105/05, the use, commercialization, registration, patenting, and or licensing of genetic use restriction technologies shall be prohibited. Furthermore, the sole paragraph of Article 6 states that “For the purposes of this Law, genetic technologies of restricted use shall be deemed to be any process of human intervention for generation or multiplication of genetically modified plants for the production of reproductively sterile structures, as well as any form of genetic manipulation which aims to activate or deactivate genes related to fertility of plants via external chemical inducers”.

Sufficiency of disclosure

Clearer definitions regarding sufficiency of disclosure have been adopted. It is tolerable to carry out standardization experiments so that an expert can reproduce the invention, without this necessarily constituting undue experimentation.

Human/animal body

A new definition of the human/animal body has been inserted, as this has implications for matter which is not patentable under Brazilian Law. All stages of development of the human/animal body, from embryo to adult forms, are included in the definition.

A full version of the Guidelines (in Portuguese) can be accessed at any of these two links:

https://www.gov.br/inpi/pt-br/servicos/patentes/pagina_consultas_publicas/arquivos/InstrucaoNormativa118_DIRPABiotecnologia_01122020.pdf

https://www.gov.br/inpi/pt-br/servicos/patentes/legislacao/legislacao/InstrucaoNormativa118_DIRPABiotecnologia_01122020.pdf/@@download/file/copy_of_InstrucaoNormativa118_DIRPABiotecnologia_01122020.pdf