

Access to genetic resources

By Aline Ferreira de Carvalho da Silva | aline.silva@kasznarleonardos.com,
Priscila Mayumi Kashiwabara | priscila.kashiwabara@kasznarleonardos.com,
and Cristiane Ruiz de Moraes Vianna | cristiane.vianna@kasznarleonardos.com

Published on May 11, 2016, the Decree # 8,772/16 regulates Law #13,123/2015, which provides rules for the access to genetic resources and traditional knowledge and benefit sharing for the conservation and sustainable use of biodiversity.

Law #13,123/2015 was enacted with the aim of simplifying access and benefit sharing. Until its enactment on May 20, 2015, this matter was regulated by the Provisional Measure #2.186-16, which was subject of harsh criticism by users as it was deemed vague and bureaucratic.

Amid the several new rules brought by the Decree # 8,772/16, we highlight the following:

- Definition of which kind of microorganisms and creole species are considered to be part of Brazilian genetic heritage;
- Establishment of rules to regularize the access to genetic resources and traditional knowledge performed before the enactment of Law #13,123/2015;
- Establishment of the National System of Management of Genetic Resources and Traditional Knowledge (SISGEN, in the Portuguese acronym) an electronic system to be implemented, maintained and managed by the Executive Secretariat of CGEN (Council Management of Genetic Resources);
- Definition of aggregated value (articles 43, §§ 1º, 2º, 4º and 5º)
- Clear definition of what is not an access of genetic resources.

In this sense, article 3 grants an official pardon to the access of genetic resources and traditional knowledge performed without prior consent before June 30, 2000. In order to benefit from the official pardon, the user must prove that the access ended before June 30, 2000. In case that the access resulted in the development of a product or technology, the end of the access may be proved by means of a copy of patent applications, certificate of plant variety or certificate of marketing approval.

Articles 103 and 104 provide rules on regularization of access performed between June 30, 2000 (when Provisional Measure #2.186-16 entered into force) and the enactment of Law #13,123/2015. This regularization must be done within one year counting from the implementation of the registration system before CGEN (Council Management of Genetic Resources). The same deadline applies to those who applied for any IP right or merchandized finished products and reproductive materials after Law #13,123/2015 entered into force (November 17, 2015) and before the implementation of the registration system.

The registration system is foreseen by article 20 and will allow CGEN to track and monitor all the steps of the production, since the benefit sharing only applies to the finished product. With regard to benefit sharing, article 54, item II of the Decree establishes that the activities of licensing, assignment and authorization of use of any IP rights on the finished product or reproductive materials are exempted from benefit sharing.

At last, articles 70 to 91 foresee penalties for failing to comply with the duties established by the Decree. Among those provisions, we highlight articles 80 and 81, which are related to the filing of IP rights applications and the release of information without the proper registration before CGEN. These provisions establish heavy fines for the lack of registration.

In case you need further information on these new regulations, our legal and technical teams are at your disposal in our offices of Rio de Janeiro, São Paulo and Porto Alegre, as well as through on the email mail@kasznarleonardos.com.