MEMORANDUM TO CLIENTS

ENVIRONMENTAL, NON-PROFIT AND EXEMPT ORGANIZATIONS – CORPORATE SOCIAL RESPONSIBILITY AND INTELLECTUAL PROPERTY

April 25, 2016

Draft of a Decree that regulates the Biodiversity Law is available for public consultation and suggestions

From April 7, 2016 through May 2, 2016, a draft of the decree that regulates Federal Law No. 13,123/2015 ("Biodiversity Law") will remain available for public consultations and suggestions. The Biodiversity Law came into force on November 17, 2015, introducing innovations for scientific research and technological development with respect to access to genetic heritage and associated traditional knowledge. It also provides for sharing of benefits deriving from commercialization of a final product or reproductive material developed from such components.

Interested parties may send contributions or comments on the final text of the Decree through the web site http://www.participa.br or by e-mail to patrimoniogenetico@presidencia.gov.br.

Companies from different sectors, such as, the pharmaceutical, food, cosmetics, biotechnology and agricultural sectors, that exploit genetic heritage or traditional knowledge may be subject to the Biodiversity Law and its regulations.

Please find below the relevant aspects of the draft decree:

- The Brazilian Heritage Genetic Council ("<u>CGEN</u>") must maintain a system to monitor activities
 arising from access to genetic resources or associated traditional knowledge, including those
 relating to economic exploitation.
- The new procedure for accessing genetic heritage or associated traditional knowledge requires registration, which can be done online. Interested parties must complete an electronic form to be prepared by the National Genetic Heritage Management System and Associated Traditional Knowledge ("SISGEN").

The purpose of this memorandum is to inform our clients about important changes and developments in the area of law. We remain at the reader's disposal for any additional information that may be desired regarding the subject matter herein.

- In order to ship samples of genetic heritage components, interested parties must register and provide details as to the origin of the samples, the name of the institution abroad, including the institution's activities and intended role.
- Parties interested in shipping samples of genetic heritage components must, before shipment, sign a material transfer agreement indicating, when appropriate, if there was access to associated traditional knowledge. Such agreement must stipulate Brazil as the relevant jurisdiction to resolve all disputes arising from the agreement.
- If irregularities are detected by CGEN after the shipment, the samples of genetic heritage components must return to Brazil or be destroyed.
- Sending samples of genetic heritage components for the provision of services abroad as part of research and technological development also requires an online registration with SISGEN. However, service provision activities do not transfer the liability for the samples to the institution abroad. In this case, the parties must sign a service agreement, which must prohibit the transfer of genetic resources samples to third parties and any kind of divergent use by the recipient institution.
- Access to genetic heritage or associated traditional knowledge in areas indispensable to
 national security and in Brazilian waters may be subject to prior authorization from the
 National Defense Council and Maritime Authority, respectively, when the interested party is:

 (i) a company, whose controlling shareholders or members are foreign individuals or entities;
 (ii) a national institution for scientific and technological research, whether public or private,
 if associated with a company domiciled abroad; or (iii) a Brazilian individual associated with,
 funded by or contracted by an entity based abroad.
- Within 5 (five) days of the registration, SISGEN will notify the National Defense Council
 and Maritime Authority to issue its consent, which must be issued within 60 (sixty) days.
 Failure to issue such consent within the 60-day period will be considered a tacit consent to
 access genetic heritage or associated traditional knowledge in areas indispensable to national
 security and in Brazilian waters. In this case, the liability for the samples will be transferred
 to the institution abroad.

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MATTOS FILHO > Mattos Filho, Veiga Filho, Marrey Jr e Quiroga Advogados

- The benefits from commercial exploitation of a finished product or reproductive material, even if produced abroad, that derives from access to genetic heritage or traditional knowledge must be shared with indigenous people, local communities and the National Sharing Benefits Fund. However, the genetic heritage or the associated traditional knowledge component in a final product must be one of its key elements and essential in its production and functional benefits or in its commercial exploitation in order to trigger the sharing of benefits obligation.
- Administrative sanctions for non-compliance with the Biodiversity Law include warning notices and fines ranging from R\$ 1,000.00 (one thousand reais) to R\$ 10,000,000.00 (ten million reais).

For additional information, please contact:

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