

**TEMPLATE FOR PEER REVIEW COMMENTS
TECHNICAL SERIES ON SYNTHETIC BIOLOGY**

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Comments on the Technical Series on Synthetic Biology		
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54	1-12	Moral, ethical and legal debates have influenced the development of animal rights in Brazil, resulting in penalties for mistreatment in the administrative and criminal spheres, as established in Law 9605/1998. Moreover, Law 11.105/2005 includes provisions on animal protection in relation to GMOs.
65	20-32	The emerging area of Synthetic Biology has a similar evolution stage of other technologies developed in the past, such as genetically modified organism and genetic engineering, raising a wide range of ethical and political issues, divergent viewpoints and heterogeneous governance approaches in national legislation.
65	39	There is an urgent need for standards to be issued on the exploration of synthetic biology at national level.
66	16	<p>Brazilian Law 11.105/2005 provides for safety standards and inspection mechanisms for activities involving GMOs and their derivatives. In addition, RN CTNBio 16/ 2018 deals with genomic alterations arising from Innovative Precision Improvement Techniques, which would not be considered GMOs.</p> <p>The legal definition of these latter organisms is based on the following criteria: “I - product with proven absence of recombinant DNA/RNA, obtained by a technique that employs GMOs as a parent; II - product obtained by a technique that uses DNA/RNA that will not multiply in a living cell; III - product obtained by a technique that introduces site-directed mutations, generating gain or loss of gene function, with the proven absence of recombinant DNA/RNA in the product; IV - product obtained by a technique where there is temporary or permanent expression of recombinant DNA/RNA molecules, without the presence or introgression of these molecules in the product; and V - product where techniques are used that employ DNA/RNA molecules that, whether absorbed or not in a systemic way, do not cause permanent modification of the genome”.</p>

		Brazil does not count as yet with a dedicated, specialized regulatory agency to enforce and ensure the effective implementation of Law 11.105/2005 and related statutes.
66	22	There is a growing number of opinions issued by CTNBio exempting from licensing requirements products presented as non-genetically modified. These decisions are not necessarily based on the best science. For the correct application of existing legal tools, as well as the introduction of standards in this regard, it is recommended the establishment of the above-mentioned regulatory agency to lead government action in this field.
66	34-40	<p>Brazil is a Party to the Cartagena Protocol to the CBD, which aims to ensure the safe handling, transport and use of living modified organisms (“LMOs”) resulting from modern biotechnology that may have adverse effects on biological diversity and, as a result, on human health.</p> <p>Since the 1980s, the emergence of environmental concerns worldwide and the adoption of several multilateral environmental agreements have resulted in better awareness of environmental challenges in Brazil and prompted the enactment of a robust and rich environmental law framework. This includes, <i>inter alia</i>, Law 9605/1998, governing environmental crimes and contraventions, regulated by Decree 6514/2008. Additionally, the states and, as regards local interests, the municipalities are empowered to issue and implement their own environmental statutes.</p> <p>Within this framework, Brazilian Law 11.105/2005, regulated by the Decree 5.591/2005, governs genetically modified organisms (GMOs), their by-products and related biosafety matters, including research and trade. The 2005 statute represents an overhaul of an earlier law on the topic, building on the experience with its implementation.</p> <p>Law 11.105/2005 provides for safety norms and inspection mechanisms for the construction, cultivation, production, manipulation, transportation, transfer, import, export, storage, research, marketing, environmental release and discharge of GMOs and their by-products.</p> <p>Informed by the principle of precaution, the Law aims to promote scientific development in the biosafety and biotechnology arena and ensure human health and environmental protection.</p> <p>The Law also outlines a dedicated institutional structure for implementation – the National Biosafety Council (CNBS) and the National Biosafety Technical Commission (CTNBio) – the latter under the Ministry of Science and Technology. Other important environmental bodies are the Ministry of Environment, the National Environmental Council and the Brazilian Institute of Environment and Renewable Natural Resources (IBAMA), the environmental body in charge of implementing the National Environmental Policy and related legislation.</p> <p>Moreover, Federal Law 13.123/2015 governs, comprehensively and in detail, access to genetic resources (GH) for scientific research, bioprospecting, and technological development. Under this Law, the Genetic Resources Management Council (CGen) is the principal institution, acting in coordination with other environmental authorities.</p> <p>This is the Brazilian governance framework for biosafety and biosecurity involving GMOs and genetic resources and which may apply to synthetic biology activities.</p>
68	3	RN CTNBio 16/2018 outlines guidelines for topical applications based on RNA – it does not classify them as Genetically Modified Organisms (art.1, §3, I to V).

Please submit your comments to secretariat@cbd.int.