

The Multi-Level Implementation of the Nagoya Protocol in the European Union

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The European Union and its 28 member states are preparing to implement the “Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization” (hereinafter referred to as the “Nagoya Protocol”),¹ the second protocol² to the Convention on Biological Diversity (CBD) of 1992. Whereas a few member states hurried ahead,³ most of them awaited the implementation concept of the EU, which was adopted by the Council on 14 April 2014 (hereinafter referred to as the EU Regulation on ABS).⁴ The Nagoya Protocol entered into force on October 12, 2014, 90 days after the deposition of 50th document (ratification) was submitted to the secretariat.⁵ Since the European Union did not wish to be the last in line to deposit a document, it was eager to finalize the legislative process before the entry into force. The Nagoya Protocol concretizes Article 15 of the CBD, which stipulates that

each Party shall take appropriate, effective and proportionate legislative, administrative or policy measures to provide that genetic resources

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1 Adopted on 29 October 2010 in Nagoya, Japan, as the Second Protocol to the Convention on Biological Diversity of 1992.

2 The first one is the Cartagena Protocol on Biosafety of 2000, in force since 11 September 2003 (ILM [2000] 1027).

3 See Norway (Norwegian Nature Diversity Act of 2009) and Denmark; [For an in-depth discussion on ABS in Denmark and Norway, see contributions to this volume by Koester (Chapter 2) and Tvedt (Chapter 7).]

4 Regulation No 511/2014 of the European Parliament and of the Council on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union.

5 Nagoya Protocol Article 33 Sec. 1

utilized within its jurisdiction have been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing (ABS) legislation or regulatory requirements of the other Party.

The EU Regulation on ABS relies on a concept of centralized regulation and de-centralized enforcement. In its initial proposal, the European Commission opted for the technical instrument of a regulation, rather than a directive. The focus of the Regulation is on user measures, and prudently leaves the regulation of access to EU-genetic resources to the member states. Its concept rests on the duty to exercise due diligence to ascertain that genetic resources and associated traditional knowledge are accessed in accordance with applicable ABS legislation. I argue that the EU approach camouflages a simplistic understanding of how the uses of genetic resources are regulated in detail. The approach relies on a narrow understanding of applicability and scope, has broad exceptions, and grants overbroad privileges to the research community. Most importantly, it ignores the administrative set-up of various pre-existing procedures, which fine-tune in many ways, the quality control of research and production. The approach wilfully downplays the difficulties of the information flow, and gives broad leeway to circumvention. Moreover, it does not install self-regulatory measures that deserve the label of due diligence so as to cushion the information problem. Thus, the draft as a user measure is not ambitious enough to complement existing and future provider measures. The analysis imposes that the EU wilfully slows down the ABS process for the sake of its research community and its industry.

This chapter substantiates this critique as follows. It will first solidify the content of the Nagoya Protocol by analysing its ambitions and shortcomings, comparing it to the Bonn Guidelines I. It will describe the concept of due diligence on which the EU Regulation on ABS is based II. It follows a counter-proposition labelled as “integrative” or “piggy-back,” which cushions the duty to ascertain Nagoya Protocol-compliance within existing procedures III. A reflection on the respective information paradigm concludes the Chapter IV.

I The 2010 Nagoya Protocol and the 2001 Bonn Guidelines Compared

Various dissenting points made the Nagoya Protocol negotiations dreadful. Consensus has remained fragile about central questions as to if the Nagoya Protocol applies to material stored in collections after 1992 (or only