

Inside EU Life Sciences

Updates on Legal Developments in the EU Life Sciences Industry

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German government has started enforcement of the Nagoya Protocol and reviews compliance of pharmaceutical companies

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The “*Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity*” is an international agreement which aims at sharing the benefits arising from the utilization of genetic resources in a fair and equitable way. It entered into force on 12 October 2014.

The Nagoya Protocol imposes a complex set of multi-jurisdictional compliance obligations on businesses active in the pharmaceutical, food, cosmetics and other life science sectors. It now has more than 100 contracting parties, including the EU. The key legal source in the EU is **Regulation (EU) No. 511/2014** 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.

The Protocol consists of three pillars. First, countries **may** require that a company seeking access to any material of plant, animal, microbial or other biological origin (“genetic resources”), receives a government authorization before acquiring it. Second, those countries **may** also impose conditions for “equitable benefit-sharing.” For example, they may require that a percentage of the profits from resulting products are paid to a public fund in that country (e.g. South Africa). Countries that impose such access and benefit-sharing (“ABS”) conditions are called provider countries. Third, all 100+ parties to the Nagoya Protocol **must** enforce compliance with the ABS-requirements of the provider countries. These are called “user countries.”

Germany has also signed the Nagoya Protocol and enacted **national legislation to implement the obligations under the Nagoya Protocol and under the Regulation (EU) 511/2014.**

Based on this law, the German Federal Agency for Nature Conservation (*Bundesamt für Naturschutz*) as the competent authority has recently taken regulatory steps to further implement and enforce the Nagoya Protocol. As such, the competent authority has now started specific outreach to pharmaceutical companies in Germany and requests detailed information about the companies' measures taken to ensure compliance with the Nagoya Protocol. The German authority, among other things, also asks whether the companies have accessed genetic resources since October 2014 and whether they have developed a product based on the use of genetic resources. Companies are obliged to respond to these requests for information. Violations of the Nagoya Protocol obligations may be subject to regulatory fines.

On 9 May 2018, the German authority has also issued a general decree and requests all recipients of research funding involving the utilization of genetic resources and traditional knowledge associated with genetic resources to declare that they exercise due diligence in accordance with the laws implementing the Nagoya Protocol (diligence declaration).

The Nagoya Protocol is a compliance challenge for many companies. Especially, pharmaceutical and biotech companies can fall under these rules. Therefore, whenever the company's business requires R&D on material of biological origin, it is worth examining whether there are obligations under the Nagoya Protocol.

In conclusion, pharmaceutical and other life sciences companies as well as companies in the food and cosmetics sector will need to review their R&D activities and consider implementing measures to consider and to comply with the Nagoya Protocol. If a company finds that Nagoya Protocol obligations are triggered, they may need to request public permits and negotiate benefit-sharing as required in the country of origin of the genetic resources. Companies also need to implement internal compliance measures to meet the legal requirements in the EU. The German regulatory agency has started reviewing these measures and it is likely that it will also enforce against any non-compliance.

Covington has a unique practice focusing on compliance with the Nagoya Protocol, embedded within its global life sciences practice. Our experience covers more than 20 countries in four continents, including Germany.

Source:

General Decree of the German Federal Agency for Nature Conservation (Bundesamt für Naturschutz), **Federal Gazette of Germany dated 9 May 2018.**

Link to Decree:

**[https://www.bundesanzeiger.de/ebanzwww/wexsservlet?
session.sessionid=93250e469fb2b796fd90a075b1dc53bc&page.navid=detailsearchlist
todetailsearchdetail&fts_search_list.selected=6bcfee881f585c6&fts_search_list.dest
HistoryId=07617](https://www.bundesanzeiger.de/ebanzwww/wexsservlet?session.sessionid=93250e469fb2b796fd90a075b1dc53bc&page.navid=detailsearchlisttodetailsearchdetail&fts_search_list.selected=6bcfee881f585c6&fts_search_list.destHistoryId=07617)**

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