

The Nagoya Protocol at Its 5th Anniversary: Legal Lessons Learned in the Pharmaceutical, Food and Cosmetics Sectors

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Life Sciences

The [Nagoya Protocol on Access and Benefit Sharing](#) is the main global mechanism to regulate the access and utilization of biological resources. The agreement entered into force nearly five years ago, on October 12, 2014, as a supplement to the 1992 [Convention on Biological Diversity](#). Today, 118 countries are a contracting party to the Protocol. The volume of national implementing rules has continued to proliferate, and with that, the impact on pharmaceutical, food, cosmetics, and other life sciences companies has become increasingly apparent.

The Nagoya Protocol applies to companies that conduct research and development (R&D) on biological materials of non-human origin. This is common for life sciences companies: micro-organisms are engineered for the production of fermented foods, pathogens are used to develop vaccines, natural toxins are the basis for new chemotherapies, and natural ingredients are used in the formulation of cosmetics.

Covington has been assisting companies in shaping, interpreting and implementing compliance with the Nagoya Protocol even before it entered into force. To mark its fifth anniversary, we take stock of key lessons learned:

- **Best practices** to implement Nagoya Protocol compliance
- **Real-life scenarios** of how the Nagoya Protocol has been enforced
- How the Nagoya Protocol shapes **everyday business transactions**
- Relevance of the Nagoya Protocol for **U.S. companies**
- Examples of the **negative impact** of the Nagoya Protocol on **R&D and innovation**
- **Future developments** for the Nagoya Protocol

If you have any questions or would like a briefing concerning the material discussed in this client alert, please contact [Bart Van Vooren](#).

How the Nagoya Protocol Works

The Nagoya Protocol consists of three elements:

- First, the contracting parties *may* regulate access to biological materials (“genetic resources”) originating from their territories. States that choose to do so, are called “provider countries”.
- Second, these provider countries *may* also require that “benefits” from using the biological materials are fairly shared with them. Together, these requirements are known as access and benefit-sharing (“ABS”) rules.
- Third, all contracting parties *must* monitor the use of biological material on their territory to ensure that companies comply with the ABS rules where the material originated.

ABS rules mostly exist in countries that are rich in biodiversity such as India, South Africa, Argentina, Brazil, France and Spain. China is likely to adopt ABS rules in 2020. Access rules typically require a permit to acquire biological materials from that country. Such a permit is usually not transferable and will almost always impose strict conditions on commercializing the results of R&D. With regard to “benefit-sharing”, two requirements are common:

- First, the obligation that a local research institution is involved in the R&D.
- Second, the requirement that if the R&D on the resource leads to a commercial product, the country of origin receives a share of the profits.

For instance, India has recently granted a permit relating to a product derived from Black Nightshade (*Solanum nigrum*) to treat hepatocellular carcinoma (liver cancer). The permit requires that if the product is commercialized, “0.2% on the annual gross ex-factory sales minus government taxes” will be paid to the Indian authority. In theory, the country of origin is expected to use these funds to support the conservation of biodiversity. In practice, the Nagoya Protocol is becoming a complex global regime to tax innovation.

The Nagoya Protocol also obliges all 118 parties to monitor and enforce compliance with the ABS rules of the other parties. This is mostly relevant for jurisdictions with technologically advanced public and private entities that conduct R&D on biological materials. Currently, the European Union (EU), Switzerland and Korea have adopted such rules. India is considering it. We provide two examples.

- The EU requires that companies file a declaration stating compliance with applicable ABS rules before submitting an application for a marketing authorization for a medicine to the European Medicines Agency. Similar obligations exist for food and cosmetics companies.
- In India, a new draft Guideline was under consultation in June 2019. It states that any person who intends to apply for an IP right for an invention based on research on biological material originating from *any party* to the Nagoya Protocol, must first prove compliance with the ABS rules of that country. European jurisdictions have not gone so far as to make patent applications conditional on compliance with the Nagoya Protocol. Nonetheless, the patent offices of e.g. France and Germany report inventions relating to biological materials to the environmental agencies, so that the latter can check compliance.

How the Nagoya Protocol Likely Applies to Your Company

Clients often find it challenging to know whether they are affected by these rules. As a principle, you should assume that whenever your business involves any R&D on any non-human material of biological origin, you should verify whether Nagoya obligations apply. In fact, you may actually have a legal obligation to perform this verification.

We provide a few examples of factual circumstances that could, since 2014, be within the scope of the Nagoya Protocol.

Pharmaceuticals

- Developing a vaccine against a pathogen that has been declared a global health emergency of international concern by the WHO, using that pathogen.
- The development of a malaria treatment from wormwood.
- Developing an active pharmaceutical ingredient from an enzyme derived from pineapple stem for treatment of burns.

Food and agriculture

- Optimizing a strain of lactic acid bacteria from Argentina, in research centers in the U.S. and Germany, for a low-fat yoghurt with a thicker texture.
- Biotechnological development by a Belgian subsidiary of a U.S. company on a drought-resistant plant from Kenya.
- Developing a synthetic sweetener based on the sweetening properties of a plant.

Cosmetics

- The claim on a cosmetic product that in Ayurvedic medicine, a botanical in the formula has been traditionally used for its anti-oxidant effects.
- A fragrance developed from a flower native to the Democratic Republic of the Congo, where the odor compounds have been acquired using headspace technology.

What Your Company Should Do If the Nagoya Protocol Applies

Approaches to compliance diverge significantly depending on the area of activity and the degree of reliance on biological materials. From the perspective of EU enforcement authorities, the following is typically expected:

- **Standard operating policies** laying out the company's process of verifying the existence of and compliance with access and benefit-sharing rules. For a large company, this may consist of multiple SOPs to handle different stages of the product development process (e.g., obtaining biological material, collaboration with third parties, patent filing and commercialization).
- **Internal measures** to communicate the implementation of the Nagoya policy to relevant employees and to provide appropriate **training**.
- **Appointment of a contact person** who has the appropriate background to deal with Nagoya compliance. This individual should also have sufficient resources to implement the Nagoya policy.
- An **internal system to track and trace** when biological materials enter the company, how they are used, and when they leave the company. This often requires a sophisticated IT platform, given the large amount of data involved.
- The process should at least be able to **document the following information** on biological materials: (i) the date and place of obtaining the material, (ii) a description of the material and its source, (iii) previous holders of the material, (iv) the presence or absence of obligations relating to access and/or benefit-sharing, and (v) whether these obligations have been complied with according to the standards set out in the compliance policy.

Organizing such a system requires significant investment of time and resources, as well as senior management buy-in. Although legal or IP typically leads the process, the cross-functional involvement of regulatory, procurement, commercial and R&D is often essential.

As an alternative to a fully-fledged, top-down compliance program, some companies have opted to build their process (and experience) through pilot projects. They would select one or a few key products, e.g., in terms of profitability and risk exposure, and check whether provider and user country rules would apply. This approach is common for companies that use some biological materials, but for whom it is not the mainstay of their business. The pilot project usually gives a good indication of what needs exist for other products, or the company more generally. For instance, the pilot often helps to identify the critical control points that should be covered by the SOP to ensure Nagoya compliance throughout the business. More generally, this bottom-up approach has proven useful for various functions to become acquainted with the Nagoya Protocol and to learn by doing.

How Nagoya Protocol Obligations Are Enforced

The Nagoya Protocol is enforced through public authorities and private entities. Public enforcement occurs both in provider and user countries, and is supported by a network that exists between those countries. Private enforcement occurs through NGOs and competitors.

With regard to public enforcement, national authorities in the EU have stepped up their compliance audits in industries that they perceive to pose the highest risk of non-compliance, i.e., the pharmaceutical, biotechnology and cosmetic sectors. This is, for instance, the case in Germany, through the German Federal Agency for Nature Protection ([Bundesamt für Naturschutz](#) - BfN). In the spring of 2018, the BfN sent Nagoya questionnaires to more than 2,500 companies. On this basis, by May 2019, the BfN conducted document based checks of 33 companies. Moreover, the BfN also conducted on-the-ground audits of four companies in the abovementioned sectors. Three of these audits were conducted following the initial document based verification, but one audit was the result of “substantiated concerns” being sent to the BfN (i.e. whistleblowing). We are also aware that audits have taken place in Denmark, the UK and the Netherlands, and outside the EU, in Switzerland.

To our best knowledge, enforcement has not yet resulted in court proceedings or sanctions in the EU, but this may come. For instance, in Germany, violation of the Nagoya compliance obligations is subject to an administrative fine up to 50,000 EUR (and possibly higher). In France, failure to comply is subject to one year imprisonment or a criminal fine of up to 150,000 EUR. Conducting “commercial” R&D without the required documentation is subject to a fine of up to 1,000,000 EUR.

With regard to private enforcement, certain NGOs have actively pursued high-profile cases accusing multinationals of “bio-piracy.” An example relates to the stevia plant, even though likely no Nagoya Protocol obligations exist in that specific instance.

In our experience, the actions of authorities and NGOs are so far not the main driver of companies implementing Nagoya compliance. Instead, requests from business partners frequently prompt companies to take action regarding access and benefit-sharing rules. We provide a few examples of how the Nagoya Protocol has begun to shape common business transactions.

How the Nagoya Protocol Impacts Common Business Transactions

The following anonymous examples are all taken from our practice, and are typical across the cosmetics, food and pharmaceutical sectors.

- Two pharmaceutical, food or cosmetics companies conclude **an R&D agreement establishing a long-term collaboration** to develop new 'natural' flavors, fragrances, or active pharmaceutical ingredients from biological materials. Given that it is often unknown at the time of the agreement what materials will be used, the agreement must contain rules to assign responsibility for compliance with the Nagoya Protocol (e.g., who will be responsible to request the permit, how will profit-sharing be decided, dissolution of the agreement if no permit can be obtained, etc.).
- A food or cosmetics company intends to **incorporate a natural ingredient** from a Nagoya Protocol party in its food supplement or cosmetic product. The marketing team wants to make claims regarding the natural ingredient. The ingredient is provided by a supplier in that country, and the claims will be based on R&D locally conducted by that supplier. The supplier should contractually guarantee compliance with the access and benefit-sharing obligations in the provider country. In this way, the cosmetics company avoids legal and reputational risk in the country where it commercializes the product.
- A food or pharmaceutical company plans to **acquire the assets or shares of another company** that conducts research on and manufactures botanical ingredients for use in food supplements and medicinal products. The M&A due diligence must thoroughly check Nagoya compliance. Non-compliance could significantly impact the value, and even the viability of the deal.
- Two pharmaceutical companies conclude a **license agreement**. The EU-based licensor has initially acquired the biological materials and has conducted non-clinical studies on it. The U.S. based licensee will continue the R&D and eventually commercialize the product. Since access permits from the provider country are often non-transferable, the licensor must warrant to the licensee that they have complied with Nagoya Protocol obligations, which may require a new authorization procedure.
- A company intends to apply for an access permit which will also require the negotiation of a **benefit-sharing agreement**. Careful planning is required from the perspective of anti-bribery legislation.

When Is the Nagoya Protocol Relevant to a U.S. Company?

The United States is not a Party to the Nagoya Protocol and does not enforce compliance with the ABS laws of provider countries. Nevertheless, U.S. companies cannot avoid much of what is discussed in this alert:

- Companies must still comply with the ABS laws of provider countries (e.g. India or South Africa). Non-compliance could be sanctioned against subsidiaries or activities in those jurisdictions.
- U.S. headquartered companies often have multiple research sites across the world, including in Switzerland, Korea, or the European Union. Even if only a small part of the R&D is conducted in such a location, authorities may expect the entire product development process to be Nagoya-compliant.
- Carving out the U.S. from a global track and trace tool may undermine its effectiveness. For instance, even if all R&D on biological materials has been carried out in the United States, a company may still be asked to provide evidence to that effect.

Negative Impact of the Nagoya Protocol on Research and Innovation

Unfortunately, the negative impact of the Nagoya Protocol on research and innovation is starting to manifest itself. As commercial R&D is confidential, it is difficult to gauge the scale of the problem. Some examples are public, including the following two on seasonal influenza.

The World Health Organization (WHO) Global Influenza Surveillance and Response System (GISRS) monitors influenza epidemiology. The system relies on rapid sharing of virus samples between members of the network. In 2018, the National Influenza Centre of a party to the Nagoya Protocol could not share an influenza sample with one of the main WHO Collaborating Centres, due to the Nagoya Protocol implementing legislation in the provider country. Specifically, the ABS rules did not allow that the Collaborating Centre would share the virus with third parties, such as other members of GISRS. The national ABS rules would also not allow that the sample be used for commercial purposes, such as marketing a vaccine. In this instance, it took months before a solution was found, so that “rapid sharing” was hindered.

In another example, an influenza virus was shared by a National Influenza Centre based in a country that is party to the Nagoya Protocol. It sent the sample to a Collaborating Centre located in another party. That virus was eventually recommended for inclusion in vaccines for the 2019 southern hemisphere influenza season. At that time, it was unclear whether the National Influenza Centre, the Collaborating Centre, or the vaccine manufacturers were obliged to comply with the Nagoya requirements in the country of origin. It took some time for the national authority to clarify the situation, even though this authority is very experienced and the ABS rules are reasonably straightforward. Although companies successfully avoided a detrimental impact on vaccine availability, the impact on the time-sensitive manufacturing process was significant.

Future Developments of the Nagoya Protocol

In October 2020, the UN Biodiversity conference will take place in China (Kunming), where final decisions will be taken on the post-2020 global biodiversity framework. As part of that process, there will be significant developments under the Nagoya Protocol as well. One of the most controversial issues is the inclusion of “Digital Sequence Information.” Currently, the Nagoya Protocol is generally interpreted to mean that it only covers access to *physical* biological materials. However, there is a perception with certain biodiverse countries that genetic sequencing of biological materials could be used to circumvent obligations of access and benefit-sharing. Hence, these countries are pushing to have *information* on the biological materials (e.g. genetic sequence data) covered by the Nagoya Protocol as well. Industry, academia and Western countries are strongly pushing back, given the negative impact on the freedom to conduct scientific research. However, the debate has become highly politicized along the North-South divide. As a result, some public officials consider it likely that as part of post-2020 biodiversity negotiations, the proponents of including genetic sequence data on biological materials under the Nagoya Protocol, will prevail.

Conclusion

Upon reviewing their R&D pipelines, many companies are likely to find that the vast majority of their activities do not trigger provider country obligations. However, user country rules do require that companies have processes in place to check whether access and benefit-sharing obligations apply. We are not aware of companies having been subject to penalties for non-compliance, but five years after the entry into force of the Nagoya Protocol, authorities have now clearly built up their internal capabilities. As a result, they have shifted from merely educating users of biological materials, to checking compliance.

Covington’s global Life Sciences team has followed these developments since the negotiation of the Nagoya Protocol, working with a variety of sectors and countries. If you have any questions concerning the material discussed in this client alert, please contact [Bart Van Vooren](#), or any other member of our Life Sciences practice:

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