COVINGTON

Enforcement of the Nagoya Protocol in the Food, Drugs and Cosmetics sectors - *state of play*

May 2018

Food, Drugs, and Cosmetics

The Nagoya Protocol to the Convention on Biological Diversity entered into force on 12 October 2014. It imposes a complex set of multi-jurisdictional compliance obligations on businesses active in the cosmetics, food, pharmaceutical and other life science sectors. It now has more than 100 contracting parties, including the European Union.

Between 2014 and 2017, regulators have mainly focused on enacting implementing legislation, raising awareness, and working with industry to understand which companies would fall within the scope of these new rules. During this period, it was considered too soon to enforce the rules, which in many jurisdictions includes criminal sanctions. Since mid-2017, this trend has started to shift. Now, in 2018, there are clear indications that the grace period has ended, particularly in Europe.

The Nagoya Protocol is a major compliance challenge for many of our clients. It is a complex legal regime that spans the globe, and implementing compliance can be costly. Companies also grapple to understand the legal, reputational and financial risks to their specific businesses. Over the last five years, Covington has been at the forefront of these developments. In various roles, our firm has worked with companies and associations to shape the rules, limit their impact, implement compliance, and has led the first litigation before EU Courts. Based on our experience, this alert provides a state of play on its enforcement around the globe.

How the Nagoya Protocol Works

The Protocol is an international treaty that consists of three main parts.

- First, countries may require that a company seeking access to any material of plant, animal, microbial or other biological origin (so-called “genetic resources”), receives a government authorization before acquiring it.
- Second, those countries may also impose conditions for “equitable benefit-sharing.” For example, some countries require that a percentage of the profits from resulting products are paid to a public fund in that country (e.g. South Africa).

About 60 countries have these two elements in their national laws, including France, India, Mexico, Brazil and China. Countries that impose such access and benefit-sharing (“ABS”) conditions are generally referred to as “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,” in reference to

the companies in their jurisdictions that use the genetic resources for commercial products.

The number of countries that have enforcement legislation is steadily increasing and currently includes, for example, the 28 EU Member States, Switzerland, Mexico and Japan.

In our experience, clients find it challenging to know whether they are affected by these rules. A good rule of thumb is the following. Whenever your business involves *any* R&D on *any* material of biological origin ("genetic resources"), you should examine further whether there are compliance obligations. The following activities could be covered by the Nagoya Protocol:

- developing a vaccine from a pathogen originating in Indonesia, that is commercialized in Japan, Korea and the EU,
- optimizing a new strain of lactic acid bacteria (LABs) from China to develop cholesterol-reducing yoghurt sold in the U.S.,
- *in silico* research by a Swiss subsidiary on genetic sequence data of a drought-resistant plant from Ethiopia.

Since the Nagoya Protocol has been in force for almost four years, many provider and user country laws are now in place. The competent enforcement authorities typically exist for about one year, and they have begun monitoring compliance and are starting to enforce.

Provider Countries: Complex National Laws

Some of the most strict "provider country" legislation is found in **India** and **South Africa**. South Africa and India have also been trailblazers in enforcement since the early 2000s, with the help of NGOs that have called out specific multi-national companies in the food, cosmetics and pharmaceutical sectors. For instance, in India, proceedings are currently pending before the Uttarakhand High Court in a case where a large pharmaceutical company was ordered to pay 20,4 million Rs (around 300,000 USD) in monetary benefit-sharing. This sum is purportedly due to local persons claiming title over the biological resources from which the pharmaceutical products are derived.

India and South Africa are also very active at the international level, putting pressure on e.g. the European Union to increase enforcement towards businesses (see further below). Supported by Brazil, these two countries also argue that the Nagoya Protocol does not merely apply to physical biological materials, but also to genetic sequence data that is used to develop commercial products. They are pushing for a decision on this point in November 2018, at the meeting of the Parties to the Nagoya Protocol in Egypt.

China is very advanced with adopting strict provider country rules. The law would require benefit-sharing to a public fund, and will impose a heavier compliance burden for non-Chinese entities than for Chinese entities. A public consultation has taken place in April 2017. Informal conversations with public officials indicates that the law may be adopted with few changes.

Brazil, a country that is crucial for the cosmetics industry, will soon become a party to the Nagoya Protocol. In November 2015 it has adopted a new access and benefit-sharing law that is generally considered reasonably straightforward. In principle, Brazil does not require prior authorization, but merely a notification (once a product has been developed) to an online platform (link here). However, Brazil has imposed fines for non-compliance under its previous law, and this is expected to occur under the new rules as well.

User Countries: Shift Towards Enforcement

The strictest "user country"-rules exist in the European Union. In all 28 EU Member States, companies must prove that they comply with the rules of the provider countries (e.g. India, South Africa). To that end, EU rules require companies to track and trace the genetic resource from origin to final product. Companies must also file a so-called "compliance declaration" to an online platform (link here). This filing must be done before requesting a marketing authorization (e.g. pharmaceuticals, novel food) or before placing the product on the market (e.g. cosmetics, food).

The EU rules also require that national authorities carry out audits of companies, and impose sanctions for failure to comply. To our knowledge, compliance checks have taken place in the Netherlands, the United Kingdom, the Slovak Republic, and Germany. These checks have focused on different sectors, including plant breeding, pharmaceutical and food companies, as well as universities. There are indications that France, Denmark and Finland are also becoming more active.

The approach taken to enforcement has been relatively uniform. This is the result of informal consultations between the enforcement authorities of the EU Member States. The German authority has been the main driver for this co-ordination, and has recently published a report of the first meeting that took place in March 2017.

This co-ordination between regulators has resulted in a high-level consensus on a risk-based approach to enforcement. In general, a multi-national company is considered a high risk because non-compliance could cause significant harm (although there is no definition of harm). However, if the company can show that it has strong regulatory and legal processes in place, with the right training for scientific and regulatory personnel, it would be considered to present a low likelihood of non-compliance in individual cases. Regarding specific sectors, there are informal signals from public officials that, in their view, the pharmaceutical and plant breeding sectors are doing reasonably well in implementing compliance. There is, however, a feeling that the food and cosmetics are lagging behind.

In practice, enforcement activities typically consists of three elements: (i) identification of entities that may be in scope, (ii) a request for information from the identified target companies, and (iii) an on-site visit by inspectors.

Regulators employ different strategies to identify users. For instance, Germany and the UK have each been working with consultants to develop IT tools to assess whether a given organisation uses "genetic resources", and therefore may be in scope of the Nagoya Protocol. The analyses use algorithms to extract information from publicly available databases, company websites, patent filings, company registers, information from trade associations, and (ironically) international certificates of compliance published by the international secretariat to the Nagoya Protocol. Companies should be aware of these data-harvesting practices to identify them as targets, and incorporate information management into their Nagoya Protocol compliance programs.

As a next step, the regulator would directly request further information from the target company. Such outreach has been both informal and formal. In the Netherlands and the UK, for example, the authorities have reached out to sectors that they knew from prior discussions on implementing legislation. Inspectors would then meet with personnel for several days to review compliance processes. In this way, the regulator would itself learn about enforcement by observing what those entities had been doing. This approach was first taken in 2016 in the Netherlands, and also occurred as of 2017 in the UK. Germany has adopted a slightly different approach. After identifying appropriate targets, trade associations

have reported that the Federal Agency writes to the company, and formally requests information on the compliance processes. It appears that an unsatisfactory reply could lead to an on-site visit by the Federal Agency.

To our best knowledge, enforcement has not yet resulted in court proceedings or sanctions in the EU. In principle, this is not excluded. For instance, in Germany, the law implementing the Nagoya Protocol entered into force on 1 July 2016. The violation of the compliance obligations is subject to an administrative fine up to 50,000 EUR (and possibly higher). Under the French law of 2016, failure to comply is subject to one year imprisonment or a 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.

Practical Recommendations

As mentioned, any cosmetics, food or pharmaceutical company can fall within these rules. Other implicated sectors are biotech, animal and plant breeding and bio-control. Thus, as a general rule, whenever your business requires R&D on any material of biological origin, it is worth examining whether there are compliance obligations.

Upon reviewing R&D and product pipelines, many companies are likely to find that the vast majority of their activities do not trigger provider country obligations. However, user countries' rules require that companies have processes in place to check *whether* access and benefit-sharing obligations apply. This necessarily implies reviewing all R&D activities. If the company then finds that Nagoya obligations *are* triggered, they must request public permits and negotiate benefit-sharing as required in the provider country.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our firm:

Bart Van Vooren	+32 2 549 52 50	bvanvooren@cov.com
Peter Bogaert	+32 2 549 52 43	pbogaert@cov.com
Brian Kelly	+44 20 7067 2392	bkelly@cov.com
Adem Koyuncu	+32 2 549 52 40	akoyuncu@cov.com
Miriam Guggenheim	+1 202 662 5235	mguggenheim@cov.com
John Balzano	+1 212 841 1094	jbalzano@cov.com
Sinéad Oryszczuk	+44 20 7067 2141	soryszczuk@cov.com