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EU Enforcement of the Nagoya Protocol on Use of Genetic Resources

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Food & Drug

This alert briefly summarises the European Union rules that enforce compliance with the Nagoya Protocol. The Protocol governs access to, and research and development on, genetic resources and related traditional knowledge. The new EU compliance Regulation imposes specific obligations on companies conducting R&D and in particular affect companies developing pharmaceuticals, medical devices, cosmetics, biocides, foods and other products, as well as plant and animal breeders.

Because of the structure of the EU rules, their real impact may only become clear during the later stages of development, but it is important to ensure that the necessary procedures are put in place from the beginning. The main obligations have applied since 12 October 2015.

I. The International Context

The Nagoya Protocol was adopted in 2010 and implements the objective under the 1992 Convention on Biological Diversity ('CBD') that the benefits arising out of research and development ('R&D') conducted on genetic resources are "fairly and equitably shared" with the countries of origin of the resources. The protocol entered into force for the EU on 12 October 2014 and organises the 'ABC' of benefit-sharing:

- **Access**: Nagoya Parties may adopt rules so that access to genetic resources or related traditional knowledge requires a permit in the form of "prior informed consent" (or PIC); and
- **Benefit-Sharing**: Nagoya Parties may require the negotiation of "mutually agreed terms" (or MAT) that regulate the sharing of benefits arising from R&D on the genetic resources; and
- **Compliance**: Nagoya Parties shall adopt appropriate measures that PIC and MAT obligations of other Nagoya Parties are complied with in its own jurisdiction.

There are currently 70 effective parties to the Nagoya Protocol, including the EU and six EU Member States. The U.S. is not a party.

II. Applicable Rules Relevant for EU Companies

From an EU perspective, the main relevant legal rules flowing from the Nagoya Protocol are:

- The so-called Access and Benefit Sharing (ABS) rules, *i.e.* the first two pillars of the 'ABC'. These are the national rules that dictate conditions for access and benefit sharing to the genetic resources (or related traditional knowledge) in the provider country. The parties to the Nagoya protocol are required to post their national rules on the International Clearing House: https://absch.cbd.int.
- The EU rules do not cover ABS rules *per se,* but cover the third pillar of the 'ABC' and enforce compliance within the EU with applicable ABS rules of Parties to the Nagoya Protocol. They are *EU Regulation 511/2014* and the *Commission*

Implementing Regulation 2015/1866. The European Union itself is not competent to organise access and benefit sharing for its Member States.

- National rules in EU Member States organise detailed procedures, administrative or criminal sanctions for non-compliance with EU rules. The Dutch rules, for instance, envisage a prohibition on marketing products in case of non-compliance with the EU Regulation.

This alert briefly summarises the key EU rules. It does not provide a comprehensive overview.

Scope of Application of the EU Rules

The EU rules only apply when a number of conditions are met.

(i) R&D in the EU

Only R&D in the EU triggers the application of the rules. R&D fully outside the EU, for instance in China, Japan, or the U.S., is not relevant. The Regulation does not define R&D and it may in certain cases be difficult to distinguish late stage R&D from steps taken for regulatory compliance or to ensure production quality. A draft Commission guidance document refers to a 'litmus test', whereby users should self-assess whether the R&D creates 'new insight' into the genetic and/or biochemical characteristics of the genetic resource. Thus, when the activity goes beyond mere description, it is considered to constitute R&D.

The European Commission has also suggested that both separate research and separate development activities may trigger the application of the rules. If this is upheld, basic research would thus allegedly be included. This is highly debatable in light of the wording of the Regulation.

(ii) R&D on genetic resources or using traditional knowledge

The R&D must be conducted on genetic resources, or traditional knowledge associated therewith. Genetic resources are defined as 'any material of plant, animal, microbial or other origin containing functional units of heredity.' Entities which conduct R&D on genetic resources are referred to as 'users.' The EU regime states that conducting R&D on the 'biochemical composition of genetic resources, including through the application of biotechnology' is also covered. Derivatives from genetic resources are most likely covered as well.

(iii) The genetic resource or knowledge was accessed in a Nagoya Protocol party as from 12 October 2014

The rules only apply when the genetic resources were accessed in a country that is a party to the Nagoya Protocol, at a time the protocol applied to that country, but not before 12 October 2014. The term access is not completely clear, since it is defined as the "acquisition" of genetic resources. The general view is that it means the initial access in the country of origin or a subsequent access in the same country through a collection system.

Access in a country also presupposes that the country exercises sovereignty rights over the resources, which excludes, for instance, access to marine genetic resources on the high seas.

Obligations under the EU Rules

(i) General due diligence obligation

Users have the obligation to ascertain that genetic resources on which they conduct R&D have been accessed and used in accordance with applicable access and benefit-sharing legislation.

(ii) Track and trace obligation

In order to comply with the due diligence obligation, users must 'seek, keep and transfer to subsequent users' a broad range of information on the genetic resources on which they conduct R&D. This means that users must:

- Exercise a sufficient level of care and effort so as to know whether the Nagoya Party has requirements concerning access and benefit sharing, and ensure that prior informed consent is obtained where necessary, and that mutually agreed terms are negotiated;
- Set up a database containing the information and documentation previously obtained, covering the entire time-period of the R&D;
- Provide this documentation and information to subsequent users to ensure a 'chain of compliance' from one user to the next.

The EU Regulation refers to these three points as the obligations to 'seek,' 'keep' and 'transfer' documentation and information.

(iii) Making compliance declarations

Under the EU rules, national competent authorities must monitor user compliance. To that end the user must make a formal declaration at 'checkpoints':

- First, when a public or private grant is received to carry out R&D on the genetic resource or associated traditional knowledge; and
- Second, at the stage of final development of a product developed through R&D on the genetic resource or associated traditional knowledge.

The second checkpoint triggers the most extensive obligations for users. Essentially, prior to seeking market approval, placing the product on the market, or even selling the result of R&D outside the Union, the user must make a formal detailed declaration on how he or she has complied with the EU obligations. A central EU-wide online tool is being developed by the Commission and Member States for uploading all declarations and a pilot phase is expected to start later this year. Parts of the declarations will be publicly accessible.

Additional Restrictions under National Laws in the EU

The EU rules will be further supplemented by national compliance rules in all Member States. For instance, in the United Kingdom, the National Measurement & Regulation Office (NMRO) has been assigned as the national competent authority. It acts in accordance with the *Statutory Instrument 2015 No. 821* of March 2015. The rules foresee civil sanctions for failure to exercise due diligence, failure to track and trace information, and failure to make the declaration. Civil sanctions include compliance notices, variable monetary penalties, and also stop notices to secure that products developed by means of R&D on genetic resources is prohibited. Failure to comply with civil sanctions, is subject to criminal sanctions.

Special Regimes

The EU regime contains special rules on R&D on pathogens causing an international public health emergency.

In that case, R&D may start without first having secured prior informed consent and negotiated mutually agreed terms. However, strict deadlines apply for doing so afterwards, and in case of non-compliance the user cannot claim any exclusive rights to the developments made via the R&D on the pathogen.

EU Measures to Facilitate Compliance

The EU Regulation contains two methods to facilitate compliance.

First, collections of genetic resources based within the Union can apply for registration, which provides a 'trusted status.' When R&D is conducted on genetic resources from registered collections, the user will benefit from a presumption of compliance as regards seeking the required documentation and information (but not the subsequent documentation obligations). When making the formal declaration, the user can 'tick the box' that the genetic resources comes from a trusted collection.

Second, associations of users and other interested parties can apply for recognition of best practices by their national authority. A best practice is a combination of procedures, tools and mechanisms that facilitate compliance. A user can indicate that he applies a recognised best practice when making the compliance declaration, and national authorities must take this into account.

Follow-up

The EU compliance regime is still in its infancy and many aspects require clarification. The European Commission intends to publish in the coming months a general guidance document clarifying the scope of application of EU rules. Thereafter, the Commission will work on sector-specific guidance documents, which may be adopted in 2017. Industry stakeholders are strongly advised to pro-actively engage in this drafting process, as it will seek to clarify the requirements and facilitate compliance.

It is also likely that the EU Court of Justice will ultimately have to interpret specific aspects of the regime.

In the meanwhile, it is important for companies to already put in place procedures for compliance that allow to at least adequately document due diligence. These procedures can then be updated when guidance of binding interpretations by the Court of Justice become available.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food & Drug practice group:

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