Historic Marine Biodiversity Treaty creates new Access and Benefit-Sharing obligations for life sciences companies | Inside EU Life Sciences

Historic Marine Biodiversity Treaty creates new Access and Benefit-Sharing obligations for life sciences companies

By Bart Van Vooren, Yuliya Gevrenova & Seán Finan on June 21, 2023
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On 19 June 2023, after almost 20 years of negotiations, the United Nations ("**UN**") member states adopted a landmark treaty [https://undocs.org/Home/Mobile?FinalSymbol=A%252FCONF.232%252F2023%252FL.3&Language=E&DeviceType=Desktop&LangRequested=False] to ensure the conservation and sustainable use of marine Biodiversity of areas Beyond National Jurisdiction (the "**BBNJ**" treaty).

One of the cornerstones of the BBNJ treaty is the creation of a new mechanism for the fair and equitable sharing of benefits arising from activities with respect to "marine genetic resources" ("**MGRs**") and "digital sequence information" ("**DSI**") from MGRs. This mechanism is groundbreaking because it will require companies to pay for the use of genetic resources beyond national jurisdiction for the first time. Until now, under the existing Convention on Biological Diversity ("**CBD**") and its Nagoya Protocol, companies were required to make (non-)monetary contributions only for the utilization of genetic resources under national jurisdiction (*e.g.*, from national territories, national seas and exclusive economic zones). The BBNJ creates new "Access and Benefit-Sharing" ("**ABS**") obligations on MGRs from maritime areas beyond national jurisdiction (*i.e.*, the High Seas and the Area).

Companies in sectors whose R&D depends on marine genetic resources will be required to contribute to share financial and other benefits. In this blog we focus on those provisions of the BBNJ which will have the most direct impact on companies.

1. Scope of the new benefit-sharing mechanism

The new benefit-sharing mechanism will cover MGRs, meaning "*any material of marine plant, animal, microbial or other origin containing functional units of heredity of actual or potential value*". This definition is broad and could cover a variety of uses of physical samples currently utilized in life sciences industries, such as marine mammal or fish-derived collagen, or extracts from algae.

The BBNJ will also apply to Digital Sequence Information ("**DSI**") on MGRs, but it does not define this term. An earlier draft from December 2022 used the term "associated data and information", which covered:

"*relevant data and information in any format, including such data and information that could be considered as* ***digital sequence information on genetic resources under the Convention on Biological Diversity***." (emphasis added)

Currently, the treaty has removed any express references to the CBD and leaves it to the Conference of the Parties to adopt any measures with respect to DSI from MGRs. The reason why the definition was removed is because State Parties to the CBD did not yet reach an agreement [https://www.insideeulifesciences.com/2022/12/23/outcome-from-cop-15-a-new-global-fund-paid-for-by-life-sciences-companies-that-use-digital-sequence-information-on-genetic-resources/?_gl=1*pkv5j9*_ga*MTA0NDk1MTYxMC4xNjU0NTk4MjE5*_ga_KSNMJSN08X*MTY3ODg4NjYwNC42MS4wLjE2Nzg4ODY2MDQuMC4wLjA.] on the definition or scope of "DSI" during COP15. As a reminder [https://www.cov.com/en/news-and-insights/insights/2023/01/cop-15-on-biodiversity-key-takeaways-for-business], there are at least three possible definitions for DSI currently under review, covering R&D in the field of: (i) genomics only (relating to DNA and RNA), or also (ii) proteomics (relating to proteins) or including also (iii) metabolomics (relating to metabolites and other macromolecules). The broader the definition, the more R&D will be subject to the new benefit-sharing obligation.

The discussions on the exact scope of DSI are expected to continue over the next two years in the context of the CBD, with a final decision planned for November 2024. What happens under the CBD umbrella, will inform the scope of the BBNJ as regards DSI on marine genetic resources.

2. Notification to the Clearing-House Mechanism

Before carrying out "activities" (*e.g.*, *in situ *collection of materials) with respect to MGRs and DSI from MGRs, interested parties will have to notify the newly created Clearing House Mechanism as early as possible and no less than six months in advance. This will allow for the monitoring of the collection and use of MGRs, as well as link it to the proper benefit-sharing obligations afterwards.

The following information must *e.g.* be provided to the Clearing-House:

- The nature and objectives under which the collection is carried out;
- The subject matter of the research or, if known, the MGRs to be targeted or collected, and the purposes for which such resources will be collected;
- The geographical areas in which the collection is to be undertaken;
- The name(s) of the sponsoring institution(s) and the person in charge of the project;
- Opportunities for scientists of all parties, in particular from developing States to be associated or involved in the project; *etc*.

Within one year after the notification, it is obligatory to notify: the repository or database where the DSI has been uploaded, where the MGRs that were collected are being held, and a report of locations where MGRs were collected, and insofar available, findings from the activities undertaken.

If the collected MGRs and DSI from MGRs have led to a commercial product or process, further information will need to be notified as soon as it becomes available, including *e.g.*:

- Where the results of the utilization, such as publications, patents granted and products developed, can be found;

- Where the original sample that is the subject of utilization is held;
- Once marketed, information, if available, on sales of relevant products and any further development.

The Clearing-House Mechanism will make this information publicly available.

3. Obligations under the new benefit-sharing mechanism

The BBNJ foresees monetary and non-monetary benefit-sharing.

Monetary obligations will be triggered by the "utilization" of MGRs and DSI from MGRs, which means "*research and development on the genetic and/or biochemical composition of marine genetic resources, including through the application of biotechnology.*"

Financial obligations could comprise:

- Milestone payments;
- Payments or contributions related to the commercialization of products, including payment of a percentage of the revenue from sales of products;
- Tiered fees paid on a periodic basis, based on a diversified set of indicators measuring aggregate level of activities by a state party.

The specifics will be further decided by the first Conference of the Parties ("**COP**"), which will be held one year after the entry into force of the High Seas Treaty. Notably, at the first COP, state parties to the treaty can make declarations, postponing the payment of the monetary contributions up to four years "*in order to allow time for the necessary implementation*". Other details, such as whether payments will be made to the state parties, or directly to the fund created under the treaty remain to be clarified.

A number of non-monetary benefit-sharing obligations are also foreseen, *e.g.*:

- Access to MGR samples to third parties;
- Access to DSI to third parties;
- Open access to findable, accessible, interoperable and reusable (FAIR) scientific data;
- Transfer of marine technology;
- Capacity-building for developing States.

4. Retroactive application of the new benefit-sharing mechanism

The benefit-sharing mechanism of the BBNJ will apply to all activities after the entry into force, and – quite uniquely – also to the "utilization" of MGR and DSI on MGR collected or generated *before* the entry into force of the BBNJ Treaty, unless a State Party makes an exception in writing signing up to the BBNJ.

The exact scope of this retroactive effect is not yet clear. For instance, a key question for companies is exactly what the retroactive obligation to share will cover, *e.g.*, a defined monetary contribution based on MGRs collected in the past; a variable monetary contribution, based on the profits generated using

those MGRs; information, research results and know-how, derived from those MGRs; or some combination of the foregoing.

Next Steps

The High Seas Treaty was opened for signature on June 19th and will enter into force 120 days after at least 60 states ratify it. Since the devil of ABS is often in the detail, entities with past or future activities relating to marine genetic resources should make an inventory of how the BBNJ might affect them. Past due diligence activities relating to ABS under the Nagoya Protocol may be helpful in this respect.

If you find that the BBNJ may affect your business, it is recommended that you work with your government on clarifying the scope of past and future benefit-sharing obligations, and making sure that they are manageable. At this point in time, it is also still possible for parties to submit, *e.g.*, reservations, or even not ratify the treaty at all.

Once the treaty enters into force, it will take at least one year after that for the first COP meeting to be organized, which will provide further clarifications for the creation and application of the benefit-sharing mechanism. Companies may wish to also discuss the possibility for State Parties to request the possible four-year delay for the application of the benefit-sharing mechanism at the first COP meeting.

Covington's unique practice on Access and Benefit-Sharing from Biodiversity stands ready to assist you.

Bart Van Vooren

Bart Van Vooren has a broad life sciences practice supporting innovative pharmaceutical, food, medtech and biotech companies on EU regulatory, commercial and strategic policy assignments. He is widely recognized for his expertise on general EU law and procedure, as well as his extensive…

Bart Van Vooren has a broad life sciences practice supporting innovative pharmaceutical, food, medtech and biotech companies on EU regulatory, commercial and strategic policy assignments. He is widely recognized for his expertise on general EU law and procedure, as well as his extensive litigation experience before the EU Court of Justice in dozens of cases.

Over the past seven years, Bart has developed a niche practice on compliance with the Biodiversity Convention and the Nagoya Protocol, a set of rules to combat bio-piracy worldwide. He has accumulated unique, practical experience in dozens of jurisdictions around the world, and has handled everything from benefit-sharing negotiations, over compliance programs, to inspections by authorities.

Finally, Bart has an active pro bono practice assisting NGOs defending the human rights of persons with a disability through strategic litigation.

During his previous professional career, Bart was a professor of EU law at the University of Copenhagen and published a couple of books with Oxford and Cambridge University Press. His academic swan song was the (now leading) textbook republished in 2020 by his former academic colleagues in 2nd edition: EU External Relations Law, available from Hart Publishing.

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Yuliya Gevrenova is an associate in the Life Sciences Practice Group. She advises clients across a wide range of regulatory, compliance and procedural issues, focusing on EU and Public International law.

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Yuliya Gevrenova is an associate in the Life Sciences Practice Group. She advises clients across a wide range of regulatory, compliance and procedural issues, focusing on EU and Public International law.

Yuliya assists multinational companies in the food, feed, pharmaceutical and cosmetics sectors to navigate complicated legal frameworks, including:

International Health law, including the impact of the WHO Pandemic treaty, the application of the International Health Regulations and the Pandemic Influenza Preparedness Framework.

International Environmental law, including issues of access and benefit sharing under the Convention on Biological Diversity and the Nagoya protocol.

Food law, including labelling and claims; coordination with national authorities during withdrawals and recalls; special rules on flavorings and enzymes, as well as GMOs and NGTs.

Chemicals (REACH, plastics, pollutants, etc.) and Environmental regulations (CSDDD, Wastewater Directive, green washing, etc.).

Animal health issues, including animal testing, transportation and feed.

As part of her pro bono practice, Yuliya advises on complex litigation strategies aimed at defending the rights of people with mental disabilities.

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Seán Finan is an associate in the Life Sciences team. His practice covers environmental, food and beverage and pharmaceutical regulation.

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Seán has specific experience in a number of key areas for EU and UK clients in the technology, food and beverage, pharmaceutical, cosmetic and consumer goods industries, including:

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Environmental and ESG compliance issues, including CSRD, CSDDD and green taxonomy issues; green public
procurement issues; extended producer responsibility obligations, etc.;

Advertising claims, particularly environmental claims and greenwashing;

General food regulation; novel food regulation; genetically modified and &#8220;precision bred&#8221;
products; and

Chemicals legislation (REACH, CLP, biocides, etc.).
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Seán has represented clients in judicial review actions involving novel foods against multiple national regulators.

Seán is qualified in both England & Wales, and the Republic of Ireland.

Seán is a co lead of the firm's Disability and Mental Health affinity group.

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