

Biodiversity and innovation

New rules for natural ingredients for food, cosmetics and pharmaceuticals

Nature remains a unique source of innovation for beauty, health and food companies. Each year, companies tap into the allure and wealth of ideas and substances in biodiversity to develop active compounds from microalgae with potential pharmaceutical applications, food colorants based on the seeds of tropical plants and foams and surfactants from tree bark – among many other products and ingredients. Consumer demand for natural products maintains its growth, which means laboratories and brands are working to find new ingredients that are both natural and effective. Ensuring legal compliance and ethical sourcing practices is a challenge, but also provides opportunities.

Nagoya Protocol: Scope and implications

In 2014, new international rules on biodiversity-based research entered into force, which affect innovation in natural ingredients. The Nagoya Protocol on access and benefit sharing (ABS) is an international UN agreement currently binding over 90 countries.

It regulates research into the genetic or biochemical components of plants, animals or microorganisms – requiring prior authorization from governments or other stakeholders. Such research would include, for example, exploring plant parts, extracts or oils for new cosmetics ingredients or for inspiration for synthetic material to include in fragrances. It would also cover activities in ingredients for functional foods or scientifically proving properties in traditional medicinal plants for use in health beverages.

The Nagoya Protocol also requires benefits derived from research, development and commercialization of natural ingredients and products to be equitably shared. Fair and equitable sharing of benefits is agreed upon through an agreement between the company or institution seeking biological material for research and development, and the group, association or other entity supplying such material. What is fair and equitable – in terms of types, timing and mechanisms for benefit sharing – depends on the particular circumstances. The Nagoya Protocol suggests possible benefits, including collaborating and sharing the results of research and development, contributing to the local economy, capacity building or paying a percentage of resulting revenues. More specific approaches to

authorizing biodiversity-based research and development and sharing resulting benefits may be determined by national laws and regulations.



Brazil: Changing approaches to ABS

On 20 May 2015, Brazil adopted Law 13.125, which establishes the procedures that companies and other organizations will need to follow to work with Brazilian biodiversity. The new law repeals a 2001 measure widely criticized as too complex and bureaucratic. Authorization to access biodiversity for research and development, until now granted by a national council, will not longer be required. Companies will have to register on an online database. Benefit sharing, previously negotiated for each individual case, will fall on the final product manufacturer, and take place through a percentage of profits going to a national trust fund or specific projects.

Monitoring compliance on ABS

The Nagoya Protocol also includes provisions on monitoring and controlling biodiversity-based research and development. Countries are obliged to put in place measures to ensure that such research and development is conducted in accordance with the legal and regulatory requirements of the country where the samples of biological material came from. These “compliance” or “user” measures, considered critical to monitoring and enforcing compliance with ABS requirements, have begun to be implemented, including in the European Union.

Evolving national laws and regulations on ABS

In ABS, it is national laws and regulations that determine the requirements and procedures that companies and other actors must follow for biodiversity-based research and development. Over 30 countries include some reference to ABS in their legal framework and many laws and regulations are currently being revised or developed, including in Mexico and Madagascar.



South Africa: New requirements for biotrade activities

In May 2015, the Department of Environmental Affairs of South Africa published amendments to its regulations on bioprospecting, access and benefit sharing. Among new requirements established is a permit for “biotrade,” defined as the buying and selling of dried, powdered, sliced or extracts of indigenous genetic and biological resources for commercial purposes. This would explicitly include the use of biological material in developing medicines, nutraceuticals, industrial enzymes, food flavors, fragrances, cosmetic ingredients and essential oils. An application for a biotrade permit must be accompanied by proof of prior consent, a material transfer agreement and a benefit-sharing agreement involving the local provider.

User measures in the EU

In 2014, the European Union adopted regulation 511, which obliges companies to gather, keep and transfer information on the origin and legal compliance of genetic resources accessed for the purpose of research and development – a requirement called “due diligence.” Additionally, the new EU rules establish certain checkpoints, including requests for public funding and marketing approval, where companies will need to prove that authorizations and permits for biodiversity-based research and development are in place. To comply with these requirements, EU regulation 511 foresees that companies may rely on “best practices” – procedures, tools or mechanisms developed by associations of users and recognized by the European Commission. For example, Cosmetics Europe, in collaboration with other associations, is currently developing a set of best practices for companies in the sector.

Looking ahead

Though questions on the precise implications of new rules on biodiversity-based research and development remain unanswered, the opportunities of ABS are becoming clearer. The Nagoya Protocol and its implementing legislation provide more guidance and legal certainty on whether and how to engage with ABS permits and agreements. Compliance measures are leading to more information requests and exchange on ABS along supply chains of natural ingredients.

ABS is also increasingly recognized as a fundamental element in the ethical sourcing of biodiversity. In this regard, ABS can be understood not only as a legal requirement, but also as a tool to increase traceability, secure supply chains, build more equitable partnerships and distinguish products in the market. It should now be an essential part of business strategies to innovating and staying ahead of consumer demand on natural ingredients.

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