



# BIOSCIENCE AT A CROSSROADS: IMPLEMENTING THE NAGOYA PROTOCOL IN A TIME OF SCIENTIFIC, TECHNOLOGICAL AND INDUSTRY CHANGE\*

A range of sectors use genetic resources and associated traditional knowledge, including the pharmaceutical, agriculture, industrial biotechnology, cosmetics, botanicals, and food and beverage. Over the past two decades, scientific and technological developments evolving markets, and different business and intellectual property models have transformed demand for access to genetic resources and associated traditional knowledge in these sectors. As a result, the Nagoya Protocol will be implemented in a very different environment from that encountered by negotiators of the Convention on Biological Diversity (CBD) in 1992. The timing of the Nagoya Protocol to adapt to these new realities, and to incorporate lessons learned from the last 20 years of access and benefit-sharing (ABS) policy implementation, could not be better.

## GLOBAL MARKETS

- ▶ The US and Europe continue to have the biggest companies, but market growth in these countries has slowed in recent years. In contrast, markets and companies of emerging economies, such as Brazil, China and India, are growing rapidly.
- ▶ The size of companies in these sectors varies enormously (table 1) from the top pharmaceutical and food companies, which earn in excess of \$50 billion annually, to very small companies, particularly in the botanicals sector.
- ▶ Scientific, technological and market changes, including numerous mergers and acquisitions, are blurring the boundaries between sectors, with increasing overlap and integration across industries.

**TABLE 1. Global markets by sector**

INDUSTRY	GLOBAL MARKETS (US\$)
Pharmaceutical	\$955.5 billion (2011)
Cosmetics	\$426 billion (2012) – natural component \$26.3 billion
Food and beverage	\$11.6 trillion (2009) – functional beverages \$23.4 billion
Seed	\$45 billion (2011)
Crop Protection	\$40 billion (2010)
Industrial Biotech	\$65-78 billion (including biofuels, 2010) – industrial enzymes \$3.3 billion
Botanicals	\$84 billion (2010)

- ▶ In the last two decades, consumer interest in “natural”, “green”, and in some regions “fair trade” products has exploded, creating significant demand for products developed from nature, and those produced in environmentally and socially responsible ways.

## RESEARCH AND DEVELOPMENT

- ▶ Research and development (R&D) budgets vary enormously between sectors. The pharmaceutical industry is the most research-intensive; combined industry and government expenditures were \$68 billion in 2010. Others, like the botanicals industry, spend very little on R&D. Products are launched in many sectors with far less than a million dollars spent on R&D.
- ▶ In many sectors, R&D is often outsourced or undertaken through external partnerships. Smaller discovery companies, semi-governmental or governmental entities, and universities often license promising products to larger companies to develop and market.

## ADVANCES IN SCIENCE AND TECHNOLOGY

- ▶ Across all sectors, the speed, capacity and precision of research on genetic resources has increased dramatically due

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to new technologies and molecular tools. This has resulted in a massive increase in the number of genetic resource samples that can be screened.

- ▶ At the same time, the “physical” amount of genetic material needed for research has shrunk. Companies also increasingly access genetic resources digitally rather than receiving physical samples.
- ▶ Scientific and technological advances are continually expanding our understanding of the natural world, including relationships between organisms, with evolving implications for how genetic resources are studied and used.

## DEMAND FOR ACCESS

- ▶ In higher tech industries like pharmaceuticals, agriculture and biotech, the need to access genetic resources is less than in previous years, through large-scale field collections, but interest persists; in lower tech industries consumer demand for novel, and natural ingredients is often a central part of product identity and marketing.
- ▶ New research tools mean that diversity found in companies’ backyards and existing collections, particularly in the previously inaccessible genomes of microorganisms, can keep researchers busy.
- ▶ Over the past 15 to 20 years the focus of research has drastically shifted towards microorganisms. This trend has been observed in a range of different industries including pharmaceuticals, agriculture, biotechnology and food. Marine organisms are also of increasing significance, but largely due to the microbes they contain. The botanicals and natural cosmetics sectors maintain an interest in plants.

## DEMAND FOR TRADITIONAL KNOWLEDGE

- ▶ The cosmetic, botanicals, and food and beverage industries use traditional knowledge (TK) associated with genetic resources in product development. TK can guide R&D efforts towards finding useful species, can help determine safety and efficacy, and is used in marketing products with an interesting ‘story’.
- ▶ With an increased focus on genes, and in particular those from microorganisms, higher tech industries like pharmaceuticals and biotech now use little or no TK associated with genetic resources in their R&D programs.

## THE NAGOYA PROTOCOL: RESPONDING TO SCIENTIFIC, TECHNOLOGICAL, POLICY AND MARKET CHANGE

Implementation of the Nagoya Protocol can respond to the following specific concerns expressed in recent years:

**Helping researchers and companies follow ABS laws** – Many researchers and companies are apprehensive about the absence of guidance on how to navigate ABS measures in many countries. In addition to supporting information-sharing mechanisms and tools at the international level like the ABS Clearing-House (Article 14), the Nagoya Protocol encourages governments to establish information dissemination and outreach programs to help stakeholders identify and follow ABS procedures.

**Legal certainty and clear, workable regulations** – Time-consuming and bureaucratic regulations, and an absence of legal certainty when accessing genetic resources from some countries, are regarded by many companies as major stumbling blocks in natural products research. The Nagoya Protocol seeks to address these concerns and create an environment of legal certainty and mutual trust by requiring Parties to designate one or more competent national authorities to oversee ABS permitting and an ABS national focal point to make information available on procedures for obtaining prior informed consent and reaching mutually agreed terms, including from indigenous and local communities (Article 13).

**Defining the scope of ABS measures** – Many in industry have expressed concern about the inclusion of biological resources within the scope of ABS measures. The Protocol, however, covers genetic resources when these are “utilized” within the definition of Article 2(c) of the Protocol, meaning “to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology”, and does not cover genetic resources that are accessed and used as commodities. Implementation of the Nagoya Protocol can help to provide guidance to companies, researchers and indigenous and local communities about which resources and activities fall within its scope, thus providing certainty and clarity about ABS implications and requirements.

**Supporting benefit sharing from the use of traditional knowledge** – Traditional knowledge associated with genetic resources is of interest to some sectors but accusations of misappropriation are a major concern. Through Parties’ implementation of Articles 7 and 12, the Nagoya Protocol can help Parties, companies and indigenous and local communities to ensure that traditional knowledge associated with genetic resources is accessed and used with the prior informed consent of indigenous and local communities and that mutually agreed terms are established.

**Building the capacity of governments** – Article 22 of the Protocol also calls for capacity-building to implement the Protocol, including the development and implementation of ABS legislation, negotiation of mutually agreed terms, and improved capacity to undertake research on national genetic resources.

