COMPLIANCE OF ACCESS AND BENEFIT SHARING (ABS): A SECTOR SPECIFIC REVIEW

Centre for Biodiversity Policy and Law
National Biodiversity Authority

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Prakash Nelliyat

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FOREWORD

Biological diversity is a global asset, with tremendous value to the present and future generations. However, the species and ecosystem are under greater threat now than ever before. Considering this fact, arresting the decline of biodiversity is a major objective of global environmental policies with initiatives at national and local levels. With this goal in mind, the Convention on Biological Diversity (CBD) was initiated on 5th June 1992 at the United Nations Conference on Environment and Development (the Rio "Earth Summit") and came into force on December 1993 as an international instrument for comprehensively addressing biological diversity. 196 nations, including India, are parties in the CBD. The objectives of the Convention include: the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of benefits arising from the utilisation of genetic resources.

India is one of the 17 mega bio-diverse countries of the world. The rich biodiversity of India provides a number of ecosystem services as well as sources of income/livelihood for millions of poor. Besides, the biological resources are raw-materials for manufacturing different consumer products and the benefit/profits options for bio-entrepreneurs. India is also the home of a vast repository of traditional knowledge (TK) associated with biological resources. However, India's biodiversity faces a number of challenges, ranging from land use changes in natural habitats to overexploitation of resources, proliferation of invasive species and climate change. Arresting the further destruction of biodiversity and its conservation is an agenda of the government. Access and Benefit Sharing (ABS) is an emerging option for biodiversity conservation and its sustainable use. ABS refers to the way in which genetic resources are accessed, and how the benefits that result from their use are shared between the people or countries using the resources (users) and the people or countries that provide them

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(providers). For the effective implementation of ABS, India enacted the Biological Diversity Act (2002) and Rules (2004) and made decentralized institutional arrangements such as; National Biodiversity Authority (NBA), State Biodiversity Boards (SBBs) and Biodiversity Management Committees (BMCs) at the national, state and regional/local levels respectively. Biological resources based industries (pharmaceuticals / modern drugs, botanical medicines - AYUSH, agricultural seeds, ornamental horticultural products, crop protection products - biofertilizers and pesticides, health/personal care products, cosmetic products, food and beverages etc.) are using various bio-resources as inputs/raw-materials for manufacturing different products. These industries are using wild as well as domesticated biological resources which include: plants, animals, microorganisms and genetic materials from forests, agriculture, wetlands and marine ecosystems. There are fundamental differences in different industries' approaches and dependencies on biodiversity in terms of: types of biological resources accessed, methods and sources of collection, volume and quantity, research and development, biotechnology applications, nature of production, dependencies on biological resources associated TK, cost benefit ratio etc.

In this context, the report **"Compliance of Access and Benefit Sharing (ABS): A Sector Specific Review"**, which emphasises on the sectoral assessment of the utilisation of biological resources will be instrumental in framing effective ABS policies and facilitating a convincing argument towards ABS for different stakeholders, especially industries.

I congratulate Dr. Prakash Nelliyat, Dr. B. Meenakumari and Shri. T. Rabikumar for this important contribution.

M S Swaminathan

INTRODUCTION

Biological resources are the fundamental source for bio-prospecting, which has been described as 'the exploration of biodiversity for commercially valuable genetic and biochemical resources'. However, the commercial value and benefits obtained from genetic and biochemical resources need to be distributed to the primary stakeholders, and communities in such a manner that it acts as a positive force for the conservation and sustainable use of biodiversity (Bavikatte and Morten, 2015). This mechanism is generally known as Access and Benefit Sharing (ABS).

For the successful operation of the ABS, countries need to implement exclusive legal and institutional measures. Further, the significance of ABS with respect to conservation of biodiversity and sustainable use of its components has to be demonstrated to various stakeholders including the industrial communities. Broadly, the genetic/biological resources are used by companies as input or raw-materials for manufacturing different varieties of products having market potential. Biological resources based industries include: Pharmaceuticals (modern drugs), Botanical Medicines (AYUSH), Agricultural seeds, Ornamental horticultural products, Crop protection products (bio-fertilizers and pesticides), Health / personal care products, Cosmetic products, Food and beverages (food processing) and others (cotton textiles, leather, paper and pulp, jute etc.).

These industrial units are using wild as well as domesticated biological resources, which include: plants, animals, microorganisms and genetic materials, available in divergent ecosystems such as: forests, agriculture, wetland and marine spots. Generally, industries use biological resources in different quantities based on the nature of products manufactured by them. Further, the application of modern biotechnology in the production process also varies substantially among the industries. For example: pharmaceuticals (modern drugs) and agricultural seeds industries collect genetic / biological resources in limited quantities for research, particularly for identifying the biochemical compound or genetic modifications with the application of modern biotechnological devices. They have provisions for their culture / multiplication. On the other hand, botanical medicines (AYUSH) and food processing

industries need biological resources as raw-materials in bulk quantities. Compared to the pharmaceutical and seed industries, the research and development (R&D) and application of modern biotechnology devices in botanicals and food processing are unlimited.

This indicates that industries are accessing biological resources with different perspectives. Hence, the value additions on biological resources in different industrial sectors vary substantially. The nature of processing, volume of investments on infrastructure, particularly in R&D and application of scientific technologies in the processing units, the kind of labour employed etc. are the determining factors. In certain cases, similar biological resources may generate different values in different industrial sectors, which makes the ABS process more cumbersome. In this scenario, sectoral assessment of utilisation of biological resources will be instrumental for framing effective ABS policy decisions. Further, sector -wise application of ABS would facilitate framing a convincing argument towards ABS for different stakeholders including industry.

This report is prepared based on the insights from the available (limited) literature on 'Sectoral Approach to ABS' as well as a series of discussions carried out with experts who are researching and operating the ABS mechanisms. Further, the exposure acquired by the author from different biological resources based industrial visits and the information obtained from interviews with the industrialists in different states of India is also incorporated.

This review paper contains three sections. Section 1 examines various issues pertaining to biodiversity management including the significance of biodiversity and the challenges for biodiversity conservation, transformation in the management policy on biodiversity, definition and characteristics of genetic/biological resources, commercial utilization of genetic/ biological resources, Convention on Biological Diversity (CBD) and the Nagoya Protocol and the emergence of Access and Benefit Sharing. Section 2 addresses ABS with respect to different industrial sectors such as: modern drugs, botanical medicine, new seed varieties, ornamental horticultural products, crop protection products, biotechnologies (in fields other than healthcare and agriculture), healthcare and agricultural products, and personal care and cosmetic products. Section 3 focuses on the CBD and the Nagoya Protocol as well as a comparative analysis of compliance of ABS in different sectors and the challenges / concerns in implementing ABS as well as the way forward in this direction.

SECTION 1

Biodiversity Issues and Management

Biodiversity is the fundamental source of life support systems on the planet earth. Human life and welfare depends on the richness of biodiversity. However, the global biodiversity is under huge threat in recent times primarily due to anthropogenic reasons. Besides, there is a paradigm shifts on the property rights over biodiversity from a global public good to a national sovereign right and transformation of management policy. In this context a thorough understanding of biodiversity, its significance and functions, and various challenges faced by biodiversity will facilitate in framing appropriate management policies.

1.1 Biodiversity Management: Significance and Emerging Challenges

Biological diversity (biodiversity) represents the variety of life on earth, which include species diversity (the numbers and kinds of living organisms), genetic diversity (genetic variations within species) and ecosystem diversity (the variety of habitats, biological communities and ecological processes). The services of ecological systems and the natural capital stocks that produce them are critical to the functioning of the earth's life-support system. They contribute to human welfare, both directly and indirectly, and therefore represent a significant part of the total economic value of the planet (Costananza *et al*, 1997).

Bio-diverse ecosystems provide vital services such as; the regulation of water flows and levels, protection against extreme weather conditions, the purification of air and water, the prevention of soil erosion, and opportunities for recreation and spiritual reflection. Besides, biodiversity offers essential resources and goods, such as food, fibre, and medicines (CBD, 2011). In brief, biodiversity is a global asset with tremendous value to the present and future generations.

However, biodiversity faces multiple challenges from various factors that include: habitat fragmentation, degradation and loss, over-exploitation of resources, shrinking genetic

diversity, spread of invasive alien species, declining forest resource base, climate change and desertification, and impacts, of various development projects including pollution.The loss of biodiversity constitutes a concern for human welfare, especially for the well-being of the poorest, since it acts as a major livelihood option for them. Hence, biodiversity loss presents significant economic challenges. In biodiversity's case its supply and demand is a major factor which also addresses various management questions pertaining to biodiversity.

Since biodiversity or biological resources are unequally distributed in the world, their supply is restricted. On the other hand, their demand is escalating universally particularly in the globalized era. Broadly, biological resources business (collection, transfer, and exchange) is progressing at an alarming rate in biodiversity rich areas of the world. This business trends on biodiversity has led to the transformation of biodiversity more from a global public good to a regional / local public good or as state property and viewed as national sovereignty. In this context, the CBD insisted their parties to follow ABS through legal and institutional arrangements for the conservation and sustainable use of their biodiversity.

1.2 Structural Transformation in Biodiversity Management

The property rights of biodiversity are a complex and challenging area. Historically biodiversity has been considered as a 'global public good' and its conservation and management are recognized as a global responsibility. However, the scenario is changed drastically in recent period, particularly with the advent of CBD and the Nagoya Protocol.

According to Pisupati (2012), the insufficient understanding of public and private goods leads to challenges, particularly for managing public goods like biodiversity. Generally, public goods that are not provided by the market are often not sufficiently distinguished from merit goods (such as education, which are provided by the market but where the social benefits exceed the private benefits). The lack of distinction and clarity on public good implies boundless policy problems to this sector. This broils organizational responsibilities and accountabilities which hinders the search for cost-efficient policy solutions.

Broadly Global Public Goods (GPGs) has the characteristics non-rivalry between users and non-exclusion from use. Non-rivalry implies that a good can be used by more than one user

simultaneously, or used more than one time. Non-exclusion means that the good is available to more than one user at no or at negligible extra cost. At a great extend biodiversity and biological resources possess these characteristics. Public goods are not (or insufficiently) provided by the market - where marginal utility must equal marginal cost for the provision to be efficient - because of the free-rider problem among potential users. (The problem of the 'free rider' in economic theory arises when individuals who do not contribute to its maintenance consume public goods/resources thereby free riding on the contributions of the rest of the community for the upkeep of the goods/resources).

Generally, in public good users are not willing to reveal their preferences and pay accordingly. Given the long lags in the production of GPGs (such as stable climate), the financing of GPGs today amounts, in effect, to a resource transfer to future generations. And as current generations in poor countries live in great poverty, they may prefer to consume and grow now rather than to provide global public goods for the future with their limited resources.A definition of GPGs should also be confined to considerations of allocation, i.e. to leave out issues of distribution. This implies that if inter-generational concerns are to be accounted for, then this must be based on future utility estimations. Considering these, biodiversity can be described as the public good cutting across countries and regions with implications for both inter-generational and intra-generational equity (Pisupati, 2012).

According to Pisupati (2012), the governance of biodiversity through the prism of national sovereignty remains both a challenge as well as an opportunity, particularly in its management as a public good for sustaining development. Since 1992, after the agreement to establish the Convention on Biological Diversity (CBD) through the UN Conference on Environment and Development (UNCED), nation states continue to have certain ideological differences on how to share biodiversity and link efforts of conservation and sustainable use with questions of ethics of equity, ways and means of accessing biodiversity, and sharing the benefits of its use. With a stronger and near global membership, the CBD provides a significant platform to discuss biodiversity governance issues.

Further, biodiversity exists in the national jurisdiction of the state also have different property / ownership rights. Biological resources exist in a natural environment (common lands) as

well as manmade environment (private lands). For example, forest, river, estuary, ocean, etc. are common properties. These areas are having huge volume of biological resources. The community, who have the traditional rights on these resources are, historically collecting different biological resources and provide to the immediate users (traders, industries, research organizations, etc.) at free of cost or at meager amount. In other words, biological resources coming from the common property areas are experiencing market imperfections, hence it is underpriced. Therefore, the existing price may not act as an economic incentive for their conservation to the local communities. On the other hand, biological resources such as grains, cereals, vegetables, fruits, fishes from aquaculture ponds and life stocks that exist in private lands (fields and gardens) are controlled by private entrepreneurs. The resources arrived from the private lands are priced in better manner and act as an incentive to flourishing agri-business. These cultured or cultivated products' market prices reveal their cost of production (Nelliyet and Pisupati, 2013).

Even through biodiversity in state jurisdiction is no more considered a global common, the diversity that occurs in areas beyond national jurisdiction, including in places such as the high seas and in Antarctica, are not governed by any jurisdiction and the biodiversity that occur within them as a resource that is common to all. Bio-prospecting in such areas has risen to very high levels necessitating discussion on governance of such common areas. Despite discussions in the multilateral agreements, such as the CBD or Conventions such as the UN Convention on the Law of the Seas (UNCLOS), there is still no clarity on how the common areas are to be governed. The recently concluded 4thmeeting of the Working Group on Marine Biodiversity in Areas Beyond National Jurisdiction (June 2011) recommended the initiation of a process on the legal framework for the conservation and sustainable use of marine biodiversity in areas beyond national jurisdiction, and to develop an agreement under the UNCLOS. This discussion could be potentially used to relook at the issue of biodiversity governance in common areas using the principle that biodiversity in these areas are common pool resources (Pisupati, 2012).

1.3 Genetic / Biological Resources: Definition and Characteristics

The Convention on Biodiversity defined: 'Biological resources': which include genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual

or potential use or value for humanity."Genetic material" means any material of plant, animal, microbial or other origin containing functional units of heredity. "Genetic resources" means genetic material of actual or potential value (CBD, 2011). According to India's Biological Diversity Act (2002), "Bio-resources / Biological resources" means: plants, animals and micro-organisms or parts thereof, their genetic material and by-products (excluding value added products) with actual or potential use or value, but does not include human genetic material" (NBA, 2010).

Origin of the biological resources / genetic resources is from nature, which is historically considered as the free gifts of nature. In other words it was created by nature with its unique and intrinsic ability. Genetic/biological resources are renewable and can be considered as a subset of biodiversity. Bio-resources and biodiversity are highly interlinked. One can interpret biodiversity as a stock and biological resources as the flow from it; they are mutually interrelated in their existence and function. Hence, the earth's biodiversity stock should be maintained intact through its sustainable utilization (extraction should be less than or equal to its regeneration) for fulfilling various human requirements for ever (Nelliyet and Pisupati, 2013).

Biodiversity exists in in-situ and ex-situ situations. In in-situ conditions, genetic resources exist within ecosystems and natural habitats. In-situ conservation is significant, where conservation of ecosystem and natural habitats and the maintenance and recovery of viable population of species in the natural surroundings and in the case of domesticated and cultivated species, in the surroundings where they have developed their distinctive properties. In the case of ex-situ conservation, conservation of the components of biological diversity takes place outside their natural habitants such as zoos, botanical gardens, and seed banks.

Genetic/ biological resources and associated traditional knowledge also have great commercial potential, and their contribution to global economy and global intellectual property regimes is enormous. They are the key resources for sustainable bio-prospective and value addition processes. Further, biogenetic resources are the primary source of valuable genes, chemicals, drugs, pharmaceuticals, natural dyes, gums, resins, enzymes or proteins of great health, nutritional and economic importance (Pushpangadan and Nair, 2005). The combined world market for products manufactured through biological resources is estimated to be over US $ 500 billion (Laird and Kate, 2002).

With the advent of new tools and techniques the power of bio-prospectives has increased considerably in recent decades. According to Pushpangadan and Nair, (2005), modern bio-prospectives include systematic search for genes, natural components, designs and whole organisms of either domesticated or wild sources with a potential for product development. Thus bio-prospective has three facets: chemical prospective, gene prospective and bionic prospective.

The indiscriminate use and extraction of biological resources by different bio-prospecting and product manufacturing industries, without consider its sustainability is a critical issues. However, biodiversity / biologicalresources conservation and sustainable use is a pre-requisite for the continuous progress of bio-prospecting and the functioning of biologicalresources based industries. In this context, CBD proposed Access and Benefit Sharing (ABS) as an instrument for biodiversity conservation and sustainable use.

1.4 Commercial Utilization of Genetic / Biological Resources and the Emergence of ABS

Genetic / biological resources are significant in economic development and enhance human well-being. The contribution of biodiversity and biological resources can broadly classified under the following heads:

- Source material: Biological resources are the major sources or input factor for developing modern drugs, botanical medicines, new seed varieties, ornamental horticultural products, crop protection products, biotechnologies (in fields other than healthcare and agriculture), healthcare and agricultural products, and personal care and cosmetic products. These products and manufacturing industries played a significant role in enhancing human welfare and the economy.





- Livelihood Option: Biological resources can provide sustainable livelihoods to rural communities, particularly the socially vulnerable communities in developing countries like India. Since sizable numbers of population in these countries are living in rural areas, where agriculture and allied activities (source of varieties of biological resources) are the major source of livelihoods. Further, village commons like wetlands, grasslands and forests are the source for different biological resources, which are historically used by villagers for their consumption and as a source of income.

- Base for Ecosystem: Biological resources can be the basis for the protection of ecosystems, and support ecological and economic goals; Biological resources and biodiversity are inseparable and complementary to each other. Different biological resources play a significant role in the formation of rich biodiversity providing its different ecological functions, which are essential for achieving various economic goals. Rich biological resources are the symptom of good biodiversity and vice-versa.

- Basis for non-monetary benefit sharing, including technical assistance and cooperation in R&D activities: Research and Development in biology is primarily on genetic or biological resources. The results obtained from it may be shared among nations without any monetary benefits. Non-monetary benefit sharing includes the involvement of research activities, development of inter-generational research capacity, infrastructure development and wider strategic inter - generational capacity development needs. These non-

monitory benefits associated with biological resources can enhance human development and satisfaction irrespective of the national jurisdiction.

- The following table (Table 1A and Table 1B) provides the ballpark estimation of various categories of the products derived from genetic resources during 2000 and 2009-2013, through two separate studies.

Table 1A: Ballpark estimation of annual markets for various categories of the products derived from genetic resources

S. No	Sector	Market (US $ Billion)		Note
		Low	High	
1	Pharmaceuticals	75	150	Some products derived from genetic resources. Low estimates: natural products from 25% of global market. High estimates 50%
2	Botanical medicines	20	40	All products derived from genetic resources. Low estimates for global botanical medicines market; high estimates include botanical medicines, minerals and vitamins.
3	Agriculture products (commercial sales of agriculture seed)	300 + (30)	450 + (30)	All products derived from genetic resources. Low estimates: final value of the produce reaching consumer 10 x commercial sale of seed to the farmers. High estimates 15 x commercial sale of seed to the farmers.
4	Ornamental Horticulture products	16	19	All products derived from genetic resources. Low estimates: based on available data. High estimates: allows for unreported sale and product.
5	Crop protection products	0.6	3	Some products derived from genetic resources. High estimates include wholly synthesised analogues, as well as semi-synthesised products.
6	Biotechnology in fields other than health care and agriculture	60	120	Some products derived from genetic resources. Low and high estimates based on assessments of environmental biotechnology.
7	Personal care and cosmetic products	2.8	2.8	Some products derived from genetic resources. Reflects 'natural' components of the markets.
	Rounded Total	**500**	**800**	

Table 1B: Global Biodiversity 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)

Source: CBD (2013g),

It is very clear that biodiversity in a broader sense and biological resources in specific have commercial or economic as well as ecological significances and its contributions to the global economy is increasing. However, biodiversity's conservation and its sustainable use are pre-requisites and also a challenge. In most cases, the commercial and business sector is progressing at the cost of the ecological or biodiversity sector. In the long run, the impact of the loss of biodiversity would reflect on the business sector. Hence, the system may not be economically and / or ecologically sustainable. For example: A mass extraction of medicinal plants for botanical drug manufacturing from a particular forest area may affect its renewability and threaten various ecological services. In this context, the Access and Benefit Sharing (ABS) principle for the conservation and sustainable utilization of medicinal plants (biological resources) attains immense significance.

1.5 Convention on Biological Diversity and the Nagoya Protocol

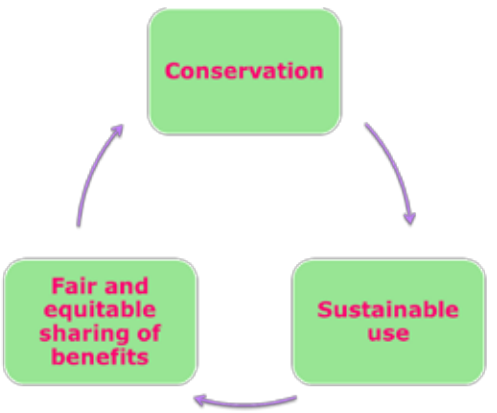
Even if biological diversity is a global asset, with tremendous value to the present and future generations, the species and ecosystem are under greater threat in recent years than ever before. Some estimates indicate the loss of 45-250 species per day and biodiversity losses have become a global concern. But biodiversity once lost is lost for ever and likely to cause serious consequences to the ecosystem and human life. Considering this fact, arresting the

decline of biodiversity (species and ecosystems) is a major objective of environmental policy at the global level, and needs to take initiatives at national and local levels.

With this perspective, the Convention on Biological Diversity (CBD) was initiated on 5th June 1992 at the United Nations Conference on Environment and Development (the Rio "Earth Summit") and come into force on December 1993 as an international instrument for comprehensively addressing biological diversity. The Convention's three objectives include: (1) the conservation of biological diversity, (2) the sustainable use of its components and (3) the fair and equitable sharing of benefits arising from the utilisation of genetic resources. These objectives need to operate in a continuous and cyclical manner (as indicated in Figure 1) towards the successful functioning of the ecological/biodiversity functions for enhancing human welfare.

The conventions have 42 Articles covering different aspects related to biodiversity conservation.

Figure 1: CBD Objectives



In a realistic sense, the third objective is more instrumental for achieving the first and second objectives of the CBD. Therefore, further advance of the implementation of the third objective was essential. The World Summit on Sustainable Development at Johannesburg, (September 2002) called for the negotiation of an international regime, within the framework of the Convention, to promote and safeguard the fair and equitable sharing of benefits arising

from the utilisation of genetic resources. The Convention's Conference of the Parties (CoP) responded at its seventh meeting, in 2004, by mandating its Ad Hoc Open-ended Working Group. After six years of negotiation, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, to the CBD was adopted at the tenth meeting of the CoP on 29th October 2010, in Nagoya, Japan (CBD, 2011).

The Protocol significantly advances the Convention's third objective by providing a strong basis for greater legal certainty and transparency for both providers and users of genetic resources. Specific obligations to support compliance with domestic legislation or regulatory requirements of the Party providing genetic resources and contractual obligations reflected in mutually agreed terms are a significant innovation of the Protocol. In other words, the protocol made a platform for compliance provisions as well as the more predictable conditions for access to genetic resources and sharing their benefits. In addition, the Protocol emphasises on the provisions of access to traditional knowledge (associated with genetic resources) owned by indigenous and local communities as well as benefit sharing to the community, when a company makes use of their knowledge, innovations and practices.

The protocol has 36 Articles containing divergent aspects including: objectives, use and scope, access of biological resources and traditional knowledge, fair and equitable benefit sharing, contribution to conservation and sustainable use, global multilateral benefit sharing mechanism, compliance with domestic legislation, monitoring the utilization of genetic resources, capacity and awareness raising, technology transfer, monitoring and reporting by parties etc. By promoting the use of genetic resources and associated traditional knowledge, and by strengthening the opportunities for fair and equitable sharing of benefits from their use, the Protocol will create incentives to conserve biological diversity, sustainably use its components, and further enhance the contribution of biological diversity to sustainable development and human well-being (CBD, 2011).

ABS refers to the way in which genetic resources are accessed, and how the benefits that result from their use are shared between the people or countries using the resources (users) and the people or countries that provide them (providers). Providers of genetic resources are governments or civil society bodies, which can include private land owners and communities. Users of biological resources are bio-prospecting industries. The ABS mechanism proposes

that whoever, accesses the genetic resources for commercial intent, should share the benefits (even at least a part) resulting from their use. In other words, the access and benefit-sharing provisions of the CBD are designed to ensure that the physical access to genetic resources is facilitated, and that the benefits obtained from their use are shared equitably with the providers. In some cases this also includes valuable traditional knowledge associated with genetic resources that comes from indigenous and local communities (CBD, 2011).

The benefits to be shared can be monetary, such as sharing royalties when the resources are used to create a commercial product, or non-monetary, such as the development of research skills and knowledge (Appendix 1). However, monetary benefit sharing is more transparent and required a rigorous economic analysis. It is vital that both users and providers understand and respect institutional frameworks such as those outlined by the CBD and in the Bonn Guidelines. These help governments to establish their own national frameworks, which ensure that access and benefit-sharing happens in a fair and equitable way. ABS is based on prior informed consent (PIC) being granted by a provider to a user, and negotiations between both parties to develop mutually agreed terms (MAT) to ensure the fair and equitable sharing of genetic resources and associated benefits (CBD, 2011).

The providers and users of genetic resources are the main actors in ABS mechanism. States have sovereign rights over natural resources under their jurisdiction. They are obligated to put in place conditions that facilitate access to these resources for environmentally sound uses. Providers agree to the terms, which include PIC and MAT, for granting access and sharing benefits equitably. Laws within the provider country may entitle others, such as indigenous and local communities (ILCs), to also negotiate terms of access and benefit-sharing. The participation of ILCs is necessary in instances where traditional knowledge associated with genetic resources is being accessed. According to the CBD, the users are responsible for sharing the benefits derived from genetic resources with the providers. They seek access to genetic resources for a wide range of purposes, from basic research to the development of new products. Users are a diverse group, including botanical gardens, industries such as pharmaceutical, agriculture and cosmetic, collectors and research institutes. However, between the providers and users of biological resources a large number of traders and intermediaries exist and play a significant role in materializing the trade or exchange.

In brief, biodiversity degradation is one of the major challenges faced at the global level. As biodiversity is a critical element for providing ecosystem services its conservation is important. Further biodiversity have significant commercial importance, as provide source materials for different industries, its sustainable use is a critical aspect.Biodiversity was seen as the common heritage for mankind to use and improve upon for millions of years. Much of the diversity, ranging from crop genetic diversity to livestock diversity and fish diversity, are all results of such an approach. However, during the past few decades, especially after the advent of CBD, we have seen a quick transition of looking at biodiversity as a common good of those countries where the biodiversity occurs (the sovereign rights principle). In this regard, appropriate management strategies have to be developed where ABS has good scope. For a thorough understanding on the operation of ABS, it is extremely important to obtain clarity on the industrial or sector-wise biological resource utilization.

SECTION 2

Access and Benefit Sharing (ABS) and Sectoral Approach

The involvement of bio-resource based industries in ABS process and the acceptance and the implementation of the ABS philosophy in their business model is an emerging challenge. According to Sarah and Rachel (2012), ABS strategies, policies and laws need to be responsive to dynamic changes in the bio-sciences and bio-economy. Industry needs to respond to the fundamental principles of ABS, raise awareness of its obligations under the CBD and Nagoya Protocol, ensure more equitable benefit sharing with providers of genetic resources and knowledge, and build the ABS principles and values into business practices.

However, experience from different countries revealed that, industries followed different approaches towards ABS. Many countries are yet to establish the legal measures for the implementation of the ABS. Countries where who come-up with the legal measures, appropriate strategies for its effective enforcement is not in place. It is important to build capacities among the stakeholders, particularly industries on the scope of ABS and the need for conservation of biodiversity for enhancing biological / genetic resources based research and business. In this regard more understanding on the application of ABS in different industrial sectors is required.

2.1 Why Sectoral Approach on ABS is required?

A recent study indicated that industries engagement with ABS has varied considerably over the past 20 years (Sarah and Rachel, 2012). In the early years of the CBD, discussions largely focused on pharmaceuticals and agriculture sectors. But the modern scientific and technological trends, the increased market demand for natural ingredients and the ratification of Nagoya Protocol by more countries significantly influences on the utilization of genetic resources other sectors too. Today, almost every sector which is involved in conducting research and development on the genetic and/or biochemical composition of genetic resources is impacted to some degree by ABS requirements.

However, industry engagement with ABS and the CBD still varies both across and within sectors. The differential involvement of sectors is largely determined by the extent of their reliance on genetic material and traditional knowledge, their size, perceived risks and values associated with the use of genetic resources and traditional knowledge, and the relevance of the CBD to their work. For example, in the agricultural sector, dependence on genetic diversity remains strong, but for many involved in this sector, ABS engagement has primarily been through the ITPGRFA, which is the primary international instrument regulating the exchange of key crops through Annex 1 of the Treaty and the Standard Material Transfer Agreement (SMTA). However, many genetic resources are not listed in Annex 1, and access to these resources, as well as to Annex 1 crops used outside of the scope of the ITPGRFA, are governed by the CBD – as well as the Nagoya Protocol (Sarah and Rachel, 2012).

Studies by Sarah and Rachel (2012) noted that in the pharmaceutical industry there has been consistent, (even if moderate), engagement with the ABS policy process. In large companies the basic elements of ABS are now accepted as standard practice. These companies have been recognizing that without an ABS agreement a sample would be useless and a very expensive final product might be contested. But smaller companies and academic institutions, awareness of the CBD obligations is more inconsistent, which should be widespread. Many small companies complain that they do not have the 'bandwidth' (internal staffing including legal experts) to undertake ABS agreements, hence they stay away from collecting genetic resources that require ABS compliance. In this divergent and inconsistent situations, the universal applicability and enforcement of ABS irrespective of the nature and the size of the units is a challenge.

Recently, the increasing consumer interest in natural ingredients has led to much greater use of genetic resources and traditional knowledge by the cosmetic industry and come forward to the ABS. However, other sectors such as: food and beverage and botanicals, which use a vast range of ingredients from many different suppliers in their formulations, have not fully grasped the legal and ethical obligations that arise from the CBD and rarely see these requirements as relevant to their business model. This is slowly changing in a few countries, as governments introduce laws that require ABS compliance before access to genetic resources is permitted (Sarah and Rachel, 2012).

At present 105 countries, including India, have ratified the Nagoya Protocol and are initiating measures for its implementation. Compared to other countries, India made substantial progress in this regard and the Box – 1 gives the brief picture on India's ABS initiatives under the Biological Diversity Act (2002).

Box – 1: India's ABS Initiatives

As an outcome of CBD initiatives, India enacted the Biological Diversity Act (2002) and Biological Diversity Rules (2004) and made decentralized institutional arrangements by creating National Biodiversity Authority (NBA), State Biodiversity Boards (SBBs) and Biodiversity Management Committees (BMCs) at the national, state and local body levels respectively, for effective implementation of ABS. The objectives of the Act are similar to the CBD objectives.

Further the various notifications issued under the Act, and the 'Guidelines on Access to Biological Resources and Associated Knowledge and Benefit Sharing Regulation (2014)' provide more clarity for implementing the ABS in the country.

At the state level, different states notified State Specific Biological Diversity Rules for the smooth implementation of ABS.

The Key provisions of the Biological Diversity Act, 2002 and Rules, 2004

Section	Persons	Activity	Purpose
Section 3 (NBA)	Foreign citizens, Non-Resident Indians (NRIs), body corporates, associations or organisations not incorporated or registered in India or incorporated or registered in India which has any non-Indian participation in share capital or management.	Obtainment of any biological resource occurring in India or knowledge associated thereto.	Research, Commercial Utilization, Bio-survey and Bio-utilization.

Section	Persons	Activity	Purpose
Section 4 (NBA)	Indian citizens, foreign citizens, NRIs, body corporates, associations or organisations incorporated or registered in India with or without any non-Indian participation in share capital or management and body corporates, associations or organisations not incorporated or registered in India.	Transfer of results of any research relating to any biological resource occurring in, or obtained from India, to any person covered under Section 3.	Transfer of research results for monetary consideration or otherwise.
Section 6 (NBA)	Indian citizens, foreign citizens, NRIs, body corporates, associations or organisations incorporated or registered in India with or without any non-Indian participation in share capital or management and body corporates, associations or organisations not incorporated or registered in India.	Application for any IPR in or outside India for any invention based on any research or information on a biological resource obtained from India.	Obtaining IPR, by whatever name called, in or outside India.
Section 20 (NBA)	Any person who has been granted approval under Section 19.	Third party transfer of any biological resources or associated knowledge there to which is the subject matter of an approval granted by the NBA under section 19.	Transfer of biological resources or associated knowledge
Section 7 (SBB)	Indian citizens, body corporates, associations or organisations which are registered or incorporated in India and not covered under Section 3.	Obtaining any biological resource.	Commercial utilization, bio-survey and bio-utilization for commercial utilization.

Exemption from ABS provision as per the Act include: (a) human genetic material, (b) value added products (products which may contain portions or extracts of plants and animals in unrecognizable and physically inseparable form), (c) 421 biological resources notified as 'normally traded as commodities', provided they are traded as commodities. Further, local people and communities, including growers and cultivators of biodiversity, and vaids and hakims, who have been practicing indigenous medicine are exempted from the requirement of providing prior intimation to SBBs for obtaining biological resources for commercial utilization or for bio-survey or bio-utilization.

Contravention or abetment of contravention of the provisions of Sections 3, 4, 6, 7, 20 or 24 of the Act amounts to a cognizable non-bailable offence.

As of March, 2018, NBA received 2183 ABS applications for different activities envisaged in the Act. There have been:

i. 395 applications for access to biological resources and/or associated traditional knowledge
ii. 51 applications for seeking prior approval of NBA for transferring results of research to foreign nationals, companies, NRIs and for commercial purposes
iii. 1575 applications for seeking prior approval of NBA for applying for intellectual property rights, and
iv. 82 applications for seeking approval of NBA for third-party transfer of the accessed biological resources and/or associated traditional knowledge.

Out of 2183 applications received by the NBA, 1262 applications have been cleared for approval, i.e. draft agreements (MAT) have been communicated to the applicants for execution. Among the 1262 applications, 764 ABS agreements have been signed which is the approval for the activities for which permission is sought by the applicant.

Out of the applications cleared for approval, 74% of the applications seek grant of approvals for accessing plants as biological resources, 7% animals and 19% micro-organisms. These applications relate to (i) biological resources or (ii) biological resources and associated traditional knowledge.

Further, the sector specific analysis of India's ABS has carried out by Gayathri and Rana (2018) and the insights are summarized in Box - 2.

Box– 2: India's ABS: Sector Specific Analysis

The sector wise analysis of ABS applications received by the NBA until October, 2017 (1853 numbers) was considered for analysis. Biological resources based industries, that are willing to share ABS, are classified under different sectors include: pharmaceuticals, research, nutraceutical, export, environmental bioremediation, and cosmetics. The summary of the analysis is given bellow:

S. No	Sector	Number of cases	%
1	Pharmaceuticals	1010	54.5
2	Research	351	18.9
3	Nutraceutical	280	15.1
4	Export	100	5.4
5	Environmental bioremediation	64	3.5
6	Cosmetics	48	2.6
Total		**1853**	**100**

Source: Gayathri and Rana (2018)

In India's ABS, the pharma sector is the dominant sector followed by the research and nutraceutical. From India the export of biological resources like neem, sea weed, cattle embryo and red sanders has shown remarkable rise in recent period.

Recently, the awareness about ABS has undoubtedly grown within and across different sectors. According to Sarah and Rachel (2012), the positive role that the CBD can play in promoting equitable relationships, conservation and best practice is now well recognized, and the political will to comply with ABS principles has evolved significantly. The Nagoya Protocol has given added impetus to this trend. While there has been growing unease about ABS in the past from both users and providers, the Nagoya Protocol has taken many of these concerns on board. However, the uncertainties in the legal and organizational procedures among various ABS stakeholders on the implementation of the Nagoya Protocol are a challenge. Without a proper certainty or clarity, it has been difficult for partnerships to develop between users and providers, despites ABS's widespread recognition. Further, there are misunderstandings about the value of genetic resources for research and development, and for commercialization.

In brief, bio-resources are having huge economic potential and are the base for many manufacturing sectors such as: pharmaceuticals, nutraceuticals, agriculture, horticulture, cosmetics and industrial biotechnology. Based on the above discussions, it is important to assess the industrial / sector wise ABS issues with consider the nature of production, factors of production involved etc. The industries are broadly classified as: Pharmaceuticals (modern drugs), Botanical Medicines (AYUSH), Agricultural seeds, Ornamental horticultural products, Crop protection products (bio-fertilizers and pesticides), Health / personal care products, Cosmetic productsindustrial biotechnology, and Food and beverages (food processing). The following section examines this issue in detail.

SECTION A

PHARMACEUTICALS

A1 Production and Market

The pharmaceutical industries are one of the pioneering industries flourishing all over the world, but at different degrees, for attacking the emerging diseases and for achieving the health security and human welfare. The advancement and the development of the industry in one part of the world countries may benefit to other part of the world/countries too. Further the pharmaceutical sector bound to develop according to the newly emerging diseases in the universe.The study done by Shearson Lehman Brothers (1991) revealed that the annual global sales of medical drugs were US$ 300 billion a year. The authors also stated that the figure may likely to grow by about 6% each year until 2001. Subsequently, Sarah (2011) made a regional based pharmaceutical industries market assessment based on the IMS Health Data (Table 2). According to this analysis the global pharmaceutical industry had revenues at US$ 955.5 billion in 2011. Out of it the North American market the world's largest, had US$ 347.1 billion (41.8%) followed by Europe at US$ 265.4 billion (26.8%).

Table –2 Total Global Pharmaceutical Markets (Unaudited and Audited) by Region

S. No	Region	2011 Revenues (US$ billions)	Growth over previous year
1	North America	347.1	3.0%
2	Europe	265.4	2.4 %
3	Asia/Africa/Australia	165.2	13.1 %
4	Japan	111.2	5.6 %
5	Latin America	66.7	8.9 %
Total		**955.6**	

Source: Sarah (2011)

The pharmaceutical industries are experiencing structural transformation in recent period. The growth in the largest pharmaceutical markets in developed nations particularly, the US, Europe, and Japan has slowed significantly in recent years but there is rapid growth experienced in developing countries / emerging economies such as Brazil, China and India (CBD, 2013). Broadly, the revenue generated in the pharmaceutical companies various substantially. The top 10 companies account for US$ 352.6 billion in sales (Table 3), which is 59.40% of total revenues from this sector. However, domestic companies outside Europe, Japan and the US are undergoing rapid expansion, with many in countries like China and India reporting sales in excess of a billion dollars.

Table 3

Revenue of the Top Ten Pharmaceutical Companies (2011)

S No	Companies	Revenue / Sales (US$ Billions)	Country
1	Pfizer	58.5	USA
2	Novartis	42.0	Switzerland
3	Sanofi-Aventis	40.3	France
4	Merck	39.8	USA
5	Roche	39.1	Switzerland
6	GlaxoSmithKline	36.2	UK
7	AstraZeneca	33.3	Sweden/UK
8	Johnson & Johnson	22.4	USA
9	Eli Lilly	21.1	USA
10	Abbott	19.9	USA
Total		**352.6**	

Source: PharmExec, 2011

The pharmaceutical industry is increasingly global in scope primarily due to medicines nature and its necessity. Previously, company might launch a number of products in one or two of the three major markets (Europe, Japan, and the USA). But these days, in order to derive a satisfactory return on research and development, pharmaceutical companies launch products in all three markets (Shearson Lehman Brothers, 1991).Given the vast sums required to bring a pharmaceutical to market, the bulk of pharmaceutical development is conducted by the private sector. Pharmaceutical companies range in size from start-up enterprises whose staff can be numbered on the fingers of one hand, to the pharmaceutical divisions of life science multinationals which may employ over 1,00,000 people (Kate and Laird, 2000).

In the pharmaceutical sector, public, private, and academic and research organizations are playing a significant role for its production and development. Despite the predominant role of the private sector in pharmaceutical development, government agencies continue to play a significant role in many countries particularly through their active involvement in pharmaceutical research. Besides, academic and research institutions also have made important contributions to pharmaceutical discovery and development. Most natural product drug discovery is undertaken today by smaller companies, government, and academia, and promising products are then licensed to larger companies for development. The demand for access to genetic resources is thus generally from smaller groups, rather than from large companies (CBD, 2013), which might be a concern when assigning the ABS.

Pharmaceutical companies are traditionally large, vertically-integrated concerns that conduct the full range of activities from creating libraries of compounds to marketing the drugs. There are few companies that produce pharmaceuticals alone. However, most of them manufacture and sell a combination of nutritional products; medical or laboratory products, devices or diagnostics; consumer health products; agricultural products; cosmetics or beauty care products; flavours or fragrances; vitamins and fine chemicals; or animal health products (CeEN, February 1998).

According to the Economist (1998), there are some 3,000 metabolic drugs on the market which can be classified into two main categories. One group consists of compounds of small molecular weight which are either 'synthetic compounds', being manmade in origin, or 'natural

products', derived from compounds isolated from plants, animals or microorganisms. These products, known in the pharmaceutical trade as 'small molecule drugs' have a molecular weight generally less than 500 daltons. The second category of products is 'biopharmaceuticals', a term comprising protein drugs, generally known as 'therapeutic proteins' and vaccines, both produced by recombinant DNA technology, and monoclonal antibodies, produced by cell fusion. Biopharmaceuticals generally have molecular weights of thousands or even tens thousands daltons, and are thus considerably bigger than 'small molecule' drugs, whose molecular weight tends to lie between 300 and 500 daltons (Kate and Laird, 2000).

A2. Biological Resources

The demand for genetic resources access in pharmaceutical has changed significantly in recent years as a result of rapid and on-going scientific and technological advances. These advances in science and technology have transformed our understanding of the natural world and our ability to study it. Earlier difficulties associated with screening natural product samples, isolating active compounds, and scaling up raw material supply are falling away, and natural products research is quicker, cheaper, and easier than even five years ago. The material that researchers and companies access has also changed, with the vast majority of research now done on microorganisms, including those found in the sea. In all cases, it is the genetic material found within organisms, rather than the organisms themselves that is of greatest interest to researchers (CBD, 2013).

Broadly, a range of natural ingredient (biological resources) has contributed to the discovery and development of drugs, including plants, microorganisms, fungi, marine organisms, insects, animal genetic resources, and human genetic resources. These natural ingredient / products, role in drug discovery and their potential role in future research efforts are significant. Despite the historical and current prevalence of plants in the pharmacopoeia, only 5 to 15% of the approximately 250,000 - 500,000 species of higher plants have been investigated for the presence of bioactive compounds, which indicated that the potential of biodiversity, for discovering new medicines are huge in near future.

Microorganisms: Microorganisms are a prolific source of structurally diverse bioactive metabolites, and have yielded some of the most important products of the drug industry,

including penicillins, aminoglycosides, tetracyclines, cephalosporins, and other classes of antibiotics. Microorganisms are also ' useful for activities other than antibiotic action, including antitumour agents (eg mitomycin, bleomycin, daunorubicin); immosuppressive agents (eg cyclosporin, FK-506, rapamycin); hypocholesterolemic agents, enzyme inhibitors, and antimigraine agents (Demain, 1998).

Microbial samples are collected from a wide range of environments, from traditional soil samples to leaf litter, tree branches, animal dung, and beetle carcasses. Each type of sample has its own characteristic spectrum of organisms. Less than 1% of all the microorganisms in our world have been identified. From that small percentage, scientists have developed, a large number of important drugs and industrial products that have changed the world we live in. According to (Kate and Laird, 2000), by searching the 99% of the microbial world that is still unknown, we are hoping to identify compounds that will be useful to pharmaceutical and other industrial sectors.

Microorganisms have a number of positive features that distinguish them from other biological resources for their discovery programme, which include:

a. Microorganisms provide a broad diversity of compounds.

b. Microorganisms are easy to preserve and maintain in ex-situ collections (although they can change genetically over time, which can influence the expression of their metabolites).

c. Microorganisms can be cultivated in laboratories to provide suitable amounts for screening; and

d. Microorganisms require only a negligible part of in situ populations to be samples; because it is only necessary to collect a very small portion of the whole organism to have a viable sample, hence the danger of unsustainable collection is reduced(Kate and Laird, 2000).

In this regard the experience from an Indian company is summarized below (Box 3)

Box - 3
Indian Pharmaceutical Company

This company (x) is a government of India undertaking, which has partnered with the Ministry of Health and Family Welfare, to set up a premium facility for production of vaccines for the National Immunization Programme and other new generation vaccines. The main objective of Company is to ensure safe and effective vaccines at affordable prices. They purchase microbial strains from the National Centre for Cell Sciences (NCCS), which collects and isolates the strains from nature in a limited quantity. Using the very small quantity of the initial collection of the strain, the required amount is cultured and maintained by the company for further use.

Company X also seeks to develop a strong R&D base for the development of futuristic vaccines, apart from manufacturing and supplying vaccines required for the Universal Immunization Programme (UIP) in India. The major steps involved in the vaccine manufacture include: identification and sourcing of seed materials, process standardisation and development, testing and procedures – human and clinical, production and manufacturing, and marketing. The cost distribution pattern of the company includes 30% for R&D, 50% for the production including the capital and variable costs, and the balance 20% as profit.

Marine organisms: Marine organisms are another prominent source of biological resources, represent a valuable resource for potential chemotherapeutic agents. The pace of investigation of marine invertebrates has increased over the past few decades, but remains the smallest component of natural products screening to date. The systematic investigation of marine environments for sources of novel biologically active agents began in the mid-1970s. From 1977 to 1987, about 2,500 new metabolites were reported from a variety of marine organisms. Broadly, marine organisms have been shown to be a rich source of bioactive compounds, many from novel chemical classes not found in terrestrial sources. However, collection of marine specimens is usually more complex and costly than expeditions to collect terrestrial plant materials.

Insects: Insects are another source of biological resources used by the pharmaceutical sector. However, very little research has taken place in this area of insect to date. Some of the pharmaceutical companies interviewed expressed a growing interest in invertebrates, and it appears that the massive diversity in insect species and the novel chemical compounds they use for defense and other purposes will receive more attention in the near future.

Animals: Animal genetic resources have a limited but significant history in natural product drug discovery. Studies revealed that 23% of all compounds contained in prescription drugs dispensed in the USA are derived from animals. Polypeptide toxins in purified form from venomous animals - snakes, spiders, insects, scorpions, snails, etc. frequently produce highly selective actions on a specific component of a biological system. Animals are also the source of hormones and other metabolites used in biotechnology and may be used in the future for xenotransplantation (e.g. breeding genetically engineered pigs to produce hearts for transplantation into humans). Animal genetic resources tend to form the basis of specialized research and development programmes, rather than acting as a component of broader screening initiatives (Kate and Laird, 2000).

Human: The use of human genetic resources is increasing rapidly in the pharmaceutical industry. The growing market for biopharmaceuticals and genetic products signifies an increasing interest in access to human genetic resources. A decision at the second meeting of the Conference of the Parties (Decision 2/11 para 2) reaffirms that human genetic resources are not included within the framework of the Convention. Although, the decision interpreted the Convention in such a way as to exclude human genetic resources from its provisions on access and benefit-sharing, this facet of access to genetic resources raises profound ethical questions. For example: the Biological Diversity Act (2002) of India does not consider human genetic resources as a biological resource and the Act defined “bio-resources / biological resources means: plants, animals and micro-organisms or parts thereof, their genetic material and by-products (excluding value added products) with actual or potential use or value, but does not include human genetic material” (NBA, 2002).

The staff at a few multinational pharmaceutical companies conducts their own field collections. The majority of companies does not conduct field collections, and rely instead on existing in-

house collections of material, or buying in compound or culture collections. Most companies 'outsource' or contract to others, the acquisition of samples for their screening programmes. They obtain samples through brokers, agents who collect on their behalf, or through specific deals with supplier organisations.

A.3. Research and Development (R&D)

The pharmaceutical industries are one of the most research intensive industry in the world. The total global expenditures on research and development in pharmaceutical sector comes around US$ 21.1 billion in 1998 and the costs of developing a single drug are estimated at between US$ 231 - US$ 500 million (DiMasi *et al*. and PhRMA 1998). The odds of a single compound becoming a drug once it enters the discovery process are generally estimated at one in 5,000 - 10,000. This indicated that the pharmaceutical research is highly complex and cost intensive.

Studies revealed that, pharmaceutical companies invest a higher proportion of sales in research and development than most other industries. In the UK, pharmaceutical research and development made up 20% of all industry research and development in 1997. Pharmaceutical industry research and development is currently focused on developing more effective drugs for a wider range of diseases; making research and development less expensive, and speeding it up so that the industry can benefit from patent protection for longer. The Pharmaceutical Industries R&D expenditures have increased from US$ 0.4 billion to US$ 4.8 billion during 1980 to 1998 (Kate and Laird, 2000).

It is difficult to evaluate the costs and time required to reach specific milestones in the research and development process and rates of success or abandonment in Pharmaceutical sector. The Pharmaceutical Research and Manufacturers of America (PhRMA) estimate that it costs more than US$ 500 million to develop a new chemical entity (NCE) including the costs of failures as well as interest costs over the entire period of the investment. The time it takes to develop a drug has lengthened, partly due to increased research and regulatory complexity, including increased understanding of biological processes at a molecular level, and a greater desire to characterise new drugs fully and takes on average 15 years to bring a product to market.

The PhRMA claims that only 3 out of every 10 NCEs introduced from the period of 1980 to 1984 made a profit, resulting in returns greater than their average after tax research and development costs. Of 5,000-10,000 molecules screened, only one becomes an approved drug. Generally drug development is a laborious process, which includes chemical improvements to a drug molecule, animal pharmacology studies, pharmacokinetic and safety studies in animals, followed by Phases 1, 2, and 3 clinical studies in humans. Pharmaceutical R&D budgets are contracting as pharmaceutical industry growth slows. Around the world, natural products research is more commonly found today in smaller discovery companies, semi-governmental or governmental entities, and universities (CBD, 2013).

It is very clear from the above discussion that the significance of research and development in the pharmaceutical companies are substantial with huge budget. Further this sector has different success rate compare to other sectors and the benefits accrued may varies from company to company. However, in this sector the profit margin may be high. All these issues might be a serious concern in imposing the ABS in the pharmaceutical sector. The following case explains about the nature of the R&D cost of a Chennai based pharmaceutical company.

Box 4
Activities of a pharmaceutical R&D Company: (Company A)

Company A is a leading R&D Company involved in the inspection, verification, testing and certification of pharmaceutical samples. It has capabilities in analytical, bio analytical and clinical trial testing along with process management, which helps pharmaceutical companies to achieve maximum safety and cost effective production. Further, Company A is a nationally and internationally recognized agency for quality checking, and certification of pharmaceutical products and drugs. The company's rough cost distribution allocates 50% to R&D, 30% towards administration charges and 20% as profit.

A.4. Ethno-botanical Approach

Historically, the use of people's knowledge and experiences of the medicinal properties of plants and other genetic resources significantly guide to drug discovery at different part of the world. This ethnobotanical approach to drug discovery has yielded most of the plant-based pharmaceuticals in use today. Of the approximately 120 pharmaceutical products derived from plants in 1985, 75% were discovered through the study of their traditional medical use. Broadly, in three primary ways the ethnopharmacological information can be used in the drug discovery process: Firstly, it act as a general indicator of non-specific bioactivity suitable for a panel of broad screens; Secondly as an indicator of specific bioactivity suitable for particular high-resolution bioassays; and thirdly as an indicator of pharmacological activity for which mechanism-based bioassays have yet to be developed. However, identify the traditional knowledge influence in a particular drug manufacturing is a difficult tasks, particularly in a situation where a company go for patenting its products.

In brief, the pharmaceutical sector is one of the predominant industrial sectors, who use wide range of biological resources for manufacturing different drugs. The R&D investments in pharmaceutical sector is relatively high when compared to other sectors and the dependency on biological resources base traditional knowledge is also transparent, but in a diminishing rate. As the pharmaceutical industries are growing at an alarming rate the scope of ABS is considerable and bringing all industries under the preview of national ABS law is an emerging challenge and required much more efforts at the national and the global levels.

SECTION B

SEED INDUSTRY

Past few decades world has experienced significant population growth and the present global population is stands around 7.6 billion. Proportionally, substantial growth has occurred in agriculture and allied activities through a transformation from the traditional farming to modern agriculture. Land under cultivation has increased considerably and intensive farming has adopted with the scientific farming and modern technology. The use of genetic resources (from traditional verities) in plant breeding and coming up with high yielding varieties of seeds is a multi-billion business and creates huge benefits to the seed companies. Hence, benefit sharing in the seed sector is an emerging issue and should be assessed with different actors including the collectors and exchangers of genetic resources, and the companies who involved in the research and development of commercial varieties. In this regard an appropriate mechanism for equitable sharing of the benefit arises from the utilization of the genetic materials in the seed sector need to be developed and implemented.

Genetic resources for food and agriculture (GRFA) underpin human well-being and are vital for food security. The need to ensure the continued use and exchange of these resources raises distinctive ABS issues. The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, together with the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), create opportunities to develop ABS solutions that are supportive of this sector (CBD, 2013a).

B.1. Policy Context

Since the dawn of agriculture, may be some 10,000 years ago, people have traded seed and foodstuffs. Crops have been widely distributed around the globe, interbred with local varieties and adapted to a host of different conditions. As a result, production of non-native Plant Genetic Resources for Food and Agriculture (PGRFA) from other regions of the world forms an important part of the agricultural production of every country. According to Kate and Sarah

(2000), the population of each country is dependent for its food on PGRFA once obtained from elsewhere. However, the emerging questions are: Are countries now self-sufficient, both for agricultural food production and for the germplasm used in plant breeding, or does our global interdependence on access to PGRFA continue?

For food production is concerned how the global exchange of seed through international trade in commercial seed is a growing concern. The study / survey carried out by Kate and Sarah (2000)of plant breeds from eleven countries (Canada, Chile, Check Republic, France, Germany, India, Japan, Mexico, South Africa, the UK, and the USA) reveal that breeders still routinely use germplasm obtained from other countries to develop new plant varieties. Thus, both for food production and for crop development, the countries of the world remain dependent on access to each other's PGRFA for food security.

However, plant breeders have at their disposal a wealth of national germplasm, and can usually access foreign germplasm from public and private collections held in their own country. This reduces their need to seek germplasm from wild. It also means that breeders, and others who subsequently obtain material from them, such as seed companies, farmers and consumers, are rarely obliged to share the benefits arising from the use if germplasm held in the collections since it is usually supplied without any such obligation.

B.2. Access the Genetic Resources and its Movement:

The improvement of existing varieties of crops and the development of new crop species will be vital for sustainable development of a nation and for food security. Both required access of genetic resources. With the help of modern biotechnology high yielding varieties of seeds are arriving in every field of agriculture, which is an emerging business. They are very much involved in the research when developing the commercial varieties. Through this seed companies are generating huge profit/benefits. Generally, seed industries are collecting the germplasam from the traditional variety of crops cultivated by the indigenous farming communities. Therefore, benefit sharing in the seed sector is a predominant one, where more discussion is required.

In the agricultural sector, countries may act both as providers and users of genetic resources for food and agriculture, with most countries being net recipients of genetic material from other countries or regions. Moreover, the innovation process is usually of an incremental nature, arising from the contributions of a variety of different actors and several different genetic resources, in different locations and at different points in the research and development process. The origin of genetic resources is also highly convoluted due to millennia of cross-border transfers, multiple parental sources, and the variety of location-specific traits that are acquired (Rachel, 2013).

Genetic resources not covered by the ABS regime of the ITPGRFA comprise many food and agricultural crops and all ornamental crops. Legal access to these resources as well as to Annex-I crops used outside the scope of the ITPGRFA, for example for pharmaceutical purposes, is thus governed by the CBD - as well as the Nagoya Protocol once it enters into force (CBD, 2013a).Based on the ITPGRFA and the Nagoya Protocol on ABS, Government of India come up with a harmonious approach (notification) which explains the conditions stated with regards to biological resources for the food crops (Box - 5).

Box– 5
MoEF&CC Notification on 17th December, 2014

India is a party to the ITPGRFA having signed and ratified the said treaty on 10th June, 2002; and whereas, the objectives of the ITPGRFA are conservation and sustainable use of plant genetic resources for food and agriculture and fair and equitable sharing of the benefits arising out of their use, in harmony with the Convention on Biological Diversity, for sustainable agriculture and food security; and Whereas, article 12 of the ITPGRFA provides for facilitated access to plant genetic resources for food and agriculture under the Multilateral System by the contracting parties; and Whereas, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization to the Convention on Biological Diversity dated the 29th October, 2010 is the instrument for implementation of access for benefit sharing provisions of the Convention on Biological Diversity; and whereas, article 4

of the said Nagoya Protocol provides that the protocol does not apply for the party or parties to the specialized instrument in respect of the specific genetic resource covered by and for the purpose of the specialized instrument; and Whereas, Section 40 of the Biological Diversity Act, 2002 (18 of 2003) empowers the Central Government to exempt certain biological resources from the provisions of the said Act.

Now, therefore, in exercise of the powers conferred by section 40 of the Biological Diversity Act, 2002 (hereinafter referred to as the said Act), and in fulfilment of the obligations of the Government of India to the ITPGRFA for providing facilitated access to the plant genetic resources for food and agriculture, the Central Government, in consultation with the National Biodiversity Authority, hereby declares that the Department of Agriculture and Cooperation may, from time to time specify such crops as it considers necessary from amongst the crops listed in the Annex I of the ITPGRFA, being food crops and forages covered under the Multilateral System thereof, and accordingly exempts them from Section 3 and 4 of the said Act, for the purpose of utilization and conservation for research, breeding and training for food and agriculture:

Provided that such purposes shall not include chemical, pharmaceutical and/or other non-food or feed industrial uses. The Department of Agriculture and Cooperation shall keep the National Biodiversity Authority informed of all crops as may be specified by it from time to time, for providing access to plant genetic resources for food and agriculture under the ITPGRFA for the purposes aforesaid.

Genetic resources based comprise use wild-collected plants, animals or microbes, including crop wild relatives, as well as landraces and commercial or elite varieties. Plant genetic resources are used in three main ways: for conventional breeding purposes, for “molecular-assisted” breeding using biotechnology, and for crop protection and the research and development (R&D) of pest, disease and herbicide resistance. About 90-95% of all genetic resources used in the plant breeding industry today are elite, modern varieties, the remaining 5-10% representing landraces or wild relatives (CBD, 2013a).

Wild species require considerable investment to become commercially viable and have risky returns. However, there is growing interest and investment in crop wild relatives, due both to consumer demand and to the fact that they contain important genes for stress resistance and improved productivity. Technological advances, greater precision and declining technology costs are dramatically increasing our understanding of their potential (CBD, 2013a).

As many agricultural products developed from genetic resources can be used for further research and development (R&D), it is also sometimes difficult to determine who are the providers and users of these resources, and to track the movement of genetic resources through different value chains and geographical locations. Many agricultural products may also reach the marketplace in a form in which they can be used both as biological resources, for direct production or consumption; and as genetic resources, which can be developed into different products. Benefit sharing can thus be complex because of the cumulative nature of breeding, because the R&D leading to the final product may require extensive exchanges that do not take place within one company, and because intermediate products themselves are sometimes marketed (Rachel, 2013).

B.3. Production and Market

The combined turnover and market share of the top ten companies in the global commercial seed market represented over $20 billion in 2009, equating to some 59% of the sector's value in that year (Table 4).

The value of this seed sector has grown from some $30 billion in 2005 to approximately $45 billion in 2011, with the United States and China having the highest valued domestic seed markets. The percentage made up by the global proprietary seed market has risen dramatically – from 46% in 2000, to 57% in 2005, reaching 94% in 2010. Genetically modified (GM) seed, as a sub-sector of this market, has also shown an increase – from 15% in 2000, to 30% in 2005, and 35% in 2010 (Rachel, 2013).

Table 4
Turnover and Market Share of Top 10 Companies in the Global Seed Market

S. No	Company	Country	Seed Sales in 2009 ($ Million)	Market Share
1	Monsanto	USA	7,297	27%
2	Du Pont	USA	4,641	17%
3	Syngenta	Switzerland	2,564	9%
4	Groupe Limagrain	France	1,252	5%
5	Land O' Lakes	USA	1,100	4%
6	KWS AG	Germany	997	4%
7	Bayer Cropscience	Germany	700	3%
8	Dow AgroSciences	USA	635	2%
9	Sakata	Japan	419	2%
10	DLF-Trifolium A/S	Denmark	387	1%
	Total (Top 10)		20,062	64%
	Others			36%

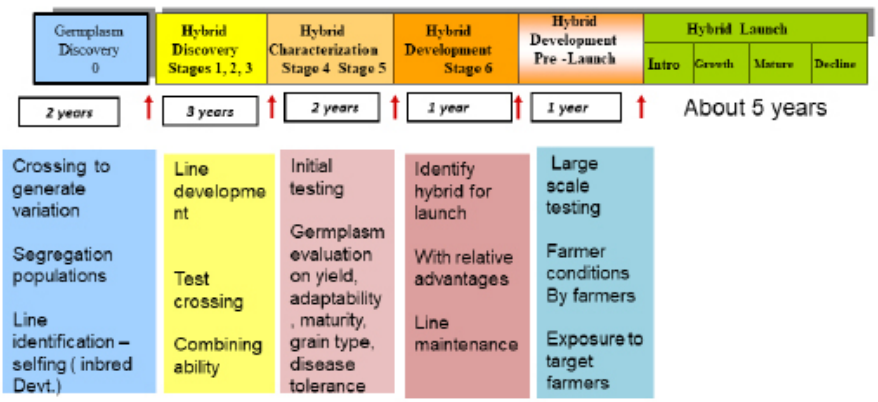
Source: Rachel (2013)

The rapid uptake of GM crops has been one of the most profound industry trends over the past 15 years, its escalation surpassing that of any new technology ever embraced by the agricultural industry. In a span of 15 years, the global area of GM crops increased more than 94 fold, from 1.7 million hectares in 1996 (the first year of commercial GM crop plantings) to 160 million hectares in 2011. Leading growers of GM crops are dominated by the United States (64 million ha), Brazil (21.4 million ha) and Argentina (21.3 million ha) While the spread of GM crops is predicted to continue, particularly in the developing world, in other areas, notably western and eastern Europe, their adoption is either static or declining, largely due to consumer resistance and stringent regulatory requirements (Rachel, 2013).Data Collected from an India based Seed Company provide the processing steps in the hybrid development and the R&D process.

Box 6: Major Processing Steps in the Hybrid development and the R&D Process

In the initial stage of seed development Germplasm discovery is the major activity, where emphasis is on crossing to generate variation, segregation populations and identification of line with designed characteristics – male and female parent – selfing (inbred development). The average time duration required for this process is around 2 years. Stage 1, 2 and 3 of the R&D is the Hybrid Discovery Stage which extend around 3 years. The major focused activity in this period includes; Line development, Test crossing and combining ability. Hybrid characterization is done in the stage 4 and 5, took around 2 years. Initial testing, Germplasm evaluation on yield, adaptability, maturity, grain type, disease tolerance of the seed are the major focus on this stage. Stage 6 focused on Hybrid Development (comes under one year) with emphasis on Identify hybrid for launch, with relative advantages, and Line maintenance. After this Hybrid Development pre-lanuch will take place for one year. In this time large scale testing, Farmer conditions by farmers and exposure to target farmers are the emphasis. Finally the hybrid launch will take place. According to the researchers, who involved in the high breed development, the entire R&D process is more cumbersome and the level of success is a challenge. Figure 2 provides a comprehensive process in the seed development.

Figure 2
Hybrid Development Process Steps



According to seed industries, it is difficult to chase the origin of the genetic materials they use. Even many years before certain genetic materials may collect and periodical modifications were done. In brief, it is extremely difficult to understand the pedigree. Companies are not doing that bio-survey and bio-prospecting and transformation of genetic materials from the field to the company. But some other seed companies are doing that. Hence the wild varieties and the influence of indigenous communities' connection with the company do not exist.

However, some oldest companies may establish connections with indigenous communities in collecting the genetic material available in the wild. Now most of or all genetic material is accessed / comes from the government agencies, like ICAR institutions and agriculture universities. For example: in the corn seed developing DuPont Pioneer's attempt is first in India. They initiated the research around 40 years back, but used only the internal germplasm. Now a day's most of the experiments are not happening the farmer's field, but the field under the company control. Hence community and their stake are completely ruled out and the ICAR Institutes and Agriculture Universities are emerging with better idea.In the seed industries case bio-resources are not always obtaining from the community. There is no provider as a community and hence benefit claimer also has not exists. Sovereign right is with the country. That case country can be the benefit claimer. If NBPGR or any universities obtaining the resources directly from the community, they should engage the agreements with the community.

B.4. R&D Cost and Economic Concerns

Brennan (1991) carried out a research on 'Economic Criteria for Establishing Plant Breeding programs'. The aim of this study was to determine the economic relationships between costs and expected returns from a plant breeding program in order to identify the minimum size of production environment necessary to a plant breeding program. Through this analysis one can justify economically the establishment. The study derived the following inferences on the cost and benefits of the plant breeding at different scenarios; which include: (a) Returns

are specified as a function of the size of the crop production industry, research and adoption lags, the expected rate of yield gain from the program, and the expected price of the crop. (b) Costs are mainly depends on the number of scientists and the costs per scientist.

1. The costs of plant breeding programs will vary markedly depending on factors such as: the degree of mechanization and the labour intensity of the program,
2. unit labour and capital costs, the degree of crossing compared to selection and evaluation of imported materials,
3. the structure of the program's operations,
5. the amount of quality testing incorporated in the program, and
6. the extension/ advisory activities associated with the program.

Therefore, it is inappropriate to generalize the results, as they will vary widely for each particular country or environment.

Generally the results are modified if spill-over effects from other breeding programs in similar environments or to other countries are taken into account. Whether or not it has its own research program, a country may be able to obtain benefits from importing technology from a similar agro-climatic region. The potential for the cost-saving impact of research in one country to spill over to another country was determined by the comparability of agro-climatic characteristics of the countries. Coefficients of spillover between each of the ecological regions were estimated. A country with agro-climatic characteristics identical to those of the country where the research is undertaken would have a potential spillover coefficient of one (so that benefits in one country would have the same potential cost-reducing impact in the other). Countries with substantially different agro-climatic characteristics would have potential spillover effects close to zero (Brennan, 1991).

Generally, seed companies are collecting genetic materials / germplasm from the repositories (national or international) or from wild at small quantities and do the research and come up with genetically modified high yielding varieties of crops. As this sectors R&D costs are substantial in the overall production costs of the genetically modified seeds, companies have huge hesitations in the involvement of ABS.

SECTION C

Botanical Industries

Botanical medicine also known as herbal medicine or herbalism is a medical system based on the use of plants or plant extracts that may be eaten or applied to the skin. Since ancient times, herbal medicine has been used by many different cultures throughout the world to treat illness and to assist bodily functions. If we examine the history, one can see plants have been the basis for medical treatments through much of human history, and such traditional medicine is still widely practiced (Kate and Sarah, 2000).In the last decade, the botanical medicine market has grown significantly, with a wide range of products containing different botanicals.

Apart from medicines botanicals are widely used for promoting health and well-being. Hence, the botanicals sector is diverse, with widely varying products, companies, markets, approaches to research and development (R&D), and regulatory frameworks. Around the world, these products go by a range of names, including herbal medicines, dietary herbal supplements, phytomedicines, phytoprotectants, and phytotherapeutic agents (CBD, 2013b). However, sometimes (particularly in recent decades) the scope of herbal medicines / products extended to beyond plants such as:fungal and bee products, minerals, shells and certain animal parts.

In contrast to pharmaceuticals, the active constituents in a botanical medicine are often not identified, and its biological activity might not be well characterized. Botanicals are no longer sold primarily as single ingredients, but as mixtures, in sports drinks, functional foods, cosmetics, and as natural alternatives to artificial colorings, flavorings and preservatives (CBD, 2013b). Modern medicine recognizes herbalism as a form of alternative medicine, as the practice of herbalism is not strictly based on evidence gathered using the scientific method. However, modern medicine make use of many plant-derived compounds as the basis for evidence-tested pharmaceutical drugs, and phytotherapy works to apply modern standards of effectiveness testing to herbs and medicines that are derived from natural sources (Kate and Sarah, 2000).

C.1. Characteristics and Scope

The Botanical medicine industry is experiencing rapid growth worldwide. Annual growth rates are between 10-20% in most countries. Botanical medicines, as distinct from pharmaceuticals, are produced directly from whole plant material. As a result, they contain a large number of constituents and active ingredients working in conjunction with each other, rather than a single, isolated active compound (Kate and Sarah, 2000). Diversity within the Botanical medicine industry is apparent in the structure and nature of participating companies. The study conducted by Kate and Sarah (2000) on botanical sector revealed that:

a. Company size and function vary widely, with some companies employing only a handful of staff, and others a few thousand.

b. Big companies might cultivate raw plant material; process material into bulk ingredients, including standardised extracts; manufacture and market finished products, or broker the exchange of raw materials or products.

c. Company philosophies and marketing strategies vary widely too. Some companies emphasise a standardised, scientifically proven effective and safe product; others are primarily in the packaging and marketing business, placing little emphasis on proven product efficacy (and sometimes quality); still others incorporate environmental and social concerns into their business practices.

d. Although a trend exists towards uniformity in the global botanical medicines market, as a result of increased emphasis on quality control, safety, and efficacy, diversity in the complex, heterogeneous industry is likely to remain marked (Kate and Sarah, 2000).

C.2. Production

Botanicals represent a range of products, include products sold as the raw herb (dried or fresh) and products that are processed to varying degrees including: tinctures (an infusion of herbs in alcohol); extracts (greater concentration of the original material produced through separation of the active material from the plant with the aid of a solvent); and standardized extracts (plant material 'standardized' to one or more chemical 'markers' (Kate and Sarah, 2000). In India, botanical medicines are available as Ayurvedic medicine has quite complex formulas with 30 or more ingredients, including a sizable number of ingredients that have

undergone “alchemical processing”, chosen to balance “Vata”, “Pitta” or “Kapha”.

Botanical companies are different in size, in nature of products, and in extent of R&D and overall products or processing approach. The industry includes small family-run companies that sell a handful of products based on traditional medicine and large pharmaceutical companies that undertake extensive R&D and produce standardized phytomedicines. In most countries, a small group of very large companies dominate the industry, with more numerous smaller companies filling niches (CBD, 2013b).

A web of transactions and range of actors are involved in the process through which raw plant material is transformed into commercial products. These include harvesters and growers, traders, exporters, brokers, bulk ingredient and processing companies, manufacturers and marketers, distributors, and retail outlets. Over the last ten years, processing has shifted largely to cheap labour centers like China and India, with raw material harvested around the world shipped to processors for extraction and then shipped on or back to the home countries of manufacturing and marketing companies (Sarah and Rachel, 2013). Accessing bulk raw material, which is then traded as a commodity, does not fall within the scope of the Nagoya Protocol. However, raw material sourcing is central to the botanicals industry and it is therefore important for policy-makers to understand. In brief, the existence of this long chain of intermediaries has to be taken into account when implementing the Nagoya Protocol (CBD, 2013b).

C.3. Market

The botanical medicine portion of the industry was around $84 billion in 2010 (CBD, 2013b). This segment of industry registered a substantial growth from 2010. A recent study estimated that by 2017, global herbal supplement, or botanicals, markets would increase to $107 billion. Global nutrition industry sales – which include dietary supplements, natural and organic foods, natural personal care, household products, and functional foods – totalled more than $300 billion in 2010. All of these categories might include botanicals to greater or lesser degrees.

Around the world, there is a growing middle class with more money and more inclination to spend on natural and preventive healthcare. Europe is the world’s largest market, led

by Germany, France, Italy and the UK. Global demand for botanical and other nutraceutical ingredients is projected to increase 7.2% annually, with emerging economies like China, India and Brazil projected to have the fastest growth in both consumption and production (CBD, 2013b).Unlike most sectors, the global botanicals market exhibited steady, if slowed, growth during the recent economic crisis. By 2020, it is predicted that China will be the largest global producer and consumer of nutraceutical ingredients.

In most countries, a small group of very large companies dominate the industry, with more numerous smaller companies filling niches. For example, in the US in 2011, 34 companies with sales greater than $100 million had total revenues of $7.27 billion; 94 companies with sales between $20 to $100 million had total revenues of $3.43 billion; and 727 companies with sales of less than $20 million had revenues of $2.06 billion (Sarah and Rachel, 2013)

C.4. Research& Development

Increasing demand from consumers for proof of safety and efficacy, industry interest in gaining control over ingredients, products, and delivery mechanisms through intellectual property rights (IPR), and expanded government oversight and regulation of this sector, has meant that in recent years, “the degree of science in supplements has gone up”. Now a days companies want to have a stronger position in terms of IPR, and so are putting more science into products, and are patenting more” (Sarah and Rachel, 2013).

Regulators require a range of data from companies to ensure the identity, purity, quality, strength, potency, and consistency of botanical drugs. Proving efficacy additionally requires clinical trials that are time-consuming and might run into many millions of dollars, and so are undertaken by only the largest companies. In addition to that found in large companies, advanced research is undertaken by government and academic research programs; companies will also make use of pharmaceutical company R&D on products that have been abandoned - e.g. *Hoodia* (Sarah and Rachel, 2013).

C.5. Traditional knowledge

Traditional knowledge is the foundation of the botanicals industry. Unlike most genetic / biological resources based sectors, botanical medicines continue to depend on traditional knowledge. Traditional knowledge is the primary guide to new ingredient and product development and is integral to acquiring approval from regulatory agencies, and is used in marketing products to consumers. Many companies today draw upon European traditional medicine because species have high levels of research to support safety and efficacy (CBD, 2013b). However, traditional Chinese medicine and Ayurveda are also the source of many new products, supported not only by long histories of traditional use but also increasingly by extensive research.

According to Sarah and Rachel (2013), traditional knowledge also plays a role in selecting and breeding, or wild-harvesting, plants with particular properties, including maximizing yields of active constituents. Traditional knowledge is accessed from literature, databases, the internet, as well as research with local communities and producers on the part of intermediary brokers, agents, or ingredient suppliers, and in a few cases marketing and manufacturing companies. However, identification of traditional knowledge elements in all the above and fixing the ABS on it is a hercules tasks, required high level of cooperation from different stakeholders.

In brief, with the growing importance of the botanical products in human health and welfare, the scope of ABS in all segments of the botanicals is tremendous. Botanical sectors normally use wide ranges of herbs as inputs (raw-materials) in bulk quantities for manufacturing different botanical products having huge markets both at domestic and international. In recent decades, botanical industries are also involved in intensive R&D. Historically the role of TK in product development and manufacturing is significant in botanical sectors.

SECTION D

Cosmetics

Cosmetics can be defined as "any substance or mixture intended to be placed in contact with the various external parts of the human body or with the teeth and the mucous membranes of the oral cavity with a view to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours" (CBD, 2013c). Cosmetics are in different applications ranging from hair care, perfumes and fragrances through to beauty and personal care, nutricosmetics, or beauty supplements, as well as the rapidly developing category of cosmeceuticals, which typically include bioactive compounds. The use of natural ingredients in the cosmetics industry has grown significantly over the past decades. This is primarily due to the growing consumer interest in health and well-being, as well as organic and fair trade products. This has led to increased demand for botanical ingredients by the cosmetic industries all over the world.

D.1. Use of Natural Ingredients

Many cosmetic and personal care products contain multiple ingredients from natural sources, most of which are well known and do not contain active compounds. However, some companies are involved in as research-intensive activities to identify interesting biochemical properties. Advances in science and technology allow companies to more effectively screen and identify active natural compounds, and many seek intellectual property protection for these, the delivery systems employed, and associated innovations. However, there is enormous variation within this sector in terms of the level of technology employed by companies, investments in research and development (R&D), and approaches to patenting (Rachel and Sarah, 2013). The trend towards use of natural ingredients is not confined to the more pure "natural cosmetics" component of the market, but is now also widespread in conventional cosmetics, including those that are "nature-inspired". Such products incorporate a wide range of plant-based materials including oils, fats and waxes, essential oils and oleoresins, plant extracts and colourants.

D.2. Global Markets

The global sales for the "natural cosmetics" segment in 2011 was about US$ 26.3 billion, representing strong growth in this sector over the past fifteen years, up from just US$ 1.4 billion in 1996. This has been due in part to increased consumer demand for healthier, more sustainable products; greater affordability of natural products; rising disposable incomes in Asian and Brazilian markets; and increased product supply of "blockbuster" categories. At the same time, economic difficulties in the United States and Europe have slowed growth in these regions.There has been a significant growth of personal care products in Asia in recent years, and the continent now leads with a global market share of 37% (Table 5). The United States and Europe account for almost 40% of the global natural cosmetics market. Within Europe, Germany and France represent the strongest markets for natural cosmetics but Asia, Brazil and Eastern/Central Europe are considered to hold the most opportunity for high growth over the next few years (Rachel and Sarah, 2013).

Table: 5
Sales of Natural Personal Care Products by region

S. No	Region	Share (%)
1	Asia	37
2	Europe	19
3	USA	19
4	Rest of the World	25

Source: Rachel and Sarah (2013)

The cosmetic industries come up with a number of different product classes, with sales for skin-care and anti-aging products in particular (Table 6). It is clear from the above table that the skin care product made a comprehensive role in the global natural personal care (cosmetics) sale.

Table: 6
Global Sales of Natural Personal Care Products by Product Class

S. No	Products	Share (%)
1	Skin care	42
2	Fragrances	10
3	Oral care	9
4	Make-up	8
5	Other toiletries	15

Source: Rachel and Sarah (2013)

Ten companies represented nearly 50%of total market sales of personal care products using natural ingredients in 2010. However, the market is considered to be highly fragmented with only three brands having a share of 3% or more. Table 2 summarizes the top ten marketers of cosmetics products using natural ingredients, and the brands offered.

Table 7
Marketers of Cosmetics Products using Natural Ingredients

S No	Companies	Natural' Brands offered	Headquarters	Total Sales 2012 US $ billion
1	Johnson & Johnson	Aveeno	USA	67.2*
2	L'Oréal	The Body Shop	France	29.3
3	Colgate-Palmolive	Tom's of Maine	USA	17.1
4	Estée Lauder	Aveda, Origins	USA	9.7
5	Shiseido	Bare Escentuals	Japan	8.3
6	The Clorox Company	Burt's Bees	USA	5.5
7	Yves Rocher	Yves Rocher	France	±3
8	The Hain Celestial Group	Jason Natural Products, Avalon, Alba, Zia Naturals	USA	1.4
9	L'Occitane	L'Occitane	Luxembourg	1.2
10	Harvest Partners	Arbonne, Nature's Gate	USA	1.1

** Note that this figure for Johnson & Johnson includes non-cosmetic products*

Source: Rachel and Sarah (2013)

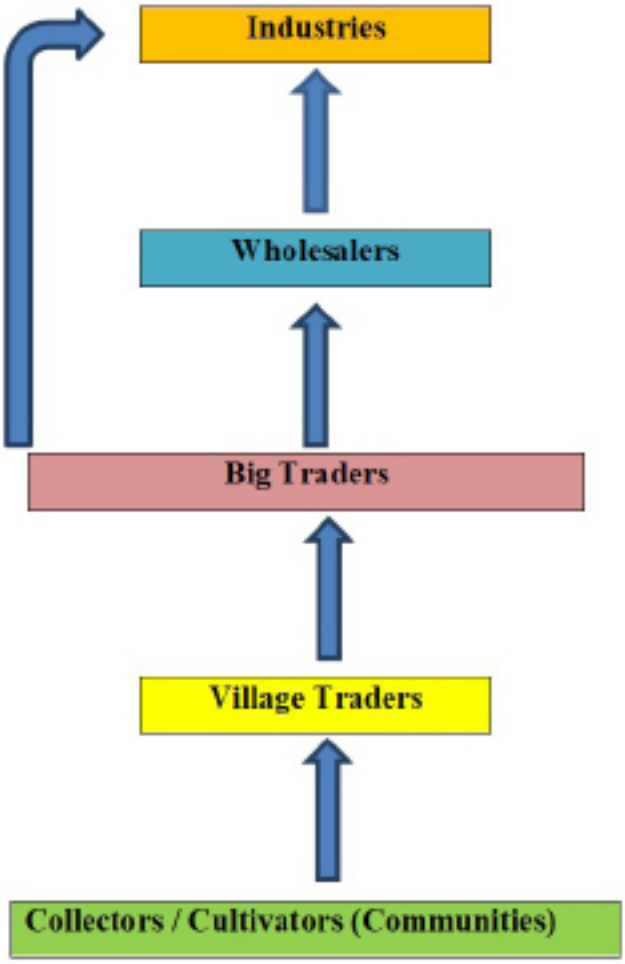
While large international companies retain most of the market share, a significant number of small and medium enterprises (SMEs) also exist. In Europe, for example, two-thirds of the 4,000 cosmetics companies are SMEs. Of interest is that companies are increasingly paying attention to biodiversity in their reporting, with 80% of the twenty largest beauty companies mentioning biodiversity in their corporate sustainability reports, and 75% indicating that they review how their supply chains impact biodiversity (Rachel and Sarah, 2013).

D.3. Supply Chain

Trade in raw-materials for the cosmetics industry takes place in a similar fashion to that for the botanicals and food sectors. These sectors are using many of the same intermediaries (biological resources) in their products manufacturing. Sometimes the same plant species are often used in more than one industry, meaning that the same material may be used as a raw-material by botanical, cosmetic or food product. Industries are using several different approaches and chains to obtain the biological resources / materials. One common model may see in mobilizing the biological resources is local dealers sourcing plants from local growers or collectors. They may purchasing already processed/dried resources. Material may pass through a number of local traders or cooperatives before it is exported. Plant material, typically hundreds of species, will then usually be stored in the large warehouses of international trading companies, the most significant of these occurring in Hong Kong, Tokyo, New York and Hamburg. These larger companies play a central role in quality control and pricing, acting as clearing-houses for the wider plant trade (Rachel and Sarah, 2013).

The studies carried out on the biological resources movements in the botanical sectors is also similar and is indicated in the following figure.

Figure - 3
Supply Chain of Biological Resources



The approach described continues to be the modus operandi for most companies in this industry, which seek low risk and cheap raw material. Another emerging model for many companies is the outsourcing of the extraction and processing to China, India or other low-cost labourcentres that have active processing facilities. Some of the larger companies are also increasingly involved in controlling the supply chain for key ingredients, giving them a greater say in the pricing of raw-material and assuring its quality and availability. This includes relationships with suppliers in developing countries, as well as outgrowing schemes in Eastern Europe and other regions.

Many of these trends are driven by markets, economics and expediency but in some cases ethically orientated cosmetics companies seek to enable better social and environmental outcomes by shortening the supply chain, investing in closer relationships with suppliers, and helping add more value and build local businesses and capacity in source countries. Typically, these practices are limited to a few ingredients rather than the entire range. This is especially the case for niche ingredients that require smaller volumes of material. While market demand for natural ingredients and products is significant, there are also other ways to develop new ingredients, which compete with natural products research within companies. Moreover, many companies have existing collections of ingredients and extracts, and numerous natural products are already on the market and can be included in products for marketing purposes (Rachel and Sarah, 2013). Broadly, the cosmetic sector has certain key trends, which include:

- There is enormous pressure on companies to constantly innovate in order to differentiate products to attract new customers and gain a marketing advantage.
- Innovation does not necessarily imply entirely new ingredients and may, for example, focus on well-known ingredients already developed in the food sector but not yet incorporated in cosmetics.
- Delivery systems that stabilise, protect and enhance cosmetic activities on the skin are a growing and significant part of industry R&D today, and most are patented.
- There is increasing cross-over between cosmetics and other sectors such as biotechnology, pharmaceuticals (cosmeceuticals), and food (nutricosmetics).

- Cosmeceuticals are an important new market, incorporating products that include active ingredients with medicinal properties such as antioxidants, and products that slow the effects of aging.
- Nutricosmetics, or "beauty foods", are also emerging as a significant new market. Ingredients such as collagen, Aloevera, grape seed and probiotics have all been used in food products with beauty claims, typically targeting skin issues from the inside out.

D.4. Research and Development (R&D)

An estimate reveled that around $9 billion is spent each year on research and development (R&D) in the cosmetic sector. Investments and approaches to R&D vary enormously among the companies based on the products they are manufacturing. Certain companies minimally process raw materials to produce simple products for local sale, others process plants and marine organisms into extracts or essential oils, some focus on time-tested formulations and do not have significant R&D, while at the other end of the spectrum are small and medium-sized intermediary companies and large, multi-national companies with R&D budgets in the hundreds of millions of US dollars undertaking advanced research on new ingredients and delivery systems (CBD, 2013c).

It is common for intermediary firms to conduct R&D on new ingredients, either upon the request of a company looking for an ingredient with certain features, or as a result of the intermediary firm selling a new ingredient and concept to brand owners or marketing companies. Companies such as Givaudan, Firmenich, Mane and Euromed will typically source raw materials but may also be involved in other aspects such as R&D and marketing. Because of the diversity of ingredients used, and the multiple supply chains involved, brand owners and retailers are often far removed from the environmental and social origins of the ingredients they purchase. Increasingly, therefore, there is a trend towards moving the burden of compliance with environmental and social standards towards suppliers that source raw materials (Rachel and Sarah, 2013).

D.5. Cross Sectoral Approach

Generally cosmetics companies are gaining market advantage by drawing the science and technology of other sectors such as pharmaceuticals (cosmeceuticals), food (nutricosmetics),

and biotechnology. The main categories of cosmeceuticals include antioxidants, peptides, growth factors, and combination products. Retinoids are used to speed up skin renewal and alpha hydroxy acids are used in chemical peels. These products are usually more expensive than others, and are produced by the largest companies, such as Estee Lauder, Lancome and Shiseido, with in-house research programmes. Lower-cost alternatives have also emerged, giving rise to the so-called "masstige" or prestige for the masses product.

In a parallel development, nutricosmetics, or "beauty foods", are emerging as a significant new market, particularly in Japan and Western Europe. Ingredients such as collagen, lycopene, lutein, green and white tea, Aloevera, grape seed and probiotics have all been used in food products with beauty claims, primarily to stave off the signs of aging and typically targeting skin tissues from the inside out (Rachel and Sarah, 2013).The interface between biotechnology and cosmetics companies is also growing. A biotechnology company, for example, may do research on gene expression for collagen and may work with a cosmetics company to do the screening to discover novel targets. Industrial biotechnology companies are also increasingly producing bio-based chemicals, essential oils, and other ingredients for the cosmetics and personal care sector.

In this context the leverage of cosmetic industries with other biological resources based industrial sectors are huge. Crossovers between these sectors require cosmetics companies to walk a fine line between different standards and legal systems. According to Rachel and Sarah, 2013, if cosmeceuticals have too high a level of activity, or if nutricosmetics contain ingredients considered to be novel foods or medicines with untested safety, governments may consider the products as pharmaceuticals or food, and seek to regulate them as such, requiring a great deal more expensive testing. This could increase costs, as well as product development times, and so possibly reduce market opportunities.

D.6. Traditional Knowledge

As cosmetic sectors relay on different kind of botanical materials, the dependency on traditional knowledge in this sector is significant. Consumer interest in what have been termed "ethnic" or "exotic" ingredients has been sustained and has even grown in recent years. These ingredients come with stories about traditional uses of plants, and consumers

associate those that "hail from distant shores with better health and more effectiveness". A number of companies are focusing on Ayurvedic and Chinese traditional medicine, as well as less formal traditional medical systems, as a source of leads. Ingredients (biological materials) long used traditionally have the advantage of having been proven safe over generations of use, and might more easily pass through the regulatory process.

While some companies are interested in the traditional use of natural ingredients, others viewed differently. Certain companies feel traditional knowledge as a potential minefield, given the difficulties associated with obtaining consent from knowledge holders (i.e., PIC), and developing workable agreements with groups with whom they may have little familiarity. Some companies are hesitant to incorporate traditional knowledge into their R&D since this might call into question their ability to patent a product or process. According to Rachel and Sarah (2013), one researcher at a large company, that undertakes advanced research said: "if traditional knowledge is there, in a way it makes the plant less useful to us. We need to find something with intellectual property protection, and traditional knowledge would reduce its patentability because it is "prior art." So in a way the ideal is to find completely unknown things that have safety and efficacy.

In brief, with the changing life style and the modernization trend the demand for cosmetic items increased in developed as well as developing nations of the world. Industries are using different biological resources and R&D is predominant in cosmetic sector. As many highly, biological resources based, value added products are manufactured in this sector, the scope of ABS is extremely high.

SECTION E

Food and Beverage

Generally, the food and beverage industry relies on biological resources more than any other sector, typically in the form of raw materials from plants and animals, rather than genetic resources. However, in recent period the scientific, technological and market changes are shifting the way in which this sector uses biological resources. Now a days, food and beverage sectors are using the genetic resources in an interesting and innovative ways. Sub-sectors of food and beverage focused on novel foods, nutrigenomics, biotechnology, nanotechnology, bioactive ingredients, processing techniques and flavours. Increasingly usage of microorganisms in bio-processing – to create new flavours, colours or synthetic forms, investigating novel ingredients and traditional foods for interesting bioactive compounds, adding new nutritive ingredients to functional foods, and developing highly specialized medical and personalized foods based on genetic resources are the common practices in food and beverage sectoe (CBD, 2013f).

Although most activities pursued by the food and beverage sector do not involve research and development (R&D) on genetic resources, the small component that do are spurring greater involvement in access and benefit sharing (ABS) issues and, thus, greater relevance of the Nagoya Protocol on Access and Benefit-Sharing and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). In India, 421 plant based biological resources are notified as 'normally traded as commodities', provided they are traded as commodities are exempted from the purview of the Biological Diversity Act. Majority of them are cultivated items used for food.

However, ABS is very new to the food and beverage sector and is not widely known or acknowledged by many of those involved. A few larger companies are increasingly aware of international obligations, stimulated in some instances by controversial cases that have revealed the challenges of integrating ABS into supply chains, but awareness remains extremely low for most companies (Rachel Wynberg, 2013f). According to Kate and Sarah

(2000), food and beverage companies have long 'prospected' in high biodiversity countries in search of alternative ingredients for their products

E.1. Use of Natural Ingredients

The global food and beverage industry uses a range of biological resources as raw-materials that are purchased directly or indirectly from farmers or from intermediate suppliers. These range from commodities such as palm oil, sugar, tea and coffee, through to smaller volumes of thousands of different natural ingredients. According to Rachel Wynberg (2013f), "while the Nagoya Protocol does not cover the commodity trade of raw materials, nor local trade or subsistence use, it does apply to the utilization of genetic resources as defined by Article 2 (c) of the Protocol, to traditional knowledge within the scope of the Convention and to the benefits arising from the utilization of such knowledge". The Indian Biological Diversity Act also provided this case through exemption. It stated that: the local people and communities, including growers and cultivators of biological resources, and *vaids* and *hakims,* who have been practicing indigenous medicine are exempted from the requirement of providing prior intimation to SBBs for obtaining biological resources for commercial utilization or for bio-survey or bio-utilization.

However, different activities of the food and beverage sector may invoke ABS requirements. These include: (a) bio-processing, where novel enzymes from microorganisms are used to make cheeses or create new flavours, colours or synthetic forms of natural ingredients; (b) innovations for existing food products that may be derived from the utilization of genetic resources. This could include the addition of a new nutritive ingredient, flavour or colour; and (c) the use of 'new' species or traditional knowledge to investigate bioactive compounds of use to the food industry, or to develop a particular food product (Rachel Wynberg, 2013f).

In the food and beverage sector the contribution of natural ingredients is a significant role as flavours and fragrances, spices, herbs, colourants and enzymes. They also form part of functional foods. Functional food can be defined as 'modified food or food ingredients that may provide a health benefit beyond the traditional nutrients it contains'. Examples may include flavonoids such as catechin or quercetin, or carotenoids such as lycopene and lutein,

which occur widely in plants, are known for their anti-oxidant properties and are believed to have a wide range of health effects. According to Rachel Wynberg, (2013f), in the US, top selling food or spice products sold as supplements in mainstream markets have seen dramatically increased sales in recent years. Such products include: cranberry (+13%), soy (+10%), ginger (+13%), kelp (+41%), cayenne pepper (+49%), tumeric (21%), and alfalfa (+46%). Other edible or food-oriented herbs include garlic, green tea, bilberry, barley, grape seed, elderberry, spirulina, and maca root

Proteins are of particular interest for sports drinks and meal replacements, to help build muscle mass, aid in weight loss, and combat ageing. Vegan and allergen-free sports products are gaining market share, including protein blends of hemp, sprouted brown rice, peas and grasses. The price of whey, a standard protein source, is volatile and so alternative plant sources of protein are also of interest to manufacturers and formulators. The functional beverage market, which includes energy drinks, sports drinks and functional waters, ready-to-drink tea and coffee, and yoghurt drinks and smoothies, as some of the most popular items, continues to grow.

Although the incorporation of 'new' ingredients based on biological resources, such as the fruit of the African baobab (Adansonia digitatis) and marula (Sclerocarya birrea) trees, is taking place, the majority of functional foods are based upon waste streams of by-products from industry (e.g. grape seed extract, lycopene, soy isoflavones, green coffee extract, omega 3 and 6 oils). These are sourced via cheap and well-established supply chains, typically based on major commodities such as soya and coffee which present few ABS issues and have well-documented safety histories.

E.2. Global Markets

Like many other sectors, the food and beverage sector also characterized by economic uncertainty and high levels of volatility in commodity, currency and stock markets. At the same time there is dynamic growth in emerging markets, increasing affluence and numbers of consumers and significant changes in science and technology. The global retail sales/revenue of food and beverages was only US$ 8.3 trillion in 2004. But it increased US$ 11.6 trillion in 2009 and US$13.3 trillion in 2011. It is further expected to reach US$15 trillion in 2014 (Rachel Wynberg, (2013f)

In 2010, functional food markets were estimated at US$7-63 billion, expected to reach US$90.5 billion by 2013.The US is the largest market for functional foods, followed by Japan and Europe, which combined attract 90% of total sales. The number of functional food introductions in the North American market increased from 200 (2006) to over 2000 (2008). Global sales in functional beverages increased from US$19 billion (2006) to US$23.4 billion (2010), with sales of energy drinks the highest in this sector, topping US$7 billion. In 2011, natural and organic foods were estimated to be worth about US$ 53 billion. Although the Fair-trade certified market has tripled since 2008, it was valued at under US$ 5 billion in 2009 and accounts for less than 2% of the overall food and beverage retail market (Rachel Wynberg, (2013f).

The following table (Tables 8) provides a picture on the total food and drink sales of the top 10 countries and regions. It is clear from the table that the sale of food and drinks in European Union, United States, China and Japan is predominant.

Table– 8: Total Food and Drink Sales of Top 10 Countries/Regions (Based on 2008-09 Data)

S. No	Countries / Regions	Total Sales(US$ billions)
1	European Union	1,268
2	United States	636
3	China	504
4	Japan	342
5	Brazil	138
6	Canada	89
7	Mexico	79
8	Australia	65
9	South Korea	56
10	New Zealand	28

Source:Rachel Wynberg (2013f)

Table 9 and Table 10 illustrates the top 10 food and drink products exporters and importers respectively. The European Union (EU) followed by the United States is the two largest exporter and importer of food and drink globally. However, studies revealed that due to rising market share in emerging economies, food and drink share of world trade has been shrinked from 20.1%(2001) to 17.8% (2010)(Rachel Wynberg, 2013f).

Table 9: Top 10 Exporters of Food and Drink Products, 2011

S. No	Countries / Regions	exports ($ billion)	Share of worldwide total exports (%)
1	European Union	97.2	16.5
2	United States	72.0	12.2
3	Brazil	46.8	8.0
4	China	44.2	7.5
5	Thailand	30.6	5.2
6	Malaysia	28.8	4.9
7	Indonesia	27.9	4. 7
8	Argentina	27.5	4.7
9	Canada	23.5	4.0
10	India	20.8	3.5

Source: Rachel Wynberg (2013f)

Table 10

Top 10 Importers of Food and Drink Products, 2011

S. No	Countries / Regions	Imports ($ billion)	Share of worldwide total Imports (%)
1	European Union	89.1	15.1
2	United States	83.7	14.2
3	Japan	52.5	8.9
4	China	36.9	6.3
5	Russia	24.3	4.1
6	Canada	23.9	4.1
7	South Korea	17.6	3.0
8	Hong Kong	15.7	2.7
9	Mexico	14.9	2.5
10	Nigeria	13.4	2.3

Source: Rachel Wynberg (2013f)

E.3. Supply chains

Supply chains for the food and beverage sector are highly variable. Generally, the traditionally comprised firms focused on agricultural production process raw food materials for further manufacture. On the other hand, those that are consumer oriented one which manufactures highly processed convenience food. However, companies are taking an integrated approach to the food supply chain with less separation of these functions between them. For example, the new scientific consortium by the Unilever company aims to "identify the nutritionally valuable varieties of fruits and vegetables from the past, in order to produce natural health ingredients for the future". If the project is successful in identifying nutrient-rich plants, the long-term aim would be to incorporate them into Unilever's food products.

There has been strong consolidation within ingredient suppliers, with the purchase of large and small firms by Archer Daniels Midland, BASF, DSM, Naturex and Nexira. Such companies will typically supply a range of ingredients to markets for food and beverage, nutrition and health, and personal care. One of the primary motivations for this trend is to market 'authentic' brands. In 2008, the largest 20 food processors commanded 20% of the global market, and further consolidation is predicted over time. The US dominates the world agri-food market, with seven of the top ten companies in this sector originating there (Table 11). The Swiss company Nestlé, now reconfigured as a "nutrition, health and wellness company, was the top ranked food and beverage company in 2012, with sales of 83.5 billion (see table - 11).

Table 11
Top 10 Food and Beverage Companies (2012)

Rank	Company	Headquarters	Food and Beverage Sales ($ Million)
1	Nestle	Switzerland	83,505
2	PepsiCo Inc	United States	65,881
3	Kraft Foods	United States	54,365
4	The Coca Cola Company	United States	46,524
5	Archer Daniels Midland Company	United States	42,639
6	Anheuser-Busch InBev	Belgium-Brazil	39,046
7	JBS	Brazil	34,770
8	Tyson Foods	United States	32,246
9	Unilever	United Kingdom-Netherlands	31,930
10	SABMiller	South Africa	31,388

E.4. Research and Development

Generally, the research and development (R&D) of food and beverage industries represents a small proportion of the investment, with innovation often "invisible" in the final product. Innovation primarily comes from know-how and on-going process improvements to existing ingredients with no known side effects, rather than R&D using new ingredients. However, some subsectors are transforming to a medium-high technology industry with greater reliance on innovation and research. A CBD, study (CBD, 2013f), highlighted research and development related key trends of the food and beverage industries, which include:

- Increased health and wellness are a major focus of the R&D activities in this sector.
- There is an increasing intersection of new molecular approaches and food innovation. For example, it has been made possible, through new technology, to identify and screen molecules arising from natural compounds in order to find those that can enhance tastes in products.

- New uses for nanotechnology are being developed, such as the intersection of nanotechnology and biology to create biological systems, and the use of microorganisms to synthesise nanoparticles.
- The emerging field of nutrigenomics is providing tailored nutritional advice and customised food products for particular individuals or populations.
- Medical foods are incorporating genetic resources to manage diseases.
- Microbial organisms are becoming increasingly important, where through biotechnology they are used to produce active compounds in much higher yields.
- Biosynthetic versions of high-value natural commodities are being developed through partnerships between producers of food ingredients, flavours and fragrances and synthetic biology companies.

In brief, food and beverage industries flourishing all over the world using wide range of biological resources (both plants and animals) and manufacture different consumer products. Broadly, ABS is a new phenomenon in this sector and required much more clarity on the lights of ITPGRFA and the exemptions on agriculture produces. The R&D in the food and beverage sector is progressing and coming up with modern dietary products with copping the demand in accordance with the changing life style of the people with the help of different biological resources.

SECTION F

Crop Protection Products

In recent decades, the crop protection products' manufacturing companies are flourishing both in developing and developed countries. For this, the role of different actor's such as, agriculture research and extension institutions, industrial and trading firms, farming communities and civil society representatives, and NGOs, is crucial. According to Kolanu and Sunil (2003), the growing demand for green agriculture products is a constraint as well as opportunity for agriculturists, producers, suppliers and traders of agricultural inputs and outputs.

Dependence on chemical fertilizers for future agricultural growth would mean further loss in soil quality, possibilities of water contamination, and an unsustainable burden on the fiscal system. Hence, there is a need to promote bio-fertilisers and bio-pesticides, for environmentally sustainable agriculture as well as for food and health security. A steady increase in organic input production infrastructure has contributed to a significant growth of organic agricultural areas in the country. Bio-fertilizers and bio-pesticides (organic inputs) are essential for organic farming, and their demand will continuously increase in the coming decades.

As the active ingredient in bio-fertilizers and bio-pesticides, microbes contribute to increasing agricultural productivity. Indeed, the commercial possibilities of microbes appear endless. Currently only 5% microbes are culturable but there are others of considerable potential value that need to be characterised by new and novel techniques. The 5% culturable microbes have been a source of valuable products (Department of Biotechnology, 2013). In the global turnover and the market of the crop protection industry, ten companies control 82%of the global pesticide market, in which more than half (54%) share was controlled by the top 4 corporations (Table 12).

Table -12: Turnover and Market Share of Top 10 Companies in the Global Pesticides Market

Company	Country	Agrochemical Sales 2009 ($ Million)	Market Share
Syngenta	Switzerland	8,491	18%
Bayer	Germany	7,544	17%
Monsanto	USA	5,007	10%
BASF	Germany	4,427	9%
Dow AgroSciences	USA	3,902	9%
Du Pont	USA	2,403	5%
Makhteshim Agan	Israel	2,374	4%
Nufarm	Australia	2,082	4%
Sumitomo Chemical	Japan	2,042	4%
Arysta Lifescience	Japan	1,196	2%
TOTAL Top 10		39,468	82%
Others			18%

Source: Raichal Waynberg (2013)

Increasingly, seed and agrochemical interests are converging, allowing companies to position themselves as major suppliers of both seed and agrochemicals. For example, the leading multinational seed company, Monsanto, genetically engineers its seed to be resistant to its own herbicides, a strategy which has helped position the company as the third largest agrochemical supplier globally. Crop protection sales have climbed steadily from $25 billion in 1990 to a global market value of almost $40 billion in 2010. Herbicides accounted for almost 50 per cent of the total crop protection market in 2009, with fungicides comprising 25.6%, insecticides 24.8% and others 3.6% (Raichal Waynberg (2013).

F.1. Research and Development

In agriculture sector continued focus on herbicide and insect resistance: One of the greatest demands in the crop protection industry is to develop new insect control traits, particularly to manage resistance. Here, chemical discovery has been aided significantly through the use of genomics to identify suitable candidates, and combinatorial chemistry which has

dramatically increased the number of products subject to biological screening. Generally, large agrochemical company may work with a smaller company to collect samples of soil microorganisms, test the microbes, and screen the DNA from these microbes to find look-alikes based on existing known insecticides. Sophisticated databases may assist to screen interesting germplasm, although researchers still rely on having the germplasm in hand.A key trend has been a shift in expenditure from conventional agrochemical research to an expansion of in-house R&D efforts on transgenic crops. First generation "input traits" of herbicide tolerance, along with insect resistance, continue to dominate R&D efforts Raichal Waynberg (2013).

Progress towards second generation "output trait" products with nutritional, environmental or other benefits has been slow, believed in part to be due to the complexities of manipulating multiple genes.Some so-called stacked traits have been developed and introduced, intended to improve the performance of transgenic crops but these demonstrate a continued focus on herbicide tolerance and insect resistance. This has led some to suggest that under current industry structure, the scope of genetic engineering as a crop improvement strategy may be limited (Raichal Waynberg (2013).

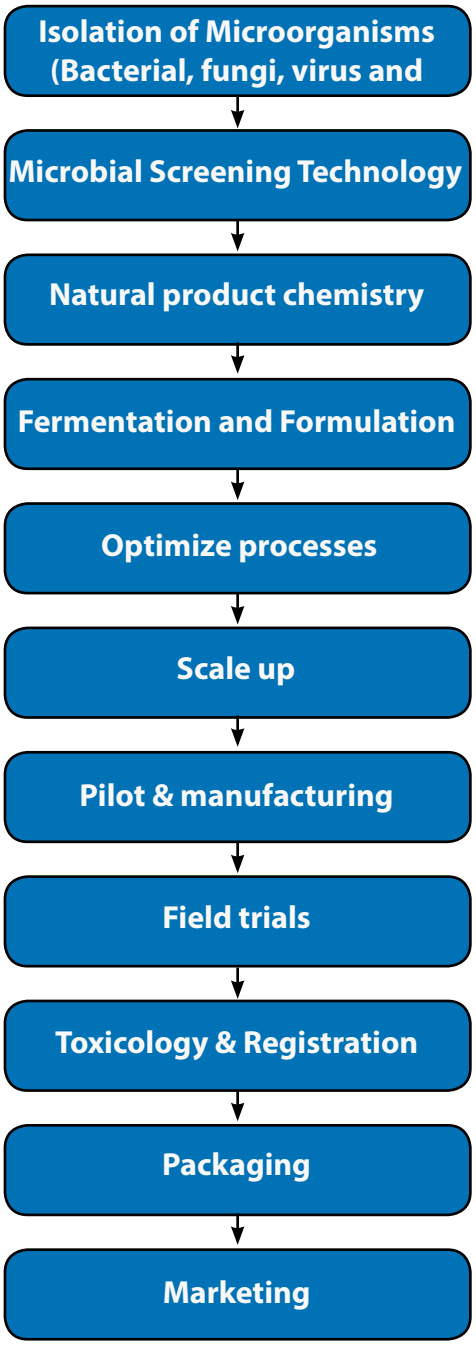
Despite the consolidation of the agricultural sector, research strategies remain tailored towards different products. For example, in contrast to the seed and plant biotechnology sectors, the crop protection and agrochemical sector uses genetic resources in a manner similar to pharmaceuticals – searching for interesting compounds, screening these for active ingredients, moving to a process of pre-development for the few that hold promise, and commercializing those that are viable. This sector therefore demands access to a much wider range of genetic resources – from *ex-situ* collections through to *in-situ* biodiversity such as microbes and insects. ABS questions are therefore highly significant for crop protection activities.

The major R&D process in bio-pesticide manufacturing (Microorganism as Bio-inputs) is worked out by Marrone (2014), is provided in the following figure (fig. 4).

The tremendous growth of the biological resources based crop protection products, as a substitute to the chemicals, in connection with the organic farming is an appreciable and environmentally friendly attempt. These companies use different kinds of biological resources, including the microbes and manufacture products for attacking the insects' problems faced by different crops. Generally, the crop protection products manufacturing companies are viewed their products differently and argues that the product they manufacture are effective substitutes for chemicals and are safeguarding the ecosystems/biodiversity (soil and water quality) and the human health (better quality of food products). Hence the ABS acceptances among them are relatively less.

However, with consideration of the biological resources predominant dependencies in the crop protection products manufacturing and it's emerging markets with the base of organic farming ABS to be initiated in this sector. In this regard more awareness among industries about the ABS is required.

Figures 4 : Research & Development Process in Bio pesticides Manufacturing



SECTION G

Horticulture

Horticulture is an another predominant section of agriculture involve biogenetic materials use and potential for ABS. Horticulture section includes a wide range of activities including ornamental horticulture, flower culture, fruits culture, etc., which involves substantial growth over a period with respect to the changing life style of the people. In contrast to seed and crop protection products, ornamental horticulture is still largely carried out by small- and medium-sized companies, which continue to rely largely on conventional breeding methods and mid-level technologies. Similarly, research and breeding of fruit species is often a focus of public institutions and universities due to the high costs involved. Across all continents, however, there is a general trend towards fewer and larger horticultural growers, and a concentration of other retail pathways (Raichal Waynberg (2013).

The global horticulture industry has been expanding steadily since the 1980s but the shift of production to developing countries has caused market prices to drop. The total world import trade value in horticulture in 2011 was $19 billion (Table 13). But it established as an increase of more than 40 per cent since 2004. Historically, the Netherlands has been the centre of world flower production, but increasingly, growing takes place in developing and newly industrialized countries, where horticulture may represent the fastest growing sector of the economy.

Table 13
World Import Trade Value in Horticulture (2011)

Category	Value	Percentage
Live plants	$7,5 billion	40%
Fresh cut flowers	$7,6 billion	40%
Bulbs, tubers and corms	$1,7 billion	9%
Fresh cut foliage	$0,9 billion	5%
Other (e.g. trees, dried flowers, etc.)	$1,1 billion	6%
TOTAL	$19 billion	100%

Source: Raichal Waynberg (2013).

G.1. Research and Development (R&D)in Ornamental Horticulture

R&D in horticulture sectors is a dynamic process. According to Raichal Waynberg (2013), ornamental horticulture tends to be far downstream of new scientific and technological developments in the agricultural sector. Such developments typically happen first in field crops, then vegetables, finally trickling down to ornamental horticulture. DNA technology is considered too expensive and the industry has stayed away from genetically modified organisms because of the expense, regulations and intellectual property issues.

Although other technological developments have impacted this industry, the fundamentals of horticultural science remain paramount. “Much of what we do today hasn’t changed since Mendel”, remarked one Chief Executive of a major ornamental horticulture company. While the industry continues to rely on conventional breeding, improved understanding of plants and their genetics has enabled old cultivars and varieties to be looked at with new eyes. Raichal Waynberg (2013) stated that comments of one of the industry representative as “we understand plants much better now andcan discern specific traits more easily. Faster breeding is now possible and is more focused – even without using genetic modification”.

R&D trends across the ornamental horticultural sector vary considerably depending upon the size, form type of horticulture and location of companies. In North America, for example, significant consolidation in the retail market has had a direct influence on some companies. The development of traits suited to these characteristics, based on improvements or extensions to existing products, comprises a major focus for these companies rather than novel R&D to develop new products. Companies are also focused on garden performance for existing products, to ensure longevity once planted. Some companies have reported a decline in new germplasm development over the last five years. This is not necessarily related to any difficulties in securing access to wild material, but rather to lengthy product development cycles, a tendency towards increased selectivity, limited markets and the complexities and cost of combining new germplasm with existing classes. One of the company representative remarked that, “it takes time to combine new germplasm and we haven’t found a lot of traits to make the investment worth it” (Raichal Waynberg, 2013).

G.2. Access of Biological Resources and Interest in wild species

The ornamental horticulture sector relies predominantly on genetic resources already available in their own or other commercially available stocks. Most of the companies may acquired this prior to the enactment of ABS laws. Almost all plants used in ornamental horticulture, and the diversity of cultivars derived through selection and breeding, came from wild plants. However, the modern-day horticulture industry has relatively low reliance on wild genetic resources, and many of the genetic resources it uses have been developed over decades and exist within industry collections.

This sector does, however, require access to new genetic material for two main reasons: (1) for the development of species completely new to horticulture, adapted from wild species, and (2) to develop new traits, colours, and characteristics that may add to established classes. In large part, however, focus is given to the development of new traits and characteristics, rather than to the development of entirely new horticultural species. Despite the potential of wild species for new ornamental products, there are challenges to get new products into the marketplace. Although a small segment of the market is looking for something “different”, companies have remarked on the difficulties of connecting consumers and growers to unfamiliar new products, largely due to a lack of awareness.In brief, the horticulture sector (particularly the ornamental horticulture) is under transformation from the wild natural species to the newel adopted one with the changing human tastes. As this sector use genetic resources for their already available stocks and on the newly identified wild once, the scope of ABS is enormous.

SECTION H

Industrial Biotechnology

Industrial biotechnology is the emerging field in bioscience which facilitates the economic growth more eco-friendly and environmental sustainable manner. Industrial biotechnology is the application of biotechnology to the eco-efficient production and processing of chemicals, materials, and bio-energy. It utilizes the extraordinary capabilities of micro-organisms and enzymes, their diversity, efficiency and specificity, to make products in sectors such as chemicals, food and feed, pulp and paper, textiles, automotive, electronics, and, crucially, energy (CBD, 2013ib). This sector covers in a wide range of industries including: chemicals, plastics, food and feed, detergents, pulp and paper, electronics, automotive, textiles, bioprocessing catalysts, and biofuels.

According to a CBD study, the industrial biotechnology has come of age in the last five years. Advances in science and technology, combined with concerns over climate change, energy security, and an interest in more efficient, cost-effective and green manufacturing processes and products, have led to rapid growth in this sector. Small and large companies, in a wide range of industries, are forming partnerships to produce biofuels, biobased chemicals, bioplastics, and a variety of consumer products like snack foods, sneakers, cosmetics, jeans,cars, medicines, vitamins, and electronics.

Industrial biotechnology companies are interested in new enzymesand metabolites from microorganisms; in particular those that can withstand industrial manufacturing conditions like extremes of temperature, pH, and pressure. Studies revealed that few companies prospect in areas with high species diversity, unique ecological niches and extreme environments, but most acquire materials through existing collections or from their own backyards. A significant development in industrial biotechnology related sectors, is the publication of thousands of microbialgenetic sequences, and the ability of researchers to transfer genetic material digitally (CBD, 2013ib).

H.1. Global Market:

During the last few years industrial biotechnology made a substantial growth and experts viewed that it may grow further in coming decades. The global revenues for goods produced using industrial biotechnology in 2010 were between $ 65-78 billion annually, including biofuels. In 2010, the ethanol and biodiesel industries reached a combined wholesale value of $56.4 billion, and this is predicted to grow to $112.8 billion by 2020. The global market for industrial enzymes was $3.3 billion in 2010; with 6.6% growth rates, 2015 revenues of $4.4 billion are anticipated. The largest industrial biotech sectors are in the US, Europe, and Asia. Government incentives and support for industrial biotechnology around the world have played a large role in its recent expansion, particularly in the area of biofuels. The world's largest energy, chemical, food, pharmaceutical and other companies have recently come to embrace industrial biotechnology, resulting in a surge of partnerships with smaller industrial biotechnology (or synthetic biology) companies (CBD, 2013ib).

Box – 7
Consumer Products Made with Industrial Biotechnology

CONSUMER PRODUCT	OLD MANUFACTURING PROCESS	NEW INDUSTRIAL BIOTECH PROCESS
Bread	Potassium bromate used as preservative and dough strengthening agent	Genetically enhanced microorganisms produce baking enzymes to enhance rising, strengthen dough and prolor freshness
Vitamin B2	Aniline and other toxic chemicals used in nine step chemical synthesis that produces hazardous waste	Genetically enhanced microbe developed for one step fermentation process, using vegetable oil as a feedstock sugar as a nutrient, and using 33% less energy
Personal care	Chemical ingredients such as propylene glycol and butylenes glycol from petroleum are used as solvents to mix ingredients	Genetically enhanced microbe produces 1,3 propanediol from renewable feedstocks, used as solvent, humectant emollient
Cosmetics	Mineral oil and petroleum jelly from fossil fuels	Metathesis chemistry applied to convert renewable vegetable oils to higher quality ingredients to replace petrochemicals
Detergent	Phosphates added as a brightening and cleaning agent, but cause water pollution	Microbes or genetically enhanced fungi produce enzyme protease enzymes remove protein stains; lipases remove grease; amylases remove starch
Textiles	New cotton textiles prepared with chlorine or chemical peroxide bleach	Use of biotech cellulose enzymes to produce peroxides, allowing bleaching at lower temperatures and neutral pH range, with higher quality product.
Paper	Wood chips are boiled in a harsh chemical solution to yield pulp for paper-making	Wood bleaching enzymes produced by genetically enhar microbes selectively degrade lignin and break down woc cell walls during pulping, reducing use of chlorine bleach and release of dioxins in the environment
Furniture	Polyurethane foam produced from petroleum	Polyols (such as Cargill's BiOH or Dow's Renuva) derived from soy and other feedstocks, mixed with other ingredi to create a flexible foam using much less energy
Polyesters	Polyester, a synthetic polymer fibre, is produced from petroleum	Bacillus microbe ferments corn sugar to lactic acid, whicl is heated to create a biodegradable polymer (e.g. Nature Works' Ingeo)
Stone washed jeans	Open pit mining of pumice, fabric washed with crushed pumice and/or acid	Fabric washed with biotech enzyme (cellulases) to fade a soften fabric, less mining and energy
Biofuels	Petroleum is cracked and distilled into gasoline and by products	Novel enzymes convert starches and cellulose in biomass into sugars. Genetically enhanced microbes convert suga to a growing range of alcohols and esters.
Beverage and food packaging	Polyester, a synthetic polymer fiber, produced chemically from petroleum; Polypropylene also made from petroleum	Bacillus microbe ferments corn sugar to lactic acid, whicl heated to create a biodegradable polymer
Plastic containers	Plastics (olefins and styrenics) used for eating utensils, beverage and food containers, and personal care products – all made from petroleum	Naturally-occurring microbial process is genetically enhanced to produce polyhydroxyalkanoates (PHAs, suc as Telles' Mirel). PHAs can also be grown in genetically e neered switchgrass plants.

Source: Sarah A. Laird (2013ib)

Box 8: Synthetic Biology

Synthetic biology broadly refers to the use of computer assisted, biological engineering to design and construct new synthetic biological parts, devices, and systems that do not exist in nature, and to redesign existing biological organisms.54 It draws upon the advances described above, and moves science from "reading the genetic code to writing it."

Synthetic biology integrates disciplines like molecular biology, engineering, computer modeling, information technology, control theory, chemistry and nanotechnology and is a set of tools that is integrated into the work of many industrial sectors.56 While genetic engineering usually involves the transfer of individual genes from one microbe or cell to another, synthetic biology assembles novel genetic pathways from standardized genetic parts that are then inserted into a microbe or cell. Industrial biotechnology researchers and companies have been using synthetic biology tools for years, including gene splicing, metabolic engineering, and directed evolution. Synthetic biology is not limited to the modification of natural organisms, but also has the potential to construct new life forms with no natural counterparts.

Applications of synthetic biology include turning microbes into 'living chemical factories' to produce fuel, industrial chemicals, or pharmaceuticals. Natural product substitutes are also a focus of research today, including the production of synthetic 'natural' rubber, 'natural' food flavors like vanilla and saffron, essential oils like vetiver, and palm oil. Amyris, based in California, has coaxed yeast to produce industrial-scale artemesinin, the antimalarial drug that now comes from Artemisia annua production in China and elsewhere. Civil society and other groups have expressed concerns that farmers will lose their livelihoods if bulk raw plant materials are replaced with synthetic biology versions of products like artemesinin, vanilla and rubber.

Since 2004, at least $1.84 billion has been invested in synthetic biology start-ups from private investors, and governments have spent millions more, but "most of those companies have made grinding progress, not breakthroughs." Although synthetic

biology has enormous potential, realizing this in practice has not been as easy as some had hoped, and many feel the hype of the last ten years has hurt the research. As Voosen put it: "The tools have outpaced the knowledge. The cost of genetic sequencing and synthesis continues to plunge, but the functions of many genes ineven the simplest forms of life, like bacteria and yeast, stubbornly hold on to their secrets. Genetic networks interact in complex, mysterious ways. Engineered parts take wild, unexpected turns when inserted intogenomes. And then evolution, a system that would drive any electrical engineer mad, tiptoes in."

The global market in 2011 for synthetic biology was $1.6billion, and this is expected to rise to $10.8 billion by2016. Products already on the market include maizesourcedbioplastics sold by DuPont and Archer Daniels Midland, biodiesel sold in Brazil by Amyris Inc., and biosynthesized 'natural' grapefruit flavour sold by Allylix. More than 20 synthetic biology products are on the market. Synthetic biology is moving more slowly than promised, but it has hit the marketplace and its role in industry will continue to grow.

In 2012, 113 civil society and environmental organizations from around the world endorsed a call for proper oversight and regulation of synthetic biology, requesting that the precautionary principle be applied to governance of these new and poorly understood activities, and that a moratorium be placed on the environmental release and commercial use of synthetic organisms until national and international laws are improved and in place to ensure their safety.

H.2. Research and Development:

The R&D sectors of industrial biotechnology are progressing considerablyover a period, but sensitive with the changes on the global economic circumstances. Small- and medium-sized companies were hit particularly hard by the economic crisis; as venture capital dried up, many struggled to reduce cash burn rates by cutting back on R&D. In industrial biotechnology, in

addition to the private sector, government research and academic institutions, undertake biotech R&D. These groups then partner with the private sector to commercialize research results and new technologies. Industrial biotech R&D is significantly less costly and less risky than biopharmaceutical R&D, and recent advances in science and technology, government mandates and incentives, and the growing interest of larger companies helped fuel a new wave of research and commercial interest.

The last decade has seen dramatic advances in researchers' ability to access the genes that encode enzymes responsible for the biosynthesis of secondary metabolites. "Genomemining", or metagenomics, allows researchers to search directly within a soil or water sample for genes without having to culture the organism. Sequencing of whole genomes has become 'commonplace, rapid, and relatively inexpensive', with thousands of whole bacterial genomes in the public literature. Genetic material can now be transferred digitally; it is now possible to collect material in one country, and send it via the internet to a laboratory in another, in a matter of days (CBD, 2013ib).

H.3. Demand for Access to Genetic Resources

Industrial biotechnology companies are interested in novel enzymes found in microorganisms, but most access material through internal or external collections; only a few undertake collections outside their country, and the use of traditional knowledge is limited or non-existent. Some companies seek out genetic diversity by collecting in areas with high species diversity, extreme environments, or unique ecological niches. Microorganisms called extremophiles are of particular interest to researchers today. Found in extreme environments like hydrothermal vents, deserts, caves, cold seeps in the deep sea, salt lakes, and subglacial environments in Antarctica, these organisms live in environments similar to those required by industrial processes.

In brief, industrial biotechnology is an emerging area emphasis on more environmental friendly product manufacturing. This sector level up further with the advent of synthetic biology. Since different biological resources and their advanced scientific knowledge are the key in industrial biotechnology, its ABS significance is debated in different forums including the CBD.

SECTION I

Nutraceuticals

The term "nutraceutical" combines two words – "nutrient" (a nourishing food component) and "pharmaceutical" (a medical drug). The name was coined in 1989 by Stephen DeFelice, founder and chairman of the Foundation for Innovation in Medicine, an American organization located in Cranford, New Jersey. 'Nutraceuticals' refers to any food ingredient or product consumed for its medical and health benefits, including the prevention and or treatment of disease. Products include dietary supplements, entire diets (eg. macrobiotic), isolated nutrients, and functional or medical foods, including 'designer' biotechnology -enhanced foods, and fortified processed foods such as cereals, soups, and beverages.

In other words, nutraceuticals is a broad umbrella term that is used to describe any product derived from food sources with extra health benefits in addition to the basic nutritional value found in foods. They can be considered non-specific biological therapies used to promote general well-being, control symptoms and prevent malignant processes. The category of nutraceuticals is expanding and innovating rapidly (Kate and Sarah, 2000).The philosophy behind nutraceuticals is to focus on prevention, according to the saying by a Greek physician Hippocrates (known as the father of medicine) who said "let food be your medicine". Their role in human nutrition is one of the most important areas of investigation, with wide-raging implications for consumers, health-care providers, regulators, food producers and distributors.

I.1. Categories of Nutraceuticals

Nutraceuticals can be classified on the basis of their natural sources, pharmacological conditions, as well as chemical constitution of the products. Most often they are grouped in the following categories: dietary supplements, functional food, medicinal food, farmaceuticals.

A dietary supplement represents a product that contains nutrients derived from food products, and is often concentrated in liquid, capsule, powder or pill form. Although dietary supplements are regulated by the FDA as foods, their regulation differs from drugs and other foods. Functional food is a category which includes whole foods and fortified, enriched or enhanced dietary components that may reduce the risk of chronic disease and provide a health-benefit beyond the traditional nutrients it contains.

Medical food is formulated to be consumed or administered internally, under the supervision of a qualified physician. Its intended use is a specific dietary management of a disease or condition for which distinctive nutritional requirements are established by the medical evaluation (on the basis of recognized scientific principle). Farmaceuticals are medically valuable components produced from modified agricultural crops or animals. The term is a combining of the words “farm” and “pharmaceuticals”. Proponents of this concept are convinced that using crops (and possibly even animals) as pharmaceutical factories is much more cost effective than conventional methods, with higher revenue for agricultural producers.

I.2. Potential health benefits

Over the years nutraceuticals have attracted considerable interest due to their potential nutritional, safety and therapeutic effects. They could have a role in a plethora of biological processes, including antioxidant defenses, cell proliferation, gene expression, and safeguarding of mitochondrial integrity. Therefore nutraceuticals may be used to improve health, prevent chronic diseases, postpone the aging process (and in turn increase life expectancy), or just support functions and integrity of the body. They are considered to be healthy sources for prevention of life threatening diseases such as diabetes, renal and gastrointestinal disorders, as well as different infections.

A wide range of nutraceuticals have been shown to impose crucial roles in immune status and susceptibility to certain disease states. They also exhibit diseases modifying indications related to oxidative stress including allergy, Alzheimer’s disease, cardiovascular diseases, cancer, eye conditions, Parkinson’s diseases and obesity.

Sara Laird and Rachel Wynberg (2013) estimated the global nutritional sale by product categories (Table - 13); which indicated that the functional foods in the tune of USD 101,836 million covers a major share (34%) followed with supplements (28%) and natural and organic foods (28%).

Table - 13
Global Nutrition Industry Sales by Product Category, 2010(USD Consumer Sales)

Category	2010	% of Market	2010 Growth
Supplements	84.5	28%	5.4%
Natural & Organic Foods	84.1	28%	7.5%
Natural & Organic Personal Care & Household Products	31.0	10%	8.8%
Functional Foods	101,836.00	34%	4.8%
Total Nutrition Industry	301,386.00		6.1%

SECTION 3

Implementing The Access and benefit sharing in Industrial Sectors: Challenges and the Way Forward

3.1 Bioprospecting Industries: CBD and the Rationale for the ABS

It is very clear from the analysis in the report that a wide range of companies are using the genetic materials / biological resources in their business model in different quantities based on their requirement. However, the companies and other stakeholders are not clear about the process of ABS and its implementation at the different levels. Similarly, the providers of biological resources are also not aware about the ABS mechanisms. Even if CBD is working with its parties on these issues, most of the users of the biological resources are not very keen on ABS, as they generally assume that ABS is an additional financial burden to them without worrying about the spirit of CBD and the Nagoya Protocol on ABS. This is a major concern as well as a challenge for the success of CBD and the ABS regime.

The CBD is a treaty between nation-states, but it is of central importance to business. Considering the provisions of the Convention, State parties have designed national laws to be implemented when any company or individual seeks access to biological resources or samples of plants, animals, or microorganisms for scientific research or as the starting point for commercial development. Since the process is related to business, the involvement of the private sector is essential for the successful implementation of the treaty. The CBD seeks to integrate conservation and sustainable use, and calls for the fair and equitable sharing of the benefits arising from the use of genetic resources.

Broadly speaking, private sectors are the major users of genetic resources. In this context, understanding the views of the private sector on CBD is important. According to Kate and Sara (2000), the nature of commercial partnerships will inevitably inform the manner in which benefits are shared in practice. They will also influence the extent to which biological resources are used sustainably and whether this use will create incentives for conservation.

The motivation from the business sectors to comply with the ABS legislations is a pre-requisite for the successful implementation of CBD and Nagoya Protocol. In this regard Kate and Sara (2000) indicated three constraints: (a) the monitoring and enforcement of legislation and agreements is difficult, since it involves tracking and identifying the source and date of collection of specimens and also a product's movement through the discovery and development pipeline, (b) the law and procedure on access is unclear in the vast majority of countries, and (c) user countries show little inclination to introduce laws to support enforcement of access agreements in the countries where companies conduct their research and development. Hence, voluntary compliance by the industry will be essential and they should realize the principles of prior informed consent (PIC) and fair and equitable sharing of benefits.

Generally, the progress in finding practical solutions to access and benefit-sharing has been hindered and industries' understanding on this is significant. The industrial survey (on bioprospecting industries from different sectors) done by Kate and Sara (2000) revealed some of the common 'myths' among the industries about the CBD and its principles: (the survey covered 264 industries include: 27 Pharmaceuticals, 34 Botanical Medicines, 34 Major crops, 48 Horticulture, 26 Crop Protection, 34 Biotechnology, 61 Personal Care)

- The CBD does not apply to the industry if they do not use endangered species or overexploit raw materials.
- The CBD does not apply to materials with no known value, derivatives such as proteins or compounds, microcorganisms, or ex-situ collections.
- The CBD does not apply to common species with wide distribution.

Further, the survey and the interviews with industrialists also provide some more insights on industries' understanding of CBD and the ABS, which are summarized below:

- A high proportion of the companies and other organisations interviewed had heard of the CBD, but many interviewees did not have a good understanding of its scope.
- Most companies and other organisations involved in access to genetic resources are still ill-informed about the implications for their business of the CBD. There is a feeling that 'business-friendly' information on access and benefit-sharing is not easily available.

- The pharmaceutical, biotechnology, crop protection and seed industries appear to be more familiar with the provisions of the CBD and national access laws than horticulture, botanical medicines and personal care companies.
- Many companies were positive about the objectives of the CBD, but the vast majority of those interviewed had major concerns about its implementation. Concerns included the lack of clarity surrounding access rules, the bureaucracy and transaction costs involved in following them, and the lack of understanding of the role of business on the part of regulators and institutions providing access to genetic resources.
- Companies felt that, at present, the treaty makes only a negligible impact on its daily business. Gradually, however, the CBD's influence over the nature of commercial partnerships involving the use of genetic resources is growing.
- Several companies mentioned that the current changes in business practice, as a result of the CBD, include: a decrease in and consolidation of corporate collecting activities; greater recourse to material from ex-situ collections; an increased role for intermediaries as brokers of access and benefit-sharing relationships in addition to suppliers of samples; and the increasing use of MTAs.
- A number of voluntary guidelines for professional scientists such as botanists, ethnobotanists and pharmacologists have been developed over the last decade. Several intermediary organisations involved in collecting genetic resources, and sometimes in supplying them to industry, have developed institutional policies and MTAs on access and benefit-sharing. A number of companies have developed policies on environmental and social issues, while some even refer to the CBD in corporate literature such as annual reports.
- Only a handful of companies have developed and adopted specific policies on the acquisition of genetic resources and benefit-sharing. It exists, predominantly in the pharmaceutical sector.

It is clear that users of biological resources, primarily the industrial communities are interpreting the CBD's principles and the ABS at large from different perspectives, where the scope of their voluntary involvement in the ABS process is extremely limited. However, the industries' involvement is important, as they are the key stakeholders in the ABS process.

Recently some of the authors criticized the operational challenges of the CBD and the Biological Diversity Act in certain specific context. However, a complete opposition on the ramification of CBD and its objectives as well as the Biological Diversity Act is not acceptable. The rational of the CBD philosophy as well as the Biological Diversity Act need to be understood and accept by all the stakeholders, including the biological resources based industries, in right spirit. The researchers and the industries need to collaborate with the concerned enforcement agencies and the issues they faced in complying the Act need to be resolved in an amicable and mutually acceptable manner, rather than contradict it or question the Biological Diversity Act itself.

3.2 Sector-wise Implementation of the Nagoya Protocol

Generally, industries hesitate in getting involved with the ABS, particularly in the initial years after the commencement of the CBD. However, the industry-wise analysis carried out in this report clearly reveals the significance of ABS in different sectors that use biological resources for their product development and manufacturing, including research. However, there are considerable variations in these different sectors on the basic steps which facilitate the ABS, including the access to biological resources over the years. As ABS is an internationally accepted principle under the CBD and operates through the Nagoya Protocol, industries need to follow the existing national ABS requirements and procedures.

Recent studies revealed that, there have been real and concrete gains under the CBD in the last 20 years. For example, large pharmaceutical companies support the need to sign agreements, reach mutually agreed terms, and share benefits. Benefit sharing packages that include a wide range of monetary and non-monetary benefits over time have become a standard practice. Bio-resource collections by pharmaceutical company staff when they go on holidays, once widespread, have become a thing of the past. National sovereignty over genetic resources is widely accepted, as is the need to get permission for any collection. However, numerous unresolved issues and concerns remain (Sarah, 2013), which require more attention in the future.

Scientific and technological advances since the CBD entered into force have changed the way companies use and value genetic resources. Significant developments include reduced demand for access to genetic resources in high biodiversity regions, as companies look

deeper within organisms found in their own backyards and existing collections (Sarah, 2013). Large pharmaceutical companies are well-informed of the CBD and avoid collections that do not have necessary approvals from provider country governments. Smaller companies and academics, however, tend to be more inconsistently informed about the CBD, and are more numerous and dispersed, and therefore difficult to monitor.

The benefits that arise from the development of a natural product pharmaceutical take many forms. Monetary benefits might include fees per sample, grants to cover permitted research programmes, profit-sharing, stakes in equity, joint ventures, royalties and the prospect of local employment opportunities. Access legislation and the negotiating position of individual provider institutions increasingly prioritises non-monetary benefits, such as the sharing of research results, participation in research, technology transfer, and training and capacity-building. Some partnerships offer help in kind, such as medical assistance and investment in local infra-structure. Others support conservation projects in the field (Sarah, 2013).

Significant strides have been made through the ITPGRFA to facilitate the exchange of PGRFA. Given that the ITPGRFA was negotiated in harmony with the CBD, the Nagoya Protocol provides an important opportunity to build on these experiences and enhance coordination and policy coherence between the environmental and agricultural sectors. Regulatory frameworks for botanicals are changing around the world. As governments seek to streamline and harmonize regulations for the safety, quality and efficacy of botanical medicines, they might usefully take note of the obligations set out in the Nagoya Protocol. Implementation of the Nagoya Protocol can therefore help to clarify industry obligations and responsibilities in relation to access and benefit-sharing. The cosmetics sector has experienced a substantial turnaround with regard to awareness in access and benefit-sharing (ABS) and commitment to ethical sourcing practices. However, realizing this new-found awareness in practice is not always straightforward or simple. The implementation of the Nagoya Protocol provides an important opportunity to respond to some of the concerns raised in recent years:

ABS is very new to the food and beverage sector and the fact that the biological resources are mostly used as raw materials and commodities also means that ABS issues may not be relevant to many users and providers operating in this sector. Some larger companies are embedding

ABS in their policies and procedures, but for most companies awareness remains extremely low. Although R&D on genetic resources in this sector is likely to continue to represent a small proportion of its overall portfolio and profits, the upward trend of using genetic resources is likely to increase the relevance of ABS for the sector.

Although much of the industrial biotechnology units are largely unaware of the CBD and the Nagoya Protocol, those companies with awareness of the CBD have voiced concerns similar to those in other sectors: a need for clarity and streamlined procedures for accessing genetic resources, ideally coordinated across regions, and a need for government departments in charge of ABS to better understand the scientific, technological and business realities of their sector.

The study by Sarah and Rachel (2012) derived the following implications of the Nagoya Protocol in different sectors and its scope and concerns: Helping researchers and companies to 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 on terms, including those from indigenous and local communities (Article 13).

Defining the scope of ABS measures – Many industries 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, as to which resources and activities fall within its scope, thus providing certainty and clarity about ABS implications and requirements.

Supporting benefits -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 on 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 on terms, and improved capacity to undertake research on national genetic resources.

The Nagoya Protocol is an international guideline to the users and providers of biological resources to operationalize the ABS mechanism. Further, it also enhances the vision of the enforcement agencies in implementing the ABS in their countries. However, the success of the Nagoya Protocol and the ABS depends on the cooperation from the various ABS stakeholders, particularly the industries. As confusion prevails among various industrial sectors about accessing the biological resources and other ABS issues, much more awareness and capacity building (which is envisaged in the protocol itself) is required. Industries' cooperation in this regard is extremely important.

In India, ABS measures have been implemented through legal measures which include the Biological Diversity Act (2002) and Biological Diversity Rules (2004). Further, the various notifications issued under the Act, and the 'Guidelines on Access to Biological Resources and Associated Knowledge and Benefit Sharing Regulation (2014)' also facilitate the implementation of the act by providing more clarity on the ABS process in the country. The

ground level implementation of the ABS in the country is progressing through decentralized institutional arrangements such as; National Biodiversity Authority (NBA), State Biodiversity Boards (SBBs) and Biodiversity Management Committees (BMCs) at the national, state and local levels respectively.

The NBA and the SBBs have organized a number of awareness generation and capacity building workshops for different ABS stakeholders including industries. This may facilitate to some extent, an improvement in the ABS process in the country in different sectors as indicated in Box – 1 and 2. However, some of the industries are coming up with their concerns and arguing that they shall be exempted from the Biological Diversity Act on certain grounds.

In India's ABS process, more applications are in Form III for obtaining approval for IPR. Section 6 of the Biological Diversity Act states that the application for intellectual property rights is not to be made without approval of the National Biodiversity Authority. It indicated that "no person shall apply for any intellectual property right, by whatever name called, in or outside India for any invention based on any research or information on a biological resource obtained from India without obtaining the previous approval of the National Biodiversity Authority before making such application". It is clear that there is no substantial progress on approvals for obtaining an IPR till 2012. However, the approvals for obtaining IPR increased from 2012 primarily due to the introduction of the 'Guidelines for Processing of Patent Applications Relating to Traditional Knowledge and Biological Material (2012)' by the Indian Patent Office, which clearly mentioned the procedures to be followed by the patent applicants who use biological materials and traditional knowledge for doing the invitation as well as the penal provision for whoever contravenes the provisions.

In brief, in India, a majority of industries are not voluntarily coming forward and complying with the Biological Diversity Act and the ABS. Some of them are not trying to understand the key concepts of the Biological Diversity Act and attempting to identify the loopholes for not abiding by the principles of the Act.

3.3 Way Forward

Biodiversity plays a significant role in human existence as well as enhancing human

welfare. However, biodiversity is under a huge threat than ever before, particularly due to anthropogenic reasons. Increasing population, drastic land use change, and higher volume of waste generation are adversely affecting the existence and richness of biodiversity and the functioning of the ecosystems and their services. As biodiversity loss is a global concern, an international treaty –the CBD – emerged with a global membership and its efforts towards biodiversity management are progressing through different programmes of the Convention including the ABS. The ABS regime made a transformation in the ownership of biodiversity from a global public good to a national sovereign right, and designated its management as a national or state responsibility. Different nations have come up with legislative and institutional measures for enhancing the national sovereignty for its different biological resources and the concerned agencies must follow the legislative measures with PIC and MAT.

The advent of CBD and the Nagoya Protocol on ABS envisaged clarity on access to biological resources by the users (industry and researchers) and the follow-up steps through ABS. The principal strategy substantiates that benefit sharing will act as an incentive for the communities, who are the custodians of biological resources in their jurisdiction, towards conservation and sustainable use of biodiversity, which ultimately makes it easy to maintain the stock of the biological resources / genetic material intact and to ensure the raw-material security for the industry. As biodiversity has a huge commercial significance, various sectors / industries who use biological resources with commercial intent must come forward and share a portion of their accrued benefit (as per the national legislation) with the community for the purpose of conservation.

It is clear that, a range of industrial sectors (including the pharmaceutical, agriculture, industrial biotechnology, cosmetics, botanicals, and food and beverages) uses genetic / biological resources and associated traditional knowledge, and manufactures different products. Over the past two decades, scientific and technological developments in bioscience involving markets, and different business and intellectual property models have transformed the 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 the negotiators of the CBD.

The Nagoya Protocol helps to address uncertainty about ABS obligations and compliance. By requiring Parties to establish competent national authorities and national focal points, the Protocol helps to ensure that those seeking access to genetic resources or associated traditional knowledge will obtain information about the relevant authority to consult, and the necessary procedures to obtain prior informed consent and establish mutually agreed on terms. The establishment of an ABS Clearing-House would also help to achieve this goal.

According to the CBD (2013bs), the market for biological resources based industries has made a substantial growth in recent times and also experienced structural transformations. 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 from the top pharmaceutical and food companies, which earn in excess of $50 billion annually, and individual seed companies with sales of $7 billion, 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. 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 (CBD, 2013bs).

Biological resources based industries are spending huge money for research and development (R&D), but the budgets vary enormously between sectors. The pharmaceutical industry is the most research-intensive sector and the combined expenditures (industry and government) were $68 billion in 2010. Other sectors, like the botanicals industry, spend very little on R&D. Products are launched in these 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.

According to CBD (2013bs), across all sectors, the speed, capacity and precision of research on genetic resources has increased dramatically due 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.

In high-tech industries like pharmaceuticals, agriculture and biotech, the need to access genetic resources, through large-scale field collections is less than in previous years, 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 the 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 (CBD, 2013bs).

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, high-tech industries like pharmaceuticals and biotech now use little or no TK associated with genetic resources in their R&D programmes.

The sector wise assessment exposed that, there are fundamental differences among different industries' approaches and dependencies on biodiversity. The types of biological resources accessed the method and source of collection, volume and quantity, research and development, biotechnology applications, nature of production, dependencies on biological resources associated traditional knowledge (TK), cost benefit ratio etc. vary considerably from industry to industry. Hence, a detailed analysis with case study on each segment of

industries with respect to its ABS is urgently required for the successful implementation of ABS in each sector.

In brief, even if industries have made considerable progress in complying with the domestic legislation pertaining to the ABS during the last decade, much more effort (cooperation and support) is required for the success of ABS to a great extent. It is also clear that understanding ABS and the level of its acceptance also varies between the different industrial sectors. Strict enforcement of the national legislation on ABS is required, but in the absence of a strong institutional and administrative network it becomes a difficult task. However, voluntary acceptance of ABS by all the industrial units, which come under different sectors, is a prerequisite for the success of ABS. Industries should come forward and amicably understand the concept and the principles of the CBD and the Nagoya Protocol on ABS and implement the same. They should realise the fact that the success of ABS is THEIR success.

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Appendix-1

Monetary and Non-Monetary Benefits

Monetary benefits may include, but not be limited to:

a) Access fees/fee per sample collected or otherwise acquired;

b) Up-front payments;

c) Milestone payments;

d) Payment of royalties;

e) Licence fees in case of commercialization;

f) Special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity;

g) Salaries and preferential terms where mutually agreed;

h) Research funding;

i) Joint ventures;

j) Joint ownership of relevant intellectual property rights.

Non-monetary benefits may include, but not be limited to:

a) Sharing of research and development results;

b) Collaboration, cooperation and contribution in scientific research and development programmes, particularly biotechnological research activities, where possible in the Party providing genetic resources;

c) Participation in product development;

d) Collaboration, cooperation and contribution in education and training;

e) Admittance to *ex-situ* facilities of genetic resources and to databases;

f) Transfer to the provider of the genetic resources of knowledge and technology under fair and most favourable terms, including on concessional and preferential terms where agreed, in particular, knowledge and technology that make use of genetic resources, including biotechnology, or that are relevant to the conservation and sustainable utilization of biological diversity;

g) Strengthening capacities for technology transfer;

h) Institutional capacity-building;

i) Human and material resources to strengthen the capacities for the administration and enforcement of access regulations;

j) Training related to genetic resources with the full participation of countries providing genetic resources, and where possible, in such countries;

k) Access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies;

l) Contributions to the local economy;

m) Research directed towards priority needs, such as health and food security, taking into account domestic uses of genetic resources in the Party providing genetic resources;

n) Institutional and professional relationships that can arise from an access and benefit-sharing agreement and subsequent collaborative activities;

o) Food and livelihood security benefits;

p) Social recognition;

q) Joint ownership of relevant intellectual property rights.

About CEBPOL

Government of India in collaboration with the Norwegian Government has established "Centre for Biodiversity Policy and Law (CEBPOL)" at the National Biodiversity Authority (NBA), an autonomous and statutory body of the Ministry of Environment Forest and Climate Change towards strengthening of expertise in Biodiversity Policy and Law in India. This programme is executed by the NBA in collaboration with Norwegian Environment Agency through the Royal Norwegian Embassy, New Delhi, India.

The Centre aims to provide advice and support to the Government of India and Norway on Biodiversity Policy and Law related issues including complex negotiations on Access and Benefit Sharing and Traditional knowledge as well as governance issues relating to biodiversity at the National and International level. The Centre proposes to help NBA in the effective implementation of International agreements on conservation, sustainable use and the associated access and benefit sharing components of it.

CEBPOL is set up as a specialized Centre of Excellence in Biodiversity Policy and Law to network, organize and consolidate expertise on issues of Biodiversity Policy and Law in India and Norway. The Centre, located at NBA, would function as an independent think tank on Biodiversity Policy and Law. In addition, CEBPOL aims to contribute to the effective implementation of the Biological Diversity Act 2002 and Rules 2004.

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