Biodiversity and the Processes of Law

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Abstract

National laws on biological resources have emerged in response to the international legal framework on biological diversity – the United Nations Convention on Biological Diversity (CBD), 1993. The Convention is the international law for conserving biodiversity, ensuring sustainable use of its components and sharing benefits arising out of the use of genetic resources. This body of law comprises principles, guidelines and protocols for national practice. Two key protocols have developed under the Convention through intergovernmental processes; one is the *Cartagena Protocol on Biosafety* in effect from 2003. The other is 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*, which entered into force in October 2014. Both these represent different dimensions of the relationship between bioresources and modern biotechnology. Distinct legal and regulatory regimes are developing for each of them at the country level.

In India the national law in compliance with the Convention, namely, the Biological Diversity Act, 2002, began to be implemented after executive rules were issued by the central government in 2004. Rules for biosafety predate this Act and the Convention. This chapter traces the broad trends that have emerged in the decade (2004–2014) of implementation of the Act, with specific focus on

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the two aspects in the CBD protocols. Firstly, it focuses on the emphasis on access, which is of interest to the plant biotechnology industry. Secondly, it highlights how the issue of biosafety has been handled under the legal regime. This chapter elaborates how the due processes of law for biodiversity and the regime for biotechnology interface with each other in a megadiverse country.

Keywords
Access • Biodiversity • Bioresources • Biotechnology • Biosafety • Convention • Law • Protocol • Regulatory

3.1 Introduction

Process is understood to be a continuous ongoing action, as it is with lawmaking and implementing the law once it is made. The term 'due process of law' implies that an individual cannot be deprived of her life, liberties or property without there being appropriate law to do so. This puts an obligation on the state to put in place laws that guard ordinary peoples against arbitrary and abusive actions. The laws may also need to be constantly updated or amended to meet the intended objectives. The processes of law and their purposes are influenced by the political economy. So it is with biological resources, hereinafter called bioresources.

The needs of the life science industry have to a large extent determined the body of law on bioresources. Nonetheless, the objectives of a law on bioresources, particularly in a country like India, can only but be multiple. For on the one hand, it is rich in bioresources and attractive to bioprospectors, while on the other hand, it is equally keen to spur bioenterprises in its territory. The law has to effectively regulate both aspects in the domestic space. At the same time, as India is a party to the CBD and subscribes to the international law, its own law has to be in line with the Convention that has developed at the international level.

Therefore, it becomes even more critical to understand the role of law and how it regulates biodiversity conservation, sustainable use and modern biotechnology and in doing so how it is able to balance seemingly conflicting ends. Firstly, as with every other law, its role is of regulating access to and use of biological material and knowledge based on which research is to be carried out. Second is to impose penalties if certain legally prescribed rules for biosafety or procedures laid down for approval of genetically modified (GM) products are violated. In doing so the aim is to either prevent from harm or provide redress for damage that might have been caused by living modified organisms (LMOs). Third is to ensure that the benefits that accrue from the access to otherwise commonly or privately held biological materials are shared equitably amongst local communities of the provider country.

Yet mere existence of international and national legal regimes does not always translate into compliance. And between governments, political and economic interests do come into play in treaty negotiations and subsequently in their application. There are practical challenges too around interpretation and implementation;

nonconformity or selective application also shapes the legal narrative on bioresources. This narrative in concept and as much in practice is dynamically evolving in response to developments at the global level and demands at the national and local level.

3.2 International Law

The United Nations (UN) Convention on Biological Diversity (CBD) is one of the most significant outcomes of the UN Conference on Environment and Development at Rio de Janeiro, Brazil, in 1992 (United Nations 1992). At Rio, the CBD emerged from the worldwide concern to protect biodiversity loss and check 'biopiracy' in the global south. Even though the process to formulate such an international law had started in 1988 (CBD 2015 undated), it was at that Rio Earth Summit at 1992 that the CBD was opened for signature. The Convention finally entered into force on 29 December 1993.

Bioresources acquire a specific definition under international law. According to Article 2 of the CBD text, 'biological resources' are:

> *genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity.*

But this may not offer enough guidance when applied in the real time locally. For the Indian experience has shown that there could be varying perceptions about what constitutes a bioresource (*more on this in the section on India's Legislation*). In the same article, the CBD defines 'biotechnology' broadly as:

> *any technology that uses biological systems, living organisms or derivatives thereof, to make or modify products or processes for specific use.*

The CBD's international protocols[1] – kinds of thematic sub-treaties – take forward and elaborate two very specific aspects of the use of bioresources. The Cartagena Protocol deals with the specific issue of biosafety when products of modern biotechnology are used. And the Nagoya Protocol deals with the issue of access and benefit sharing (ABS) with respect to bioresources.

3.3 Cartagena Protocol

The *Cartagena Protocol on Biosafety* (CPB) entered into force on 11 September 2003 as a supplementary agreement to the CBD. Amongst the articles in the CBD text, Article 19 specifically deals with the *Handling of Biotechnology and*

[1] In international law, a protocol is a legal instrument that is subordinate to a convention and is meant to take forward the convention's objectives, while also either amending the convention or further detailing an aspect of it (as in the case of the Biosafety Protocol of the CBD).

Distribution of its Benefits. Paragraph 3 of the said Article expressly requires that countries who are members of the CBD:

> *shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.*

The Protocol comprises the set of rules to be followed by member countries of the Protocol in case of movement of living modified organisms (LMOs) across borders. It prescribes safety measures for the transboundary movement of LMOs. LMOs as defined by the Protocol 'biotechnology' is the application of:

> *a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or*
>
> *b. Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection;* – Paragraph 3(i)

The Protocol is premised on the precautionary approach. This is derived from Principle 15 of the Rio Declaration on Environment and Development (UNEP 1992).[2] Accordingly, advocating precaution its 40 articles elaborate the international regime on biosafety. It is based on the idea that a country cannot exercise caution and regulate LMOs unless it is aware of them being transported into its area. Therefore, it requires for Advance Informed Agreement (AIA) to be signed before LMOs are shipped to another country. This means both the exporting and the importing country regulations on biosafety must provide for an AIA procedure. The Protocol in a way accepts that there will be trade in LMOs between countries. For most products of modern biotechnology have commercial applications. However, as per the Protocol, GM products to be exported as food and feed and for processing do not require an AIA (CBD 2000).

The implications of the precautionary approach in environmental decision-making are that:

- It requires preventive action in the face of uncertainty about a technology.
- It shifts the burden of proof on the technology provider and scientific community to persuade users about the safety of the technology.
- It puts the liability on the proponents and developers of the activity, for example, in the context of modern biotechnology for any false or misleading information, the responsibility will be that of all the people and institutions associated with the technology.

[2] Principle 15: In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation. (UNEP 1992)

– It requires a defining liability of a user of a technology done so with the knowledge of the risks involved.
– It requires an assessment of a wide range of alternatives to the possibly harmful actions be explored before deploying the risky technology.
– It insists that public participation be increased in decision-making.

It follows that a law premised on the precautionary principle (PP)[3] must incorporate all these elements.

Meanwhile, there is no agreement worldwide on the degree of risk from LMOs. Nonetheless, what makes biosafety a risk-prone endeavour is that LMOs do not follow the laws of the land; they follow the laws of nature. The risk factor is due to reasons internal to the LMO and its new genome; it is also external vulnerabilities that it can generate for human and ecological health. Risk in this context is the probability or chance of danger or harm to human and ecological health from the use of LMOs and their application in the open environment. The Cartagena Protocol prescribes all three elements of what must form a risk analysis framework:

- Risk assessment
- Risk management
- Risk communication

Negotiations for this Protocol began under the CBD in 1994, and it took nearly a decade-long process for countries to agree on a text and for the text to enter into force. This was due to the opposing viewpoints on the issue of safety of LMOs. For there are countries that consider the risk factor and are opposed to LMOs, while those pro-LMOs are opposed to any strong legal restrictions on their use.

As of 2014, 194 countries world over are members of the CBD. But the success of this international law depends on the capacities of individual countries and their government's commitment to the very idea of biosafety. Amongst the many challenges in the implementation of CBD is the fact that one of the key proponents of biotechnology products – USA – is not a party to the CBD. Moreover, in its own biosafety framework, the USA regards GM products, such as novel foods 'substantially equivalent' to those that are made without the use of genetic engineering (GE). As per the USA, products of GM do not trigger any special regulatory consideration. The Coordinated Framework for Regulation of Biotechnology (1986) in the USA focuses on the nature of the product and not on the process by which they are produced. In fact, the reason that the USA has to date kept out of the CBD is because of the Convention's treatment of biotechnology. Given that it is not a party to the CBD, it is also not a member of either of the protocols that have developed under it.

The European Union (EU) as a whole has rejected the idea of substantial equivalence with respect to novel foods, containing or consisting LMOs (Schuazu 2000).

[3] In broad terms, the precautionary principle works on a premise that an action should not be taken if the consequences are uncertain and could be potentially dangerous.

This points to the competing regulatory approaches between the USA and EU on the issue of biosafety. The differences are not simply in the domestic regulatory framework, but also in the systemic principles that make the foundation of the regulation. EU member countries by and large are for the precautionary approach towards modern biotechnology. As per this approach, biosafety laws can be made less stringent only once there is adequate proof that LMOs/GM products are safe. This is seen more in line with the idea of sustainable use, an idea taken forward in the CBD. The value of EU collectively holding to its position on biotechnology is better understood by the fact of how critical Europe's role is for global environmental governance and the international law in this area (Vogler 2005).

In Asia, there are few, if any, coordinated regional-level regulatory approaches to biosafety despite the fact that most countries in the region are members of the CPB. Those that are there, such as the South Asia Biosafety Program, are activities funded by US donor agencies to engage the governments in India, Bangladesh and Pakistan in the making of national regulatory frameworks for GM products.[4] Individually these countries are at different stages of updating their biosafety regulatory framework.

3.4 Nagoya Protocol

Before a plant, genetic material or any other bioresource can be altered at the genetic level, it has to be accessed by and be physically available to the potential user for such alteration. The raw (genetic) material as it exists in nature may be from a particular region in the world, while the laboratory or enterprise with the technology to either undertake research on it or use it for developing a commercial product might be in the location of another political territory. This creates another legal challenge – to evolve international rules that are globally respected and locally applicable, for lawful access to bioresources.

These are the rules contained in the other significant Protocol under the CBD, which is 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*. It entered into force in October 2014 after 6 years of intergovernmental negotiations (Secretariat of the Convention on Biological Diversity 2011). As of October 2015, 68 countries including India are members of the Protocol. As the title suggests, it deals specifically with the issue of access and benefit sharing (ABS). The Nagoya Protocol is premised on the principle that states have *sovereign rights* over their bioresources. This principle has been enunciated by its parent convention, namely, the CBD. Post-CBD, bioresources are no longer the 'common heritage of humankind' for anyone to access freely.

[4]The South Asia Biosafety Program (SABP) is an international development programme conducted with the support of the US Agency for International Development (USAID).

The assertion of sovereign rights over bioresources means that national governments can legally provide for the recognition of their people's rights over bioresources in their local areas. The idea of sovereignty does not give the government itself the power to sell. In practical terms it means that local communities have a legally protected position from which to negotiate the terms of access, when the life sciences industry seeks bioresources from their areas. It follows that the Nagoya Protocol does not apply to areas beyond national jurisdiction (ABNJ), where countries do not have sovereign rights, for instance, the ocean bed or marine areas outside territorial waters of a country.

The Convention and the Nagoya Protocol seek to ensure that access to local bioresources does not happen without due process of law. It is meant to effect returns for the provider country or community in return for access. One of the three key objectives of the CBD, as stated in Article 1, is:

> *fair and equitable sharing of the benefits arising out of the utilisation of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.*

'Appropriate access', after due consideration of rights of indigenous peoples and local communities over the bioresources present in their areas, has to be provided for by the law implementing the CBD and its Nagoya Protocol.

The Convention insists that access to genetic resources and reciprocal transfer of technologies must be relevant to the purposes of conservation and sustainable use of biodiversity. This is clearly laid out in Articles 15 and 16 of the CBD. Biodiversity-rich countries like India are required by CBD to facilitate access to their genetic resources by non-Indians. But technology-rich countries are too required to provide access to technology. The purpose of the Nagoya Protocol is to elaborate the mechanism of ABS to be applied by both provider and user countries. But the provider countries are under relatively more pressure to set up appropriate processes of law for the access of bioresources by outsiders and non-national persons, natural or legal.

Few other (user) countries have policies or guidelines to regulate their domestic players seeking access from (provider) communities/countries. For example, Australia has a national genetic resources policy: *Nationally Consistent Approach for Access to and the Utilisation of Australia's Native Genetic and Biochemical Resources* (NCA), 2002 (Natural Resource Management Ministerial Council 2002). The government of Japan has too framed Guidelines on Access to Genetic Resources for Users in Japan, 2005 (METI and JBA 2005). Given the nature of the issue, it is not sufficient to simply have a domestic-level ABS law. The user countries must be willing to co-operate and comply with the ABS regime of the country providing bioresources. Further, user countries must also provide for legal and administrative mechanisms for benefit sharing in their own jurisdictions when using India's bioresources/people's knowledge.

EU Regulation No. 511/2014 on compliance measures for users from the Nagoya Protocol adopted by the European Commission on 16 April 2014 entered into force on 9 November 2015. The EU Regulation defines 'user' as *a natural or legal person that utilises genetic resources or traditional knowledge associated with genetic resources.* It lays down a set of obligations for users (in Chapter II, Article 4), for them to be compliant with the NP, requiring access to be only on mutually agreed terms. The Regulation makes it mandatory for (first) accessors and subsequent users to maintain an internationally recognised certificate of compliance. The first such certificate, issued to a researcher from the University of Kent in the UK, was deposited by India at the CBD's ABS Clearing House on 7 October 2015 (Secretariat of Convention on Biological Diversity 2015).

3.5 India's Legislation

In India there are a range of legislation and regulations, which are relevant to the conservation and use of bioresources and associated people's knowledge. But those key for bioresources and biotechnology are:

- The Biological Diversity Act, 2002 (and corresponding rules, notifications, guidelines, etc.)
- Rules for Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms/Genetically Engineered Organisms or Cells, 1989 (issued under the Environment Protection Act, 1986)

This chapter discusses the processes of these two frameworks, which are most critical from the regulatory point of view for access and biosafety. Other than these, several intellectual property laws [such as the Indian Patent Act, 1970 (and its three amendments), as well as the Protection of Plant Varieties and Farmers' Rights Act, 2001, and its implementing rules and notifications] and guidelines of the central government also have a bearing on bioresources. But these are not the intended subject matter of this chapter and therefore not elaborated.

The legal regime discussed in this chapter was drafted when the policymakers saw India primarily as a provider country. But in the last two decades, given the macroeconomic 'reforms', there has been a discernible shift in governmental perception in also considering India's interests as a user country. The life sciences industry is being actively encouraged in the country. Thus, India's policymakers do not wish to impose too onerous access conditions through the regulatory regime, as it also sees itself as a user country that in reciprocity wants to be able to access technology with equal ease from developed countries. This in part explains the processes of law on bioresources and particularly how its ABS and biosafety provisions are evolving.

3.5.1 The Biological Diversity Act

The Biological Diversity Bill was first placed before the lower house of the Parliament of India in 2000. From there it was referred to a Department-related Parliamentary Standing Committee on Science and Technology, Environment and Forests. The Committee gave its report in December 2001(Rajya Sabha Secretariat 2001). Both houses of the Indian Parliament passed the Biological Diversity (BD) Act in 2002. After this lawmaking process, the Bill became an Act coming into force in 2003, precisely a decade after the CBD entered into force.

The BD Act draws its objectives from the CBD and thereby conservation and sustainable use of biodiversity are the first two of its aims. The third objective is to ensure equitable sharing of benefits arising out of use. For the purposes of this chapter, it would also be important to understand the manner in which the BD Act defines 'bioresources':

> *"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;*

According to Section 2(c) of the national BD Act, biological resources are:

> *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.*

The 'use' envisaged in the biodiversity framework is primarily that for the needs of the life sciences industry.

The extent of coverage of the definition for bioresources in the national law was contested before the National Green Tribunal (NGT) in 2013[5] (Kohli and Bhutani 2013), a decade after the Indian BD Act came into force. The biodiversity board of Madhya Pradesh (MP) chose to take a substantially expanded meaning of the terms 'biological resources' and 'commercial utilisation' used in the BD Act. That by expectation of the MP SBB would widen the net to bring in activities under the ABS regime, which could effect more benefit sharing.

The Act also lays out an institutional framework for the implementation of the provisions of the law. The National Biodiversity Authority (NBA) is the apex institution set up to implement the BD Act and was established on 1 October 2003, as a functionary of India's Environment Ministry. The NBA is at the head of the institutional structure, with state-level biodiversity boards (SBBs) to be established in all 29 states of India.[6] The All India Biotech Association (AIBA) that gave its suggestions to the Parliamentary Committee considering the BD Bill, 2000, had recom-

[5] Cases against the MP SBB by companies such as Agro Solvent and Lilason Breweries fought before the Bhopal Bench of the NGT.

[6] List of State Biodiversity Boards as on 18 November 2015. http://nbaindia.org/link/241/34/1/SBBs.html

mended that the biotech industry be given representation in the NBA and the SBBs. Out of the 29 SBBs, 21 have also either drafted or notified their state-level Biological Diversity Rules. The law also requires local-level biodiversity management committees (BMCs) to be set up in every village or municipality. Each of these institutions has a role to play in the process of regulating access, determining benefits and monitoring violations.

Sections 3, 4 and 6 of BD Act together with Rules 14–19 of the BD Rules lay down the procedure to be followed for access to Indian bioresources and/or associated traditional knowledge. The law, in line with the CBD, makes clear that its main focus is to regulate the use of bioresources and related people's knowledge by non-Indian persons. Thereby, the Act focuses on regulating access by non-Indian persons, both natural and legal. The procedure for access by Indian persons is less regulated, with both local people and traditional healers not under its purview, and neither there being as strict rules for Indian companies as compared to non-Indian. While foreign persons have to take permissions prior to any sort of access including research, biosurvey and commercial utilisation, the law requires Indian enterprises to merely inform the relevant SBBs in the state in which they are based. When it comes to seeking intellectual property (except in the case of plant variety protection), both Indians and foreign entities have to mandatorily take permission from the NBA. In all these instances, the NBA and the SBBs are required to consult the local-level BMC, in both rural and urban areas.

A schematic diagram depicting the access procedure designed by the NBA explains the process.

The NBA sets up several thematic expert committees to develop guidelines and oversee the implementation of specific aspects of the law. One of these is the Expert Committee on Access and Benefit Sharing (EC on ABS) to carry out its functions in this area.[7] This is a standing committee that is periodically reconstituted with members drawn from diverse backgrounds. The EC on ABS processes access applications. After the 18-step access procedure is followed, the NBA enters into an ABS agreement with the access applicant (Fig. 3.1).

The access procedure involves consulting not only SBBs but also the local-level BMCs, which are to be set up in every local body (see Step 5 in the diagram). This is how the idea of sovereignty principle that CBD lays down is sought to be realised through the India's BD Act. Yet the Act only insists on consultation and not prior informed consent of BMCs. In practice this consultation if at all is taking place wherever they have been established in the country. The local-level procedure is also meant to identify the legitimate 'benefit claimers', to whom benefits can be channelised to once an ABS agreement is in place.

Growers and cultivators from within the local communities in an area do not need to intimate any government body, i.e. the SBBs, to access resources, as domestic companies (whether small firms or large corporations) need to do before such

[7] NBA Office order dated 6 January 2015 on Reconstitution of Expert Committee on Access and Benefit Sharing for processing the applications received by NBA. http://nbaindia.org/uploaded/committee/OO_Re__EC_on_ABS.pdf

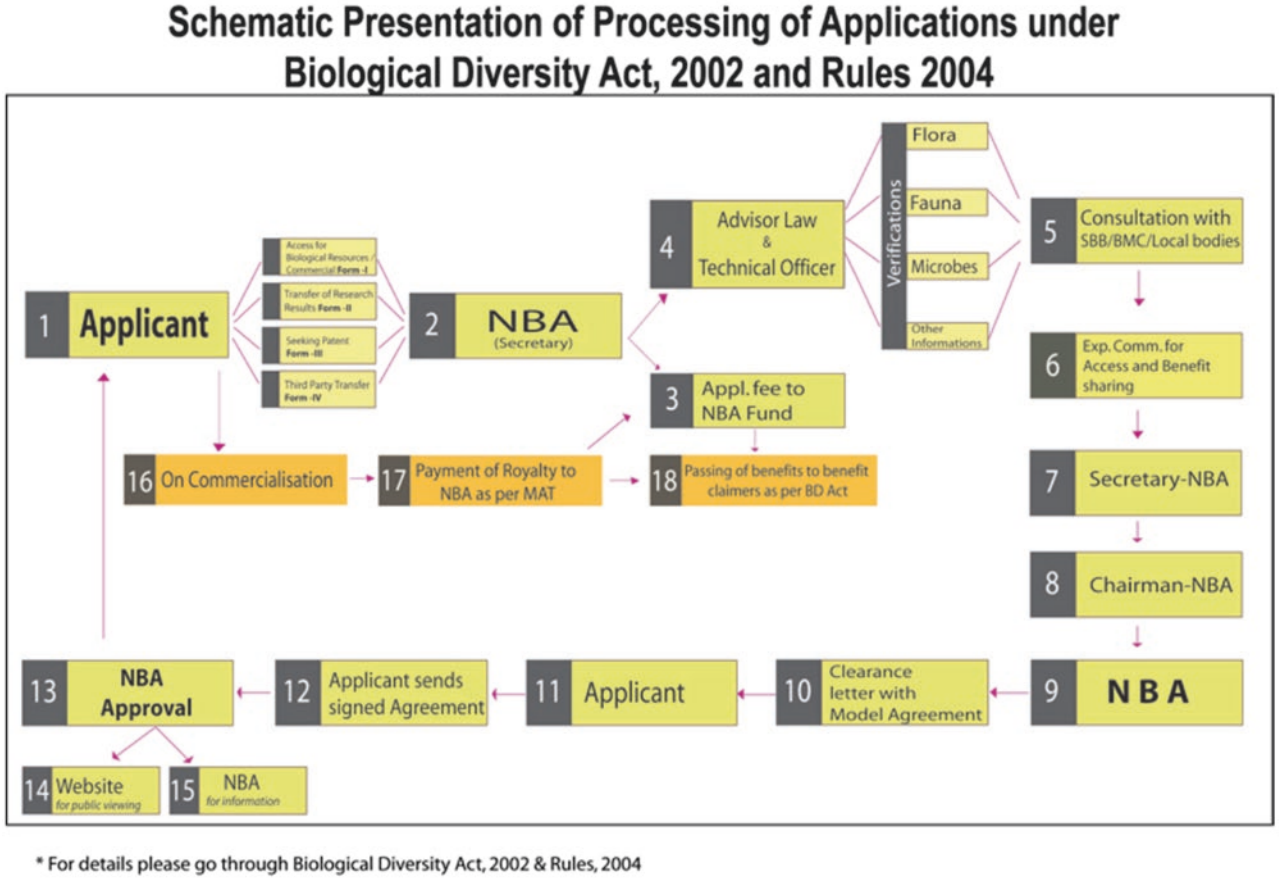

Fig. 3.1 Access application process (Source: NBA website http://nbaindia.org/content/684/62/1/applicationprocess.html)

access [Section 7]. There are three other exemptions to the ABS requirements, which are important to understand the regulatory framework around access and determining benefits. These are:

1. Exemption [under Section 6(3) of the BD Act] to any person making an application for any intellectual property right (IPR) under the Protection of Plant Varieties and Farmers' Rights Act of 2001 (as these are dealt by the Ministry of Agriculture, rather than Environment Ministry).
2. Exemption (under Section 40 of the BD Act) for 190 bioresources, categorised into three, medicinal plants, spices and horticultural crops, and listed as normally traded commodities (NTCs) pursuant to the provisions of the law[8]; however, this only applies when the species is traded as a commodity and not when used as a raw material in R&D.
3. Collaborative research projects (under Section 5 of the BD Act) that involve the transfer or exchange of bioresources or information between institutions, including government-sponsored institutions of India; these projects have to be approved by the central government and conform to their relevant policy guidelines, details of which have to be given in the proforma designed by the NBA.[9]

Access vis-à-vis Indian bioresources/people's knowledge is usually granted for four kinds of uses, when users approach the NBA through the prescribed forms:

(i) Form I – Research/commercial purposes/biosurvey/bioutilisation
(ii) Form II – Transfer of results of research
(iii) Form III – Approval for obtaining IPR on inventions based on any research or information on a bioresource obtained from India
(iv) Form IV – Third-party transfer of already accessed bioresource/knowledge

With the 'new' ABS guidelines issued by the NBA in 2014 (discussed in Section 3.2), another category for grant of access has been added. This is through a prescribed Form B, which is for processing access for bioresources to Indian researchers/government institutes for conducting non-commercial research or research for emergency purposes. As of 11 November 2015, the NBA had granted a total of five such approvals for access.[10] Applicants seeking access to any Indian bioresource or related people's knowledge must approach the NBA with the prescribed form along with payment of the requisite fees. Any of these access types could be relevant for the biotech industry.

The publicly available information on the access approvals shows how the maximum number of approvals granted from when NBA started processing applications in 2006 up to 11 November 2015 is 209 (Fig. 3.2). Under the Form III category for

[8] Vide notification S.O. No. 2726(E) dated 26 October 2009 issued by MoEFCC.

[9] Prescribed proforma. http://nbaindia.org/uploaded/docs/Proforma-act2002.doc

[10] As per NBA data available on http://nbaindia.org/content/683/61/1/approvals.html as on 18 November 2015.

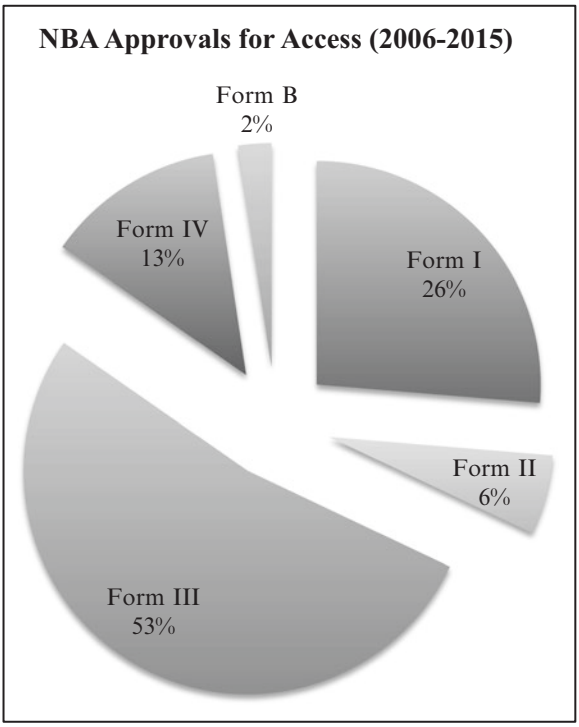

Fig. 3.2 Approvals for access granted by the NBA (2006–2015) (Compiled by the authors from data on the NBA website, as accessed on 18 November 2015)

seeking IPR, more than half – 110 out of a total of 209 applications approved – are for IPR on new methods, processes, herbal or medicinal compositions, etc. There are only about five applicants for IPR, which are either from departments of biotechnology from different universities in India or are from the Department of Biotechnology of the Government of India's Ministry of Science and Technology itself.[11] Only after the approval by NBA can patent examiners proceed to allow patents on biotechnology-related inventions, with due reference to the guidelines by the Indian Patent Office in this regard.

The interesting thing to note respect to the IPR approvals is that all except one (in which the co-applicant is from the USA) are for Indians.[12] But the main objective of the BD Act was to arrest 'biopiracy' by foreign persons. Nonetheless, the provision in the law [Section 18(4)] that empowers the NBA to *take any measures necessary to oppose the grant of IPR in any country outside India on any bioresource obtained from India or knowledge associated with such bioresource which is derived from India* has never been invoked.

[11] The full list as of 18 November 2015 can be accessed from the NBA website: http://nbaindia.org/uploaded/Approvals/FormIII_11NOV15.pdf

[12] The full list as of 18 November 2015 can be accessed here: http://nbaindia.org/uploaded/Approvals/FormIII_11NOV15.pdf

With reference to the context of biotechnology, the information on access approvals also reveals that very few of the access approvals explicitly mention if and when the access is for biotechnological purposes. For example, out of the 55 cases of Form I access approvals, two were granted to a professor, in the Department of Biochemistry and Biotechnology, University of Munster, Germany, one for leaves from certain trees in the biodiverse Mudumalai Wildlife Sanctuary in South India to be able to isolate microorganisms in the leaf tissues and the other for access to soil samples from a chitin-/chitosan-producing plant.[13] ABS agreements were signed between the applicant and NBA in 2007 and 2008, respectively.

Perhaps the most talked of access approvals for the biotech industry are the three granted in 2007 wherein Form II approval for transfer of research results (in this case brinjal varieties) was granted to M/s Maharashtra Hybrid Seeds Company Ltd. (Mahyco).[14] This cross-border transfer of Indian bioresources entailed shipping out parental seeds gathered from the crossing of Mahyco's transgenic Bt brinjal/eggplant event (EE-1) containing cry1Ac gene in the Mahyco Research Centre, Maharashtra, with brinjal/eggplants that were imported from:

(i) East West Seeds, Bangladesh
(ii) Bangladesh Agriculture Research Institute, Bangladesh
(iii) University of the Philippines, Philippines

In January 2013 it was reported by the media that due to public pressure, the NBA had filed a legal case against the US transnational Monsanto and its Indian counterpart Mahyco, for failing to seek the approval of NBA before accessing six local brinjal varieties, which it was using to develop its GE brinjal products. However, the issue of possible genetic contamination of biodiversity in the receiving countries, namely, Bangladesh and the Philippines, never really became an issue, despite all three countries being members of the Cartagena Protocol.

Form IV access is also sought by several private seed companies and agricultural research institutes for the export of seed and planting material from India. Notable in this context is the access approval granted by the NBA to the international agricultural research centre based in India – ICRISAT[15] – for the export of seeds of transgenic groundnut to South Africa for testing.[16] Likewise, M/s Bayer Bioscience Pvt. Ltd. was granted approval by the NBA to export Bt cotton hybrids to Pakistan for research and trial purposes, for which an ABS Agreement was signed on 9 July

[13] Application nos. 92 and 151: http://nbaindia.org/uploaded/Approvals/FormI_11NOV15.pdf

[14] Access application nos. 68, 69 and 70 for which agreements were signed between the company and NBA on 24 April 2007. http://nbaindia.org/uploaded/Approvals/Form-II_30.09.2015.pdf

[15] The International Crops Research Institute for the Semi-Arid Tropics (ICRISAT) in Patancheru, in the Southern Indian state of Telangana, functions under the aegis of the CGIAR; it had developed transgenic groundnut events by introducing the coat protein gene of groundnut rosette assistor virus (GRAV cp) into groundnut varieties JL 24 and ICGS 44.

[16] Access application no. 97 by Dr. William Dar, Director General, ICRISAT, followed by an ABS Agreement signed with NBA on 8 October 2007 for a one-year period.

2010.[17] Apart from pure research, seed companies too seek NBA approval for the export of GE seeds to other countries for field trials, as with Bt cotton hybrids to Pakistan by Rasi Seed Pvt. Ltd., Nuziveedu Seeds Pvt. Ltd., Nath Biogenes (I) Ltd. and Prabhat Agri Biotech Ltd. all in the year 2012.[18] Transfer of bioresources between different country offices of transnational seed corporations or between them and their sub-licensees also requires seeking NBA approvals if Indian bioresources are being sent out. This has been the case with Rasi Seed Pvt. Ltd. exporting Bt cotton hybrids to Monsanto Pakistan for field trials in 2012, as well as Bayer sending foundation seeds of commercial hybrid rice cultivars to Bayer Crop Science Inc. Philippines in 2014.

The industry experience gives it a basis to seek for changes in the ABS regime. While it continues to seek access, it would rather not be under strict legal obligations for either biosafety or benefit sharing. The resistance from industry can be anticipated; it will always seek favourable conditions for its own functioning. This is also the motivation of the Ayurvedic Drug Manufacturers' Association (ADMA), which is an important stakeholder that relies on access for an assured supply of bioresources. Yet it does not want any benefit-sharing obligations. The NBA needs to bring this largest single industry sector that benefits from access to bioresources on board for the success of its own benefit-sharing regime.[19]

3.5.2 Guidelines for ABS

India's BD Act has a clear definition for those the law regards as legitimate 'benefit claimers', once access to bioresources or people's knowledge takes place. They are *conservers of biological resources, their by-products, creators and holders of knowledge and information relating to the use of such biological resources, innovations and practices associated with such use and application*.[20] Meanwhile, SBBs have been struggling to harness back benefits from the bioindustry, whether for generating funds for *in situ* conservation or for sharing with local communities.

This triggered off much discussion in India on the need for guidance on access and benefit sharing. In the absence of clear instructions from the Centre, some state governments, like MP and Kerala, began to issue their own access forms and guidelines. The MP SBB issued a notice requiring all those using bioresources for commercial purpose to apply in the prescribed Form I to the Member Secretary of the SSB.[21] Kerala directed not only industries registered in India and commercially utilising bioresources but also local self-government institutions to regulate access to the people's biodiversity registers (PBR), where local knowledge is documented

[17] Form IV application no. 376 by M/s Bayer Bioscience Pvt. Ltd., Hyderabad, India.

[18] The complete list of these Form IV approvals is available on the NBA website: http://nbaindia.org/uploaded/Approvals/FormIV_11NOV15.pdf

[19] http://nbaindia.org/blog/646/47//RepresentativesofA.html

[20] Article 2(a) of the BD Act.

[21] MP SBB Notice. http://www.mpsbb.info/ImportantNotice.aspx

by BMCs under the processes of the BD Act. The Principal Secretary, Environment of the State Government of Kerala in a circular issued in early 2013, gave specific instructions to local bodies against permitting an external agency to access the PBR without the knowledge of the government or the Kerala SBB.[22]

The need for guidelines clearly came from the practical difficulties encountered by the implementing SBBs, as well as the lack of benefits accruing to local communities through BMCs. In a letter by the Member Secretary of the MP SBB to the NBA dated 3 April 2013, there is an emphatic mention that *in the absence of any guideline by the NBA for access and benefit sharing to the State Biodiversity Board, we are not able to implement third and most important objective of the Biological Diversity Act, 2002 and* i.e. *access and benefit sharing.* The then environment minister Jairam Ramesh had also reiterated that by virtue of the powers vested by the BD Act, SBBs can regulate the use of bioresources by the domestic industry. Local-level BMCs in each state also have the power [under Section 41(3) of the BD Act] to levy charges for the access of bioresources for commercial purposes.[23] Realising that the BMCs cannot actively pursue ABS unless they themselves are aware of their rights and responsibilities, the NBA issued a set of guidelines for the operationalisation of BMCs (National Biodiversity Authority 2013).

Finally, in April 2013, the NBA drafted and made public two sets of guidelines, one on access and the other on benefit sharing, seeking comments on the same. These two separate documents were subsequently merged. However, the document was not publicly accessible until May 2014, after the NBA was asked by the NGT in March 2014 to issue guidelines in the light of increasing confusions on the issue, which led to more than a score of cases being filed by industry before the NGT and several benches of the High Court of MP. Eventually, on 21 November 2014, the NBA and the Ministry of Environment, Forests and Climate Change (MoEFCC) issued a consolidated set of *Guidelines on Access to Biological Resources and Associated Knowledge and Benefit Sharing Regulations, 2014* as mandatory for ABS (MoEFCC 2014). These guidelines not only seek to streamline the access procedure but also expand on the concept of benefit sharing, adding to what is already provided for on the issue in the BD Act.

These guidelines for ABS are pursuant to India's commitment to the Nagoya – the international regime (IR) on ABS, which entered into force on 12 October 2014.[24] The MoEFCC in August 2014 had designated the NBA as the 'competent national authority' for the purposes of the Nagoya Protocol. The IR forms the essential backdrop for the ABS guidelines in India. To operationalise the guidelines, the

[22] The text of the state government circular in Malayalam is available here: http://keralabiodiversity.org/images/news/circular_pbr.pdf

[23] Section 41(3): The biodiversity management committees may levy charges by way of collection fees from any person for accessing or collecting biological resource for commercial purposes from areas falling within its territorial jurisdiction.

[24] The full text of the *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization* can be accessed at https://www.cbd.int/abs/about/

NBA constituted another Expert Committee to revise the existing ABS Agreement formats.[25]

The BD Act lists six broad types of benefit sharing that can be realised when either access takes place or approval for IPR is granted. This includes joint ownership of IPR to either NBA or an identified benefit claimer, transfer of technology, involvement in research and development endeavours, setting up venture capital funds or payment of compensation. The 2014 Guidelines broadly convey that sharing of benefits may be done either through a monetary or nonmonetary mode. A list of options, both monetary and nonmonetary, is contained in an Annexure I to the notified guidelines. They prescribe that when India's bioresources are accessed and commercially utilised, the applicant shall have the option to pay the benefit sharing ranging from 0.1 to 0.5 per cent at graded percentages of the annual gross ex-factory sale of the product, which shall be worked out on the basis of annual gross ex-factory sale minus government taxes. The experience of the 10-year practice of implementation of the BD Act in India prior to the issuance of the guidelines has shown a preference for monetary benefits in ABS arrangements, though the collection in the National Biodiversity Fund has been far less than anticipated. And the said fund is meant to finance conservation and also facilitate benefit sharing with local communities (Table 3.1).

The new guidelines only marginally add to what the existing BD Act and Rules lay down on the ABS issue. The only area where the guidelines introduce something new is a category of access that allows an Indian researcher or government institution to carry or send Indian bioresources out for basic research to avert emergencies like epidemics, pandemics, etc. That apart the ABS guidelines issued do not fully explain the reasoning or the process through which the percentages have been determined or how the various figures for payment have been arrived at. They also don't explain why in some instances there are direct payments to local-level committees and in others it is not envisaged. Thereby, the intended users of the guidelines do not get any guidance on that aspect of the thought process of the policymakers. A supplementary note to the notification issuing the guidelines, indicating the reasoning, would have helped to better understand the real objectives (Kohli and Bhutani 2015).

The BD Rules, 2004, also give administrators the power to restrict or prohibit access to biological resources on account of overriding public interest or for protection of environment and conservation of biological diversity. But since information on the rejected applications is not publicly available from the NBA, it is not easy to assess how often this power is used in the name of conservation, particularly when access applications relate to biotechnology. The NBA only makes known that a total of 1131 applications were received by it since 2003 up to 16 November 2015. The section on 'closed' applications on the NBA website does not give the reasons for

[25] Expert Committee to revise the existing ABS Agreement formats as on 18 November 2015 is here: http://nbaindia.org/uploaded/pdf/Oo_extension_Tenure_EC%20_revising_existing_Agreement_formats.pdf

Table 3.1 Understanding the 2014 ABS guidelines[a]

1. Access of a bioresource for commercial utilisation/biosurvey/bioutilisation for commercial utilisation		
Condition	**Payment by trader**	**Payment by manufacturer**
Where no prior benefit-sharing (BS) agreement with Joint Forest Management Committee/Gram Sabha/ forest dweller/cultivator	1–3% of the purchase price	3–5% of purchase price
Further sale of biological resource by a trader to another trader/manufacturer	1–3% of the purchase price (*in case there is proof of supply chain*, *then BS only on amount for which BS has not been paid earlier*)	3–5% of purchase price
Where there is prior BS agreement with JFMC/Gram Sabha/forest dweller/cultivator	Not less than 3% of purchase price	Not less than 5% of purchase price
High economic value bioresource like Red Sanders	Upfront payment of not less than 5% of 5.0%, on the proceeds of the auction or sale amount, as decided by the NBA or SBB into a designated fund	Upfront payment of not less than 5% of 5.0%, on the proceeds of the auction or sale amount, as decided by the NBA or SBB into a designated fund
Where access leads to commercial utilisation, optional benefit sharing on ex-factory sale price	Rs.1 lakh (0.1%); Rs.1–3 lakhs (0.2%); above 3 lakhs (0.5%)	Rs.1 lakh (0.1%); Rs.1–3 lakhs (0.2%); above 3 lakhs (0.5%)
2. Access for transfer of research results		
Condition	**Payment to NBA**	**Payment to SBB/BMC**
With complete details disclosed of potential commercial value	3–5% of the monetary consideration	
3. Access for intellectual property rights		
Condition	**Payment to NBA**	**Payment to SBB/BMC**
In case of commercialisation	Monetary and/or nonmonetary benefit as agreed with NBA	
Applicant assigns licences the process/ product/innovation to a third party for commercialisation	3–5% of the fee received (in any form including the licence I assignee fee) and 2–5% of the royalty amount received annually from the assignee/licensee, based on sectoral approach	

(continued)

Table 3.1 (continued)

4. Transfer of research results for research/commercial utilisation		
Condition	**Payment to NBA**	**Payment to SBB/BMC**
When the resource is not of high value	Monetary and/or nonmonetary benefit as mutually agreed	
	2–5% (following a sectoral approach) of any amount and/or royalty received from the transferee, throughout the term of the agreement	
Where resource is of high value	In addition to the above, also an upfront payment, as mutually agreed between the applicant and the NBA	

[a]This table first appeared in a paper by Kohli and Bhutani in the *Economic and Political Weekly* Kohli and Bhutani (2015)

such closure in 173 cases,[26] though as per the procedure applications are usually terminated due to the applicant giving incomplete information (National Biodiversity Authority 2014).

3.5.3 Rules for Biosafety

The BD Act has very specific provisions in its text on biotechnology. It lays down legal obligations on biosafety for the government of India to follow. According to Section 36(4)(ii) of BD Act, it is mandatory for the government of India to undertake measures:

> *to regulate, manage or control the risks associated with the use and release of LMOs resulting from biotechnology likely to have adverse impact on the conservation and sustainable use of biological diversity and human health*

No other legislation in India imposes such legal obligations on the state with respect to biosafety. Yet despite the fact that the first LMO – transgenic Bt cotton crop – was approved for commercial release in India in 2002, this provision of the law has never been invoked by the central government in the history of the BD Act, 2002. But there are few instances of state governments attempting to use the BD Act

[26]The list of closed applications is available on NBA website at http://nbaindia.org/text/22/Closed.html, as accessed on 18 November 2015.

in the interest of biosafety. One such instance is that of the government of Karnataka, which through its SBB directed that for R&D and biosafety trials for any (GE) Bt crop, the prior permission of the SBB would have to be taken.[27]

The only other environmental legislation – the Environment (Protection) [EP] Act, 1986 – was made before LMOs had become an issue. Under the EP Act, the key rules on biosafety are the *Manufacture, Use, Import, Export and Storage of Hazardous Micro-organisms/Genetically engineered organisms or cells, 1989*.[28] These Rules were issued by the Ministry of Environment, Forests and Climate Change (MoEFCC) under India's key environmental law – the EP Act, 1986. The Rules (1989) establish the Genetic Engineering Appraisal Committee (GEAC) as the main body under the Environment Ministry to both process applications for GE use and oversee biosafety. As an expert body, it was set up to scientifically appraise and recommend approvals on the commercial application of genetic engineering (GE) in agriculture, pharmaceutical and other related sectors. In the current biosafety regulatory framework in the country, GEAC is one of the three approval-granting authorities with respect to GE. The GEAC follows a case-by-case system of screening applications. The MoEFCC then takes the final call (Bhutani et al. 2014).

The other relevant bodies at the central level are the Recombinant DNA Advisory Committee (RDAC) and the Review Committee on Genetic Manipulation (RCGM). The former is meant to review developments in biotechnology at national and international levels and recommend suitable and appropriate safety regulations for India in recombinant research, use and applications.[29] The latter is to monitor the safety-related aspects in respect to ongoing research projects and activities involving GE organisms/hazardous microorganisms.[30] Both these committees are in the Department of Biotechnology (DBT), which functions under the Ministry of Science and Technology. Within each institute undertaking R&D in modern biotechnology, the Institutional Biosafety Committee (ISBC) is required to be set up. While at the state and district levels, the SBCC and the DLCCs, respectively, are required to be functioning.

Apart from the Rules of 1989 enforced by the Environment Ministry, the biosafety regime also comprises a set of executive rules, which are the responsibility of other governmental ministries and departments under them.[31] For instance, the DBT regulates biosafety through the following executive rules:

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[27] Letter No. FEE 77 ENV 2011 dated 21 January 2012 from Secretary, Government of Karnataka, Forest Ecology and Environment Department to the Member Secretary, RCGM, DBT, Government of India.

[28] The full text can be downloaded from the Ministry website as accessed on 18 November 2015: http://envfor.nic.in/sites/default/files/geac/notification.html

[29] Rule 4(1) of the GE Rules, 1989.

[30] Rule 4(2).

[31] The full list of rules and their texts can be downloaded from the DBT website: http://dbtbiosafety.nic.in/

1. Recombinant DNA Safety Guidelines, 1990
2. Revised Guidelines for Research in Transgenic Plants, 1998
3. Protocols for Food and Feed Safety Assessment of GE Crops, 2008

Meanwhile, in May 2003, the Union Ministry of Agriculture in India had set up a task force, chaired by the agricultural scientist Prof. M S Swaminathan for the formulation of a policy on application of genetic engineering in agriculture. The task force recommended that a national law be legislated and an independent biotechnology regulatory authority, which would oversee biosafety concerns, be established.

The government of the day also moved to revamp the biosafety regime of the country through first drafting a National Biotechnology Development Strategy, 2007 (Department of Biotechnology 2007). This was followed by the Union Ministry of Science and Technology, through the DBT drafting a new biosafety law: National Biotechnology Regulatory Authority Bill, 2008.[32] The public opposition to it led to the attempt being shelved. Thereafter, discussions on a stand-alone law on biosafety – the Biotechnology Regulatory Authority of India (BRAI) Bill – have (re)surfaced. The National Biotechnology Development Strategy, drafted back then in 2005 as a 10-year vision document, is also up for revision. All these processes of law and policymaking will have to factor in the demands of the Cartagena Protocol.

Anyhow, law is not only made by legislatures or contained simply by executive authorities. The judiciary is also a source of law. Judgments and judicial orders passed by courts form another body of law on a subject. Over the years, ordinary citizens and non-governmental organisations have filed cases in public interest for a proper biosafety system to be set up in the country. The key ongoing litigation in the highest court of the land – the Supreme Court of India – is that of *Aruna Rodrigues and Others* versus *Union of India and Others* [Special Leave Petition (Civil) No. 260 of 2005].[33] In this case, the petitioners approached the Court under its writ jurisdiction[34] to ask for necessary directions so that biosafety regulation is undertaken by independent scientific agencies.

3.6 Conclusions

The legal and administrative frameworks to govern access to bioresources and enforce biosafety may seem to be developing quite independently of each other both at the international and the national level. And their respective processes, as the

[32] The text of the proposed law can be downloaded as on 18 November 2015 at: http://dbtindia.nic.in/Draft%20NBR%20Act_%2028may2008.pdf

[33] The full text of the original petition filed in 2005 can be accessed here: http://ddsindia.com/www/PDF/PIL_October27.pdf

[34] The Supreme Court of India has original jurisdiction to issue writs – a formal written order – for the protection of fundamental rights under Article 32 of the Constitution of India and under Article 139 to enforce other than fundamental rights.

Indian regulatory regime clearly exhibits, take place under different central ministries and government departments. Yet the two aspects of governance with respect to bioresources, namely, ABS regulations and biosafety mechanisms, have obvious interlinkages. The access framework is a means for the bioindustry to acquire through due process of law the bioresources it needs for its operations.

The experience of the law on bioresources is an example of how the dominant economic system can come to bear on implementation. Both ABS procedures and biosafety rules are premised on the fundamental principle of privatisation of bioresources and the development of proprietary technologies. In such a scenario, the prevalent thinking is that to sell more is to have more. Given the orientation, how the implementation of the law will proceed will depend not only how the bioindustry responds to the regulatory regime but also how much the BMCs at the local level act as spaces for community sovereignty, rather than merely environmental watchdogs or benefit claimers when bioresources are traded. Though evidence points to the fact, very few benefit-sharing cases have resulted despite the due process of law followed for the access procedures.

Nevertheless, ABS has dominated both the CBD landscape globally and the implementation of the BD Act domestically. The operating principle is that access to biological material for bioenterprises is inevitable and not to be restrained. This is seen as a means to integrate with the global trading system. Therefore, the regulatory system is constantly under pressure to safeguard bioresources while it tries to better itself in selling those very bioresources through an ABS system. The challenge for the state functionaries is to be able to use the BD Act for both marketing and conserving bioresources.

Conservation is also an aspect that brings the objectives of the two CBD protocols – Cartagena Protocol and the Nagoya Protocol – in convergence. In fact, it can be said that the ABS regulatory regime requires conservation to be considered at the point of both access and when imposing the terms and conditions for benefit sharing, and biosafety regimes require that conservation be undertaken whenever the release of an LMO is being considered or is already approved for released. After all, both processes of law have to meet the objectives of their parent treaty CBD. Bioresources and people's knowledge systems around them are the actual and potential source of products and processes that can serve the needs of society. Yet at the ground level in areas where both bioresources are accessed from and where outputs of modern biotechnology are either field tested or released in the open environment, there remain genuine concerns about conservation despite the law for biodiversity.

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