ISSN: 0972-7566 | Vol. 20 | No.1 & 2 | March, July 2018

ASIAN BIOTECHNOLOGY AND DEVELOPMENT REVIEW

Asian Biotechnology and Development Review

This journal is abstracted/indexed in CAB International, Scopus, Elsevier Database and EBSCO host™ database.

The editorial correspondence should be addressed to the Managing Editor, *Asian Biotechnology and Development Review*, Research and Information System for Developing Countries (RIS). Zone IV-B, Fourth Floor, India Habitat Centre, Lodhi Road, New Delhi-110003, India. Telephones: 24682177-80. Fax: 91-11-24682173-74. E-mail: ravisrinivas@ris.org.in Website: http://www.ris.org.in

RNI Registration No. DELENG/2002/8824.

Asian Biotechnology and Development Review

Asian Biotechnology and Development Review

Vol. 20 No. 1&2 March, July 2018 ISSN: 0972-7566

RIS
Research and Information System
for Developing Countries
विकासशील देशों की अनुसंधान एवं सूचना प्रणाली

Asian Biotechnology and Development Review
Vol. 20 No. 1&2, pp 1-2

Editorial Introduction

K. Ravi Srinivas*

This issue has five articles and a book review.

The first article by Kshitij Kumar Singh discusses implications of merger of Monsanto and Bayer and the question of patentability of GM crops in India. The Competition Commission of India has approved the merger, subject to certain conditions. The question of patentability of GM crops and the scope of protection of plant varieties in India are to be decided by the Supreme Court as the case involves, *inter alia*, Nuziveedu and Monsanto. The author has analyzed legal provisions and arguments advanced in the courts, highlighting need for the clarity in law and practice in this debated issue. Globally, the merger has raised concerns about concentration and monopoly power in the hands of a few corporations of a crucial input (seeds) in agriculture. Scholars have argued usefulness and limitations of competition law and policy. In the Indian context, there is a need for critical engagement with the issues discussed in the article by Kshitij Kumar Singh. ABDR has published articles on this and the related topics, and will continue to publish relevant articles on the themes.

The word 'stakeholder' has become a cliché. Nevertheless it has become an important topic concerning GM crops as both supporters and opponents of the GM crops invoke the idea of stakeholders to add legitimacy to their respective views. But how to identify stakeholders' interest and gain their trust is a vital question. Anurag Kanauijia and Sujit Bhattacharya based on, *inter alia*, field study of stakeholders and literature review identify some issues in governance and roles and power of the regulatory bodies. They have emphasized call for institutions that promote 'trust' and provide for transparent mechanisms so that stakeholders' concerns are appropriately addressed. They are in favour of evidence -based policy- making; and have suggested that it should go beyond mere objective evidence to

* Managing Editor, ABDR and Consultant, RIS. Email: ravisrinivas@ris.org.in

include precautionary principle. Given the challenges in incorporating precautionary principle in governance of controversial technologies, this has to be developed further.

Governance of genome editing has become a 'hot' topic among scientists, regulators and policy- makers. Perhaps not a month passes without any initiative on this by different stakeholders. Global consensus is obviously elusive but even for countries that have credible governance mechanisms in science and technology; genome editing poses many new challenges as the scope of application of genome editing is too diverse and is consistently expanding. The technology control dilemma, as has been analyzed by David Collingridge, is all the more relevant for governance of genome editing (1). It has also been suggested that framing CRISPR as a revolutionary technology than as a normal technology is desirable (Mariscal and Petropanagos(2018).. In the article on human genome editing, Roli Mathur discusses ethical issues concerning human genome editing by giving an overview of the global development and issues in India in governing human genome editing. Given the allure and anxieties over human genome editing, her article suggestions would facilitate progress of science, taking into account ethical concerns and need to protect public interest. We plan more articles on genome editing in the forthcoming issues.

RIS
Research and Information System
for Developing Countries
विकासशील देशों की अनुसंधान एवं सूचना प्रणाली

Asian Biotechnology and Development Review
Vol. 20 No. 1&2, pp 3-25

Bayer-Monsanto Merger and India's IP Approach to Agricultural Biotechnology: Navigating through a complex web of law and policy

Kshitij Kumar Singh*

Abstract: Bayer-Monsanto merger has triggered a fresh debate about its potential implications on the agricultural biotechnology sector. The increasing concentration of agricultural innovations in the handful of giant companies raises concerns for policy- makers and a range of stakeholders, comprising scientists, farmers, inventors, breeders and small and medium business enterprises. The controversial past of both the companies in different parts of the world and particularly in India creates suspicion as to the functioning of the merged entity. The merger coincides with the progression of an important case on agricultural biotechnology based on Monsanto-Nuziveedu contest that reached the Supreme Court of India after passing through Delhi High Court decision. The legal journey of this case reflects IP climate of India for agricultural biotechnology, highlighting the uncertainties and potential gaps as to the operability of two conflicting legislations,the Patents Act 1970 and the Protection of Plant Variety and Farmers' Rights Act 2001. Against this backdrop, the present paper attempts to analyse two important aspects: first potential implications of merger of Bayer-Monsanto on agricultural sector, particularly in India, and second evolving jurisprudence on IPR relating to agricultural biotechnology in India.

Keywords: Bayer-Monsanto merger, plant varieties, patents, innovation, agricultural biotechnology

Introduction

India witnessed a significant growth in a following few important areas, pharmaceuticals and agriculture through policy interventions and innovative laws. The recent merger of agricultural-biotech giant Monsanto with the pharmaceutical giant Bayer opened discussions and debates as to Indian IP approach to agricultural biotechnology and innovation. Both the companies

* Assistant Professor, Campus Law Centre, Faculty of Law, University of Delhi.
E-mail: singh.genetic@gmail.com

have a controversial record in India, as the first compulsory licensing was issued against Bayer over lifesaving cancer drug and the other targeted for invoking compulsory licensing and a bunch of other legislations such as Essential Commodities Act, State Price Control Orders, Rules of Competition Commission of India. The commonality between the two is their dominant position in the market and exorbitant licensing fee charged by them to manipulate market, posing obstacles to accessibility of technology. They have been playing similar song with varying lyrics having serious implications for stakeholders. The timing of merger coincides with the Delhi High Court's decision against Monsanto's patent claim over Bollgard II technology, and the case is pending before the Supreme Court of India that may decide future of agricultural innovation and clarify India's legal position on the same. The situation triggers us to revisit IP law and policy relating to agricultural biotechnology in India and functioning of Monsanto in India and analyse current and future trends of Indian Agricultural Biotechnology Sector. The paper focuses on two important aspects, first, the implications of the Bayer-Monsanto merger worldwide and particularly on Indian Agriculture Sector and second, evolving jurisprudence of Indian IPR system relating to agricultural biotechnology that sets the future trend for agricultural innovation. The attempt of the paper is to locate, connect and highlight relevant issues to be addressed through further deliberation and policy interventions.

Bayer-Monsanto Merger: Global Perspective

Bayer-Monsanto merger has been given green signal in many countries after securing varying reservations. The Antitrust regulators of the USA gave a provisional go ahead to the deal while reserving condition that the Company would off-load $ US 9 billion in assets; which get sold to fellow German chemical company, BASF. The deal further binds Bayer "to divest certain intellectual property and research capabilities, including R&D projects, as well as its nascent 'digital agriculture' business that focuses on effective sensor technology, smart analytics and selective spray systems" (Trager, 2018). Similarly European Union also cleared the merger on the condition that Bayer sells off duplicative businesses. India has also approved the merger with certain conditions,and so has been done by China, Brazil and Canada. Despite these clearances, the National Farmers Union (NFU) in the

USA has raised serious concerns regarding a disturbing trend emerging out of the mergers, and described Bayer-Monsanto merger as "the latest and most disturbing round of consolidation among the handful of companies that control both US and global agricultural markets." NFU based its argument in the light of two other mergers of Dow Chemical and DuPont to form DowDuPont and Switzerland-based agrochemical and seeds firm Syngenta and China's state-owned Chem-China. Competition law experts predict further reduction in the number of credible agro-based companies with this merger (Trager, 2018).

Does change in name will change the Game?

To get rid of the infamous name Monsanto, Bayer made a statement: "Bayer will remain the company name. Monsanto will no longer be a company name. The acquired products will retain their brand names and become part of the Bayer portfolio" (Detrick, 2018). Monsanto had a controversial past, since its inception as a chemical business entity to an agro-biotech giant; it attracted a lot of criticism. Monsanto was credited with the production of chemical agent 'Orange' that has been weaponised in Vietnam era. It also falls among the companies, which produced DDT, which was banned subsequently. Gradually, Monsanto entered in producing GMOs, and hitherto been facing a number of protests (Detrick, 2018). In comparison to first Green Revolution spearheaded by Norman Borlaug, the second Green Revolution, involving GM food crops, was not that successful, given the vehement opposition against it all over the world (baring USA and Canada), especially by European nations, which do not recognize GMOs as a significant contributor to the progress of agri-food industry (Oury, 2018).

Given the situation, the moot question is whether the change in the name would be enough to change the rules of the game? Though the name Monsanto would be gone, however, some of its brand names would still be very much with the Bayer portfolio. These brands have generated a lot of controversy, e.g. the pesticide Roundup though have been the best known pesticide, however, its active ingredient glyphosate has been listed as a harmful ingredient by California in 2017. EU Parliament also took a stringent action through a non-binding resolution to ban the pesticide by 2022, though, later; it granted a five-year extension (Detrick, 2018).

Therefore, just getting rid of an infamous name would not be enough unless there is a change in the policy as the Greenpeace campaigner Dirk Zimmermann rightly observed: "More important than giving up the Monsanto name would be a fundamental transformation in the new mega-company's policies" (Barfield, 2018). He was, however, susceptible regarding such a change and added further that Bayer have "no interest in developing future-proof, sustainable solutions for agriculture" (Barfield, 2018). Many activists have also the fear that the merger would result in further reduction of competition in agricultural sector, "limiting farmers' and consumers' choices if they want to avoid GM and chemically treated crops" (Barfield, 2018). Against these allegations and suspicions, Bayer has committed itself through various statements to go by the sensitivities of its consumers as it maintained: "We will listen to our critics and work together where we find common ground." However, it further added that "agriculture is too important to allow ideological differences to bring progress to a standstill" (Barfield, 2018). Irrespective of the Bayer's statement and change in the nomenclature, Monsanto's past may still affect the merged entity on similar counts. Monsanto has been criticized on numerous counts including "a) it poisons humanity, b) it's a monopoly, c) it crushes small farmers by forcing them to buy its products, d) it harms the environment, e) it promotes junk food" (Oury, 2018). These critics may intensify their attack against the new merged brand.

Do we need Agricultural Biotechnology to feed the world?

In the prevailing situation, there is a need of an inventive approach to feed a large population; giving space to modern technologies in addition to genetic engineering. The technological advancements in the form of artificial intelligence, big data and precision agriculture provide a great hope in this regard. These developments can work not only in the growth of food production but in its preservation too. Here it's worth mentioning that one of the studies conducted by McKinsey reveals that one- third of the food produced each year is wasted, costing US $940 billion (Oury, 2018). This could be promoted through application of precision agriculture in a range of agricultural operations, including sowing, harvesting, irrigation and transport to numerous hazards namely weather, diseases and consumer demands. Investors are mobilised to invest in precision agriculture or what is also termed as "intelligent agriculture"; for example a well known tractor brand John Deere bought Blue River, a Californian start-up "that makes intelligent machines for farmers to scan fields, recognize crop seeds and make it easier to get rid of weeds."(Oury, 2018). In addition to this, Monsanto too acquired the Climate Corporation start-up to facilitate weather information and services. Here the pertinent issue is whether the necessity highlighted by the agro-biotech companies to go for GM crops to feed the world is properly assessed in the light of other underlying factors, which continue to contribute in food production as well as food preservation or not (Oury, 2018).

Implications of Bayer-Monsanto Merger

It is suspected in a survey that the merger could have a negative impact on the independent farmers and farming communities as the merged company would control data about farm practices, increase prices, diminish quality, choice and seed varieties, which farmers have been using due to their compatibility to the climate variability (Friends of the Earth, 2018). One of the concerns expressed by the experts is that the merger may lead to reduction or elimination of competition in the emerging technologies such as "digital farming" and the Company would very likely avoid disruptive innovation that can pose significant challenge to their position in the seed and crop protection value- chain (Sharma, 2018). This may stifle radical innovation in agricultural sector, and may have severe implications on start-ups and small and medium enterprises involved in agro-biotechnology (Sharma, 2018).

Bayer-Monsanto Merger-Indian Perspective

The Competition Commission of India (CCI) has approved the Bayer-Monsanto Merger with the condition that the merged entity would need to provide non-exclusive licensing of its genetically modified (GM) and non-GM traits, currently commercialised in India or to be introduced in the near future on a fair, reasonable and non-discriminatory basis. It has also attached a caveat with the approval that the merged entity will follow a policy of non-exclusive licensing of non-selective herbicides or their active ingredients (Mukherjee, 2018). In addition to aforementioned conditions, the CCI has asked for numerous trade-offs from Monsanto in lieu of its approval; namely the merged entity will provide access to Indo agro-climatic data without any charge to the Central Government and its institutions to be used for public benefit; it will divest its glufosinate ammonium (a non-selective herbicide), crop traits of cotton and corn, and hybrid seeds of its vegetables businesses; and it should divest shareholding in Maharashtra Hybrid Seed Company Limited (MMBL) (26 per cent) to an independent entity (Mukherjee, 2018).

The issues pertaining to this merger in India are: whether the merger would treat biotechnology sector differently and try to repair the controversial image of Monsanto. Whether it will tackle properly the IP climate of India. After facing the compulsory licensing in pharmaceuticals, whether Bayer has learned the socio-economic conditions of India, which influence the IP practices. Few of these concerns were reflected in the public comments invited by CCI before the approval for the merger. The All India Kishan Sabha (AIKS) expressed its concern: "AIKS believes that with the merger, the monopoly will be further consolidated and questions of technological choice, economic fairness and goal of ensuring quality inputs at affordable rates, environmental sustainability would all be at stake" (Mathew, 2018). In its response to CCI's call for public comment, the National Seed Association of India (NSAI) also cautioned:

> It is essential for the CCI to stipulate that post-merger, large entities such as Monsanto and Bayer will strictly follow the Indian IP law wherein access to the GM traits will be provided to the breeders as rights and the developer of the GM traits will collect the trait value as per the provisions under Section 26 of the PPVFR Act under which it can make a claim. The PPVFR Authority can determine the trait value in the form of benefit share from the seed sale of all varieties, which contain the trait (Mathew 2, 2018)

Currently, three mammoth entities after the mergers, Bayer-Monsanto, Chem China-Sygenta and Dupont-Dow as mentioned earlier hold almost 100 per cent of the IPR on GM traits and consumes "enough market power through IPR, distribution networks and R&D, especially for future projects focusing on traits, pesticides, herbicides, biologics, Big Data and digital agriculture" (Mathew 2, 2018). These merger activities present a problematic perspective.

IPR and Agricultural Biotechnology

The technological advancements in agricultural sector make intellectual property regime shaky to adjust the subject matter in the proper regime. Sometimes the new subject matters challenge the existing intellectual property regime in a way that leads to enormous confusion in the scope of protection of numerous IPRs. This has led to a controversy among patent applications in plant sector as the subject matter rests at the intersection of Patents Act and Plant Variety Act. Though there has been some uniformity placed by the TRIPS Agreement and UPOV Model, however the flexibilities under the same provide enormous opportunities to the member- nations of the WTO to define IPR regime in their own way, much suited to their respective socio-economic conditions. This relativity, however, must conform to the mandate of the TRIPS Agreement, or to put it simply must not violate the minimum standards of the Agreement. The subject matter for IPR in agricultural biotechnology, particularly, relating to plant has been of a great concern for developing countries, especially, agro-based economies. The IPR regime has been defined in a way that tilts more in favour of corporate giants rather than other stakeholders, including farmers and small plant breeders (Bedasie, 2012). There has been persistent confusion as to the scope of patents and plant variety legislations world over as the IPR frameworks vary from one country to another.

Overlapping of Patent and Plant Variety Legislations

The overlap between patent and plant variety legislations makes a great impact upon the enforcement of rights under the respective legislations. It may lead to a situation where effective exploitation of the patent holders' rights cannot be made without infringement of the rights of plant breeders and *vice versa*. This may make an adverse impact on the farmers' rights, as they don't get farmers' privilege under patent law but only under the plant variety law. The introduction of the plant variety law itself was a great departure from the traditional practice; based on free sharing of knowledge (Bedasie, 2012). Here, the issue is whether there is a genuine need to enclose this free sharing with a right based framework and if so whether the current regime cherish and respect this sharing to any extent in the form of farmers' privileges.

International Regime for Protecting Plant Variety

Article 27.3 (b) of the TRIPS Agreement obliges member-nations of the WTO to ”provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof”. The rationale behind creating a *sui generis* legislation for plant varieties was that the criterion for patenting namely novelty, inventive step and disclosure was difficult to meet. The other reason was in line with the larger public interest, ensuring a broader accessibility of plant varieties to farmers and small plant breeders and in avoiding an excessive monopoly offered by patents.[1]The global recognition of legal protection of plant breeders' rights took place in 1938 when a global association (ASSINSEL) of plant breeders' rights system was set up, followed by the UPOV Convention in 1961. The Convention confers breeders' rights to everyone who has bred a new variety and adheres to the DUS (Distinctness, Uniformity and Stability) rules. The varieties and its breeders must bear a name or have to be known.[2] The UPOV 1961 was modelled on "open source system" of plant breeding, which contains an exemption that allows anyone to make crosses with a protected variety from a competitor to breed a new and better variety. It ensures free access to germplasm. The UPOV Convention 1961 has been revised thrice in 1971, 1978 and 1991. The open source system faced a challenge under the UPOV 1991 with the introduction of a novel concept of "Essentially Derived Varieties" (EDV) to regulate breeder's rights to improve existing varieties based on mutations, introgressions or genetic modifications.[3] This limits the rights of the plant breeders to those varieties having substantial improvements setting higher standards of protection. Article 15 (2) of the UPOV 1991 has also remained controversial from the perspective of farmers, as "it prescribes a limitation of the farmer's privilege to save seed for propagating the product of the harvest they obtained by planting a protected variety 'on their own holdings', within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder" (Blakeney, 2012).

Overlapping of Patents and Plant Variety Laws in the USA and European Union

Position in USA

In the USA, the Court of Appeal for Federal Circuit tried to resolve the potential conflict between patent protection and plant variety protection in *Pioneer*[4] Case. The case establishes coexistence of two laws on the same subject matter. Pioneer's patents covered inbred and hybrid corn seed products along with a certificate of protection under the Plant Variety Protection Act (PVPA) for the same seed-produced corn varieties. The defendants placed an objection to patents by maintaining that the plant variety protection had removed seed produced from plants to seek protection offered by patents. The Federal Circuit rejected this argument noting that the Supreme Court held that "when two statutes are capable of co-existence, it is the duty of the courts to regard each as effective." (Blakeney, 2012)

Monsanto Co. v. McFarling[5]also recognises coexistence of both the laws. In this case, Monsanto's patents for glyphosate covered tolerant plants, genetically modified seeds of such plants, specific modified genes, and method of producing genetically modified plants.[6] Monsanto stipulated that the sellers of the patented seeds had to enter into a "Technology Agreement" that the seeds were to be used 'for planting a commercial crop only in a single season' that the purchaser would not 'save any crop produced from this seed for replanting, or supply saved seeds to anyone for replanting' (Blakeney, 2012). A farmer named McFarling, purchased Round-up ready soybean seed in 1997 and 1998 and signed the Technology Agreement. He saved a small amount of patented soybean seeds and instead of selling it he planted it, saved these seeds to be planted in the next season. He saved the same for the following season. The saved seeds retained the genetic modifications of the Roundup ready seed. Mr. MacFarling maintained that while saving the seed for his own use he violated the agreement as to plant variety and not the patents. The Court declined to restrict the patent law by reference to PVPA, and Mr. McFarling was found to have infringed Monsanto's patent (Blakeney, 2012). This recognizes the patent rights in genetic traits contained in the seeds.

Position in EU

Taking note of the UPOV Convention, the European Patent Office under Article 53 (b) excludes patenting of 'plant or animal varieties or essentially biological processes for the production of plants or animals'. However, this exclusion does not apply to microbiological processes or the products thereof. What is essentially biological process has been explained by Rule

23b(5) of the EPC, which maintains that a process for the production of plants and animals is essentially biological 'if it consists entirely natural phenomenon such as crossing or selection'(Blakeney, 2012).

Article 4.2 of the European Biotechnology Directive prescribes that 'Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.' This creates a silver line for patenting of plant varieties too if the claimed subject matter is not confined to a particular plant variety. This position had been clarified in Novartis/Transgenic Plant[7], where the EPO's Enlarged Board of Appeal categorically observed: "In the case of plant variety rights, an applicant had to develop a plant group, fulfilling in particular the requirements of homogeneity and stability, whereas in the case of a typical genetic engineering invention, a tool was provided whereby a desired property could be bestowed on plants by inserting a gene into the genome of a specific plant" (Blakeney, 2012). Referring to the legislative intent of the legislations, the Board maintained, "the development of specific varieties was not necessarily the objective of inventors involved in genetic engineering" (Blakeney, 2012).

In plant variety-patent contest, the term "essentially biological process" play a vital role as it is recognised as an exclusion to patents. Article 2.2 of the Biotechnology Directive defines essentially biological process for the production of plants and animals as consisting 'entirely of natural phenomena such as crossing or selection'. The legislative intent behind introducing this term has been tested and clarified in two important cases by the EPO's Enlarged Board of Appeal (EBA). In the first case, a broccoli patent was filed by Plant Bioscience Ltd. (Norwich/UK) for a 'method for selective increase of the anticarcinogenic glucosinolates in brassica species'[8] (Blakeny, 2012). The second case involved the tomato patent application, and was filed by the Israeli Ministry of Agriculture for 'method for breeding tomatoes having reduced water content and product of the method'[9](Blakeney, 2012).

Among several issues, the EBA was encountered with an important issue: what should be the degree of human intervention/technological advancement that goes beyond "essentially biological process" bar? The EBA responded by identifying following criteria to determine whether a process is non-essentially biological:

(i) The totality of human intervention and its impact on the result achieved is to be determined.(ii) This has to be judged on the basis of the essence of the invention. (iii) The impact must be decisive. (iv) The contribution must go beyond a trivial level. (v) The totality and the sequence of the specified operations must neither occur in nature nor correspond to the classical breeders' processes. (vi) The required fundamental alteration of the character of a known process for the production of plants may lie either in the features of the process, i.e. in its constituent parts, or in the special sequence of the process steps, if a multistep process is claimed10 (Blakeney, 2012).

The EBA had reiterated the requirement that the invention must have a technical character in both the cases Broccoli and Tomato, and it shall be the basis of the determination of plant breeding method to be patentable (Blakeney, 2012). Therefore, if a process of sexual crossing and selection includes within it an additional step of a technical nature, that by itself introduces a trait into the genome or modifies a trait in the genome of the plant produced, so that the introduction or modification of that trait is not the result of the mixing of the genes of the plants chosen for sexual crossing, then that process leaves the realm of the plant breeding and, consequently, is not excluded from patentability (Blakeney, 2012).

The current state of plant breeding involves high technologies to develop certain traits that can be better protected through patents rather than through plant varieties to avoid exemption allowed under the former. There has been a significant increase in the plant-related patent applications that shows this preference and avoids open system of plant innovation or seed exchange. Although France and Germany have included an exemption for plant breeding akin to that of plant variety legislation;, there have been a strong opposition by plant breeding companies for changing this position and disallowing further breeding of progeny containing a patented trait. These companies have made explicit request to their competitors to abandon plant-breeding programmes, which "allegedly infringe their patent applications with the immediate effect of dramatically hampering innovation and posing a threat to those companies which are trying to develop competitive varieties." (Blakeney, 2012) Open innovations in plant breeding sector have been experiencing jolts and jerks by the current tendency of exclusivity practiced by breeding companies with strong portfolios.[11]

Since the overlapping becomes unavoidable, compulsory cross licensing is suggested as a possible solution; preferred in European Union to balance interest of different right holders (Blakeney, 2012). Article 12 of the EU Biotechnology Directive 1998 covers those situations in which a breeder cannot avail or exploit a plant variety without infringing a prior patent. It provides that in such situations, the breeder may apply for a compulsory license for non-exclusive use of the patent, which will be granted 'subject to payment of an appropriate royalty'. Reciprocally, a compulsory licence also applies in situations where a patent holder cannot exploit an invention without infringing a plant variety right (Blakeney, 2012). As an alternative, the creation of prior right may exclude the subsequent creation of another right. A more inclusive approach that is followed by many countries is the inculcation of a similar exception in patent law as provided under the plant variety protection (Bedasie, 2012).

Overlapping of Patents Act and Plant Variety Act in India-Monsanto-Nuziveedu Contest

Though India has two well-defined IPR legislations relating to plants, The Patents Act 1970 (as amended in 1999, 2002 and 2005) and the Protection of Plant Variety and Farmers' Rights Act 2001 (PPVFRA), the advancements in technology, however, create subject matters that fall at the intersection of these two and lead to an overlapping. While enforcing the one Act, there is a probable chance of infringement of the other. Monsanto's case[12] in India reflects this overlapping, and has become the first case on biotechnological invention that reached Supreme Court of India. The interpretation by the Court would have far-reaching implications for agricultural innovation. Monsanto case in India has attracted a number of regulatory steps comprising price control legislation to fix licensing fee, demand by the State Governments to revoke Monsanto's patent over Bollgard technology, demand for invoking compulsory licensing for Monsanto's patent over its Bollgard technology and an investigation in its licensing deals. Here, the paper focuses upon the patentability issue and its relevant interfaces.[13]

What is the Monsanto's technology all about?

One of the main facets of GM crops is that they acquire an insect-resistant trait through genetic engineering/modification, and Monsanto's case falls under this category. Monsanto developed pest-resistant technology, popularly known as Bt technology, to enable farmers to have better yields of crops. Bt technology involves introgression of certain genes of *Bacillus thurgingiensis* (Bt), naturally occurring bacteria, into the genome of cotton-seeds to ensure that the resulting crops develop resistance against certain pests of the lepidopteron species (Reddy, 2016). In Bt cotton "the genome of the bacteria, *Bacillus thuringiensis*, codes for a protein which eliminates the bollworm insect." To obtain this, "Bt trait genes are inserted into a variety in a laboratory through a biotechnology process, which after transformation is known as a 'transgenic variety'. The Bt trait from this variety is then transferred into other varieties by traditional plant breeding methods" (Banerjee *et al.* 2018). Monsanto's technology works effectively against Bollworm pests that destroy cotton crops in India. The technology promises to reduce or even in some cases eliminate use of pesticides by farmers (Reddy, 2016) Monsanto developed two generations of Bt technology, the first generation was not patented by Monsanto in India, while the second generation Bt technology has been licensed under the trademark Bollgard-II variety ®and is patented (Reddy, 2016).

How Monsanto took its business Forward?

As per the entries in the patent register, Monsanto has licensed this patent to its joint venture in India, called Mahyco Monsanto Biotech (India) Ltd (MMBL), which has in turn entered into sub-licences with approximately 40 Indian seed companies. These seed companies evolve their own seed varieties, which can be protected under the Protection of Plant Varieties & Farmers Rights Act, 2001, and these seeds are then introgressed with Monsanto's patented gene technology (Reddy, 2016).With the introduction of Monsanto Bt technology, crop yields improved significantly but Monsanto's licensing practices were highly criticized for exorbitant licensing fee and overcharging for seeds. It has also been alleged that the Bt seeds loses their ability to resist pests in time. This placed farmers in a situation of debt and insecurity in the case of crop failure. It has also been alleged that due to these reasons, farmers were forced to commit suicide. This was the cited reason why states started regulating prices in 2016 (Dhillon, 2018).

Monsanto-Nuziveedu Dispute

Following this scenario, a controversy arose out of the sublicense agreements between MMBL and a third party Nuziveedu, executed on 10 March2015. As per the licensing terms including the payment of trait fee, Monsanto procured Nuziveedu Cotton transgenic variety seeds as the "Donor Seeds", and allowed them to develop genetically modified hybrid cotton planting seeds. Monsanto also licensed its registered trademarks: *BOLLGARD and BOLLGARD-II (Padma, 2018)*. Nuziveedu refused to pay the process fee to Monsanto as per the licensing agreement and agreed to pay the "trait fee" only as fixed by the State Government.The Agriculture Ministry had issued a notification in May 2016 under the Essential Commodities Act to virtually deprive MMBL of its patent on Bt cotton technology (Fernandes, 2018). Due to continued marketing and sale of hybrid cotton by Nuziveedu without paying the licensing fee as per the terms and conditions of the licensing agreement, Monsanto instituted a civil suit before the Delhi High Court for infringement of its patents and trademarks by Nuziveedu (Padma, 2018)

Nuziveedu placed its defence by making a contention that the enforcement of the infringement suit relating to Monsanto's patent is liable to be rejected as the subject matter of the patent falls under one of the exceptions of the Patents Act, i.e. Section 3 (j).[14] It had also made a counterclaim that "the patent granted to Monsanto is liable to be cancelled besides praying for declaration that the Agreements are valid and binding and performance of the consequent obligations." (Padma, 2018)

While making the counterclaim, Nuziveedu also contended that the Bt cotton developed by it and its subsidiaries had its own distinct characteristics separate from the Bt trait[15](Padma, 2018). It asserted that new varieties developed by them differ significantly from the donor seeds patented by Monsanto. Nuziveedu also argued that Monsanto did not transfer the specific method of transformation; and that only the seeds of the transgenic variety were given (Padma, 2018). Here, the question arises, whether the seeds of transgenic varieties given to Nuziveedu were free of cost or under the stipulation of the licensing agreement? If the access is under certain stipulations it should have been respected. The second question arises whether after giving seeds under a license agreement Monsanto still have the right, which extends to seeds or has been exhausted.

The patent granted by the Indian Patent Office to Monsanto comprised 27 claims, which covered method for producing a transgenic plant with increased resistance to insect on account of a 'nucleic acid sequence', derived from the DNA of Bt (*Bacillus thuringiensis)* bacteria and the process to insert it in plant cells'(Padma, 2018).The invention included identification of desired gene (Cry2Ab) from the DNA of BT (*Bacillus thuringiensis*) bacteria, making (synthesising) nucleic acid sequence by copying the Cry2Ab for insertion into a plant cell, and the method of inserting the said nucleic acid sequence into a plant cell (Banerjee, 2018). More specifically, the contested Patent No. 214436 was entitled as "METHODS FOR TRANSFORMING PLANTS TO EXPRESS BACILLUS THURINGIENSIS DELTAENDOTOXINS". It was questioned on claims 25-27 that contains biotechnological invention containing infusion of Bt gene into the cotton genome. This Bt bacterium eradicates pests afflicting cotton-plant (Sinha, 2018)

Judgment of the Single Bench

As regards to the issue of revocation, the Court did not accept Nuziveedu's arguments that Monsanto's invention is not maintainable under the Patents Act; however, it held that Nuziveedu cannot be injuncted. The court maintained, "the pre-mature termination of the Agreements was illegal and arbitrary and the parties would remain bound by their respective obligations." The court directed that the trait fee must accord to the prevalent local laws (Padma, 2018). It was well in tune with Nuziveedu's contention that it would pay fees determined as per the price control order made by the government and not those fixed by MMBL in its licensing agreement. Aggrieved by the decision of the Court, MMBL made an appeal with the belief that a patent right devoid of freedom to fix the price was a truncated right (Fernandes, 2018). It is to be noted that Justice Gauba affirmed that GM traits involve "laboratory processes and are not naturally-occurring substances." They are man-made and, therefore, could be protected under the Patents Act (Fernandes, 2018). Monsanto and Nuziveedu preferred appeals to the Division Bench with their respective concerns. The former was concerned over continued supply of Donor Seeds under the Agreement with revised trait fee while the latter was interested in the revocation of patents (Padma, 2018).

Decision by the Division Bench

Relying on the import of 'essentially biological process' from European Patent Convention, the Division Bench held that transgenic plants with the integrated 'Bt Trait' produced by hybridization falls under the category of essentially biological process' which is excluded from the patentability and therefore the patent rights of Monsanto over the gene are not maintainable (Padma, 2018). The court observed that "the nucleic acid sequence which was the invention in question had no existence of its own and after introgression, the seed material had to undergo further steps of hybridisation to suit local conditions. Thus, the product was not 'microorganism'."(Banerjee, *et al.* 2018)

The division bench comprising Justices S. Ravindra Bhat and Yogesh Khanna were not impressed with the line of argument made by Justice Gauba that genetic traits are the outcome of a lab made process and not a naturally occurring substance. The court observed that though gene constructs having artificial indicia can be protected under the Patents Act, however, once they become a part of a plant or a seed, they can only be protected under PPVFR Act rather than Patents Act if they conform to the requirements prescribed under the former (Fernandes, 2018). The Court suggested Monsanto that the apt legislation for its subject matter is PPVFR Act under which Section 65 explicitly provides that a "suit can be filed against infringement of a variety registered under the Act and in such a suit the court may even grant an injunction and award either damages or a share of the profits"(Banerjee and Rajdeep, 2018).The court also held that patents and plant varieties systems are mutually exclusive and not complementary to each other and suggested Monsanto to apply for registration under the PPVFR Act while granting it three months period to make an application in this regard (Padma, 2018).

Here the reasoning given by the court needs more clarity, and it may give rise to certain questions, e.g. if a gene is isolated and then modified to make it compatible to perform certain action in the body, the gene is always needed to be inserted in the body to work with the help of other components of the body and it may not work in isolation. Would the modified gene, which is the product of human ingenuity, be discarded from being patented? Here the clarity as to what is claimed, what is protected and to what extent a patent right's extend on a product should have been clearly explained.

The logic given by the Court that "the moment the DNA containing the nucleotide sequence (subject patent) is hybridized to produce the transgenic seeds/plants; the seeds/plants fall within the purview of the PV Act" is inconsequential as the patentee had limited its claim to selected genetic sequence as inserted into a plant genome and not a plant (Reddy, 2018). The case reflects a situation where two different rights under two different legislations on the same subject matter are to be enforced. More specifically, the issue is to what extent the rights of patentee extend and how that could be defined if the same is present in a seed, which is protected under the PPVFR Act. Whether Monsanto has patent rights limited to gene sequence or it can be extended to seeds? If yes, how the patent right could be exercised? It is the general trend that in infringement cases, the right of the patentee has been extended to product also that contains the genetic trait developed by the patentee by substantial human intervention.

On the import of "essentially biological process" to the present case, it is noticeable that as a matter of fact in Bt cotton, the gene, which produces the bollworm killing toxic protein, is derived from a soil bacterium, but insertion of this natural isolate in Bt cotton-plants is a complex affair and it could not be inserted straight away into the cotton genome. It has to be modified in such a manner that is acceptable to the plant and "it has the components attached so that the production of the toxic protein is switched on and off at particular points in the life-cycle of the cotton plant" (Fernandes, 2018). The location of the gene construct in the desired plant genome plays an important role in determining production of the toxin, its potency, the crop yield, its quality and other properties of the plant. The insertion of the gene constructs in the plant genome requires human ingenuity to produce desired result as one among the several insertions may end up with success. These insertions are termed as 'events' and 'an event which is carefully chosen after screening for patent would produce the best set of desired result' (Fernandes, 2018). As mentioned earlier while determining when essentially biological process becomes non-essentially biological process, the emphasis should be given on the dominating factor that controls results and confers characteristics to the product.

The court maintained, "what was granted was not a patent over the product, or even the method, but of identification of the "event", i.e. the place in the genetic sequence of the DNA where the CryAB2 protein, in the plant cell." (Reddy, 2018).This interpretation by the Court has been questioned as to the claim construction. It was apparent from the claims under the granted patent that it has two components, "first, selection of a particular genetic sequence of a microorganism (the equivalent of a product) and second, its placement in a particular location of the cotton genome where it will be most effective in producing a toxin (the equivalent of a process)" (Reddy, 2018). It is maintained that the claim construction by the Court could not define precisely the nature of the invention at dispute and left the confusion open (Reddy, 2018).

To bring more clarity as to the patent-plant variety interface, it is important to understand the definition and scope of the terms "variety" and "microorganisms". The definition of "variety" can be found under Section 2 (z) (a) of the PPVFRA. It defines variety as "a plant grouping except microorganism with a single botanical taxon of the lowest rank and includes transgenic varieties too"[16] Microorganism is understood as "a living thing that is too small to be seen with the naked eye. Examples of microorganisms include bacteria, archaea, algae, protozoa, and microscopic animals such as the dust mite."[17] Here, the moot questions would be whether the same subject matter could attract two different forms of protection e.g. the genetic traits developed by a particular technology is given patent protection while the seeds having a certain characteristic defined by a taxonomy or plant grouping may be covered by the plant varieties protection. If this is so, how to determine the extent and limit of these two sets of rights, i.e. patent rights and plant variety rights; e.g. can the patent over a technology/gene responsible for developing a trait will extend to the seed too protected under the plant variety legislation? Since the court recognized the mutual exclusivity of the two legislations, i.e. the Patents Act and the PPVFR Act against the complementarity, there always remains a probability of infringement of a legislation while enforcing the other unless there is a clear demarcation of their applicability.

As regards to the legality of termination of the licensing agreements, the court observed that if "the obligation of a seed developer is not to charge more than what the law prescribes, it cannot legally collect it, till the law is overborne." The Court reasoned that in an agro-based economy, it is but obvious to balance interest of farmers against those of innovators (Padma, 2018). Here, the justification for balancing the interest of farmers against the innovators seems apt but the process of balancing the interest must focus on the larger picture as to what would be the potential impact of innovation on the interests of farmers and consumers. Moreover, it should be done by looking at the proper recourse and exploring other viable options available under the legislations or sometimes available through policy interventions. Legislative provisions are always open for the interpretation by the court, and this is the beauty of common law system where judges play a pro-active role by providing certainty through their interpretations and if the situation requires, may direct the government for needed changes. To keep the sanctity of legislative intent intact, the rule of purposive construction may be a guiding force for interpreters.

The Division Bench delivered the final judgement as for revocation of the patent due to the fact that Monsanto apparently agreed to waive its right to trial, which was considered as "either a as either incredibly brave or incredibly over-confident" (Reddy, 2018). Monsanto was granted a certificate of leave to appeal to the Supreme Court on the ground that the case involves a substantial question of law (Reddy, 2018). As the result, Monsanto approached to the Supreme Court of India. As of now, the Court sustained the Division Bench decision and it would be interesting to see how the Court respond. The denial of patents to MMBL would enable the seed companies to insert the insect resistant Bt trait in varieties, and its seeds farmers can save and use in the next season (Fernandes, 2018).

Agricultural innovators reacted strongly against the High Court decision that it will have an adverse impact on innovation and Indian agro-based companies; however, various farmer groups and NGOs welcomed the decision as it protects the interest of farmers and small breeders. Government organizations are following wait and watch policy. Few reactions are worth mentioning here, which reflect some thoughtful considerations. While expressing his opinion in the favour of PPVFR Act to cover plant traits, Additional Solicitor General Tushar Mehta maintained that widely-used traits like Monsanto's are to be considered as "Standard Essential Patents (SEPs). which everyone has a right of access but not for free and has to pay as decided by the regulator." He was of the opinion that "PPVFR Act is a complete code balancing the interests of all stakeholders like breeders, trait developers and farmers" (Fernandes, 2018).

One of the premier public research institutions responsible for agricultural innovation in India, the Indian Council of Agricultural Research (ICAR) adopted a wait and watch policy and a senior official maintained: "The Delhi HC has interpreted the patent law in a specific manner. The Supreme Court is looking at it. If the patent invalidation is legally correct, the Supreme Court will also uphold it. Otherwise, it will disagree. Whatever be the decision, it will become jurisprudence. That is when we need to study its impact on India's seed development capability." As regards to the innovation concerns, he further added: "We can always put up the case with the government. Law is not static. It will adapt; it will evolve. And IPR laws are evolving" (Mathew , 2018b).

Conclusion

Bayer-Monsanto merger would have far-reaching implications on agro-based economies, including India. The increasing acquisition of the agricultural business and innovation by handful of giant companies may lead to a monopoly in market and research. The goals of research and innovation may tilt more in favour of corporate interests against the interest of farmers, small companies and indigenous breeders. Developing countries should be watchful to secure interest of stakeholders and public at large against ill effects of this merger. As of now, it would be too early to comment on the forthcoming outcomes of this merger; however, given the controversial past of Bayer, a constructive result can only be expected if it learns from the past and promotes fair practices in doing business and dealing with stakeholders. On a practical level, Bayer has to deal with the IP climate of India as to the protection of agricultural inventions and plant varieties. The uncertainty as to the operability of the Patents Act and PPVFR Act would be a great challenge for Bayer, as it has to read the situation and come up with a plan to seek effective form of protection. As regards to India's IP approach to agricultural biotechnology, there is a need to clearly demarcate operability of conflicting legislations and set a clear policy that may lead to agricultural innovation and protect interest of stakeholders. Judiciary plays a proactive role in common law countries through its innovative decisions and shape legal trend by bringing clarity in law and explaining current legal position over an emerging legal problem. While interpreting the conflicting legislations, the courts have the responsibility to keep the sanctity of legislative purposes intact. The dilution of one in favour of another cannot be considered as a scientific approach. However, if the situation demands a legislative change or a policy intervention, the courts can take that stand within the permissible limits. Protecting the interest of farmers and other stakeholders is necessary in an agro-based economy like India; however, the significance of innovation in promoting the social good should also be realized. It must be inquired that what sort of innovation is required for a particular socio-economic condition, ensuring its positive impact on economy and public good. Defining the IPR regime with clarity and establishing a healthy IP practice would create a positive image for other countries to invest in India and establish their R&D entities. It would also encourage potential indigenous companies in agricultural sector to expedite the IP -related activities and file IPR applications. The cutting-edge technologies in agricultural sector pose enormous challenge before law and require a dynamic role of judges to set the judicial trend. It is encouraging that court contests are coming up in agricultural biotechnology in India, and the Nuziveedu case has reached to the Supreme Court that may define the legal pathway for agricultural innovation.

Endnotes

1 European Plant Science Organisation, Statement Plant breeders' rights and patent rights, 8 June 2011 Brussels, available on www.epsoweb.org/file/961

2 European Plant Science Organisation, Statement Plant breeders' rights and patent rights, 8 June 2011 Brussels, available on www.epsoweb.org/file/961

3 European Plant Science Organisation, Statement Plant breeders' rights and patent rights, 8 June 2011 Brussels, available on www.epsoweb.org/file/961

4 *Pioneer Hi-Bred International Inc. v. J.E.M. Ag Supply Inc.* 200 F.3d 1374 (Fed. Cir. 2000),

5 *Monsanto Co. v. McFarling* 302 F.3d 1291 (Fed. Cir. 2002)

6 US Patents Nos. 5,633,435 and 5,352,-605.

7 Novartis/Transgenic Plant [2000] O.J. EPO 511.

8 Patent specification EP 1069819, published 24.7.2002.

9 Patent specification EP 1211926 published, 26.11.2003

10 Eg Case G1/08, at p.35

11 European Plant Science Organisation, Statement Plant breeders' rights and patent rights, 8 June 2011 Brussels, available on www.epsoweb.org/file/961

12 *NUZIVEEDU SEEDS LTD. AND ORS. V. MONSANTO TECHNOLOGY LLC AND ORS.*FAO (OS) (COMM) 86/2017, C.M. APPL.14331, 14335, 15669, 17064/2017

[13] See generally Singh, Kshitij Kumar. 2016. "Intellectual Property Rights in Agricultural Biotechnology and Access to Technology: A Critical Appraisal". *Asian Biotechnology Development Review.*18: pp. 3-23.

[14] *Section 3(j): "plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals."*

[15] Nuziveedu and its subsidiaries have applied for IPR protection for their cotton varieties under the Protection of Plant Varieties and Farmers' Rights (PPVFR) Act 2001.

[16] Section 2 (z) (a) of the PPVFRA: "variety" means a plant grouping except micro organism within a single botanical taxon of the lowest known rank, which can be—

(i) defined by the expression of the characteristics resulting from a given genotype of that plant grouping;

(ii) distinguished from any other plant grouping by expression of at least one of the said characteristics; and

(iii) considered as a unit with regard to its suitability for being propagated, which remains unchanged after such propagation, and includes propagating material of such variety, extant variety, transgenic variety, farmers' variety and essentially derived variety

[17] Biology Dictionary available at https://biologydictionary.net/microorganism/

References

Banerjee, Joyeeta & Rajdeep. 2018. "The future of genetically modified crops in India". *Forbes, India* 21 May. Retrieved from http://www.forbesindia.com/blog/technology/the-future-of-genetically-modified-crops-in-india/

Barfield, Tom. 2018. "Bayer to ditch Monsanto name after mega-merger (Update)" *PHYS ORG* 4 June. Retrieved from https://phys.org/news/2018-06-bayer-ditch-monsanto-mega-merger.html

Bedasie, Sileshi. 2012. "The Possible Overlap Between Plant Variety Protection and Patent: Approaches In Africa With Particular Reference to South Africa and Ethiopia". *1 Haramaya Law Review* 1: p.125. Retrieved fromhttp://www.haramaya.edu.et/wp-content/downloads/law_journal/Haramaya_Law_Review_1_1.pdf

Blakeney, Michael. 2012. "Patenting of plant varieties and plant breeding methods". *Journal of Experimental Botany*. 63(3): pp. 1069–1074. Retrieved from https://academic.oup.com/jxb/article/63/3/1069/473047

Detrick, Hallie. 2018. "RIP Monsanto: The Agriculture Giant Americans Loved to Hate". *Fortune* 4 June. Retrieved from http://fortune.com/2018/06/04/bayer-monsanto-merger-name/

Dhillon, Disher. 2018. "Without its GM cotton patents, Monsanto may stop doing business in India". *Business Insider India* 12 April. Retrieved from https://www.businessinsider.in/without-its-gm-cotton-patents-monsanto-may-stop-doing-business-in-india/articleshow/63731936.cms

Fernandes, Vivian. 2018. "The Delhi High Court order on patenting on GM traits is confidence-shattering". *Financial Express*12 April. Retrieved from https://www.financialexpress.com/opinion/the-delhi-high-court-order-on-patenting-on-gm-traits-is-confidence-shattering/1130018/

Friends of the Earth. 2018. "Poll: Farmers Overwhelmingly Oppose Bayer-Monsanto Merger" *Eco Watch* 14 May. Retrieved from https://www.ecowatch.com/farmers-bayer-monsanto-merger-2547420027.html

https://www.businesstoday.in/current/corporate/bayer-monsanto-merger-gets-approval-most-developed-markets-eyes-india-now/story/276089.html

Mathew, John C. 2018a. "Bayer-Monsanto merger gets approval in most developed markets; eyes on India now". *Business Today* 2 May. Retrieved from

Mathew, John C. 2018b. "Testing Times". *Business Today* printed Edition 1 July. Retrieved from https://www.businesstoday.in/magazine/the-hub/merger-bayer-ag-monsanto-cotton-seeds-competition-commission-of-india/story/278875.html

Mukherjee, Sanjeeb. 2018. "Competition Commission of India okays Bayer-Monsanto merger but with riders". *Business Standard* 21 June 21 Retrieved from https://www.business-standard.com/article/economy-policy/competition-commission-of-india-okays-bayer-monsanto-merger-but-with-riders-118062100038_1.html

Oury, Jean-Paul. 2018. "Should we be afraid of the Bayer-Monsanto merger?". *European Scientist* 08 June. Retrieved fromhttps://www.europeanscientist.com/en/editors-corner/should-we-be-afraid-of-the-bayer-monsanto-merger/]

Padma, T.V. 2018. "Explainer: SC Will Not Stay High Court Order in Monsanto v. Nuziveedu Case"*The Wire*, 14 May. Retrieved from https://thewire.in/the-sciences/explainer-sc-will-not-stay-high-court-order-in-monsanto-v-nuziveedu-case

Reddy, Prashant. 2016. A Monsanto case that could alter the dynamics of technology transfer to India**.** *IP Kitten* 4 March**.** Retrieved from http://ipkitten.blogspot.com/2016/03/a-monsanto-case-that-could-alter.html

Reddy, Prashant. 2018. "Delhi HC Delivers Deadly Blow To Agro-Biotech In Monsanto-Nuziveedu Ruling". *Bloomberg Quint Opinion* 26 April. Retrieved from https://www.bloombergquint.com/opinion/2018/04/26/delhi-hc-delivers-deadly-blow-to-agro-biotech-in-monsanto-nuziveedu-ruling

Sharma, M M. 2018. *"Bayer-Monsanto merger: CCI please stop this merger & save Indian farmers' suicides". The Economic Times Blogs*26 February. Retrieved from https://blogs.economictimes.indiatimes.com/et-commentary/bayer-monsanto-merger-cci-please-stop-this-merger-save-indian-farmers-suicides/

Sinha, Pratistha. 2018. Monsanto Technology LLC And Ors Vs. Nuziveedu Seeds Ltd. And Ors, *IIPRD Blog-IPR Discussion* 15 May 15. Retrieved from https://iiprd.wordpress.com/2018/05/15/monsanto-technology-llc-and-ors-vs-nuziveedu-seeds-ltd-and-ors/

Trager, Rebecca. 2018. "Bayer–Monsanto merger momentum". *Chemistry World* 31 May. Retrieved from https://www.chemistryworld.com/news/bayermonsanto-merger-momentum/3009088.article

RIS
Research and Information System
for Developing Countries
विकासशील देशों की अनुसंधान एवं सूचना प्रणाली

Asian Biotechnology and Development Review
Vol. 20 No. 1&2, pp 27-45

The GM Crop Debate in India: Stakeholders' Interests, Perceptions, Trust and Public Policy

Anurag Kanaujia* and Sujit Bhattacharya**

Abstract: A critical assessment of the Genetically Modified (GM) crop debate in India was undertaken to identify key determinants leading to conflicts among stakeholders. The assessment was based on the field study of different stakeholders across the agriculture value chains supplemented with close study of the debate from scholarly literature, policy documents, etc. The study points out some key stakeholders missing in the GM governance and lack of clarity in defining roles and power of regulatory bodies. It proposes a model for understanding the conflict, and argues that this model can be useful in addressing disconnect among stakeholders. It concludes with the argument for the need of developing institutions, which can promote trust among stakeholders.

Keywords: GM crops, Technology, Food policy, Regulation, Sustainability, Innovation policy, Agriculture

Introduction

The use of GM crops in Indian agriculture is a contentious issue with questions concerning their biosafety and regulatory framework, and the need for introduction of these crops for increasing agricultural productivity and food security. GM crop technology is a part of the high impact, high risk, new and emerging science and technologies (NESTs); having the potential to profoundly influence government's preferences, economic priorities, technological capabilities, societal norms, ethical and moral framework, cultural beliefs, regulation of risks, and distribution of benefits. Due to their

* PhD Candidate,CSIR-NISTADS, New Delhi. Email: anuragkanaujia01@gmail.com

** Chief Scientist CSIR-NISTADS and Professor, Academy of Scientific and Innovative and Research (AcSIR) at NISTADS Campus. Email: sujit.personal@gmail.com

novelty, high-growth rate, and potentially broad impacts on society and industry structures (Cozzens, *et al.* 2010), NESTs incite strong response from societal groups as the underlying argument is that there is a need to go beyond the 'predictability model of science' as emerging technologies are exhibit unknown environment risks and uncertainties which have no precedence. The established forms of risk assessment may not be applicable to the new technology (Giddens 1999, Beck 2006). There is a growing demand for public participation in scientific and technical decision- making (Bijker 2002). The debate is on the governance of S&T, including all sorts of ethical, legal and societal issues (ELSI), which go beyond narrow innovation and economic aspects. These conflicts and different motivations/ viewpoints contribute to the emergence of groups, which influence technological interventions. Thus, addressing social concerns associated with the introduction of these new products of knowledge economy are essential to exploit them (Sahai 2004, Frewer, *et al.* 2004).

The potential stagnation of agricultural productivity in India due to declining soil quality, shrinking land resources and shortage of water for irrigation is a challenge that the modern food systems are currently facing. GM crops entered the scenario as a promising technology to address some of the problems of productivity and sustainability (Bruce 2012, Qaim 2009, Prakash 2001). Government had pushed for adoption of new agricultural technologies, focusing on horticulture in non-traditional and GM crops in mainstream agriculture practices (Herring 2014, EPW Corrospondent 2003). Various projects to develop indigenous GM varieties were undertaken, and successful development of a GM mustard variety by an Indian university indicates towards growing research capacity. However, with this as well, successful translation from laboratory to agricultural field has not happened. Issues of regulation and governance in management of innovations are the challenges in successful utilization of the technology.

It is necessary to develop a social understanding of innovation and adoption among the policy- making bodies as well. As is seen with GM crops in India, without the consideration of the social component, a successful translation is very unlikely to happen (Bijker, *et al.*, 1987). It is with this background that the present study is important for the development of conducive environment for exploiting technology. We have looked at the various systemic developments over the time and attempted to identify various positions and stakeholders in the GM crops' debate in India. The field interviews conducted with different individuals across four Indian states allowed us to pinpoint different stances on the use of GM crops in agriculture. Along with the interviews and insights from the existing literature on regulation, innovation and technology adoption, a model has been proposed to represent process of public perception development. This model underlines role of strong institutions in building public trust along with the supplementary role of informal institutions in the absence of strong formal regulatory institutions (Estrin and Prevezer 2011, Torniainen and Saastamoinen 2007).

The dialogue space for utilization of progressive agricultural practices and technologies in the past few years is populated by an intense debate on the adoption of Genetically Modified (GM) crops. Opinions regarding the relevance of this technology vary significantly among people with different interests. A very broad characterization of these opinions into two groups is between those promoting adoption of technology and the ones opposing its uptake (Bruce 2012, Curtis, McCluskey and Wahl 2004, Poortinga and Pidgeon 2005, Verma 2013, Sahai 2004). As the dialogue between these groups is ratcheting over time, *new intermediate stances* are appearing on the canvas of GM technology adoption. For instance, even with the moratorium on the commercial release of GM crops, varieties of GM cotton, brinjal, soybean and mustard[7] have found a market in many states; Bangladesh and Sri Lanka are cultivating Bt brinjal while cultivation of any food crops with genetic traits is not allowed in India.

We argue that characterization of opinions on GM crops can be much more informed by examining variations of stances that happen due to the changing political landscape, policy failures, and regional changes, as has been seen from increasing regional influences across national policies. Literature on social constructivism (see for example (Andrews 2012)), technology adoption/diffusion models (Rogers 2003) among others emphasizes importance of social perceptions about a technology and the role of social groups in directing discourse of a technological debate over time; underscores the need for comprehensive identification and definition of concerned groups. This study is an attempt of assessment based on this ideological discourse, to identify stakeholders, and to understand what discriminates emerging intermediate stances in the GM debate.

Underscoring the Debate and the Context

Since the introduction of Bt Cotton in 2002, there have been varying views about the efficacy of the technological input, and proponents of these views have kept facing off, trying to evaluate associated opportunities and risks. This debate over the utility of GM crops has rejuvenated recently with the development of new GM mustard variety (DMH-11) in Delhi University. While a community of scientists and policy-makers motivated by the potentials of the technology have a positivist stance to favour commercial release of DMH-11, an influential and significant group of stakeholders (including farmer organizations, NGOs etc.) has an extreme precautionary view and is opposed to the idea of genetic modification of edible crops, in particular, and agricultural crops, in general. The release was approved by the Genetic Engineering Appraisal Committee (GEAC); like in 2009 for *Bt* brinjal, and has again come under review by the Ministry of Environment and Forest to satisfy public after protests against the approval of mustard variety by farmers' organizations. This shows that the debate over the use of GM crops in India has not really moved forward from 2009 and the respective groups have yet to evolve in opinion about the GM technology.

It is important to draw attention on the observations made in the recent panel report (United News of India 2017) on GM mustard by the parliamentary standing committee on science and technology, environment and forest. This report highlights shortcomings in the regulation and review mechanism of GM crop field trial data. The panel recommends a participatory decision-making process with clarity on 'all probable impacts of technology' (The Indian Express 2017). These observations are highly pertinent to the present debate as they have come at a crucial juncture of GM crop debate. There are other issues such as apprehensions regarding an intent of controlling food supply by foreign firms; the opposition to indigenously developed mustard variety by prominent national universities[6] question. This is a predominant basis used by some stakeholders for challenging more traditional positivist stance of promoting indiscriminately new technologies. Prakash (2001) and Verma (2013) argued that results in unfamiliarity of consumer with the technology along with 'lack of reliable information on the current safeguards in place, a steady stream of negative opinion in the news media, opposition by activist groups, growing mistrust of industry, and a general lack of awareness of how our food production system has evolved' and are major factors dictating societal outlook towards GM crops .

Table 1: Stakeholder positions emerging from literature

Stakeholder	Broad Classification	Major Position
Consumers and Farmers	Technology User	Precautionary
Producers and Market	Technology Provider	Positivist
Developers	Technology Developer	Proponents, Positivist
Regulators and Managers	Intermediary Bodies	Protectionism, Positivism
Civil Society Groups/ NGOs	Intermediary Bodies	Extreme Precautionary

As per the observations in the field studies conducted with different stakeholders, the role of intermediary bodies acting as social capital generators is important in resolving such technological impasses (*see* for example (Knorringa and Staveren 2006, Metcalf 1995)). However, the importance of such impartial institutions has not been realised yet as is evident from the failure to introduce a viable biotechnology regulatory authority bill since the inception of the of the draft framework in 2010. The competition among stakeholders was on account of varying normative frameworks they possess. Some believe that existing knowledge is enough for regulation and is compatible with best practices ; others reason that knowledge available is insufficient for taking decisions or new regulatory and system failures may happen if additional information is not collected. With such a standoff among them, this is an opportunity to look at different stakeholders and understand their concerns with a better insight in concern with the perspectives of GM crops.

The close analysis of the literature and review of the biotechnology regulatory framework related documents like draft biotechnology regulatory act, BRAI-2010 (PIB 2012) made it clear that many of the important stakeholders were missing from the regulation processes. The bottom-up decision-making is largely absent in the project proposal appraisal bodies; mainly as the criteria for selection of experts is guided by beliefs about credentials and does not merit the situational and tacit nature of knowledge with the experts. This has a contribution towards public perception about the credibility of the body. Although experts try to look at ecological and health issues due to genetically modified crops it is restrictive, as it does not include practitioner's of such a knowledge, like farmers.

Table 2: Stakeholders positions emerging from field interviews

Stakeholder	**Broad Classification**	**Major Position**
Consumers	Technology User	Precautionary
Farmers	Technology User	Ambivalent
Developersand Producers	Technology Provider	Proponents
Regulators	Intermediary Bodies	Unsure and Positivistic
Managers	Intermediary Bodies	Precautionary
Civil Society Groups/ NGOs	Intermediary Bodies	Extreme Precautionary
Political Leaders/ Executives	Intermediary Bodies	Precautionary and Positivist

We have observed that bodies like the National Seed Corporation which have the mandate to develop seed industry in the country have not been involved in the development process of GM seeds. There have been concerns on the efficiency of this corporation; this calls for strengthening this entity and making it an active partner in the GM crops governance, regulation and distribution process. We have argued that institutions should be supported to reinvent themselves to regain public trust and bridge trust deficit generated due to earlier shortcomings in the governance. New bodies like Food Safety and Standards Authority of India (FSSAI) are placed at strategically advantageous positions in the agricultural value chain and can bring in stakeholders together and establish a participatory and inclusive regulation mechanism for evaluation and release of new products. There have been other concerns like seed distribution, information asymmetry, unfair trade practices, etc. which have led to the current concerns over GM varieties. In this debate, it would be useful to look at the article titled "*The future of food*" in which Noemie Bisserbe of the business standard (Bisserbe 2009) has expressed that *India with its current status in the GM debate is unprepared to tackle GM crop proliferation* on account that Government is immature in regulating GM crops, and is influenced easily by corporate agenda. Farmers are largely unaware of biotechnology advances and cannot tap into potential it offers. Three key concerns raised in the article are variable productivity by GM or *Bt* cotton, possibly based on the soil condition and environmental factors of the farms in which they are grown; lack of public investment in agriculture in India leading to a shortage in exploitative capacity; and unethical practices adopted by some biotechnology firms to bypass environmental impact assessment, which create an atmosphere of distrust among stakeholders. Like this many other articles have come to fore in pointing out these gaps in the Indian governance and regulatory system. These gaps have led to a systemic crisis contributing to a state of system failure.

Prevailing Crisis

The established system is unable to tackle with the challenge that a new technology has posed to the society. "Disconnect between the actors of system"; one of the ingredients of System failure condition arises when we do not know the stakeholders in the innovation system. The role of institutions like government and public researchers is to identify and include these stakeholders in regulatory systems. In the absence of various system components different failure conditions can happen. Lock-in effect, path dependency, inertia, etc. are some such situations. The Innovation system literature provides a distinct perspective for looking into these dimensions of interlinked components involved in the growth, development and adoption of new technologies (Freeman 1995, Lundvall 1992). Innovation system framework on the other hand has some limitations. It can provide a theoretical account of linkages only between various parts of the ecosystem, but not an in-depth analytical account of strategies for promoting innovation.

In the Indian regulatory set-up comparisons between cases with known characteristics are done subjectively using only experience and wisdom of decision-maker. In present, where problems entail issues from multiple dimensions, this subjectivity is vulnerable to high risk of bad decision-making. Thus, a more evidence based procedure for predicting outcomes is desirable. The policy landscape for GM crop adoption is shaped by group perspectives which are based on divergent views about GM technology. Scientific experts, government agencies, civil society, etc. have their own understanding of the technology with their own set of beliefs and doubts. Scientific experts, for instance, look at available experimental evidence from animal testing and field trials. Farmers on the other hand have informal knowledge including understanding of risk factors, which contest classical risk approach. There is no mechanism which allows them to be participant in the governance system. A clear disconnect between the research conducted in the laboratories and the regulations placed can be observed throughout the story of GM crops in India as there has been a policy tussle for more than a decade now without any conclusive decision-making. This disconnect can lead to underutilization of human resource and wastage of economic and natural resources (Victor and Horowitt 2012). The use of models to understand progress of science is a recommended way to address subjectivity. A model works as a common framework of assumptions for authors of varied disciplines (Callon 1995).

Conceptual Framework: Informal institutions as tools to strengthen weak institutional set-up

The conceptual framework is derived from innovation systems framework (Freeman 1995, Lundvall 1992, Vogt 2013) social constructionism (Bijker, Hughes and Pinch, 1987, Berger and Luckmann 1991, Stewart 2002, Andrews 2012), strategic management literature (Cozzens, *et al.* 2010) and institutional economics (North, 1997, Torniainen and Saastamoinen 2007, Estrin and Prevezer 2011). Innovation systems literature is useful in understanding of the development of regulatory mechanisms for GM crops. From an Innovation systems perspective, it can be argued that, the importance of creation and development of institutions, and interactive learning capability of different actors in the innovation system are to be catalysed through creation of networks to provide some insights towards enhancing trust and perception. This underlines that along with economic capital, the social capital is also an important driver for successful translation.

Social constructivism can help understanding changing policy landscape due to the technologies and their interactions with the society. Construction of concepts like formal and informal institutions, property rights and associated costs and benefits to understand the development of anti-GM sentiments in India are based on institutional economics framework. These concepts have been chosen instruments for analysis because they conveniently align with existing systemic factors (Estrin and Prevezer 2011), and thus seem to be a valid choice.

Formal institutions are openly codified as in they are established and known through official channels. While informal institutions are created and enforced outside official channels. Both formal and informal institutions have the role of shaping incentives to players engaged in regulation and innovation (Helmke and Levitsky 2004, North 1991, Estrin and Prevezer 2011). Numerous studies have flagged the requirement of public trust on GE technology, regulatory bodies and impact assessment structures for successful commercialization and adoption of GM crops (Frewer, *et. al.* 2003, Frewer, *et. al.* 2004, Moon and Balasubramanian 2004, Sahai 2004, Finucane and Holup 2005, Poortinga and Pidgeon 2005). The role of perception about possible risks and sincerity of government in assessment of these risks is considered crucial in creation of the trust (Zucker 1986), ultimately leading to successful commercialization of GM crops. Environmental Risk literature underlines that although scientifically assessed risk and public perception of risk are often different, consumers base their choices about the technology on the perceived risk (Curtis, *et. al.* 2004). Herein, role of informal institutions becomes important for strengthening formal institutions by creating trust and favourable perceptions. Through their compatibility with the system and complementarity to the formal institutions, they can assist formal institutions in solving long standing problems, and thus ensure efficient functioning of a system (Helmke and Levitsky 2004).

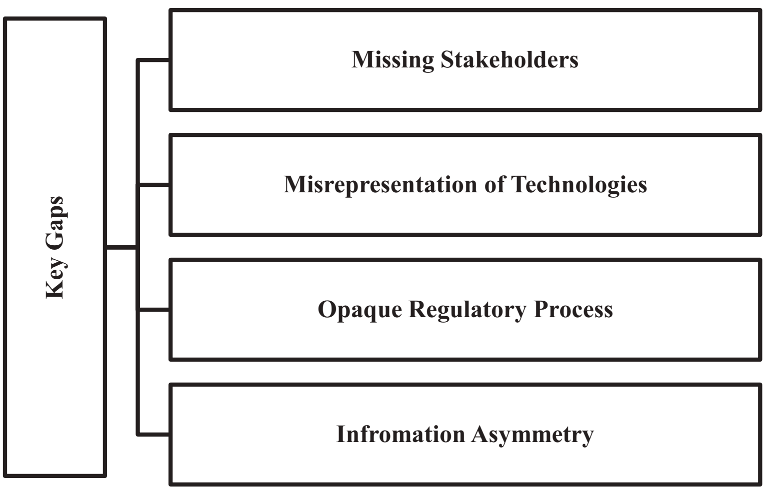
Stakeholder Analysis

Identification of categories of stakeholders is based on their systemic situations in the framework/structure of GM innovation, regulation and governance. Group interest emerges as the primary reason for supporting or opposing adoption of a technology which is the key discriminant distinguishing groups. We find that civil society groups and NGOs serve as a support gathering and lobbying machineries for the consumers and producers in the regulatory space. The existing binomial characterization of stakeholders gets further classified into consumers, benefactors (producers/market), developers, regulators and managers, etc. in representation of intermediate stances that have mixed opinions about the use of the GM technology in agriculture.

Our field study and close reading of the literature highlight that crucial stakeholders are not visible or the visible stakeholders do not have well defined roles and positions in the regulatory discourse. This is a major missing gap in the dialogue over adoption of GM crops.(see figure 1). Thus to delineate the stakeholders and making them part of the overall system is a major aspect we underscore. An information asymmetry exists among different actors, which is leading to escalated debate. There is a significant misrepresentation of new technologies as one solution is to all problems instead of simultaneous exploration of alternate technologies which contribute to development of unusually high expectations from these technological interventions. This asymmetry leads to varying perceptions of technology and prevents a constructive dialogue for progress in conflict resolution.

Figure 1: Key Gaps that contribute to the continuation of GM crop debate in India

The field study has also identified that institutional framework is suffering from trust deficiency and with the regulatory process being highly opaque. Researchers undertaking field trials are largely disconnected from



the regulatory system and have poor connection with the policy and market mechanisms. Farmers have mixed experience with Bt cotton, but still higher expectation because of it being a technologically advanced product. On the other hand, the seed price, crop failure, loans are the issues relevant to farmers. Government policy articulation and existing institutions which had major role in the past are missing in the current regulatory framework.

We can draw lessons from the related policy discourses such as green revolution, that have direct or indirect links with the present challenges of GM food crops. However, relying too much on past experiences can also slow down progress by putting impediments in the implementation of technological interventions. These observations lead us to develop a matrix of regulation and innovation activities presented in Table 3; and form the basis for a system flow diagram presenting interactions of these factors in the development of trust among the stakeholders.

Table 3: The Matrix of Regulation and Innovation Activities

Factor **Effect**	**Perception**	**Policy**	**Information**	**Environment**
Perception → ↓		Farmer Training, Market Support	Internationally acceptable norms on testing	Inclusion of Farmers and Civil society in decision making
Policy	Chain of command for Field trials		Robust monitoring and follow up mechanisms	Promoting oilseed cultivation by large landholders
Information	Farmer Training, Field trial results	Decision Making authority to credible regulatory body		Private bodies get services from government laboratories
Environment	Efforts by scientific experts to explain the technology	Seed pricing control, Availability of competing seeds	Transparent evaluation mechanisms and field trial results	

An Aetiological view of debate

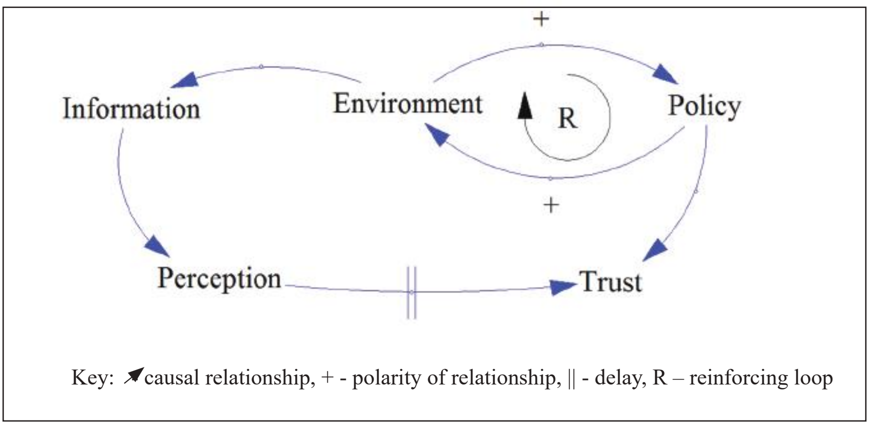
The major position of stakeholders is important in deciding the discourse of the technology development. Government's position is characterized by a strong proactive stance which has been traditionally supportive of technology development. In case of GM crops, however, it has been observed that the state policies are easily influenced by the dominating actor in the system of governance. This is clear at several instances, like the 2009 moratorium on Bt brinjal by reversing decision of Genetic Engineering Appraisal Committee (GEAC) (Bawa and Anilakumar 2013, Herring 2014). This is again seen with the review of decision of the GEAC on GM mustard; Dharwad Mustard Hybrid, DMH-11, developed indigenously. Farmers on the other hand have a new technology which claims to be more efficient, with increased yields and reduced reliance on chemical pesticides (Prakash 2001, Sahai 2004, Qaim 2009, Bruce 2012, Verma 2013, Herring 2014). Biotechnology firms which represent the corporate sector in the case of GM crops have a reputation of following unethical practices to bypass product assessment systems and get government approval. The civil society groups and NGO have regularly claimed that biotechnology firms flaunt environment regulations for their economic benefits. The results of these varying points of view led to an atmosphere of distrust among different stakeholders (Bawa and Anilakumar 2013, Waltz 2009, Verma 2013). For instance in case of the American public, a strong trust exists in its regulatory agencies (FDA, USDA, and EPA), which had eventually contributed towards a higher public acceptance of GM food. However, to promote trust and adequately address concerns about the risks, there is a need for measurement and monitoring mechanisms for cultivation of GM crops (Prakash 2001, Bawa and Anilakumar 2013, Stewart 2002). In some states of India, the informal institutions replaced ineffective formal institutions leading to enhanced governance experiences and development of efficient system (Estrin and Prevezer 2011). A successful regulatory strategy would be one where 'regulatory authorities anticipate and design commercial use as a real world experiment'. This would be possible if claims of eco-efficiency benefits and uncontrollable risks from GM crops are checked through measurable biophysical effects, and a greater moral-legal responsibility is assigned to agro-industrial operators dealing with GM products (Levidow and Carr 2007).

Traditionally in the Indian regulatory structure, government appointed bodies take the final call on release of crops in the environment (commercial release), which reflects that people have faith on government taking fair decision. The GM debate, however, has shown us a new scenario where this system of regulation fails with rising trust deficit between the government and public at large. In such a situation, new intermediaries can create a chance to push the debate toward closure helping in bridging e gap between different stakeholders (Sell 2010). A System Flow diagram showing the proposed mechanism of trust building exercises has been developed (Figure 2). The flow diagram shows involvement of Policy, Information availability and institutional environment as factors in this socio-economic process. The delay between states of perception and trust is a result of different activities performed by stakeholders. According to the authors, this delay can be understood to some extent from conceptual framework of Social Construction of Technology (SCOT) framework, contributing towards the closure of debate through various social mechanisms (Bijker *et. al.* 1987). The model proposes that Policy and Environment are bound together in a reinforcing loop; this arrangement feeds into the public perception and trust paradigms. Environment encompasses available infrastructure, market linkages, seed supply, local resource evaluation and management services available to farmers, etc. It is a construct referring to various social and physical factors impacting organizational decision-making outside organization's boundaries (McGee and Sawyerr 2003). Also defined as a set of external factors, characterized by their uncertainty and complexity, which can change and cause reflections in the organization (Tsuja and Mariño 2013). There is direct linkage between environment and information availability about the crop varieties. Information asymmetry among the stakeholders leads to unpredicted losses and unwanted effects on ecology and economy due to mismanagement of available resources. Quality of institutions can play central role in bridging information asymmetry and facilitating trust building. In return, trust in the institutional arrangements enhances institutional stability(Zucker 1986, Torniainen and Saastamoinen 2007, Cassar, *et. al.* 2014).

A regulatory policy and its implementation on the other hand comprises a set of ideas or a plan of what to do in a particular situation that has been agreed to officially by a group of people, a business organization, a government, or a political party. In other words, these constitute the institutional framework for regulation. Policy and its implementation is related directly to the level of trust people put in the government schemes. Say a faulty policy is likely to cause losses to the people who will grow weary of government's inability to understand and contemplate societal requirements (Luigi, Sapienza and Zingales 2006, Guido 2008, Cassar, et. al. 2014). A study by Cassar *et al.* 2014 on the relationship between trust and institutions outlines that absence of strong formal institutions, cultural origin and trust influences behaviour of individuals in the market. They find that trust can develop as a by-product of better formal institutional quality, while in absence of strong formal institutions trust may act as a substitute for formal institutions in supporting exchange between the players (Cassar, et. al. 2014).

Figure 2 : A system flow diagram showing process of accumulation of trust through multiple activities that contribute to acceptance or rejection of a technological intervention by the society.

Policy as such also affects environment by affecting one or the other components like market linkages. Previous studies associated presence of strong formal institutions with less cheating by players in the market



and a greater cooperation between them. The link between availability of reliable information and public perception is unidirectional as formal institutions usually originate in organizational settings unaffected by the public perceptions and/or culture. It is the quality of these institutions and the nature of policy enforcement that affects perceptions and trust through variable environment (Cassar, *et. al.* 2014). Public perception and government policy feed into public trust about a technology over time. There would be a delay associated with conversion of perception capital into trust capital, and it can cause changes in public trust in a particular technology based on policy environment and perception factors. Perception or a belief or an opinion, often held by many people and based on how things would seem, is an instrumental factor in customer evaluating an innovation and consequences associated with adoption. Thus, attractiveness at first glance does not ensure adoption models to explain how many factors influence innovation perception (Venkatesh, *et al.* 2003).

Final Remarks

Our findings lead us to posit that identification of stakeholders and their stances can enable convergence between divergent groups by developing institutions that promote 'trust' and create transparent mechanisms for governance involving divergent stakeholders. Group interest emerges as the primary reason for supporting or opposing adoption of a technology which is the key discriminant distinguishing groups. We find that civil society groups and NGOs serve as support gathering and lobbying machineries for the consumers and producers in the regulatory space. The existing binomial characterization of stakeholders gets further classified into consumers, benefactors (producers/market), developers, regional variation and governance structure, which can be distinguished by 'power' and 'prestige' coming from different roles assigned to an institution.

The policy landscape for GM crop adoption is shaped by group perspective, which is based on divergent views about GM technology. Scientific experts, government agencies, civil society, etc. have their own understanding of the technology with their own set of beliefs and doubts. We have attempted to provide a plausible framework, a model that identifies the factors that impede interactions among stakeholders. Trust and perception are the key variables we posit need to be strengthened for conflict resolution among stakeholders.

It is useful to draw from innovation systems perspective which underscores (a) the importance of creation and development of Institutions and (b) interactive learning capability of different actors in the innovation system catalysed through creation of networks to provide some insights towards enhancing trust and perception. This underlines that along with economic capital, social capital is also an important driver for successful translation. Social mechanism and social shaping of technology provide clues to understanding changing policy landscape.

The model proposed can provide a way to place groups in the socio-politico-economic policy landscape based on the interests and the opinions about the technology/artefact in question. Finally, we conclude by stressing that evidence based analysis can be useful to identify requirements for directing and shaping a policy landscape and to utilize the potential of a technology. However, evidence based policy-making as argued in this paper has to be moved beyond objective evidence to incorporate precautionary principles.

Acknowledgement: The authors acknowledge support given by CSIR-NISTADS and AcSIR for this research. We thank the State Agriculture Departments, Seed Corporations and subject experts who requested to remain anonymous for their support to the field survey. We thank Prof Prajit Basu and Dr Madhav Govind (Doctoral Advisory Committee Member of Sh Anurag Kanaujia) for their insightful comments. We thank NRAS, India, for providing the opportunity to Sh Anurag Kanaujia to participate in the Mentoring Initiative sessions of the workshop, and IndiaLICS 2017 for the opportunity to present this work in front of leading scholars. Authors also thank 15th Globalics Conference for the opportunity to present their work on "the GM crop debate in India" which helped in development of this paper.

Declaration: The authors declare no conflict of interest.

References

Andrews, Tom. 2012. "What is Social constructionism." *Grounded theory review*, 1 June.

Banerjee, Rajarshi. 2018. *Genetically Modified Processed Foods in India.* Press Conference, New Delhi: Centre for Science and Environment.

Bawa, A. S., and K. R. Anilakumar. 2013. "Genetically modified foods: safety, risks and public concerns - a review." *Journal of food science and technology* 1035-1046.

Beck, Ulrich. 2006. "Living in the world risk society." *Economy and Society* 35 (3): 329-345. https://doi.org/10.1080/03085140600844902.

Berger, P, and T Luckmann. 1991. *The social construction of reality.* London: Penguin Books.

Bijker, Wiebe E. 2002. "The Oosterschelde Storm Surge Barrier: A Test Case for Dutch Water Technology, Management, and Politics." *Technology and Culture* 43 (3): 569-584.

Bijker, Wiebe E, Thomas P Hughes, and Trevor J Pinch. 1987. *The Social Construction of Technological Systems.* Cambridge, Massachusetts: MIT Press.

Bisserbe, Noemie. 2009. "The future of food." *Business Standard*, January 30. Accessed 2017.

Bruce, Toby J A. 2012. "GM as a route for delivery of sustainable crop protection." *Journal of Experimental Botany* 63 (2): 537-541.

Callon, Michel. 1995. "Four Models for the Dynamics of Science." In *Handbook of Science and Technology Studies*, 29-63. SAGE Publications.

Cassar, Alessandra, Giovanna d'Adda, and Pauline Grosjean. 2014. "Institutional Quality, Culture, and Norms of Cooperation: Evidence from Behavioral Field Experiments." *The Journal of Law and Economics* 57 (3): 821-863. https://doi.org/10.1086/678331.

Cozzens, Susan, Sonia Gatchair, Jongseok Kang, Kyung Sup Kim, Hyuck Jai Lee, Gonzalo Ordóñez, and Alan Porter. 2010. "Emerging technologies: quantitative identification and measurement." *Technology Analysis & Strategic Management* 22 (3): 361-376. https://doi.org/10.1080/09537321003647396.

Curtis, Kynda R, Jill J McCluskey, and Thomas I Wahl . 2004. "Consumer Acceptance of Genetically Modified Food Products in the Developing World." *AgBioForum* 7 (1 & 2): 70-75.

EPW Corrospondent. 2003. "Thrust on New Crops." *Economic and Political Weekely* 920.

Estrin, Saul, and Martha Prevezer. 2011. "The role of informal institutions in corporate governance: Brazil, Russia, India, and China compared." *Asia Pacific Journal of Management* 28 (1): 41-67.

Finucane, Melissa L, and Joan L Holup. 2005. "Psychosocial and cultural factors affecting the perceived risk of genetically modified food: an overview of the literature." *Social Science and Medicine* 60 (7): 1603-1612. https://doi.org/10.1016/j.socscimed.2004.08.007.

Freeman, Chris. 1995. "The 'National System of Innovation' in historical perspective." *Cambridge journal of economics* (19): 5-24.

Frewer, L, J Lassen, B Kettlitz, J Scholderer, V Beekman, and K G Berdal. 2004. "Societal aspects of genetically modified foods." *Food and Chemical Toxicology* 42 (7): 1181-1193. https://doi.org/10.1016/j.fct.2004.02.002.

Frewer, Lynn J, Joachim Scholderer, and Lone Bredahl. 2003. "Communicating about the Risks and Benefits of Genetically Modified Foods: The Mediating Role of Trust." *Risk Analysis* 23 (6): 1117-1133.

Giddens, Anthony. 1999. "Risk and Responsibility." *The Modern Law Review* 62 (1): 1-10. https://doi.org/10.1111/1468-2230.00188.

Guido, Tabellini. 2008. "The Scope of Cooperation: Norms and Incentives." *Quarterly Journal of Economics* 123: 905-950.

Helmke, Gretchen, and Steven Levitsky. 2004. "Informal Institutions and comparative politics: A research agenda." *Perspectives on politics* (Cambridge University Press) 2 (4): 725-740.

Herring, Ronald J. 2014. "On risk and regulation: Bt crops in India." *GM Crops & Food* 204-209. doi:10.4161/21645698.2014.950543.

Knorringa, Peter, and Irene van Staveren. 2006. *Social capital for industrial development: operationalizing the concept.* ISS Staff Group 3: Human Resources and Local Development, Vienna: UNIDO - United Nations Industrial Development Organization. hdl.handle.net/1765/21665.

Levidow, Les, and Susan Carr. 2007. "GM crops on trial: technological development as a real-world experiment." *Futures* 39 (4): 408-431. http://oro.open.ac.uk/id/eprint/6752.

Luigi, Guiso, Paola Sapienza, and Luigi Zingales. 2006. "Does Culture Affect Economic Outcomes?" *Journal of Economic Perspectives* 23-48.

Lundvall, B A. 1992. *National Systems of Innovation: Towards a theory of innovation and interactive learning.* London: Pinter.

Lundvall, Bengt Ake, ed. 1992. *National Systems of Innovation: Towards a Theory of Innovation and Interactive Learning.* University of California.

McGee, Jeffrey E, and Olukemi O Sawyerr. 2003. "Uncertainty and Information Search Activities: A Study of Owner–Managers of Small High-Technology Manufacturing Firms." *Journal of Small Business Management* 41 (4): 385-401. Accessed January 2018. doi:10.1111/1540-627X.00089.

Metcalf, Mike. 1995. *Forecasting Profit.* Boston: Kluwer Academic Publishers.

Moon, Wanki, and Siva K Balasubramanian. 2004. "Public Attitudes toward Agrobiotechnology: The Mediating Role of Risk Perceptions on the Impact of Trust, Awareness, and Outrage." *Applied Economic Perspectives and Policy* 26 (2): 186–208. https://doi.org/10.1111/j.1467-9353.2004.00170.x.

North, Douglass C. 1991. "Institutions." *Journal of Economic Perspective* (American Economic Association) 5 (1): 97-112. http://www.jstor.org/stable/1942704.

North, Douglass C. 1997. *The Contribution of the New Institutional Economics to an Understanding of the Transition Problem.* WIDER Annual Lectures 1, Helsinki: UNU World Institute for Development Economics Research.

PIB. 2012. *Regulatory Authority to be Set Up on Bio-Technology.* Press Information Bureau, GOI, Ministry of Agriculture.

Poortinga, Wouter, and Nick F Pidgeon. 2005. "Trust in Risk Regulation: Cause or Consequence of the Acceptability of GM Food?" *Risk Analysis* 25 (1): 199-209. https://doi.org/10.1111/j.0272-4332.2005.00579.x.

Prakash, Channapatna S. 2001. "The Genetically Modified Crop Debate in the Context of Agricultural Evolution." *Plant Physiology* 126: 8-15.

Qaim, Matin. 2009. "The Economics of Genetically Modified Crops." *Annual Review of Resource Economics*, June 26: 665-693.

Rogers, Everett M. 2003. *Diffusion of Innovation.* New York: Simon and Schuster.

Sahai, Suman. 2004. "Distrust of GM Foods: Addressing Crisis of Confidence." *Economic & Political Weekly* 2340-2341.

Sell, Susan K. 2010. "Cat and Mouse: Forum Shifting in the battle over intellectual property enforcement." Washington: IGIS research seminar.

Stewart, R B. 2002. "Environmental Regulatory decision making under uncertainity." *Research in law and economics*, 76.

The Indian Express. 2017. "Decision on GM crops should be reconsidered: House Panel." *The Indian Express*, December 19. Accessed December 20, 2017.

Torniainen, Tatu Juhani, and Olli Juhani Saastamoinen. 2007. "Formal and informal institutions and their hierarchy in the regulation of the forest lease in Russia." *Forestry: An International Journal of Forest Research* 80 (5): 489-501. https://doi.org/10.1093/forestry/cpm033.

Tsuja, Peter Yamakawa, and Jhony Ostos Mariño. 2013. "The Influence of the Environment on Organizational Innovation in Service Companies in Peru." *Review of Business Management.* Accessed January 2018. doi:10.7819/rbgn.v15i49.1586.

United News of India. 2017. *Panel report tabled in parliament says 'no' to genetically modified crops.* News, New Delhi: United News India. Accessed December 20, 2017.

Venkatesh, Viswanath, Michael G Morris, Gordon B Davis, and Fred D Davis. 2003. "User Acceptance of Information Technology: Toward a Unified View." *MIS Quarterly* 27: 425-478. Accessed 2018. doi:10.2307/30036540.

Verma, Smita Rastogi. 2013. "Genetically Modified Plants: Public and Scientific Perceptions." *International Scholarly Research Notices Biotechnology* 2013. http://dx.doi.org/10.5402/2013/820671.

Victor, Hwang, and Greg Horowitt. 2012. *The Rainforest: The Secret to Building the Next Silicon Valley.* Los Altos Hills: Regenwald.

Vogt, Dennis. 2013. "Innovation Perception from a Customer Perspective: Recognition, Assessment, and Comprehension of Innovations." Dissertation, School of Management, Economics, Law, Social Sciences and International Affairs, University of St. Gallen.

Waltz, Emily. 2009. "Battlefield." *Nature*, September 3: 27-32. Accessed February 2, 2016.

Zucker, Lynne G. 1986. "Production of Trust: Institutional Sources of economic structures, 1840-1920." *Research in Organizational Behaviour* 8: 53-111.

RIS
Research and Information System
for Developing Countries
विकासशील देशों की अनुसंधान एवं सूचना प्रणाली

Asian Biotechnology and Development Review
Vol. 20 No. 1&2, pp 47-58

Ethical Considerations in Human Genome Editing–An Indian Perspective

Roli Mathur*

Abstract: Recent developments in technology have opened many options in genome editing. Concerns are raised on ethical aspects in genome editing, particularly in human genome, and they have resulted in a wider debate on means and ends in human genome editing. Although there is no consensus on governance of human-genome editing; countries have initiated steps to govern human-genome editing, considering immense scope it offers, risks posed and lines that divide for what is permissible as an experiment vis a vis what is permissible as a therapy or a treatment. This paper gives an overview of the global debate and the Indian perspective. It suggests recommendations for a way forward so that governance is based on the sound ethical principles and considerations, and, society as a whole benefits without hampering interests of the generations to come and through an approach that balances risks and benefits.

Keywords: CRISPR, human-genome editing, ICMR guidelines, gene drive, bioethics

Introduction

Gene editing involves use of molecular scissors for adding, cutting, removing or replacing base pairs of DNA in order to bring in a change in the genome. For many years, the technology has been in use in agriculture, and since the last decade, scientists have been trying editing techniques on humans to remove deleterious mutations or unfavourable genes causing a variety of genetic disorders or conditions. There is an immense value of this technology since it facilitates accurate and precise copy- and- paste and search -and -replace option. After the year 2013, there has been a lot of rapid advances in this area, and applications in a variety of areas have emerged, such as drug development, gene surgery, animal models, genetic variation,

* Scientist E & Head, ICMR Bioethics Unit, National Centre for Disease Informatics and Research, ICMR Complex, Bengaluru. Email: rolimath@gmail.com

material, fuels and food. Genome editing has been successfully used in many organisms while using different methods of repair and in different diseases *in vitro* or cell lines. Basic and applied research advances have been made in many biological systems of plants and animals in preparing disease models and in therapeutic applications. Clustered, regularly, interspaced, short palindromic repeat (CRISPR) is a powerful technology that edits DNA efficiently with precision and alters genes thereby providing a potential cure to many of the genetic conditions; this is a rapid and efficient method that has been tried in in both *in-vitro* and *in-vivo* systems. CRISPR works as a pair of scissors and Cas 9 is the protein that unzips DNA. There are other genome-editing techniques, like zinc finger nuclease (ZFN) and Transcription activator life effector nuclease (TALEN),which can offer wide therapeutic potential (ICMR, 2017).

The technology seems to be simple, and holds enormous promise to bring in a cure for a variety of diseases; there is immense potential for its misuse, which may result in unethical and controversial outcomes. Gene editing has been restricted and even prohibited in several countries as a potential threat; especially for reproductive purposes, thus allowing gene-editing tools to be used only in somatic cells or non-reproductive adult cells (Howard *et al*, 2018). There are number of methodologies for genomic editing; however, CRISPR/ Cas9 has been found by many quite economical, easy, taking lesser time and also having a higher degree of accuracy. It has been noticed that unlike other methods, CRISPR may transfer genetic changes to the next generation (Dong *et al*, 2015). At present, India needs clear-cut guidelines, and a debate has already started in the country and it very important to deliberate and discuss its ethical uses in the society. Efforts are required to identify safeguards and frameworks needed to encourage safe use of this technology for betterment of human health.

International Position

There has been research on gene editing in human embryos in China, USA and UK (Ledford, 2015). Due to its pros and cons, there are different perspectives towards gene editing in many countries. Some accepted it while others debate over it. Studies have been done in China, and researchers have shown partial success in editing embryo genome (Liang *et al* 2015, Zhang *et al* 2017, Zhang *et al* 2015). UK in 2011commissioned Human Fertilization and Embryology Authority (HFEA) to study mitochondrial gene replacement therapy (MRT) and assessed it in terms of efficacy and safety. The HFEA panel reported to the Government, and MRT was allowed, and later was considered for use in US(Craven *et al* 2016, Garasic and Sperling 2015, Castro 2016)). US Food and Drug Administration (FDA) allowed use of enucleated donor embryos to resolve problems of infertility among older women. Although the ethical issues continue to arise, UK legislature permits MRT as it has the potential for treatment of mitochondrial diseases and infertility. A group of experts in the Europe had initiated a debate on the societal benefits and drawbacks of the technology and proposed some general principles (Chneiweiss *et al*.2017).In June 2014, the Office of Science Policy, National Institutes of Health (NIH), had held a meeting with investigators and advisory committees for an update on the clinical experience with genome editing technologies (Corrigan-Curay *et al*. 2015). A position brought out paper in 2017 by the American Society of Human Genetics (ASHG) on germline genome editing supported somatic and preclinical germline research; however, it found it premature for translation for clinical use and emphasized the need for more basic science research and encouraged ethical and social discourse (Ormond *et al*, 2017). US FDA regulates clinical trials on gene editing in the United States of America. As NIH limits funding for gene editing, funding is being sought from private agencies (Grant, 2016). The potential for treating diseases and related ethical concerns have been considered, and recently there was a call by the NIH for inviting applications for funding through a common fund to support somatic cell genome editing research to develop tools for gene editing in humans (Fogleman *et al* 2016, NIH 2018). The UK has advanced tremendously in research and clinical use of CRISPR-Cas9, and in the US cautious research is being performed; a joint statement was issued by the National Academy of Sciences and National Academy of Medicine on Human Gene Editing in 2015 (Cicerone and Dzau, 2015). It was observed that there was no strict ban against germ line experiment worldwide. Studies and experiments performed in the USA were in accordance with the NIH guidelines under the stringent vigilance of the FDA. A joint international committee of researchers, lawyers and ethicists have released a report on

Scientific, Medical and Ethical Considerations of Human Gene Editing encouraging experiments only for the therapeutic purposes to treat certain genetic disorders (NAP, 2017). It insists that this technique should not be used for phenotypic enhancement of human race by improving strength or intellect. In 2015 in a meeting of the UNESCO, a panel of scientists, philosophers, lawyers and government officials called for a temporary ban on genetic “editing” of human germline, and asked for a public debate. In UNESCO, in round-table meeting in 2018, experts' opinion was that before to carry out any human-genome editing, benefit- risk assessment should be made to assure its safe use (UNESCO 2015a, UNESCO 2018). In March 2018, an Association for Responsible Research and Innovation in genome editing' (ARRIGE) was set up to connect scientists from across the world to discuss technical and research governance issues and to reflect on all ethical, societal and regulatory aspects raised by genome-editing technologies. The first meeting was held involving stakeholders from academia, patient groups, regulators, private organisations as well as public in Paris in 2018 (Enserink 2018, Montoliu *et al.,* 2018). In September 2016, Nuffield Council came up with a paper on ethical aspects of genome editing to understand ethical aspects, review existing policies and to make recommendations for future policy or legislation (Nuffield Council on Bioethics, 2016). Very recently, in July 2018, it has released another report on genome editing and human reproduction addressing social and ethical issues. The report recommends research on genome editing to continue, and explained the need for social research to understand societal implications (Nuffield Council on Bioethics, 2018). OECD has prepared a report on gene editing for advanced therapies, highlighting issues related to governance and policy. It discusses importance of public engagement, building regulatory systems, and encouraging innovation for public benefit (Garden and Winickoff, 2018). An international Summit on Human genome editing was held in 2015 at Washington in the US, and the next is planned in Hong Kong in November 2018. This will bring together various stakeholders from across the world to debate on ethical aspects of genome editing. Japan is in the process of conducting a public consultation of the draft guidelines that allow gene editing for research in early human development but does not permit reproductive manipulation of embryos (Cyranoski, 2018).

Indian Position

In India, the trials of CRISPR-Cas9 technology to edit human germline need discussion as the issues of gene editing are not yet addressed at policy level. Research in India follows ICMR guidelines {ICMR National Ethical Guidelines for Biomedical and Health Research involving human Research, 2017 and National Guidelines for Stem Cell Research, 2017. Therapeutic potential and the Indian National Ethical Guidelines have addressed the ethical issues briefly (ICMR 2017, ICMR and DBT 2017)}. These guidelines have a section discussing ethical concerns and challenges that need careful consideration and would provide some directives for research involving gene editing and highlighting ethical challenges related to use of this technology. Recently, an MoU between ICMR and the National Institute of Health and Medical Research (INSERM), France, has been signed (March, 2018) at New Delhi, India. The MoU, has identified the prime areas for research, including bioethics with focus on Ethics and regulatory issues of gene editing techniques along with other areas such as diabetes, metabolic disorders and rare diseases.

Experts have suggested that before conceptualization on the pattern of germline gene editing research, India needs clear-cut detailed guidance, and a debate and should develop on the area of research in somatic cell therapy, as it has less hazards of inheritance of unexpected mutations in the progeny. While genome editing holds promise to personalized medicine, it is important to consider ethical implications of this scientific advancement, which has unclear and not well-understood challenges, especially in Indian context. Due to the challenges and ethical concerns raised by genome-editing technology, scientific community and other stakeholders must engage in a broad-based discussion to map the way forward for this technology.

Ethical Concerns

Balancing benefits and risks: Any technology if needs to be successful, it is important that its benefits are greater than risks; to ensure that there should be minimal damage to living beings and environment. Human germline gene editing can possibly be associated with numerous risks to participants or to future generations; its benefit-risk ratio needs to be assessed to justifying research in this area (Mittal, 2018). There are unclear risks of CRISPR-Cas germline editing therapies (CGET) -one of them is irreversible changes in germline, or the risks of inaccurate genome editing, implications for future generations, including interactions with other genetic variations and environment. Once genetic change introduced, it would be permanent and may have long-term effects. Prenatal determination of sex has been considered illegal in India as per the PNDT Act (MoH&FW, 2018); however, people may find a way of going around to determine prenatal sex as gene editing technology has high chances of being misused for prenatal testing and damaging further sex ratio; which is already disturbed in most parts of India. There can be increase in unmonitored and unreported foetal manipulations in *in- vitro* fertilization clinics across the country. The ethics of creating children with genetic editing needs a lot of debate (Ishii, 2017a). Close oversight and follow up of cases is important where ever gene editing research involves clinical applications (Sugarman, 2015). There are scientific concerns related to producing off target mutations, cleaving unintended sequences, causing mutations, while finding out safe and efficient delivery methods and possible unknown risks (Zhang and Tee *et al.*, 2015). There are enormous concerns and ethical questions related to application of this technology in human beings and the changes in the germ line or zygote. Similarly, there are also concerns regarding application of this technology in animals and the possible lateral transfer and emergence of irreversible damage to biodiversity, and ethics of animal experimentation. There can be risks to environment due to ecological disequilibrium and thus this needs to have protection against ecological damage on human health or on long-term consequences. As on date, there is no clarity on biosecurity issues, but it requires vigorous benefit-risk evaluation and to take care of the expectations of the public. In addition, genome-editing technology should not be an obstacle since there are enormous therapeutic potentials related to genetic changes in somatic cells. There is need to undertake clinical trials to make edits in somatic cells for treating genetic conditions. Changes made in the somatic cells remain limited to the treated patient, and they would not pass on to next generation. Use of somatic cell gene editing holds great prospects of clinical applications, and are being tried for the research on sickle cell disease and thalassemia (Nature India, 2018). However, there is a concern about unintended off target editing which needs careful evaluation of the method involved. A thorough case by case review of both scientific as well as ethical concerns are to be done before the study is conducted (Cicerone and Dzau 2015, Patrao-Neves and Druml 2017).

Autonomy and Respect for Persons

An important component of research is ensuring that the research participants are well informed and understand details before they voluntarily agree to participate in research. The knowledge and the awareness about genetic technologies are very limited to the general public, and often viewed as taboo. Detailed explanations of available choices are to be given along with the counselling, and this includes explanation of the procedures, possible outcomes and implications of gene editing including their long-term effects. Each participant as an autonomous individual has the right to decide about the choice he or she would like to make, such as a reproductive decision or about gene editing. Since there are possibilities that germline genome editing may create accidental alterations to germline, which can be heritable and may get manifested in future generation; therefore even the unborn children become the indirect participants. In such a scenario, an individual is actually making a choice on behalf of the unborn child. It is difficult to maintain autonomy of a fetus and the right of the unborn child to have its future right to know or not to know and right to privacy (UNESCO 2015b). Research involving gene editing technique requires a very long-term follow-up of children produced by this method. There are possibilities of many of the unknown side effects/genetic diseases, which may develop later to such children. Thus, the period of follow- up needs to be defined and implemented strictly. There are also concerns related to misuse in ART clinics, breach of privacy and confidentiality; leading to possible stigmatisation or discriminations or labelling of the person in an undesirable manner (Ishii, 2017b). Safeguards to provide adequate protections for individual identity, dignity and rights are important.

Social Inequality and Justice

There are ethical, legal and social issues (ELSI) regarding potential use of embryo gene editing for clinical purposes and need careful research, its dissemination, research on ELSI, meaningful stakeholder engagement, education and dialogue (Howard *et al.*, 2018). There are possibilities that embryo germline editing could be exploited in non-therapeutic research, such as for producing designer babies with selected qualities. If humans control gene editing and it becomes available commercially on the basis of the affordability, people may choose designer traits such as eye colour, height, hair colour, skin complexion, physical endurance of offspring and thereby creating a socio-economic divide leading to inequality in the society. There are unanswered questions related to high costs of technology, when it should be used, its availability, how to ensure benefit sharing and access. There can be enormous societal concerns and improper understanding in the public in the absence of effective communication. There are implications to providing solutions in agriculture, pest resistance, sustainable farming and also for curing life-threatening diseases such as cancer, muscular dystrophy, diabetes, thalassemia etc. which need to be explained. Community engagement and education may play a very important role in making technology acceptable and removing any unwarranted scare. There is a need to take people on board and dealing with concerns related to socio-economic or religious or other cultural beliefs or societal issues. Access must also be assured in cases where the technology is useful. It can be expected that with any new technology, there can be issues that are related to appropriate steps to make available these technologies to a common man at an affordable cost, issues related to marketing and commercialisation, economic interests restricting therapeutic use, IPR and patenting, and unknown implications for the future of our society. In addition, there is need for accountability of all involved stakeholders and transparency in the conduct of research. Both positive and negative findings of research should be communicated and published so that they can be brought out in public domain for further discussion with stakeholders (ICMR, 2017). Therefore, the genome editing technology must go through a rigorous scrutiny to ensure that the benefits can be reaped by future generations

Recommendations

There is a need to conduct more research, involving a thorough assessment of potential immediate as well as long- term risks and benefits. Research is essential before clinical applications, if any to be permissible in future. There is also a need to move ahead not only in science but also in social and ethical aspects, and these may be built to proposed research. Adequate safeguards should be in place for protection, training and capacity-building of research personnel, sensitivity to societal issues and implementation of ethical requirements to maximise benefits and protect them from harms. Better understanding about the issues related to rights to technology, patenting, ownership and access of technology, protection of rights of individuals, safety issues, protection against any discrimination is required. It is important for India to invest in the ongoing global debate to understand and put in place an appropriate ethical and regulatory framework. This would let science grow while safeguarding interests of the population and its future generations. That is a need for better governance, creating advocacy to dispel fear and to support better research. Awareness should be created among not only the clinicians and researchers but amongst the public at large for initiating a healthy dialogue and discussion to take care of any unnecessary and unwarranted hype or scare related to this technology. Efforts should be made to bring together all the stakeholders, including academia, industry, government agencies, regulators, civil society and others for settingup specific guidelines in view of socio-cultural norms and ensuring their appropriate implementation to support science and society. This would help science progress while addressing ethical concerns and protecting public interest.

Conclusion

There is absence of aplenty research on genome editing and conclusions are mostly premature and possibly more theoretical. Genome editing shows the pathway for the future with potential promise for curing diseases and improving human health but it comes with some challenges and with it of a need to take a cautionary approach. Science should be moving forward, and ways are to be explored for encouraging more ethical and socially relevant research. It is right time to explore and research for our future generations to see how to attain progress without causing harm to individuals or disturbing ecological balance and biodiversity. In India, there is an urgent need for open dialogue regarding use of genome editing technology to manipulate human genome for seeking solutions towards improvement in human health.

References

Castro RJ. 2016. “Mitochondrial replacement therapy: the UK and US regulatory landscapes”. *J Law Biosci*..3(3):726–35.

Chneiweiss H, Hirsch F, Montoliu L, Müller AM, Fenet S, Abecassis M, *et al*. 2017. “Fostering responsible research with genome editing technologies: a European perspective”. *Transgenic Res.* 26(5):709–13.

Cicerone Ralph J. and Victor J. Dzau. 2015. *National Academy of Sciences and National Academy of Medicine Announce Initiative on Human Gene Editing* Available at http://www8.nationalacademies.org/onpinews/newsitem.aspx?recordid=05182015.

Corrigan-Curay J, O’Reilly M, Kohn DB, Cannon PM, Bao G, Bushman FD, *et al*. 2015. “Genome editing technologies: Defining a path to clinic”. *Mol Ther*. .23(5):796–806.

Craven L, Herbert M, Murdoch A, Murphy J, Lawford Davies J, and Turnbull DM.2016. “Research into Policy: A Brief History of Mitochondrial Donation”. *Stem Cells*. 34(2):265–7.

Cyranoski, David. 2018. “Japan Set to Allow Gene Editing in Human Embryos. Draft guidelines permit gene-editing tools for research into early human development, but would discourage manipulation of embryos for reproduction”. *Nature.* October 3.

Dong S, Lin J, Held NL, Clem RJ, Passarelli AL, and Franz AWE. 2015. “Heritable CRISPR/Cas9-mediated genome editing in the yellow fever mosquito, Aedesaegypti”. *PLoS One*. 10(3):1–13.

Enserink M. 2018. *Interested in responsible gene editing? Join the (new) club*. Available at http://www.sciencemag.org/news/2018/03/interested-responsible-gene-editing-join-new-club.March 27, 2018.

Fogleman S, Santana C, Bishop C, Miller A, and Capco DG. 2016. “CRISPR/Cas9 and mitochondrial gene replacement therapy: promising techniques and ethical considerations”. *Am J Stem Cells*. 5(2):39–52.

Garasic MD and Sperling D. 2015. “Mitochondrial replacement therapy and parenthood”. *Glob Bioeth*. Taylor & Francis.26(3–4):198–205.

Garden, H. and D. Winickoff. 2018. “Gene editing for advanced therapies: Governance, policy and society”, *OECD Science, Technology and Industry Working Papers*, 2018/12, OECD Publishing, Paris. http://dx.doi.org/10.1787/8d39d84e-en

Grant Evita V. 2016. “FDA regulation of Clinical Applications of CRISPR-CAS Gene-Editing Technology”. *Food and Drug Law Journal*. 71(4): 608-34.

Howard HC, Van El CG, Forzano F, Radojkovic D, Rial-Sebbag E, De Wert G, *et al*. 2018. “One small edit for humans, one giant edit for humankind? Points and questions to consider for a responsible way forward for gene editing in humans”. *European Journal of Human Genetics*. .26(1):1–11.

Howard Heidi C, Carla G. van El, Francesca Forzano, Dragica Radojkovic, Emmanuelle Rial-Sebbag, Guido de Wert, Pascal Borry, and Martina C. Cornel. 2018. “One small edit for humans, one giant edit for humankind? Points and questions to consider for a responsible way forward for gene editing in humans”. *European Journal of Human Genetics* (https://doi.org/10.1038/s41431-017-0024-z).

ICMR and DBT. 2017. *National guidelines for stem cell research*. Indian Council of Medical Research and Department of Biotechnology. Available from https://icmr.nic.in/sites/default/files/guidelines/Guidelines_for_stem_cell_research_2017.pdfLast accessed on 2018 5th October.

ICMR. 2017. *National Ethical Guidelines for Biomedical and Health Research Involving Human Participants*. ICMR. Available fromhttp://www.ncdirindia.org/Ethics/Download/ICMR_Ethical_Guidelines_2017.pdf Last accessed on 2018 October 5th

Ishii, Tetsuya. 2017a. "The ethics of creating genetically modified children using genome editing". *Curr Opin Endocrinol Diabetes Obes*. 24(6):418-423.

Ishii, Tetsuya. 2017b. "Germ line genome editing in clinics: The approaches, objectives and global society". *Brief Funct Genomics*. 16(1):46–56.

Ledford H. 2015. "The landscape for human genome editing". *Nature.* 526:310–311.

Liang P, Xu Y, Zhang X, Ding C, Huang R, Zhang Z, *et al*. 2015. "CRISPR/Cas9-mediated gene editing in human tripronuclear zygotes. Protein Cell". *Higher Education Press.*6(5):363–72.

Mittal RD. 2018. "Gene Editing in Clinical Practice". *Indian J ClinBiochem.* 33(1):1-4.

MoH&FW. 2018. *Pre-Conception & Pre-Natal. Diagnostic Techniques Act, 1994 and Rules with Amendments* Ministry of Health and Family Welfare, Government of India.

Montoliu L, Merchant J, Hirsch F, Abecassis M, Jouannet P, Baertschi B, *et al.* 2018. "ARRIGE Arrives: Toward the Responsible Use of Genome Editing". *Cris J.* 1(2):128–30.

NAP. 2017. *Human Genome Editing: Science, Ethics, and Governance*. National Academies of Sciences, Engineering, and Medicine. Washington, DC: The National Academies Press. doi: Available from: https://www.nap.edu/catalog/24623

Nature India. 2018. "Armed with CRISPR scissors, Indian Scientists look at curing the incurable". *Nature India*. August 2018.

NIH. 2018., *Turning discovery into health. To launch genome editing research program Somatic Cell Genome Editing aims to develop tools for safe and effective genome editing in humans*. National Institute of Health. Available at https://www.nih.gov/news-events/news-releases/nih-launch-genome-editing-research-program 2018 January 23

Nuffield Council on Bioethics. 2016. *Genome Editing: An Ethical Review*. .128. Available from: http://link.springer.com/10.1007/978-3-319-34148-4

Nuffield Council on Bioethics. 2018. *Genome editing and human reproduction.* 183 Available from: http://nuffieldbioethics.org/project/genome-editing-human-reproduction

Ormond K.E., Mortlock D.P., Scholes D.T., Bombard Y. Brody L.C., Faucett W.A *et al.* 2017. "Human Germline Genome Editing". *Am J Hum Genet*. Elsevier .101(2):167–76.

Patrão-Neves M and C. Druml 2017. "Ethical implications of fighting malaria with CRISPR/Cas9". *BMJ Glob Health*. 2:e000396.

Sugarman J. 2015. "Ethics and germline gene editing". *EMBO Rep*. 16(8):879–80.

UNESCO. 2015a. *UNESCO panel of experts calls for ban on "editing" of human DNA to avoid unethical tampering with hereditary traits*. United Nations Educational, Scientific and Cultural Organization. Available at http://www.unesco.org/new/en/media-services/single view/news/unesco_panel_of_experts_calls_for_ban_on_editing_of_hu/

UNESCO. 2015b. *International Bioethics Committee. Report of the IBC on Updating Its Reflection on the Human Genome and Human Rights*. UNESCO. (July):1–30. Available from: http://unesdoc.unesco.org/images/0023/002332/233258E.pdf

UNESCO. 2018. *Roundtable on "Genome Editing: Why Ethics Matter?" 24.09.2018 - Social and Human Sciences Sector*. United Nations Educational, Scientific and Cultural Organization. Available at http://www.unesco.org/new/en/media-services/single-view/news/roundtable_on_genome_editing_why_ethics_matter/

Zhang XH, Tee LY, Wang XG, Huang QS, and Yang SH. 2015. "Off-target effects in CRISPR/Cas9-mediated genome engineering". *Mol Ther - Nucleic Acids*. IOP Publishing..4(11):e264.

Zhang Z, Zhang Y, Gao F, Han S, Cheah KS, Tse HF, *et al*. 2017. "CRISPR/Cas9 Genome-Editing System in Human Stem Cells: Current Status and Future Prospects". *Mol Ther - Nucleic Acids*. Elsevier .9:230–41.

RIS
Research and Information System
for Developing Countries
विकासशील देशों की अनुसंधान एवं सूचना प्रणाली

Asian Biotechnology and Development Review
Vol. 20 No. 1&2, pp 59-87

Sustainability in Crop Research and Agricultural Models: Promoting Reliance on Neglected and Underutilised species

Abhinav Jha*
Kunal Sinha**
Manish Dubey***
Ravi Chauhan****

Abstract: "Green Revolution" has been one of the most touted achievements in Indian agriculture. The term refers to a phenomenal rise in productivity experienced by the major food grain- crops, such as wheat, rice and maize. However, the revolution has left us with a legacy of declining biodiversity and stagnant rural income. Even as we celebrate our self-sufficiency in foodgrains production, we need to understand that Indian agriculture is dependent on a basket of around 30 crops, accounting for more than 80per cent of our agricultural output. Not only is this limited basket a drag on our environment but also on our input resources. It is time to recognise the fact that India is home to many useful plant species with superior nutritional and medicinal properties, and they should be developed in terms of market size to achieve economic growth. Currently, the agricultural system is lopsided in terms of cultivation and research; focusing on a few crops, this needs to change in the near future. Aggressive breeding programmes using advanced biotechnological tools such as tissue culture, micropropagation, genomics and bioinformatics are the need of the hour. While the Indian Council of Agricultural Research (ICAR) has put into place some resources to look at the future potential crops, more needs to be done. This study looks at these issues and proposes a multi-faceted policy approach to tackle them. If the proposed changes can be brought about to the agricultural system, we may be able to achieve an increase in biodiversity along with the growth in rural income.

Keywords: Agricultural Research, Biodiversity, Neglected and Underutilised Species

Introduction

The Delhi Declaration on Agrobiodiversity Management, adopted by the participants at the 1st International Agrobiodiversity Congress, held in

* Research Scholar, Center for Studies in Science, Technology and Innovation Policy, School of Social Sciences, Central University of Gujarat. Phone: 9643606837 Email: 9abhinavj@iima.ac.in
** Assistant Professor, Center for Studies in Science, Technology and Innovation Policy, School of Social Sciences, Central University of Gujarat. Email: kunalsinhajnu@gmail.com
*** Research Scholar, Center for Studies in Science, Technology and Innovation Policy, School of Social Sciences, Central University of Gujarat.
**** MSc 2nd Year, School of Life Sciences, Central University of Gujarat.

New Delhi, India, in November 2016, discussed the immediate need for a shift to an agricultural system, which is more inclusive in its utilization of different species of plants and animals existing in nature (Archak *et al.,* 2017; Paroda *et al.,* 2017). Many of the big challenges we are facing today include climate change, large scale losses in biodiversity and food insecurity and can be attributed to changes that have taken place in the recent decades in techniques and practices of agriculture (Gonzalez, 2011; Kotschi, 2007).

Some of the major trends in the recent-past are towards agricultural integration; greater orientation towards demands of the market and simplification (Meehan *et al.,* 2011; Galt, 2008). Agriculture lately requires cultivators be the part of the system that consists of research and extension agencies, certification agencies, input supply chains, processors, output distributors, marketing agencies, etc. Agricultural decisions are being undertaken less and less with a subsistence orientation and more with an eye for what the market demands. Along with this orientation has emerged the trend of simplification, where cultivators endup growing same cultivars of the same crops every year (Rusch *et al.,* 2016; Brush *et al.,* 1992). Gradually the world has seen a decrease in variety of plants cultivated and reaching end consumers. A few plants included already in the system are allocated more resources in terms of research, extension, inputs and marketing, while others face declining resources for their cultivation and continued inclusion in the crop basket.

At present of the 7000 or so species globally cultivated, only 150 or so are grown on an economically reasonable scale; while three crops, Rice, Wheat, and Maize account for around 50per cent of the global consumption of protein and caloric sources (Bala Ravi *et al.,* 2010; Prescott-Allen and Prescott-Allen, 1990). In India not only do we possess more than 45,000 species of plants, but we are home to some of the most varied food cultures on the planet. Our population has relied on a wide variety of plants to augment their sources of food, medicines, fodder, etc. However, even we are not immune to the present crisis of biodiversity loss and agricultural simplification (Bhattacharjee, 2009).

Neglected and Underutilized Species (NUS) are those plants that are grown for different purposes within a niche, localized region and have not been taken up on a larger scale. Such plants include pseudo-cereals (amaranth, buckwheat, etc.), fruits, vegetables, legumes, oilseed crops, etc. Several of them have the potential to be scaled up to improve farmers' income in different regions. Moreover, including more NUS in the crop basket is also in accordance with the global action plans such as the United Nations' (UN) Sustainable Development Goals (SDGs), the Aichi Targets of the Convention on Biological Diversity (CBD), as well as the key national policies of the Government of India (GoI), such as 'Doubling the Farmers' Income by 2022', and the National Food Security Mission (NFSM).

It needs to be understood that agriculture, health and the environment are related to one another (Mabhaudhi *et al.,* 2017).Any policies for any of these must take into consideration the other two as well. These kinds of nexus-based insights are important for deciding future research agendas and planning. Promoting NUS is a way to improve agricultural health, environmental health as well as population health.

In this paper, we have discussed the potential and ways in which these species can be incorporated in a broader way within the agricultural system; problems associated with monocropping and the need for NUS from the national perspective; also covered neglected and underutilized species (NUS) identified in India and their use, and role of biotechnology in harnessing neglected and underutilized crops. And lastly, section deals with the efforts undertaken at the national level to promote the spread of underutilized species, and policy recommendations needing implementation to broaden cultivation and consumption of underutilized species. And, in conclusion, it discusses avenues for future research.

The Need for Promoting NUS in Agriculture

At present, Indian agriculture suffers from declining landholdings, inexperienced farmers, declining soil fertility, increased incidence of pests and diseases etc. Combined with the threat of climate change, rising prices of inputs such as seeds and agrochemicals, and greater prevalence of abiotic stressess such as droughts, etc. agriculture has become a highly risky proposition. Some of these problems can be attributed to relatively recent practice of mono-cropping (Evans, 2004; Hussein and Samad, 1993). Mono-cropping is continual cultivation of the same crop species on the same piece of land year after year as opposed to multi-cropping or crop rotation where different crop species are cultivated on the land in a planned manner. Typically any cultivation of crop depletes soil of a particular nutrient profile, while some crops add nutrients to the soil. Alternatively, if a piece of land is allowed to lie fallow, microorganisms in the soil may recharge the soil with nutrients. Mono-cropping which is reminiscent of a factory style production system doesn't allow depleted nutrients to be replenished naturally, leading the need for artificially manufacture nutrients. This leads to financial burden on the farmers. Moreover inexperienced farmers are liable to use too much of agrochemicals on their land causing their run off into local water-bodies and thus groundwater contamination (Abhilash and Singh, 2009).

Apart from this mono-cropping also relies on a limited number of crop cultivars grown on a large swathe of contiguous land area. In this case, particular pests and diseases tend to spread rapidly resulting large-scale destruction of the crop (Rusch *et al.,* 2016; Meehan *et al.,* 2011). Even if the crop isn't affected by pests and diseases, marketing such a large output results in a low price realization and low bargaining in terms of negotiating selling price. Attempts to tackle these issues by raising productivity require increased usage of inputs such as irrigation, fertilizers and agrochemicals. These pollute the environment and also place a burden on the limited natural resources of the cropping region (Rodell *et al.,* 2009; Singh and Singh, 2002).

In contrast, biodiversity provides numerous benefits including generation of much needed resources such as food, wood, fresh water, etc.; regulates changes in environment including climate regulation, pest/disease control, etc.; and provides aesthetic benefits in the form of landscape beauty, recreational aspects, cultural heritage and spiritual significance (Cardinale *et al.,* 2012). Biodiversity also known as "species diversity" or "species richness" refers to the presence of multiple types of organisms coexisting within the same biosphere. Hence there is a need to understand importance of crop variety in the present day agricultural systems. Moreover, promoting crop variety helps in promoting ecosystem services, besides an avenue for diversification of income streams.

This is particularly important for India since low agricultural incomes have resulted in widespread dissatisfaction, protests, and ample suicide cases by farmers. The issue has received widespread political attention, and recently the Indian Prime Minister, Mr. Narendra Modi, has declared the intention to double farmers' incomes in next seven years, by 2022. He has declared a seven-point programme; in which the last point is regarding the need to focus on supplementary income sources such as horticultural crops, livestock farming, etc. to diversify sources of incomes for farmers (NITI Aayog, 2017). Hence, it can be seen that crop diversification is a strategy with advantages for both the agriculturalists and the environment. The next section discusses some of the important NUS identified in the country and their uses.

NUS of India

India is one of the seventeen countries recognized internationally as "megadiverse" housing; a significant portion of the Earth's species. India houses around 10per cent of the planet's flora and fauna and have thousands of plant and animal species endemic to the region (Sarkar, 2011). Besides it also is home to several hitherto unknown but regionally well-adapted land races developed through arduous trial and error processes of thousands of years of agricultural practices. Research interest in such species, labelled as "underutilized", "neglected", or "orphan", has been on the rise in the recent decade.

It is very difficult to define NUS and many terms such as "neglected", "orphan", "underutilized", etc.; they are used interchangeably. However, the terms do not reflect any information in terms of geography (underutilized where?), social (underutilized by whom?) or economic (underutilized to what degree?) implications. With regard to geographical distribution, a crop species can be underutilized in one region and may not be in others. Similarly, for social implications, many crop species contribute to daily diet of millions of people (for example in sub-Saharan Africa) but their poor marketability may make them underutilized in economic terms (Stamp *et al.,* 2012; Padulosi *et al.,* 2002). There are also many neglected crops grown only in their centres of origin by traditional farmers but are very important for the subsistence of the local community. Some species may be distributed globally but occupy certain niches in the local ecology and also in the production-consumption systems (Gruere *et al.,* 2009). Although some confusion still remains with the definition of NUS; what is important is to understand cause of low level of use and/or neglect of certain crops to design ways for their improvement. The Global Facilitation Unit for Underutilized Species (GFUUS) identified 11 criteria defining NUS (Table 1). However, for this paper, the NUS are defined as crop species under-exploited for their contribution towards food security, health (nutritional/medicinal), income generation and environmental effects.

Table 1: Criteria for Characterizing a Species as NUS

• Require only limited external inputs for production
• Suitable for organic production
• Suitable for cultivation on marginal land (poor soil fertility, etc.)
• Suitable for stabilization of fragile ecosystems
• Fit into small-scale farming systems
• Possess traditional, local and/or regional importance
• Easy to store and process by resource-poor communities
• Market opportunities available
• Possess high nutritional and/or medicinal value
• Offer multiple uses
• Traditional knowledge

Source: GFUUS (2006)

Such species remain high potential source for fulfilling various goals, including food security, improving health outcomes, providing environmental sustainability and improving agricultural incomes. There is a multi-faceted need for research in these species including their genetic make-up, optimum cultivation techniques, distribution networks, and consumption practices. There is also a need to incorporate these crops within the larger agricultural system prevalent in the country such as the seed certification and provisioning system, the input financing system, etc. and to inform consumers regarding their benefits to expand market demand for them (Ebert, 2014).

In India, several species of food and medicinal plants are considered underutilized due to lack of their mainstream visibility (cultivated in specific regional pockets, and having limited consumption). Such plants include phalsa, jamun, custard-apple, amla, bel, ber, and tamarind. There are many other tropical fruits yet to be exploited at the national level and their genetic base explored and enhanced. These include barhal (*Artocarpus lakoocha*), chironji (*Buchanania lanzan*), dillenia (*Dillenia indica*), Makhana(*Euryale ferox*), manasari (*Mimusops elengi*), rose apple (*Syzygium jambos*), hogplum (*Spondia spinnata)* and tropical almond (*Terminalia catappa*) (Arora, 2014). While a complete and exhaustive list will be too long for inclusion here, a limited list is given in Table 2. Table 2 makes an important contribution to survival ability of poor people throughout the developing world due to their richness in micronutrients such as vitamins and minerals such as iron, zinc, etc. However despite their excellent potential for diversification of dietary pattern, they have not attracted significant attention of researchers regarding their development and incorporation into formal agricultural extension system.

Table 2: Neglected and Underutilised Species of India

Crop Species	Usage	Characteristic Region
Pseudo Cereals		
Grain Amaranth	High Protein, High Iron	Himalayan Belt
Buckwheat	High Protein, High Iron, Zinc and Selenium	Central North
Chenopods	High Protein, High Carotene	Gujarat ghats
Millets	Drought Tolerant	All regions, except North India
Oil seeds		
Perilla	Good for Cold	North-Eastern States
Paradise Tree	Insect Resistant	Odisha
Pulses		
Rice Bean	High Protein, Drought Tolerant	North-Eastern States
Faba Bean	High Protein, Substitute for Milk	North-western Plains
Adzuki Bean	High Protein, High Folate	Western Himalayas
Fruits		
Bael	Anti-oxidant, Stimulates Pancreas	Subtropical hills and plains regions
Jackfruit	Rich in Thiamin and Riboflavin	Tropical regions of India
Star Fruit	Rich in Vitamin C, Fibre	Southern states and Western coast of India
Karonda	Rich in Potassium, Anti-Bacterial	Himalayan region and Western Ghats

Indian cherry	Anti-Ulcer, Laxative	Himalayan region and Western Ghats
Kokam	Valuable Fat, Anti-Microbial	Western Ghats
Phalsa	Astringent, Good for Stomach ailments	Himalayan region
Vegetables		
Kankoda	Rich in Vitamins, Good for Lactating Women	Deccan Plateau
Atriplex	Rich in Vitamin E, Good for Animals	Saline Areas of Gujarat and Rajasthan
Tree Tomato	High in Pectin	Meghalaya and Sikkim
Bird-Eye Chili	Local Stimulant, Good for Stomach ailments	North-Eastern States
Chow-Chow (*Sechium Edule*)	Dissolving Kidney Stones, Arteriosclerosis and Hypertension	North-Eastern States
Kakrol	Ulcers, Piles, Liver Sores	Assam, Meghalaya and Manipur
Kartoli	Appetizer, Chest problems, Urinary Retention	Meghalaya and Tripura
Other Crops		
Jojoba	Acne, Psoriasis, Sunburn	North-western Plains
Guayule	Bio-Fuel, Feedstock for Synthetic Rubber	North-western Plains
Tumba	Jaundice, Rheumatism, Urinary Disease	Rajasthan and Gujarat
Makhana	High Protein, Helps in Cardiovascular Health	Northern part of Bihar

Source: Compiled by author from various sources including Rai *et al.* (2005), Thakur (2014), Joshi *et al.* (2002), Dua *et al.*(2009), etc.

Some of the issues faced in the spread of NUS crops include lack of ready availability of their cultivars, inadequate policies for encouraging their spread, limited interest among producers, absence of technical information such as package of practices and lack of consumer knowledge. These species are not able to compete commercially with major commodity crops and hence receive lesser interest from policy-makers, researchers and extension community.

In the Indian context, there is an additional issue of lack of documentation regarding number and extent of such species, due to lack of adequate ethno-botanical surveys and studies. While individual researchers have documented many species on discretionary basis, there is a need for more systematic surveys and studies. The first research efforts were led by the All India Coordinated Research Project (AICRP) on Under-utilized plants (UUP) in 1982 at the National Bureau of Plant Genetic Resources (NBPGR), New Delhi. This project aimed at documenting various underutilized crops and worked towards building a collection which could be used for their conservation. Later this project was renamed as the All India Research Network on Underutilized Crops, wherein more than 100,000 accessions could be collected for evaluation. Some other important studies in this regard were by Paroda (1979), Mal (1988), Paroda and Mal (1989), Joshi *et al.* (2002), Joshi (2005), etc. However despite all these, only a tip of the iceberg has been explored; much remains to be searched.

Biotechnology to Promote NUS

Although NUS possess some beneficial properties, their yields are generally low making them unattractive to farmers (Nelson *et al.,* 2004). Increasing yield potential in major crops has largely been attributed to aggressive breeding and biotechnology programmes. Advances in plant genomics now provide breeders advanced tools that allow study of whole genome to accelerate breeding efforts. Research should focus on sequencing genomes of priority NUS and applying advanced translational techniques using model crops (Cannon *et al.,* 2009). NUS are important germplasm resource for future crop improvement for nutrient dense and stress tolerant crops (Castañeda-Alvarez *et al.,* 2016). Thus, genetic sequencing of NUS would aid in identifying genes that confer beneficial traits for crop improvement of other species.

There are four main functionalities of biotechnology that are routinely used in breeding programmes. These are: (1) Tissue culture and Micropropagation, (2) DNA fingerprinting for genetic diversity assessment, (3) Marker-assisted selection and related genomics, proteomics, transcriptomics, metabolomics, and (4) Production of genetically modified organisms (GMOs) or transgenic (Jain and Gupta, 2013)

The review on application of different biotechnological tools has been low, except in the area of micropropagation. Genetic diversity, genetic maps, MAS and genomics were done more on trees. For example, the entire *Populus* genome has been sequenced, and public and private EST libraries for conifers have more than one million entries (Dawson *et al.,* 2009b). Gene discovery and association genetic studies are likely to become important in the near future. For GM, most of the work has been done on development of protocols rather than on direct deployment activities (Bhattacharjee, 2009). A few examples of biotechnology research work on underutilized crops are as follows.

Tissue Culture and Micropropagation

Tissue culture is a process of overriding reproductive barriers between distantly related crop relatives, and micropropagation is an *in-vitro* process by which vegetative multiplication is carried out through rooting of micro-cuttings, somatic embryogenesis or organogenesis. It can be used to clone larger numbers of plants from genotypes of particularly desirable characteristics. Micropropagation is also used to eliminate diseases from germplasm and as a convenient method for *in- vitro* transfer of breeding material (Jain and Gupta, 2013; Goodman, 2004).

A substantial number of activities including in-vitro propagation (microcuttings or somatic embryogenesis) have been undertaken on a number of species such as *Abelmoschus manihot* (bele), *Aegle marmelos* (bael), *Coriandrum sativum* (coriander), *Ipomoea batatas* (sweet- potato), *Lablab purpureus* (hyacinth-bean), *Plectranthus esculentus* (Livingstone potato), *Ricinodendron heudelotii* and *Sesamum indicum* (sesame) (Dawson *et al.,* 2009a; Giuliani, 2012). There have been reports on exchange of knowledge between institutions to produce disease-free germplasm. For example, ARC-Roodeplaat has used tissue-culture techniques to produce virus-free planting material of *Ipomoea batatas* and to rapidly reintroduce *Plectranthus esculentus* to small groups of farmers in areas of South Africa from which the species was lost. In China's Shandong Province, a micropropagation project distributed virus-free *Ipomoea batatas* that led to a 30per cent increase in yield and adoption across 500,000 ha (Lidder and Sonnino, 2012).

DNA Fingerprinting and Genetic Diversity

Genotypic characterization using molecular markers to assess genetic diversity is an important part of pre-breeding programme. It also plays an important role in developing conservation strategies such as identification of duplicates or mismatches in rationalizing *ex situ* germplasm collection. Molecular markers can also be used to certify varieties, determine presence or absence of diseases and assess reproductive biology of species, among other applications (Gupta *et al.,* 2002; Khan *et al.,* 2016).

A large number of NUS have been characterized using different types of molecular markers to assess genetic diversity. Molecular diversity has been assessed within and among populations of *Adansonia digitata* (baobab), *Bactris gasipaes* (peach palm), *Vitellaria paradoxa* (shea nut); among accessions of *Artocarpus heterophyllus* (jackfruit), *Sesamum indicum* (Sesame); and among accessions of different related species of *Eleusine coracana* (finger millet), and *Ipomoea batatas* (sweet- potato) (Dawson *et al.,* 2009a; Dawson *et al.,* 2009b, Jamnadass *et al.,* 2009). Molecular fingerprinting has also been used to rationalize germplasm collections. Molecular profiles of groups of accessions, which appear morphologically identical have been compared to identify duplicates in the collection. These approaches are being used to rationalize genebanks of NUS of sweet-potato, cassava and yam; of Eleusine coracana and Ceratonia siliqua (locust bean gum) (Lidder and Sonnino, 2012).

Genetic Maps, Marker-assisted Selection (MAS) and Other ‘omics’

A lot of research has developed linkage maps and understood association between markers and genes controlling proportion of variations in a trait. By establishing an association, markers can be used to understand complex traits and assist in selection called MAS; making the process much faster compared with the conventional breeding methods (Phogat *et al.,* 2006; Thorup *et al.,* 2000).

Genomics, a ‘second-generation’ biotechnology tool, is used to identify genes and their functions in an organism. By revealing gene sequence similarities and common arrangements of genes (synteny), genomics raises prospect of information gathered on a species, which may benefit work on others. Genomics involves a wide range of activities, including the production of expressed sequence tags (ESTs), genome sequencing, gene function determination, comparative analysis (exploring synteny, cross-identification of candidate genes, etc.), physical mapping, through use of another discipline called bioinformatics. The information gathered is then incorporated into selection and breeding programmes. Proteomics (the study of proteins) and metabolomics (the study of metabolites) can be combined together with genomics into a biotechnology meta-analysis to resolve many issues, which cannot be addressed through conventional breeding approaches (Cooper *et al.,* 2004; Bennetzen, 2002; Bennetzen, 1997).

Genetic/linkage maps have been developed of *Chenopodium quinoa* (quinoa). There has been recent identification of EST sequences in a few species: *Cajanus cajan*, *Ceratonia siliqua*, *Chenopodium quinoa*, *Diospyros kaki, Eleusine coracana*, *Eragrostis* tef, *Ipomoea batatas*, *Sesamum indicum* and *Setaria italica* to form basis for MAS programme in these species (Gimode *et al.,* 2016). In *Manihot esculenta*, *Cajanus cajan* and *Setaria italica*, identification of markers for drought stress were targeted, while in Eleusine coracana both salt tolerance and drought stress were considered with a view to enhance production in marginal and degraded environments. Yu (2009) reported genomic SSRs for 18 NUS, which could be used for further genetic analyses of them.

Production of GM or Transgenic Organisms

GM is use of recombinant DNA and asexual gene transfer methods to alter structure or expression of specific genes and traits in an organism. The product of GM, a transgenic, is one that has been transformed by insertion of one or more genes, called 'transgenes', from another, often unrelated, organism. Transferred genes may theoretically contribute to a range of properties such as resistance/tolerance to biotic and abiotic factors, improved nutritional status, and better management options (such as reduced tillage) (Krishna *et al.,* 2009).

GM activities in NUS include taking genes involved in fatty acid synthesis in *Coriandrum sativum* and *Garcinia mangostena* (mangosteen) to transform *Arabidopsis thaliana* and oil seed rape (canola), respectively, to understand metabolic pathways of seed oil production. Salt tolerance related to sorbitol accumulation was studied in *Diospyros kaki*, which was transformed with a *Malus domestica* (apple) gene (Moller, 2005).

Transgenic *Eleusine coracana* was produced by different approaches, and an introduced gene from *Porteresia coarctata*, encoding a serinerich-protein, was shown to increase salt tolerance (Carra *et al.,* 2012). *Leucaena leucocephala* was transformed with a gene from aspen that down-regulated lignin biosynthesis, and may have a future role in the use of species for pulp and paper manufacture as well as in fodder production (Lidder and Sonnino, 2012).

Biotechnology can be extremely advantageous for improvement of NUS; however major concerns include level of investments and need for interventions being decentralized, participatory, and multidisciplinary with open access to germplasm and information. Also to promote sustainability, farmer's existing practices should be given importance rather than imposing new management methods (Jaenicke and Höschle-Zeledon, 2006). In many cases, biotechnology can be applied only through centralized facilities. In fact, research is often undertaken in developed countries (e.g. in Europe and North America) and the underutilized crop is actually grown in developing countries (e.g. in Africa, Asia or Latin America). In this case, there is a danger that farmers may lose rights over genetic resources of underutilized plants that they once held. If the biotechnological tool is used with commercial interests, then intellectual property rights protection to biotechnology processes and modifications are likely and may impede benefits to poor farmers (Spielman *et al.,* 2006).

Efforts Undertaken by the ICAR to Promote NUS

The Indian Council of Agricultural Research (ICAR) is the nodal body for agricultural research in the country. As parts of its efforts towards improving agricultural production in the country, the organization is involved in cataloguing and conservation of plants and other natural resources having potential to improve agricultural production in future. One of the agencies involved in these efforts is the National Bureau of Plant Genetic Resources (NBPGR), which is implementing several projects to catalogue plant biodiversity, setup information networks on plant genetic resources, evaluate new plant species and identify potential future crops, promote *in-situ* conservation efforts for landraces by setting- up local seed systems and community seed banks, and manage any intellectual property rights (IPR) based issues arising out of these activities(Table 3).

Table 3: Status of Base Collections in National Genebank at the NBPGR

Crop / Crop Group	Number of accessions conserved
Cereals	**1,64,041**
Paddy	1,09,153
Wheat	33,475
Maize	11,179
Others	10,234
Millets	**58,557**
Sorghum	25,926
Pearl millet	8,156
Minor millet	24,475
Forages	**6,984**
Oats	1,383
Clover	597
Teff	297
Marvel grass	334
Others	4,373
Pseudo Cereals	**7,410**
Amaranth	6,025
Buckwheat	1,020
Others	365
Legumes	**66,222**
Chickpea	14,699
Pigeonpea	11,617
Mung bean	4,224
Pea	4,198
Cowpea	3,842
French Bean	3,985
Clusterbean	4,315

Table 3 continued...

...Table 3 continued

Horsegram	3,066
Ricebean	2,171
Others	14,105
Oilseeds	**58,757**
Groundnut	13,832
Oilseed brassica	11,369
Safflower	7,365
Sesame	10,163
Soybean	4,080
Sunflower	1,402
Others	10,546
Fibre	**15,674**
Cotton	10,030
Jute	3,290
Mesta	2,016
Others	338
Vegetables	**26,278**
Tomato	2,595
Brinjal	4,456
Chilli	4,959
Okra	3,711
Onion	1,131
Others	9,426
Fruits & Nuts	**275**
Buchanania	97
Others	178
Medicinal & Aromatic Plants & Narcotics	**8,019**
Opium poppy	432
Ocimum	608

Table 3 continued...

...Table 3 continued

Tobacco	2,270
Others	4,709
Ornamental	**656**
Marigold	364
Others	292
Spices & Condiments	**3,114**
Coriander	1,055
Fenugreek	1,304
Others	755
Agroforestry	**1,646**
Sesbania	647
Others	999
Duplicate Safety Samples (Lentil, Pigeonpea)	**10,235**
Trail Material (Wheat, Barley)	**10,771**
Total	**4,38,639**

Source: NBPGR (2018).

As can be seen in Table 3, the accessions for the three principal crops (rice, maize, and wheat) number is the highest, while the accessions for the NUS such as millets, forages, pseudo cereals, etc. are much lower. This is both a function of less efforts dedicated to cultivating the NUS and lesser resources dedicated to research projects focusing on NUS.

One of the major projects undertaken by the NBPGR for the promotion of NUS is the 'All India Coordinated Research Network on Potential Crops' (AICRNPC). This project focuses on a few promising NUS with the intent of developing superior genotypes for different agro-climatic regions and to standardize package of practices for cultivation of these crops (Table 4).

Table 4: Focus Crops for the AICRNPC

FOOD CROPS
PSEUDOCEREALS
Grain amaranth (*Amaranthus* spp.)
Buckwheat (*Fagopyrum* spp.
Chenopodium (*Chenopodium* spp.)
Job's tear (*Coix lacryma-jobi*)
FOOD LEGUMES/ PULSES
Rice bean (*Vigna umbellata*)
Adzuki bean (*Vigna angularis*)
Faba bean (*Vicia faba*)
Winged bean (*Psophocarpus tetragonolobus*)
OILSEEDS
Perilla (*Perilla frutescens*)
Paradise tree (*Simarouba glauca)*
VEGETABLES
Kankoda (*Momordica dioica*)
Winged bean (*Psophocarpus tetragonolobus*)
FODDER CROPS
Amaranth (*Amaranthus* spp.)
Salt bush (*Atriplex* spp.)
Fodder tree species
ENERGY, HYDROCARBON AND INDUSTRIAL PLANTS
Jojoba (*Simmondsia chinensis*)
Guayule (*Parthenium argentatum*)
Jatropha (*Jatropha curcas*)
Tumba (*Citrullus colocynthis*)
Paradise Tree (*Siimarouba glauca*)
Perilla (*Perilla frutescens*)

Source: NBPGR (2018).

Table 4: Focus Crops for the AICRNPC

FOOD CROPS
PSEUDOCEREALS
Grain amaranth (*Amaranthus* spp.)
Buckwheat (*Fagopyrum* spp.
Chenopodium (*Chenopodium* spp.)
Job's tear (*Coix lacryma-jobi*)
FOOD LEGUMES/ PULSES
Rice bean (*Vigna umbellata*)
Adzuki bean (*Vigna angularis*)
Faba bean (*Vicia faba*)
Winged bean (*Psophocarpus tetragonolobus*)
OILSEEDS
Perilla (*Perilla frutescens*)
Paradise tree (*Simarouba glauca)*
VEGETABLES
Kankoda (*Momordica dioica*)
Winged bean (*Psophocarpus tetragonolobus*)
FODDER CROPS
Amaranth (*Amaranthus* spp.)
Salt bush (*Atriplex* spp.)
Fodder tree species
ENERGY, HYDROCARBON AND INDUSTRIAL PLANTS
Jojoba (*Simmondsia chinensis*)
Guayule (*Parthenium argentatum*)
Jatropha (*Jatropha curcas*)
Tumba (*Citrullus colocynthis*)
Paradise Tree (*Siimarouba glauca*)
Perilla (*Perilla frutescens*)

Source: NBPGR (2018).

This project has been in operation from the 1980s onwards. The financial outlay for this programme is as in Table 5.

Table 5: Financial Outlay on the AICRNPC (INR Millions)

	VI Plan	VII Plan	VIII Plan	IX Plan	X Plan	XI Plan
Pay and Allowance	1.3156	2.109	12.679	20.653	48.493	82.139
T.A.	0.176	0.136	0.825	1.05	2.398	3.28
Contingency	0.43	0.552	2.91	2.94	11.058	15.415
Non-recurring contingency	0.263	0.237	2.065	0.742	2.15	3.278
Total	**2.185**	**3.034**	**18.479**	**34.107**	**64.099**	**104.112**
ICAR Share	1.941	2.3	15.044	28.051	49.201	79.5
Universities Share	0.244	0.734	3.435	6.056	14.898	24.612

Source: NBPGR (2018).

Table 6: Salient Achievements of the AICRNPC (INR Millions

Multilocationtrials/ Experiments conducted	2008-09	2009-10	2010-11	2011-12	2012-13
Breeding	63	50	48	49	57
Germplasm	38	50	55	54	53
Agronomy	19	21	15	19	41
Quality evaluation	7	15	15	18	12
Varieties released	2	-	1	-	1 (Id.)
Germplasm evaluated (Acc.)	800	1402	1741	1038	770
Crosses attempted to generate variability	85	95	95	105	125

Source: NBPGR (2018).

Salient achievements of the AICRNPC are presented in Table 6.

Table 7: Varieties released by the AICRNPC

Crop	Varieties	Year of ID/ release	Economic product	Average yield (q/ha)	Traits	Recommended areas
GRAIN AMARANTH						
1	SKNA 21 (GA-3)	2008	Grain	12.58	High grain yield	States of Gujarat and Jharkhand
2	RMA- 4	2008	Grain	13.9	High grain yield	States of Rajasthan, Jharkhand and Orissa
3	RMA-7	2010	Grain	14.66	High grain yield	Rajasthan, Gujarat, Orissa, Maharashtra, Haryana, Delhi states
RICE BEAN						
1	VRB-3	2012	Grain	17.08	High grain yield	North-West and North-East Hill Regions of India

Source: NBPGR (2018)

However, in terms of output, the AICRNPC has had few successes. They have released only four varieties for commercial cultivation. (See Table 7)

Apart from this, the NBPGR also implements other projects on a piece-meal basis through its regional centres and departments.

Policy Changes Required

The adoption and incorporation of underutilized species face several obstacles as has been explained earlier. In order to overcome these challenges we need a coordinated policy response that tackles the challenge on multiple fronts, in order to successfully resolve the issue. Policy responses need to be coordinated across research centres, horticultural policies of the government, extension efforts, marketing support provided to farmers, and other supplementary infrastructure being used within this sector. Only a coordinated approach can break the lock-in situation created by the current set of policies.

On the research front, we need policies such as:

- Detailed study of current research on underutilized species to identify gaps and systematically plan for future studies.
- Training of skilled workers to conduct appropriate genetic studies required. Also incentivizing collection and classification of new specimen on a large and systematic basis to uncover new and useful species.
- Conducting experiments to optimize breeding, agronomy and the quality of the new species discovered through exploratory studies. Any improved varieties developed in this process is to be released in a planned way to the larger community of cultivators to ensure maximum exposure.
- Using increased technology such as Information Technology (IT), to ensure better database structuring, monitoring, documentation, and diffusion of any and all research output to the target audience.
- Conducting regular interactions with traditional farmers from various ethnic communities including those living in remote areas to document their knowledge and cultivation practices as well as germplasm material which they use. Also conducting regular ethno-botanical surveys amongst the forest dwelling tribals and people living in other unexplored areas to uncover previously undiscovered useful species.
- Conducting regular workshops, training meets and discussion sessions to ensure that all members of the system become aware of and are able to address evolving Intellectual Property Rights (IPR) issues that arise from development, diffusion, and use of new plant species. Such issues will include aspects like sharing of access and benefits, transparency, legal agreements for resource sharing, and equity.

On the Horticultural Policy front we need policies such as:

- Defining a priority based funding programme for advanced research on selected underutilized species. Such programme needs to focus on conservation and use of species at the national level and to supplement these species within the current crop basket being used for subsistence and commercial purpose.

- Conservation efforts to take a multi-pronged approach with both in-situ and on-farm conservation of underutilized species. This can be complemented with ex-situ conservation approach using long-term seed storage vaults such as the one at the National Bureau of Plant Genetic Resources (NBPGR), etc. However field genebanks in the form of living crops grown on the ground are the best conservation and development approaches.
- The current usage of wild species to be complemented by incentivizing homestead cultivation of the same so that overexploitation of natural resources doesn't occur.
- In addition to the above afforestation efforts; re-population of degraded forests is to be encouraged to maintain and further enrich species diversity and horticultural basket.
- Ensuring the spread of Indigenous Traditional Knowledge (ITK) with regard to the sustainable use and collection of various underutilized species.

On the research and extension front policies that need to be made include:

- Raising awareness regarding underutilized species among the cultivation community to ensure that practitioner interest is raised. Extension resources are to be spent on awareness building workshops and exhibitions regarding various horticultural crops (fruits, vegetables, and herbs) and their diversity of uses as food and medicine. These efforts can be supplemented by the utilization of mass media resources such as the print media, TV, radio, and other IT- based platforms, such as mobile phones, SMS alert services, etc.
- Research related to tissue culture and micropropagation, DNA fingerprinting, genomics, bioinformatics, and other biotechnological studies of NUS needs to be stepped up. If transgenics are the future then adequate studies regarding their safety need to be conducted.
- Techniques related to multiplication of planting material, and distribution of the same is to be encouraged among the cultivation community.

- Systematic crop planning procedures are to be developed keeping in mind local conditions including endemic species, agro-climatic details, and commercial potential.
- Packages of practices that are optimized for different locations are to be developed for various species to realize superior yield, high nutritive values, achieve high market demand, etc. This will help in easing diffusion of new species in different places.
- Mechanisms need to be evolved to incorporate new species within the existing seed supply infrastructure to ensure that promising varieties are taken to the next level and good quality of seed material, planting material, or *in-vitro*/ tissue cultured material is made available to cultivators. This would ensure diffusion at a mass level and boost production levels, promote domestic markets and increase the incomes of the cultivating households.

To improve the marketing support provided to farmers we need policies that include:

- Information regarding market pricing and infrastructural support for better market access for perishable products.
- Development of processing units to improve shelf life of perishable products. Also to provide employment opportunities to the rural population for better income generation.
- Infrastructure support in terms of market development, building of marketing networks, transportation facilities, and better communication.
- Special export-oriented programmes to focus on production of high-value items such as exotic vegetables, spices, fruits and fruit juices, canned fruit pulp, etc.
- Apart from the above, other supplementary policies such as provision of special training, field visits, subsidised agricultural machinery, etc. need to be provided after due study and feedback from the cultivators.

The current commercial focus on a select number of crops and their continual mono-cropping is a cause for worry. As more and more agricultural resources get directed to these few crops, many other useful crop species would experience genetic erosion. Already many landraces are on the verge of disappearing due to the perception as unviable or less profitable.

In such a case, it is required that innovative technologies focusing on both cultivation and post-harvest management are imparted to the cultivators to enable them to grow these underutilized species. This will improve both bio-diversity and increase rural incomes.

Conclusion and Way Forward

It is clear that the current reliance of the agricultural and food systems on a handful of crop species and even within them a few selective cultivars is unsustainable. Not only does this make the system more vulnerable to pests and diseases, but also ineffective in terms of nutritional, environmental and economic goals. The lack of ecological diversity affects other factors like climate, soil health, pest control, etc. and makes the population more vulnerable to malnutrition and diseases. Hence it is important to be able to grow a large and diverse basket of crops to preserve ecological balance and human life in a sustainable manner.

In India we have a number of crop species which we can consider to have the potential for further commercial scaling. These species are endemic to local conditions and hence well adapted to survive local stresses both biotic and abiotic. Moreover, they are a good source of micronutrients such as vitamins, iron, etc. while possessing medicinal uses also. They are grown in a number of regions and by several ethnic communities, but are on the verge of being lost due to privileging of "modern" and scientific knowledge systems over Indigenous Traditional Knowledge systems (Rai *et al.,* 2005; etc.). Due to these disadvantages it is imperative that the research, extension, and policy systems recognize the importance of these species and work towards their incorporation in the formal agricultural systems.

Biotechnology can play a significant role here both in cultivation and conservation of these species. Advanced tools like tissue culture, micropropagation, DNA fingerprinting, genomic studies, marker based selections, bioinformatics, and transgenic techniques can speed up breeding programmes resulting in an aggressive flow of new crops agro-ecologically suited, commercially viable and offering ecosystem services. In this regard, the ICAR through the NBPGR has undertaken a significant effort in the form of the AICRNPC. However, the outputs of this project have not been able to break the cycle of rice, wheat and maize farming using mono-cropping techniques.

To break the above cycle and introduce new crop species into the agricultural system, it is necessary to take a multi-faceted approach with policy measures addressing multiple issues at different fronts. The most skewed areas that need attention are research system, the horticultural policy system, the extension system, the marketing support system, along with a host of supplementary systems that affect agricultural infrastructure. We are on the verge of losing many important landraces which have been developed over many generations, because cultivators perceive them to be unviable. To break this perception, the entire agricultural system needs to work together to make new crop species viable and a competitive avenue for diversification. If we can achieve this we can combat one of the most pervasive environmental problems of our times, the decline in bio-diversity, along with a sustainable means of economic growth.

In terms of further research we need more studies regarding underutilized species including their responses to biotechnological tools and techniques, and more studies examining the impact of ICAR research institutes or projects focusing on neglected and underutilized species, and more looking at policy level frameworks that can deal with multi-faceted problems by looking at the complex ways in which policies interact with each other to produce certain outcomes.

References

Abhilash, P. C., & Singh, N. 2009. Pesticide use and application: an Indian scenario. *Journal of hazardous materials*, *165*(1-3), 1-12.

Archak, S., Tyagi, R. K., Agrawal, A., & Mathur, P. N. 2017. Delhi Declaration provides a Roadmap for Agrobiodiversity Management. *Indian Journal of Plant Genetic Resources*, *30*(1), 88-91.

Arora, R.K. 2014. Diversity in underutilized plant species - an Asia-Pacific perspective. In: B. International (ed.), Bioversity International, New Delhi, India.

Bala Ravi, S., T.K. Hrideek, A.T.K. Kumar, T.R. Prabhakaran, B. Mal and S. Padulosi. 2010. Mobilizing neglected and underutilized crops to strengthen food security and alleviate poverty in India. *Indian Journal of Plant Genetic Resources*, *23*, 110–116.

Bennetzen, J. 2002. Opening the door to comparative plant biology. *Science*, *296*(5565), 60-63.

Bennetzen, J. L., & Freeling, M. 1997. The unified grass genome: synergy in synteny. *Genome Research*, *7*(4), 301-306.

Bhattacharjee, R. (2009). Harnessing biotechnology for conservation and increased utilization of orphan crops. *Atdf Journal*, *6*, 24-32.

Brush, S. B., Taylor, J. E., & Bellon, M. R. 1992. Technology adoption and biological diversity in Andean potato agriculture. *Journal of Development Economics*, *39*(2), 365-387.

Cannon, S. B., May, G. D., & Jackson, S. A. 2009. Three sequenced legume genomes and many crop species: rich opportunities for translational genomics. *Plantphysiology*, *151*(3), 970-977.

Cardinale, B. J.; E. Duffy, A. Gonzalez, D.U. Hooper, C. Perrings, P. Venail, A. Narwani, G.M. Mace, D. Tilman, D.A. Wardle, A.P. Kinzig, G.C. Daily, M. Loreau, J.B. Grace, A. Larigauderie, D. Srivastava and S. Naeem. 2012. Biodiversity loss and its impact on humanity. *Nature, 486*(7401), pp 59-67

Carra, A., Sajeva, M., Abbate, L., Siragusa, M., Sottile, F., &Carimi, F. 2012. In vitro plant regeneration of caper (Capparisspinosa L.) from floral explants and genetic stability of regenerants. *Plant Cell, Tissue and Organ Culture (PCTOC)*, *109*(2), 373-381.

Castañeda-Álvarez, N. P., Khoury, C. K., Achicanoy, H. A., Bernau, V., Dempewolf, H., Eastwood, R. J., ... & Müller, J. V. 2016. Global conservation priorities for crop wild relatives. *Nature plants*, *2*(4), 16022.

Cooper, M., Smith, O. S., Graham, G., & Lane, A. 2004. Genomics, genetics, and plant breeding: a private sector perspective. *Crop Science*, *44*(6), 1907.

Dawson, I. K., Hedley, P. E., Guarino, L., &Jaenicke, H. 2009a. Does biotechnology have a role in the promotion of underutilisedcrops? *Food Policy*, *34*(4), 319-328.

Dawson, I. K., Lengkeek, A., Weber, J. C., &Jamnadass, R. 2009bManaging genetic variation in tropical trees: linking knowledge with action in agroforestry ecosystems for improved conservation and enhanced livelihoods. *Biodiversity and conservation*, *18*(4), 969.

Dua, R. P., H.L. Paiger, B.S. Phogat and S.K. Sharma. 2009. *Underutilized crops: Improved varieties and cultivation practices.* New Delhi: NBPGR

Ebert, A. W. 2014. Potential of underutilized traditional vegetables and legume crops to contribute to food and nutritional security, income and more sustainable production systems. *Sustainability*, *6*(1), 319-335.

Evans, P. 2014. Development as institutional change: the pitfalls of monocropping and the potentials of deliberation. *Studies in comparative international development*, *38*(4), 30-52.

Galt, R. E. 2008. Pesticides in export and domestic agriculture: Reconsidering market orientation and pesticide use in Costa Rica. *Geoforum*, *39*(3), 1378-1392.

GFUUS. 2006. "What do we mean when we talk about Underutilized species". *Global Facilitation Unit for Underutilized Species* <http://www.underutilized-species.org/spotlight/what_are_underutilized_species.html> (Last accessed on 24/06/2017)

Giuliani, A. 2012. Study context: the potential of neglected and underutilized species to contribute to livelihoods. In *Developing Markets for Agrobiodiversity* (pp. 15-23). Routledge.

Gonzalez, C. G. 2011. Climate change, food security, and agrobiodiversity: Toward a just, resilient, and sustainable food system. *Fordham Environmental Law Review*, 493-522.

Goodman, M. M. 2004. Plant breeding requirements for applied molecular biology. *Crop Science*, *44*(6), 1913.

Gruère, G., Nagarajan, L., & King, E. O. 2009. The role of collective action in the marketing of underutilized plant species: Lessons from a case study on minor millets in South India. *Food Policy*, *34*(1), 39-45.

Gupta, P. K., Varshney, R. K., & Prasad, M. 2002. Molecular markers: principles and methodology. In *Molecular techniques in crop improvement* (pp. 9-54). Springer, Dordrecht.

Hussein, M. Y., & Samad, N. A. 1993. Intercropping chilli with maize or brinjal to suppress populations of Aphis gossypiiGlov., and transmission of chilli viruses. *International journal of pest management*, *39*(2), 216-222.

Jaenicke, H., &Höschle-Zeledon, I. 2006. *Strategic Framework for Underutilized Plant Species Research and Development: With Special Reference to Asia and the Pacific, and to Sub-Saharan Africa*. Bioversity International.

Jain, S. M., & Gupta, S. D. 2013. *Biotechnology of neglected and underutilized crops*. Berlin, Germany: Springer.

Jamnadass, R., Lowe, A., & Dawson, I. K. 2009. Molecular markers and the management of tropical trees: the case of indigenous fruits. *Tropical Plant Biology*, *2*(1), 1-12.

Joshi, V. 2005. Some promising under utilized industrial crops for cultivation on wastelands of India. *Natural Product Radiance*, *4*(5), 396-404.

Joshi, V., P.L. Gautam, B. Mal, G.D. Sharma and S. Kochhar. 2002. "Conservation and use of underutilized crops: An Indian perspective." in J.M.M. Engels, V.R. Rao, A.H.D. Brown and M.T. Jackson (eds.), *Managing Plant Genetic Diversity*, IPGRI, Rome, Italy

Khan, F., Azman, R., Chai, H. H., Mayes, S., & Lu, C. 2016. Genomic and transcriptomic approaches towards the genetic improvement of an underutilised crops: The case of Bambara groundnut. *African Crop Science Journal*, *24*(4), 429-458.

Kotschi, J. 2007. Agricultural biodiversity is essential for adapting to climate change. *GAIA-Ecological Perspectives for Science and Society*, *16*(2), 98-101.

Krishna, V., Zilberman, D., & Qaim, M. 2009. Transgenic technology adoption and on-farm varietal diversity. In *International Association of Agricultural Economists Conference. Beijing, China*.

Lidder, P., & Sonnino, A. 2012. Biotechnologies for the management of genetic resources for food and agriculture. In *Advances in genetics* (Vol. 78, pp. 1-167). Academic Press.

Mabhaudhi, T., Chimonyo, V. G., Chibarabada, T. P., & Modi, A. T. 2017. Developing a Roadmap for Improving Neglected and Underutilized Crops: A Case Study of South Africa. *Frontiers in plant science*, *8*, 2143.

Mal, B. 1988. Underutilized plants programme in India–concepts and future perspective. In *Life Support Species: Diversity and Conservation. Proceedings of the CCS/ICAR International Workshop on Maintenance and Evaluation of Life Support Species in Asia and the Pacific Region* (pp. 4-7).

Meehan, T. D., Werling, B. P., Landis, D. A., &Gratton, C. 2011. Agricultural landscape simplification and insecticide use in the Midwestern United States. *Proceedings of the National Academy of Sciences*, *108*(28), 11500-11505.

Møller, B. L. 2005. Plant biotechnology in Europe: a changing environment and landscape. *Trends in plant science*, *10*(12), 562-564.

NBPGR. 2018. “All India Coordinated Research Network on Potential Crops”. National Bureau of Plant Genetic Resources. <http://www.nbpgr.ernet.in/AICRN_on_PC.aspx> (Last accessed on 24/06/2017).

Nelson, R. J., Naylor, R. L., &Jahn, M. M. 2004. The role of genomics research in improvement of” orphan” crops. *Crop Science*, *44*(6), 1901.

NITI Aayog. 2017. “Doubling Farmers’ Income Rationale, Strategy, Prospects and Action Plan”.<http://eprints.cmfri.org.in/12621/1/Doubling%20Farmers%27%20Income_2017_Ramesh%20Chand_NITI%20AYOG.pdf> (Last accessed on 25/06/2017).

Padulosi, S., Hodgkin, T., Williams, J. T., &Haq, N. 2002. 30 Underutilized crops: trends, challenges and opportunities in the 21st century. *Managing plant genetic diversity*, 323.

Paroda, R. S. 1979. Plant resource of Indian arid zones for industrial uses. *Arid land plant resources. Inter CASLAS, Texas*, 261-281.

Paroda, R. S., & B. Mal. 1989. New plant sources for food and industry in India. In: GE Wickens, N. Haq and P. Day (eds),*New Crops for Food and Industry,* Chapman and Hall, London, 135-149.

Paroda, R.S., Tyagi, R.K., Mathur, P.N., Agrawal, A., Archak, S., Agrawal, R.C., Dsouza, S., (Editors) . 2017. *Proceedings of the ‘1st International Agrobiodiversity Congress: Science, Technology and Partnership’*, New Delhi, India, November 6-9, 2016. Indian Society of Plant Genetic Resources, New Delhi and Bioversity International, Rome, 152 p.

Phogat, B. S., Dua, R. P., & Arora, R. K. 2006. Germplasm Introduction of Underutilized and New Crops. *Indian Journal of Plant Genetic Resources*, *19*(3), 404-417.

Prescott-Allen, R., & Prescott-Allen, C. 1990. How many plants feed the world. *Conservation Biology*, *4*, 365-374.

Rai, N., B.S. Asati, R.K. Patel, K.K. Patel and D.S. Yadav. 2005. Underutilized horticultural crops in north eastern region. *ENVIS Bulletin Himalayan Ecology*, *13*, 46-52.

Rodell, M., Velicogna, I., &Famiglietti, J. S. 2009. Satellite-based estimates of groundwater depletion in India. *Nature*, *460*(7258), 999.

Rusch, A., Chaplin-Kramer, R., Gardiner, M. M., Hawro, V., Holland, J., Landis, D.&Woltz, M. 2016. Agricultural landscape simplification reduces natural pest control: a quantitative synthesis. *Agriculture, Ecosystems & Environment*, *221*, 198-204.

Sarkar, J. 2011. REDD, REDD+ and India. *Current Science*, *101*(3), 265-265.

Singh, D. K., & Singh, A. K. 2002. Groundwater situation in India: Problems and perspective. *International Journal of Water Resources Development*, *18*(4), 563-580.

Spielman, D. J., Cohen, J. I., & Zambrano, P. 2006. Will Agbiotech Applications Reach Marginalized Farmers? Evidence from Developing Countries. *Agbioforum*, *9*(1), 1522-936X.

Stamp, P., Messmer, R., & Walter, A. 2012. Competitive underutilized crops will depend on the state funding of breeding programmes: an opinion on the example of Europe. *Plant breeding*, *131*(4), 461-464.

Thakur, M. 2014. Underutilized food crops: treasure for the future India. *Food Science Research Journal*, *5*(2), 174-183.

Thorup, T. A., Tanyolac, B., Livingstone, K. D., Popovsky, S., Paran, I., & Jahn, M. 2000. Candidate gene analysis of organ pigmentation loci in the Solanaceae. *Proceedings of the National Academy of Sciences*, *97*(21), 11192-11197.

Yu, J. W., Dixit, A., Ma, K. H., Chung, J. W., & Park, Y. J. 2009. A study on relative abundance, composition and length variation of microsatellites in 18 underutilized crop species. *Genetic resources and crop evolution*, *56*(2), 237-246.

RIS
Research and Information System
for Developing Countries
विकासशील देशों की अनुसंधान एवं सूचना प्रणाली

Asian Biotechnology and Development Review
Vol. 20 No. 1&2, pp 89-97

Regulating Genome Edited Crops and European Court of Justice Ruling

K.Ravi Srinivas*

Abstract: Regulating Genome Edited Crops (GEC) is emerging as an important issue as such crops is expected to be cultivated commercially in many countries within the next few years. GEC are not Genetically Modified Crops because there is no insertion of foreign gene or DNA in them and the process of genome editing does not involve adding foreign genetic elements in them. But the European Court of Justice in its ruling given in July 2018 has declared that GEC should be regulated as GM crops. This has resulted in controversy as it is feared that if GEC are to be treated as GMOs it would create regulatory hurdles and confusion among public. This note discusses the issues in regulating Genome Edited Crops, in light of this decision

Keywords: Genome Edited Crops, CRISPR, European Court of Justice, Regulation, GMO

Introduction

To state that genome editing is emerging as the most important application in biotechnology in recent times would be no exaggeration. It is equally true that it has raised hopes and concerns among stakeholders. One reason is that its scope is wide and it provides new tools that are more precise and time taken to develop applications and products is considerably shorter. Another reason is that technology is advancing so fast that whether the regulatory system can keep pace with this to regulate the technology, efficiently and to avoid risks and adverse consequences. Regarding agricultural biotechnology Genome Editing of Crops is a boon as it enables faster development of new varieties of crops with desired traits (Wolt, 2017; CAST, 2018). The

* Managing Editor, ABDR and Consultant, RIS. Email: ravisrinivas@ris.org.in

advent of Genome Editing as next generation technology is expected to help in overcoming the controversy over GM vs. non GM Crops (Hefferon and Herring, 2017). Because GEC are not Genetically Modified Crops as there is no insertion of foreign gene(s). It is an efficient process with distinct advantages as explained in the (Table 1).

Table 1: Procedural and biological characteristics of genome editing relative to other methods of crop and livestock improvement.

	Precision	Time to Achieve	Changes from Original Parental Genome	Requires Genetic Transformation	Requires Genetic and Molecular Understanding of the Trait
Genome Editing	High	Months	Targeted edit(s); often no other changes, though edits at locations with sequence similarity to the target(s) may occur	Sometimes	Yes
Conventional Breeding (Crosses)	High for the trait determinant (governed by selection; typically introgresses at the same genomic location as in the donor); other donor DNA that introgresses is determined at random	Years	Introgressed gene and closely linked sequences from donor parent; after backcrossing, ~5% other donor DNA distributed at random through the genome	No	No
Random Mutagenesis	None	Months; with extensive backcrossing, years	Many and random; with extensive backcrossing, ~95% identical to parent	Sometimes	No
Conventional Genetic Engineering (Transgene Insertion)	None	Months to a few years	Presence of transgene; interruption of native DNA sequence with transgene	Yes	Yes

Source : CAST (2018) P 9.

Regarding regulation, broadly speaking whether product per se should be the focus of the regulation or should regulation be focused on process or method is the issue. This product vs. process as the basis has been a contentious issue ever since regulation of GM crops was envisaged. At the risk of over simplification, it can be stated that while many countries including USA, Argentina and Canada have been using the product based approach, the European Directives are based on the process approach. In addition European regulation gives importance to precautionary principle. In regulating GMOs this differentiation lies at the core of the GMO wars between Europe and USA (and few other countries) that resulted in, inter alia, case before WTO. However, it is not as simple as that, as identifying regulations solely on this basis is not possible.

Regarding regulating genome edited crops, a survey done last year found that among the 33 countries and EU examined, and, of the 33 countries, 24 countries allowed commercial cultivation of GMOs , 15 countries and EU used process based regulation, while 14 countries used product based regulation, and, four countries did not have well defined regulatory framework. There is divergence among large countries that have either approved commercial cultivation or approved import of GM crops for feed in regulation. Argentina, USA, Canada, Philippines and Bangladesh adhere to product based regulations while EU, Brazil, China, New Zealand and Australia have adopted to process based regulation (Ishii and Araki, 2017).

But when we examine the regulations little deeper it is clear that despite this broad product and process differentiation the core issue

Table 2: The regulatory concept of genetically modified (GM) crops in 34 countries.

Jurisdiction	Commercial cultivation 2015 (million hectares)[*1]	Regulatory concept[*2]	Ratification of Cartagena Protocol on Biosafety[*4]
USA	70.9	Product	No
Brazil	44.2	Process	Yes
Argentina	24.5	Product	No
India	11.6	Process	Yes
Canada	11	Product	No
China	3.7	Process	Yes
Paraguay	3.6	N.D.	Yes
Pakistan	2.9	Process	Yes
South Africa	2.3	Process	Yes
Uruguay	1.4	Product	Yes
Bolivia	1.1	Process	Yes
Australia	0.7	Process	No
Philippines	0.7	Product	Yes
Brkina Faso	0.4	Process	Yes
Myanmar	0.3	N.D.	Yes
Mexico	0.1	Product	Yes
Colombia	0.1	Product	Yes
Spain[*3]	0.1	Process	Yes
Sudan	0.1	Product	Yes
Honduras	<0.1	Product	Yes
Chile	<0.1	N.D.	No
Portugal[*3]	<0.1	Process	Yes
Vietnam	<0.1	N.D.	Yes
Czech Rep.[*3]	<0.1	Process	Yes
Slovakia[*3]	<0.1	Process	Yes
Costa Rica	<0.1	Product	Yes
Bangladesh	<0.1	Product	Yes
Romania[*3]	<0.1	Process	Yes
EU	No (Yes in some countries[*3])	Process	Yes
UK	No	Process	Yes
Japan	No	Product	Yes
Rep. Korea	No	Product	Yes
New Zealand	No	Process	Yes
Russian Fed.	No (prohibited)	Product	No

[*1]The area of cultibation is based on ISAAA Brief 51–2015 http://isaaa.org/resources/publications/briefs/51/executivesummary/default.asp)

[*2]See the interpretation of relevant laws and regulations in Table S1.

[*3]Spain, Portugal, Czech Republic, Slovakia, Romania.

[*4]As of August 25, 2016.

Source: Ishii and Araki (2017); P 47 is linked to, inter alia, definition of GMO and definition of other factors such as , novel trait. Biotechnology regulatory regimes in each country have their own their histories and despite claims of sound science and universality of science and technology the regulatory trajectories tend to be different and often to that country unique Wright, 1994; Gottweis, 1998; Jasanoff, 2005; Gupta, 2013).

The EU Directive on the deliberate release into the environment of genetically modified organisms of 2001 (Directive 2001/18/EC) under Article 2(2), defines GMO as an organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination. Obviously under this the process aspects of making a GMO matter. To make sense of the regulatory aspects one has to look at Annex 1A, part 1 and part 2, as they respectively indicate, practices that constitute genetic modification and practices that are deemed not to constitute genetic modification. Through Article 3(1) and Annex I B, the Directive, exempts GMOs obtained by mutagenesis or cell fusion from the scope of application of the Directive. Thus the Directive has set a comprehensive definition for GMOs and this process based definition ensures that 'what does not occur naturally and/or natural recombination' could be interpreted only within the scope defined by Article 2(2), read with Annex1A, Annex 1B and Article 3(1).

In USA the framework or what is known as Framework for Regulation of Biotechnology has been implemented since 1986 and regulation is carried out by the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and the US Department of Agriculture (USDA). These agencies are responsible for regulation depending upon the category of the product. Under this only the final plant product would be regulated, irrespective of process. This framework is based on the premise that the biotechnology process adopted is assumed to be safe, in the absence of scientific evidence indicating otherwise. Thus products are regulated on case by case basis, by one of the relevant/responsible agency. This Framework is now likely to be revised as the USDA in June 2018 came up with a notice of intent to update the regulations responding to advances in technology. Technically in USA, the GEC are not treated as GMOs.

Between the two approaches of product and process, the regulators can opt for one and still differentiate it from the regulatory frameworks of USA and EU respectively. For example, Canada uses product based regulation. But by applying the concept of novel trait, the safety of the product is determined by the presence of this novel trait. Novel trait is defined as "a trait which is both new to the Canadian environment and has the potential to affect the specific use and safety of the plant with respect to the environment and human health.". This definition delinks the process adopted from defining novel trait.

In India, the binding rules are framed under "Rules for manufacture, use/import/export & storage of hazardous microorganisms/genetically engineered organisms or cells, 1989". Under this The gene technology and genetic engineering have been defined as 1) "Gene Technology" means the application of the gene technique called genetic engineering, include self-cloning and deletion as well as cell hybridization.2) "Genetic engineering" means the technique by which heritable material, which does not usually occur or will not occur naturally in the organism or cell concerned, generated outside the organism, or the cell is inserted into said cell or organism. It shall also mean the formation of new combinations of genetic material by incorporation of a cell into a host cell, where they occur naturally (self-cloning) as well as modification of an organism or in a cell by deletion and removal of parts of the heritable material". India also uses a case by case approach to regulate biotechnology products (Ahuja, 2018; Srinivas, 2017). If one goes by these definitions it can be presumed that GEC also will be regulated under Rules for manufacture, use/import/export & storage of hazardous microorganisms/genetically engineered organisms or cells, 1989.

Argentina perhaps is the first country to have a regulatory framework that have regulations explicitly made for regulating products derived from New Breeding Techniques (NBT). In this regulation is done on a product to product basis, using the concept of 'novel combination of genetic material' (Whelan and Lema, 2015) Chile and Brazil have moved on similar lines, with regulation on a case by case basis and regulate only if there is an insertion of foreign gene (Schmidt, 2018).

The global debate on GEC took a new turn when the European Court of Justice (ECJ) ruled in July 2018, that they have to be regulated as GMOs (Callaway, 2018). Giving its judgment, the ECJ ruled that techniques and methods of directed alteration of genetic material (in this case genome editing) constitute a genetic modification and cannot be exempted under mutagenesis exemption. In other words they have to treated as GMOs under the EU regulation applicable to GMOs. This means that rules applicable for risk assessment and authorization will be applicable to all categories of releases of plants and animals obtained by genome editing. The rationale for such a ruling has been provided in the judgement elaborately and it states

" 48 It thus follows from the material before the Court, first, that the direct modification of the genetic material of an organism through mutagenesis makes it possible to obtain the same effects as the introduction of a foreign gene into that organism and, secondly, that the development of those new techniques/methods makes it possible to produce genetically modified varieties at a rate and in quantities quite unlike those resulting from the application of conventional methods of random mutagenesis.

49 Moreover, as stated in recital 4 of Directive 2001/18, living organisms, whether released into the environment in large or small amounts for experimental purposes or as commercial products, may reproduce in the environment and cross national frontiers, thereby affecting other Member States. The effects of such releases on the environment may be irreversible. In the same vein, recital 5 of that directive states that the protection of human health and the environment requires that due attention be given to controlling risks from such releases.

50 Furthermore, it has been emphasised, in recital 8 of that directive, that the precautionary principle was taken into account in the drafting of the directive and must also be taken into account in its implementation. Emphasis is also placed, in recital 55 of Directive 2001/18, on the need to follow closely the development and use of GMOs.

51 In those circumstances, Article 3(1) of Directive 2001/18, read in conjunction with point 1 of Annex I B to that directive, cannot be interpreted as excluding, from the scope of the directive, organisms obtained by means of new techniques/methods of mutagenesis which have appeared or have been mostly developed since Directive 2001/18 was adopted. Such an interpretation would fail to have regard to the intention of the EU legislature, reflected in recital 17 of the directive, to exclude from the scope of the directive only organisms obtained by means of techniques/methods which have conventionally been used in a number of applications and have a long safety record" (ECJ, 2018).

The interpretation of Directive combined with emphasis on precautionary principle means that irrespective of stage of development GEC will have to be regulated as GMOs. This is in contrast to the opinion espoused by Advocate General. While this verdict has pleased environmental groups and others, who wanted the GEC and other products developed using new techniques and processes as GMOs, many scientists and organizations that represent science and scientist are disappointed. The reason is such an understanding goes against the almost consensual view among scientists that GEC should be regulated as plants developed using traditional plant breeding and not as GMOs. The European experience with GMOs has been different that of USA or Canada. The public response to GMOs in Europe has been far from positive. The GMO tag if applied to GEC would make it all the more difficult to convince the public that they are safe and desirable. Besides acting as a constraint in R&D it will also discourage commercial investment in producing them. The regulatory costs could be too expensive for developers. The verdict has in fact heightened the need for more deliberations and debates on regulating plants developed using new techniques and processes. Its impact is likely to be felt elsewhere also. In not accepting the opinion of the Advocate General advocating a broad interpretation, the Court struck to the position that exemption should be confined only to conventional techniques and methods of random mutagenesis which had been adopted in a number of applications and with a long safety record. By giving emphasis to possibly irreversible effects on the environment, it indicated that advanced risk assessment was necessary. The verdict was criticized as a move that could push back efforts in Europe in developing GECs. Nature Biotechnology in an editorial piece cautioned that Europe's law makers 'have some stark choices to make' including reversing the ECJ decision and exempt GEC from regulation under the mutagenesis exemption (Nature Biotechnology, 2018).

While the EU is grappling with this verdict and is yet to come up with a comprehensive plan to regulate Genome Edited Crops, the inevitable reverberations will impact regulatory regimes elsewhere. If EU finally opts for regulating them as GMOs, that is likely to result in another transatlantic divide on regulation of agricultural biotechnology. Whether that will result in another round of dispute(s) before WTO is not clear. But what is certain is that in regulating GEC across the globe, there could be a sense of déjà vu coupled with new challenges and opportunities.

Although it can be argued that in terms of science and policy, GEC are not GMOs and are based of advancements that are far better than genetic engineering techniques, making the public understand this is not easy. Because edited can be interpreted as modified. But in public perception, unless properly communicated this can result in a misunderstanding that while they are different from GMOs, they are not natural and hence potentially risky or unsafe or something that can better be avoided. Despite the argument that GEC are as good as plants developed by traditional plant breeding, convincing the public, that genome editing per se is safe and based on sound science and also are similar to plants developed using traditional plant breeding techniques will not be easy, particularly in countries, where GMOs are not favored by majority of the public. Another issue is, given the debates on regulating human genome editing and the ethical issues in human genome editing, public perception could be impacted by these debates, resulting in public perceiving that genome editing per se, is a technology that is risky and can result in blurring boundaries between what are acceptable and what are not. Hence public engagement is important to enhance the credibility and acceptability of GEC. In this the lessons from controversies over GMOs are important.

From a technology governance perspective, it is obvious that regulating genome editing is going to be more challenging that regulating genetic engineering. Whether the current governance frameworks are sufficient for this is a big question. With respect to GEC, current frameworks might need a relook and revision. An important question is whether the two major approaches (product, and, process) are sufficient to regulate GEC or do we need better approaches and sui generis solutions that go beyond product vs. process mode of approaching the regulatory issues. It is likely that the regulatory issues will have trade related impacts. It is too early to state that there will not be another round of trade wars that are similar to GMO wars or trans-Atlantic divides over GEC. But what is certain that governance of genome editing will be far more challenging than governing the previous generations of genetic engineering and biotechnology applications and products. These are interesting times as well as challenging times.

References

Ahuja, V. 2018. "Regulation of emerging gene technologies in India " BMC Proceedings2018 12; (Suppl 8) :14

Callaway, E. 2018. "CRISPR plants now subject to tough GM laws in European Union Top court's ruling threatens research on gene-edited crops in the bloc", available at https://www.nature.com/articles/d41586-018-05814-6

CAST. 2018. "Issue Paper 60: Genome Editing in Agriculture: Methods, Applications, and Governance", Council for Agricultural Science and Technology; Ames: Iowa

ECJ. 2018. "Judgement of the court (Grand Chamber) 25 July 2018, In Case C-528/16, REQUEST for a preliminary ruling under Article 267 TFEU from the Conseil d'État (Council of State, France), made by decision of 3 October 2016". Accessed on September 25, 2018 from http://curia.europa.eu/juris/document/document.jsf?text=&docid=204387&pageIndex=0&doclang=EN&mode=req&dir=&occ=first&part=1&cid=3961034

Gottweis H. 1998. "*Governing Molecules. The Discursive Politics of Genetic Engineering in Europe and in the United States*". Cambridge:MA, MIT Press.

Gupta, A. 2013. "Biotechnology and Biosafety", in Robert Falkner (Ed.), *The Handbook of Global Climate and Environment Policy*. London: John Wiley & Sons, Ltd. Pp 89-106

Hefferon, K L. and Herring, R J. 2017."The End of the GMO? Genome Editing, Gene Drives and New Frontiers of Plant Technology," *Review of Agrarian Studies*, vol. 7, no. 1, available at http://ras.org.in/7d7edc7ecf0c4d5a04189e9cad6e829f

Ishii,T and Araki, M. 2017. "A future scenario of the global regulatory landscape regarding genome-edited crops". *GM Crops & Food*. 8(1): 44–56.

Jasanoff, S. 2005. "*Designs on Nature: Science and Democracy in Europe and the United States*". Princeton, NJ: Princeton University Press

Nature Biotechnology. 2018. "Gene-edited plants cross European Event Horizon", 36 (9): 776, accessed on October 10, 2018 from https://www.nature.com/articles/nbt.4256?WT.ec_id=NBT-201809&spMailingID=57392017&spUserID=ODkwMTM2NjI1NQS2&spJobID=1482485271&spReportId=MTQ4MjQ4NTI3MQS2

Sarah Schmidt. 2018. "To Regulate Or Not To Regulate: Current Legal Status For Gene-Edited Crops". Accessed on August 12, 2018 from http://www.global-engage.com/agricultural-biotechnology/to-regulate-or-not-to-regulate-current-legal-status-for-gene-edited-crops/

Srinivas, KR. 2017."Regulatory Regime for GM Crops in India in Genetically Modified Organisms in Developing Countries", in (Ed) Ademola A. Adenle, E. Jane Morris and Denis J. Murphy, Cambridge University Press; Pp 236-246

Whelan, AI and Lema, MA. 2015. "Regulatory framework for gene editing and other new breeding techniques (NBTs) in Argentina". *GM Crops & Food.* 6 (4): 253-265

Wolt, J D. 2017. "Safety, Security, and Policy Considerations for Plant Genome Editing" in Donald PW and Yang, B (Ed), *Progress in Molecular Biology and Translational Science*. Amsterdam: Elsevier 215-241

Wright S. 1994. *Molecular Politics: Developing American and British Regulatory Policy for Genetic Engineering, 1972–1982*. Chicago:Chicago University Press

RIS
Research and Information System
for Developing Countries
विकासशील देशों की अनुसंधान एवं सूचना प्रणाली

Asian Biotechnology and Development Review
Vol. 20 No. 1&2, pp 99-101

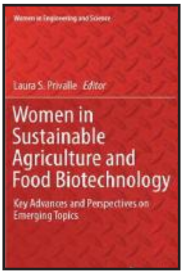
Book Review

Women in Sustainable Agriculture and Food Biotechnology

Editor: Laura S. Privalle

Publisher: Springer; Year: 2017

Pp: 153; Price: USD 119.99



While there have been biographies of the women scientists, who contributed to biosciences, but so far, there was hardly any publication that compiled write-ups by women- scientists, who reflected upon their own experiences of being scientists. Thus, this is a unique attempt to fill this gap in the literature. Its introductory chapter describes briefly the work of twenty-eight pioneering women in agriculture and biotechnological research; chronologically drawn from as early as second century BC to the present century.

Mary-Dell Chilton described her research work on using *Agrobacterium* for transferring DNA to plant cells; a methodology that has played a key role in developing GM crops. Chilton shared her concerns regarding the challenges of climate change and growing population; as she felt that GM technology would play a critical role in addressing these critical issues.

Nina Fedoroff chronicled her exciting journey from a plant biologist to being a S&T Adviser to the US Secretary of State. She narrated how her meeting with Barbara McClintock made her work on the plant biotechnology, leading her to develop rDNA technology and cloning of plant species; which was the introduction of GM technology in crops. She also described her work with the regulatory agencies, as she was a part of their scientific advisory panel on applied genetics. Given the challenge of climate change, she believed that GM technology would help addressing the problem and developing climate-resilient agriculture. Sue MacIntosh described her contributions on plant biotechnology, starting with her career in *Bt* group at Monsanto and in the development of Br crops, including aspects of regulation of biotechnology-based crops. Laura S. Privalle provided an account of the race for the development of Bt-based crops in early 1990s. Describing her own experience in developing a Bt-Maize while working in CIBA-Geigy firm (now Syngenta), she pointed out, that in addition to the technical challenges, there were issues related to the regulatory challenges in getting approval for cultivation and commercialization of GM crops, particularly in Europe.

Jennifer Kuzma briefly gave an account of her career, starting as a scientist, and then shifting to policy analysis and academics as a professor in policy and social sciences. She was of the view that '*opening up of regulatory processes to a greater diversity of people and perspectives might remedy the inequity and increase procedural justice*'. (P.94)

Kathleen E. Kennedy discussed her efforts and experiences in the Education and Training Program at the North Carolina Biotechnology Center, where she was the part of the team that imparted biotechnology education and training to develop human resource for biotechnology industry. She credited the growth of biotechnology industry in the North Carolina area to the '*synergistic impact'* of combination of such capacity-building efforts along with academic research, small company start- up and large company recruitment.

Florence M. Wambuga shared her experience on promoting agricultural biotechnology in Africa and backlashes she received from the anti-GM groups. She stated that her *Nature* article titled "*Why Africa needs agricultural biotech*" published in 1999 paved way for many positive developments toward promotion of biotechnology in Africa, particularly in Kenya. She highlighted the success of her "Africa Harvest Foundation" in its efforts to enact biosafety laws in several African countries.

Carrie Mess started with the humble submission that she was not a science graduate or a biotechnologist. She talked about the benefits of growing GM soybeans and other crops in her farms largely from consumer perspective. She thanked the women- scientists who actually created choices; from which she benefitted a lot.

These memoirs draw- on to read as they have covered the advancement of agricultural biotechnology since 1980s and described how these women -scientists played significant role in nurturing and fostering emerging R&D in plant biotechnology. The narratives also highlighted pro-technology stances of all the contributing women authors, which can be seen as quite a positive development; considering those periods when not many women were involved in science.

However, the write-ups did not focus much on the issue of the sustainable agriculture, as claimed in the title of the book. The arguments made by the contributing authors and editor did not provide much insights and evidences on how to justify GM technology as a tool for sustainable agriculture. Secondly, most of these women authors worked for private agricultural companies, which were inherently pro-GM; therefore a pro-technology stance taken by them was as such no surprise.

Nevertheless, this edited book would be a good inspiring read for women students and women scientists, who desire to pursue career in agricultural biotechnology. This can also be a reference book for policy makers, academicians and researchers interested in biotechnology and may help address pressing challenges of climate change and growing population.

–Amit Kumar
Research Associate, RIS
Email: amit.kumar@ris.org.in

Guidelines for Contributors

1. ABDR is a refereed multi-disciplinary international journal. Manuscripts can be sent, preferably as email attachment, in MS-Word to the Managing Editor, Asian Biotechnology and Development Review, Research and Information System for Developing Countries (RIS), Core 4B 4th Floor, India Habitat Centre, Lodhi Road, New Delhi 110003, India (Email: ravisrinivas@ris.org.in; Tel. +91-11-24682177-80; Fax: +91-11-24682173/74). Submissions should contain institutional affiliation and complete mailing address of author(s). All submissions will be acknowledged on receipt.
2. Manuscripts should be prepared using double spacing. The text of manuscripts should not ordinarily exceed 7,000 words. Manuscripts should contain a 200 word abstract, and key words up to six.
3. Use 's' in '-ise' '-isation' words; e.g., 'civilise', 'organisation'. Use British spellings rather than American spellings. Thus, 'labour' not 'labor'.
4. Use figures (rather than word) for quantities and exact measurements including percentages (2 per cent, 3 km, 36 years old, etc.). In general descriptions, numbers below 10 should be spelt out in words. Use thousands, millions, billions, not lakhs and crores. Use fuller forms for numbers and dates— for example 1980-88, pp. 200-202 and pp. 178-84.
5. Specific dates should be cited in the form June 2, 2004. Decades and centuries may be spelt out, for example 'the eighties', 'the twentieth century', etc.

References: A list of references cited in the paper and prepared as per the style specified below should be appended at the end of the paper. References must be typed in double space, and should be arranged in alphabetical order by the surname of the first author. In case more than one work by the same author(s) is cited, then arrange them chronologically by year of publication.

All references should be embedded in the text in the anthropological style–for example '(Hirschman 1961)' or '(Lakshman 1989:125)' (Note: Page numbers in the text are necessary only if the cited portion is a direct quote).

Citation should be first alphabetical and then chronological–for example 'Rao 1999a, 1999b'.

More than one reference of the same date for one author should be cited as 'Shand 1999a, 1999b'.

The following examples illustrate the detailed style of referencing:

(a) Books:

Hirschman, A. O. 1961. *Strategy of Economic Development*. New Haven: Yale University Press.

(b) Edited volumes:

Shand, Ric (ed.). 1999. *Economic Liberalisation in South Asia.* Delhi: Macmillan.

(c) Articles from edited volumes:

Lakshman, W. D. 1989. "Lineages of Dependent Development: From State Control to the Open Economy in Sri Lanka" in Ponna Wignaraja and Akmal Hussain (eds) *The Challenge in South Asia: Development, Democracy and Regional Cooperation*, pp. 105-63. New Delhi: Sage.

(d) Articles from Journals:

Rao, M.G., K. P. Kalirajan and R. T. Shand. 1999. "Convergence of Income across Indian States: A Divergent View". *Economic and Political Weekly,* 34(13): pp. 769-78.

(e) Unpublished Work:

Sandee, H. 1995. "Innovations in Production". Unpublished Ph.D thesis. Amsterdam: Free University.

(f) Online Reference:

World Health Organisation. 2000. "Development of National Policy on Traditional Medicine". Retrieved on March 31, 2011 from http://www.wpro.who.int/sites/trm/documents/Development+of+National+Policy+on+Traditional+Medicine.htm

Asian Biotechnology and Development Review (ABDR) is a peer reviewed, international journal on socio-economic development, public policy, ethical and regulatory aspects of biotechnology, with a focus on developing countries. ABDR is published three times a year with support of Department of Biotechnology, Government of India and UNESCO by Research and Information System for Developing Countries (RIS), a New Delhi based autonomous think-tank, envisioned as a forum for fostering effective policy dialogue among developing countries on international economic issues.

This issue has five articles and a book review. The first article analyzes the merger of Bayer and Monsanto and the legal regime for protection plant varieties and patentability of seeds in India. The second article discusses stakeholders' interest and trust in GM crops debate in India and suggests measures to enhance trust and greater engagement with stakeholders. The third article examines the ethical and regulatory issues in Human Genome Editing and maps the global developments with suggestions for regulators in India. The fourth article explores the technology and policy issues related to underutilized crops, stresses their importance for nutrition and biodiversity and proposes measures to enhance their role. The last article deals with regulating Genome Edited Crops and whether they should be regulated as GMOs or not, in light of the verdict of European Court of Justice. The book review is on a volume that highlights contributions of women scientists to development of agricultural biotechnology and its regulation.

RIS
Research and Information System for Developing Countries
विकासशील देशों की अनुसंधान एवं सूचना प्रणाली

Core IV-B, Fourth Floor
India Habitat Centre
Lodhi Road, New Delhi-110 003
Ph.: +91-11-24682177-80
Fax: +91-11-24682173-74
Email: dgoffice@ris.org.in
Website: www.ris.org.in