7 From Genetic Engineering to Gene Editing: Harnessing Advances in Biology for National Economic Development

Chandra Sekhara Rao Nuthalapati

Abstract

This chapter has examined the nature and adoption of biotechnologies, socio-economic impacts, regulatory frameworks and concerns for rising farm incomes in a cross-country perspective. The product development in biotech has been moving from just insect/herbicide resistance to breaking yield barriers, drought tolerance and quality enhancing traits, just from 3 to 31 crops, a large share of acreage in developing countries and increasing penetration of public sector. The frontiers have been moving forward with the fundamental breakthrough in the form of CRISPR-Cas 9 technique with wide-ranging applications. A rigorous study of peer-reviewed literature shows that GE crop cultivation has increased yields and net income, reduced pesticide usage and helped conserve tillage. Biosafety laws have been stifling product development, and therefore harnessing biotechnologies necessitate enabling policies like a legal framework for bio-safety, labelling and trans-boundary movement. Developing countries need to put in place regulations for the new plant breeding techniques on par with the conventional plant breeding techniques. The policy implications have been then drawn for utilization of opportunities in advancement of biotechnology for developing country agriculture.

Keywords

Yield effect · Selection bias · Halo effect · Employment · Regulatory framework · IPRs · Drought tolerance · Labelling · Consolidation

JEL Classification

J4 · K19 · L1 · O3 · Q10 · Q16

C. S. R. Nuthalapati (✉)
Institute of Economic Growth, University of Delhi Enclave, New Delhi, India

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7.1 Introduction

Theory of growth attributes unequal adoption of technologies due to lack of institutions as one of the major reasons for differential growth of countries in the world (Acemoglu and Robinson 2012). Technological change, according to Schultz, brings in new factors of production and act as 'low-priced sources of permanent income streams' for economic growth. Slow growth in traditional agriculture is explained by the dependency upon a particular set of factors of production, the profitability of which has been exhausted. The way forward then lies in the farmers acquiring, adopting and learning how to use effectively a profitable new set of factors (Schultz 1964). Biotechnology is both a general-purpose enabling technology and a source of radical innovation. It presents an opportunity to introduce a variety of genetic traits into farming systems around the world that replace, compete with or otherwise affect the value of existing production techniques and products. The recent advances in biology increase our understanding of life so much that experts say these discoveries are likely to define changes in the way we live in the twenty-first century. In fact, the twenty-first century is predicted to be the century of biology. The biotech sector got a big boost from deciphering of human genome in the new century, which is being widely regarded as the 'biological equivalent of landing on Moon' (Rao and Dev 2010).

Food crisis of 2007 brought back the 'classical development paradigm' which views agriculture as an engine of economic growth, industrialization and structural transformation and stresses on uni-modal strategy of modernizing the entire agricultural sector, including the smallholder sector rather than just the high-value segment (Durr 2016). Many developing countries are passing through the 'Schultz' stage, where rising agricultural incomes fall behind the rapidly growing non-farm incomes, exacerbating rural-urban disparities (Barrett et al. 2010: 451). While China and India are the striking examples of this phenomenon, countries in Africa continue to be food insecure, and East Asian countries suffer from large food imports (Otuska 2013: 7–8). Lack of modernization of agriculture is one of the reasons for 'middle income trap' that has been haunting countries like Brazil, Mexico, Malaysia, Argentina, South Africa, China and India (Eichengreen et al. 2013; Armstrong and Westland 2016).

The decline in agricultural productivity due to climate change is estimated to be to the tune of 10–38% in individual crops by 2050, and spatial spread is likely to be adverse to developing countries and regions (Muller and Robertson 2014; Rao 2015). Further, the scope of agriculture is expanding in the world to cater to the rising demands in non-food applications like fuels, fine chemicals and other products (Zilberman et al. 2013). Concerted efforts are needed to counter the reversal of secular decline in food prices after the 1990s in most countries of the world including India (Dev and Rao 2010; Rao et al. 2015). Apart from the level of prices, excessive volatility and spikes are one of the most critical economic and food security challenges (Swinnen and Riera 2013). To sum up, there is a pressing need to modernize small farm agriculture and raise agricultural productivity in view of the need to put back agriculture as engine of growth in line with 'classical development paradigm' as well as issues arising out of climate change, expanding role of agriculture to non-food requirements, raising food prices and price volatility. Then, the issue to be addressed is whether and how the rapidly diffusing biotechnologies can serve this purpose. We present a framework here to follow in this chapter.

7.2 Conceptual Framework

Theoretically, there can be both positive and negative impacts of any technology, including agricultural technologies, which can both be direct and indirect. It is noteworthy that technology has impacts on adopters, on non-adopters as well as on populations unrelated directly to the production process of the sector. However, the actual extent of these impacts is moderated by the available infrastructure, political, socio-economic contexts of regions as well as the characteristics of the adopters along with asset distribution patterns (Adato et al. 2007).

There is a consensus in the extant literature on poverty-reducing effects of agricultural growth (Ahluwalia 1978; Mellor 2006). The experience of poverty reduction in poor agrarian societies reveals that raising the productivity of small-scale farming is the key requirement to overcome poverty, because the poor are concentrated in the rural areas and their livelihoods are based on agriculture (Lewis 1954; Rao and Dev 2010). Beyond the obvious effects, technologies can increase growth and employment opportunities in rural non-farm sector and thereby contribute to poverty reduction (Mellor 2006). This in turn will have an upward pressure on wages. However, the poverty-reducing effects of technology depend on the nature of technology, nature of poverty and type of institutions in the adopting region (de Janvry and Sadoulet 2002). The predominantly rural nature of poverty and hunger in the contemporary world makes productivity-enhancing technologies exceedingly important (WB 2007). Technologies can also play big role in enhancing the nutrients required to alleviate hidden hunger and achieve sustainable development goals (Bouis et al. 2019).

Several studies have shown that seed-fertilizer technologies of the 1960s made a positive impact on agricultural growth, helped in diversifying to high-value crops and made a dent on poverty in Asia and Latin America, while the African continent could not derive significant gains for lack of necessary policy support and unavailability of improvements in crops of local interest (Hazell 2009; Pingali 2012). It is clear from Green Revolution experience that new agricultural technologies cannot be harnessed without enabling policy framework.

This chapter looks, in a cross-country perspective, at nature of biotechnologies and their diffusion patterns, provides a critical evaluation of the impact of the genetically engineered (GE) crops on farm incomes, analyses evolving regulatory frameworks and examines consolidation in seed and agricultural biotechnology and emerging countervailing forces for smallholder agriculture. This chapter does not go into the biosafety issues and remains confined to agronomic and socio-economic impacts and policy-related issues.

7.3 Changing Landscape of Biotechnologies

Standard narrative in development literature posits that predominantly multinational-developed biotechnologies will be tailor-made to the cultivation requirements of industrial agriculture of developed countries and the crops and traits of importance to resource-poor farmers in developing countries will be bypassed (Rao 2004; Rao and Dev 2009). However, the recent shifts in both technology development and adoption across developing countries allay these fears to some extent, though issues arising out of concentration in the seed industry continue to be of concern. These issues are dealt with later in this chapter.

The foremost among the recent shifts is moving of technology frontiers from genetic engineering to gene editing (Hefferon and Herring 2017), leaving out many of the unintended consequences of introducing a foreign gene through the development and adoption of SU (sulphonylurea)-tolerant canola in the USA. It uses a new gene editing method called CRISPR (clustered regularly interspaced short palindromic repeat). The past few years have witnessed a higher share of developing countries in the total area covered under the GE crops, viz. 53% of the 189.8 million hectares (Table 7.1), and this contrasts with the early years of commercialization. Brazil (26%), Argentina (12%) and India (6%) occupied nearly 85% of the area under these crops in developing countries in 2017.

Commercialized crops moving beyond four crops (soybean, maize, cotton and canola) and public sector, despite diminished funding and regulatory and IPR hurdles, moving ahead and bringing out GE products in several crops are further indicators of moving frontiers. The portfolio of technologies encompassed 31 crops in 2018, and all of them were being commercialized in different countries (Table 7.2). Most prominent among them are drought-tolerant (DT) soybean in Argentina; DT sugarcane in Indonesia; Bt brinjal in Bangladesh; Bt cotton in China, Pakistan and India; virus-resistant (VT) bean in Brazil; VT potato and VT papaya in Argentina; and VT papaya, petunia, sweet pepper and poplar in China. There are approved events now that break yield barriers, afford protection against abiotic stresses like droughts and enhance quality of product (Fig. 7.1). The DT maize was commercialized and is grown in 12 lakh hectares in 2016, and the Water Efficient Maize for Africa (WEMA), donated by the private sector, is likely to be commercialized soon in Kenya. There has been a move towards GE food crops with white maize in S. Africa; non-browning apples, late-blight-resistant potato, sweet corn, sugar beet and papaya in the USA; and Bt brinjal in Bangladesh. However, the private sector still has bulk of these new biotech crop products, despite some progress by the public sector.

7.3.1 Gene-Edited Crops

Notwithstanding the advantages of genetic modification via transgenesis for the introduction of a wider range of traits not available through conventional or mutational breeding, its scope is limited for traits that depend on a small number of

Table 7.1 Country-wise area under genetically engineered crops and approved events in developing countries

Country	Total area under GE crops in Mha	Soybean		Maize		Cotton		Other crops with commercialized biotechnology
		Area in Mha	GM events commercialized (numbers)	Area in Mha	GM events commercialized (numbers)	Area in Mha	GM events commercialized (numbers)	
Brazil	50.2	33.7 (97%)	11	15.6 (90%)	106	0.94 (84%)	12	Mosaic virus-resistant bean; fast-growing eucalyptus; borer-resistant sugarcane
Argentina	23.6	18.1 (78%)	13	5.2 (97%)	77	0.25 (98%)	3	Drought-tolerant soybean; virus-resistant potato
India	11.4	–	–	–	11	11.4 (93%)	6	DMH-11 mustard hybrid cleared by GEAC is waiting for government clearance
China	2.9	–	–	–	73	2.9 (95%)	8	Virus-resistant papaya, petunia, sweet pepper, poplar
Paraguay	2.96	2.68 (96%)	1	0.27 (42%)	22	0.01 (100%)	3	–
Pakistan	3.0	–	–	–	6	3.0 (96%)	2	–
S. Africa	2.73	0.74 (75%)	1	1.96 (85%)	72	0.004 (100%)	6	–
Uruguay	1.1	1.23 (98%)	5	0.06 (86%)	17	–	–	–
Bolivia	1.3	1.283 (100%)		–	1	–		–
Philippines	0.6	–		0.812 (65%)	105	–		–
Total	99.7	57.73	31	23.90	490	18.50	47	–

Source: ISAAA (2017) and Brookes and Barfoot (2018a) and other reports
Note: Figures within the parentheses represent adoption rates of GE crops

Table 7.2 Approved GE technologies (events) in public and private domains

Sl. No.	Crop	Public	Private	Total
1	Maize	0	231	231
2	Cotton	4	59	63
3	Potato	23	46	69
4	Argentine canola	0	41	41
5	Soybean	0	41	41
6	Carnation	0	19	19
7	Tomato	3	8	11
8	Rice	5	3	8
9	Alfalfa	0	5	5
10	Sugarcane	2	3	5
11	Papaya	4	0	4
12	Polish canola	3	1	4
13	Apple	0	3	3
14	Chicory	0	3	3
15	Sugar beet	0	3	3
16	Melon	0	2	2
17	Poplar	2	0	2
18	Rose	0	2	2
19	Safflower	0	2	2
20	Squash	0	2	2
21	Tobacco	1	1	2
22	Bean	1	0	1
23	Creeping bentgrass	0	1	1
24	Eggplant	0	1	1
25	Eucalyptus	0	1	1
26	Flax	1	0	1
27	Petunia	1	0	1
28	Plum	1	0	1
29	Sweet pepper	1	0	1
30	Wheat	0	1	1
31	Cowpea	1	1	2
	Total	53	480	533

Source: isaaa.org

known genes. In reality, many desirable traits are the result of complex interactions of several gene products (Jander et al. 2003; Till et al. 2007). Further, the integration of transgenes into the host genome is non-specific, sometimes unstable and is a matter of public concern when it comes to edible crop species (Stephens and Barakate 2017; Jaganathan et al. 2018). Moreover, the insertion of foreign gene into the crop cultivar is the central point for the unending controversies on their use. Even after occupying nearly 12% of the world cultivated area, more than 90% of the GM crop acreage is under insect resistance and herbicide tolerance, without any solution for breaking yield barriers or addressing abiotic stress. The gene editing methods have

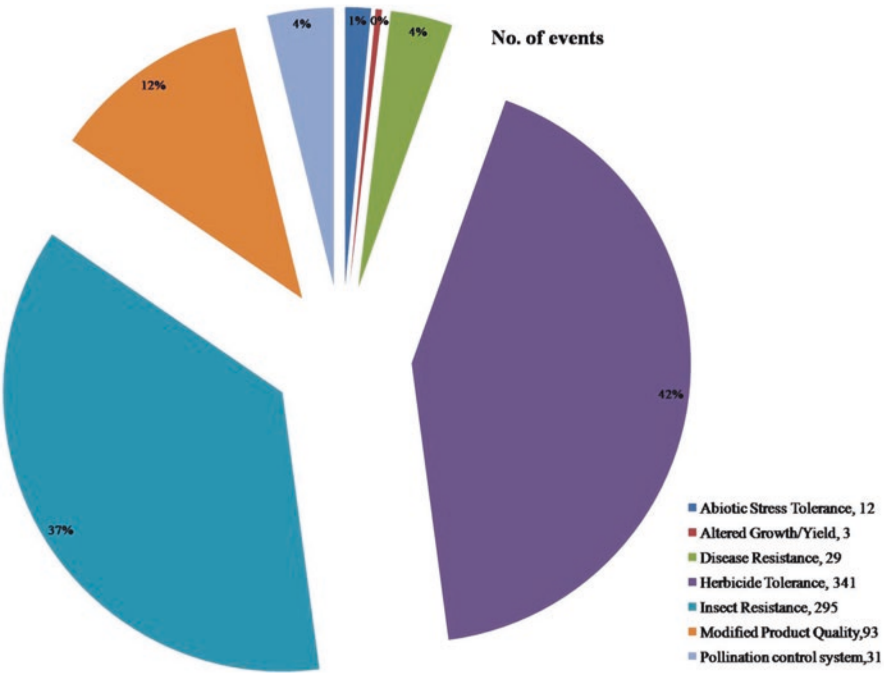

Fig. 7.1 Commercialized genetically engineered (GE) traits

arrived in this background that simplified the whole process of varietal development with desired traits.

A diverse set of gene editing tools called new breeding technologies (NBTs) are revolution arising basic molecular biology research and taking it to an entirely new level (Hefferon and Herring 2017; Adenle et al. 2018). The new breeding techniques (NBTs) make it possible to bring about genetic changes more precisely by targeting specific sites in the genome and allows clear-cut and reliable mutations, setting them apart from genetically engineered crops (Zaidi et al. 2019). Though the first-generation gene editing techniques like zinc-finger nucleases (ZFNs) and transcription activator-like effector nucleases (TALENs) have this potential, they are time-consuming and expensive. The development of the fundamental breakthrough gene editing technique called CRISPR-Cas9 altered the landscape so much and involves simple designing and cloning methods for precise changes in the genome in crop plants (Jaganathan et al. 2018). Other possible modalities include precise DNA sequence editing, gene replacement and simultaneous enhancement of multiple traits (stacking), as well as promoter and regulatory element engineering for altered gene expression patterns (Zaidi et al. 2019). Gene editing technologies or NBTs are rapid, precise and efficient compared to other means of developing desired characteristics in plants, viz. transgenesis, chemical- or radiation-induced mutagenesis and conventional breeding.

NBTs do not involve introduction of new gene sequences and may direct only one or a few nucleotide changes within a plant genome. The gene editing methods enable the plant breeders to know exactly where a change has been made in genome, leave no trace of that process and allow simultaneous editing of all copies of a gene. Consumer benefits such as enhanced nutrient content, prolonged shelf life or improved colour, odour, flavour and texture of the plant can be incorporated simultaneously with producer benefits, such as improved pest resistance or yield (Bortesi and Fischer 2015).

NBTs such as genome editing will be able to contribute substantially to global food and nutritional security with judicious applications and scientifically informed regulation (Zaidi et al. 2019). It should be kept in mind that breeding techniques are generally complementary and not mutually exclusive, that all are essential tools in addressing the challenges of agriculture (Schaart and Visser 2009).

Two applications of gene editing that are commercially approved for production are bruising- and browning-resistant potato using RNA interference technique (by reducing polyphenol oxidase levels) and SU-tolerant canola developed using Rapid Trait Development System, a more precise form of mutagenesis (Seyran and Craig 2018). The USA has so far declared five applications of CRISPR-Cas 9 to not to regulate under the purview of GMOs. These are non-browning button mushroom, waxy corn with enriched amylopectin, green bristlegrass with delayed flowering time, camelina for increased oil content and drought-tolerant soybean.

7.4 Empirical Evidence on Impacts

Several rigorous research studies have focused on the agronomic, environmental and socio-economic impacts of GE crops, just as the debates and controversies have been leading to intense scrutiny of biosafety-related issues of agricultural biotechnologies (Qaim 2009, 2016). Both meta-analyses of studies on impacts (Table 7.3) and crop-wise individual studies (Table 7.4) show higher yields, lower pesticide use and better net returns.

Meta-analysis by Klumper and Qaim (2014) has found a 22% yield increase associated with 68% profit gain and 38% reduction in pesticide expenditure. The longitudinal studies over the past 19 years show that GE crop cultivation created additional gains of USD 186 billion, conserved biodiversity by saving cultivation of 152 Mha of land (Brookes and Barfoot 2015, 2018a). Evidence from Tables 7.3 and 7.4 point to higher yield gains in developing countries as pest attacks are not effectively controlled in the absence of these technologies. The causative mechanism can be expressed in a damage control framework, following Litchenberg and Zilberman (1986) as Eq. 7.1:

$$Y = F(x)\left[1 - D(z,;\mathrm{Bt},;N)\right] \tag{7.1}$$

where Y is the effective crop yield; $F(.)$ is the potential yield without insect/weed damage, which depends on variable inputs, x; $D(.)$ is the damage function

Table 7.3 Results of meta-analyses on performance of genetically engineered crops

Study	Number of studies covered	Region or crop	Yield gain over conventional	Profit over conventional	Costs over conventional	Pesticide cost over conventional
Klumper and Qaim (2014)	147	All crops	21.57%	68.21%	NS	−39.15%
		IR crops	24.85%	68.78%	5.24%	−43.43%
		HT crops	9.29%	NS	NS	−25.29%
Areal et al. (2013)	133	Developed countries	NS	16 euros/ha	11 euros/ha	
		Developing countries	0.35 tonne/ha	188 euros/ha	−25	
		All countries	0.28 tonne/ha	166 euros/ha		
		Bt corn	0.55 tonne/ha	523 euros/ha		
		Bt cotton	0.30 tonne/ha	84 euros/ha		
		HT soybean	0.03 tonne/ha	16 euros/ha		
Hall et al. (2013)		All countries		66%	23%	
Finger et al. (2011)	177 –maize	Maize – all countries	3.9%		−66.6%	
	454 –cotton	Cotton – all countries	46.3%	86.3%		−48.2%
		India	50.8%	32.5%		−30.0%
		China		−120%		−71.7%
		S. Africa	NS	114%		−51.7%
		Australia	NS			−22.0%
		USA	NS			NS
Gruere and Sengupta (2011)		Cotton	36.2%	58.1%	16%	42%

(continued)

Table 7.3 (continued)

Study	Number of studies covered	Region or crop	Yield gain over conventional	Profit over conventional	Costs over conventional	Pesticide cost over conventional
Carpenter (2010)	168	Developed countries				
		All crops	6%			
		Corn	7%			
		Cotton	7%			
		Soybean	7%			
		Developing countries				
		All crops	29%			
		Maize	85%			
		Cotton	30%			
		Soybean	21%			

Note: NS indicates not significant

Table 7.4 Impacts of genetically engineered crops in different countries

Country	Studies	Percent change in			
		Crop/trait	Physical yield	Pesticide/ herbicide cost	Gross margin in monetary value
India	Kathage and Qaim (2012);	Bt cotton	24		50
	Rao and Dev (2009)		32–47	–13 to –56	70–251
China	Pray et al. (2002)	Bt cotton	19	−67	340
	Qiao (2015)	Bt cotton	34	−50	NA
South Africa	Thirtle et al. (2003)	Bt cotton	22	−36	28
Mexico	Traxler et al. (2003)	Bt cotton	11	−77	12
Argentina	Qaim and de Janvry (2003)	Bt cotton	33	−47	42
USA	Falck-Zepeda et al. (2000);	Bt cotton	10	36	NA
	Carpenter et al. (2002)				
Australia	Fitt (2003)	Bt cotton	0	−48	NA
Argentina	Qaim and Traxler (2005)	HT soybean	0	−42	9
USA	Marra et al. (2004)	HT soybean	0	−33	–
Canada	Brewin and Malla (2012)	Ht canola	10	−54	4
South Africa	Ghouse et al. (2009)	Ht maize	85	79	440
		Bt maize	6	−41	124
Philippines	Yorobe and Smale (2012)	Bt maize	34	−52	54
USA	Fernandez-Cornejo et al. (2005)	Bt maize	9	NA	NA
USA	Kniss (2008)	Bt sugar beet	–	−68	–

Note: NA not available in the study

determining the fraction of potential output being lost to insect pests (it can take values in the 0–1 interval); and *N* is the exogenous pest pressure and can be reduced by either pesticide applications (*z*) or Bt technology adoption. Bt technology will reduce insecticide use if farmers use lots of insecticides in conventional crop. On the other hand, this technology can help in reaching potential yield *F*(.) by reducing *D*(.), if they were not using chemical insecticides for effective control of pests in the conventional crop. Similar finding of higher yield gains in the developing countries was observed in the case of weed control through use of GE crops by Brookes (2005) in Romania on herbicide-tolerant (HT) soybean (29–33% increase); Smale et al. (2012) in Bolivia on HT soybean (30% increase); and Kalaitzandonakes et al. (2015) on HT maize in Kenya.

The positive yield effects have been noticed in all the Bt cotton growing countries, except in Australia, where the reduction in pesticide expenditure led to benefits by increasing gross margin to the tune of 79 Australian dollars per hectare (Table 7.4). Apart from that, cultivating herbicide-tolerant soybean and sugar beet enabled the cultivators to raise another crop in the same field and additionally led to conservation of tillage (Marra et al. 2004; Kniss 2008), apart from enabling the farmers to spend time on non-farm activities through reduced time in weed management in soybean (Fernandez-Cornejo et al. 2005; Qaim and Traxler 2005).

Huge welfare gains from adoption of GE crops are shown to people of developing countries in the economy-wide models, despite trade barriers in the EU countries (Anderson et al. 2008; Anderson 2010). On the other hand, there are studies that show positive indirect effects of adopting GE crops. Bt cotton adoption in India increased household employment and income (Subramanian and Qaim 2009), especially for the hired female workers (Subramanian and Qaim 2010; Rao and Dev 2009), as well as calorie intake (Kouser and Qaim 2013). Adopting women farmers valued labour-saving benefit more in Bt corn grown in S. Africa, while men preferred yield-enhancing benefit, signalling gender perspectives in looking at new technologies (Ghouse et al. 2016). Globally, the reduction in pesticide sprays is estimated to have saved 671 million kilograms (8.2% reduction) of active ingredient, and the environmental impact associated with herbicide and insecticide use on these crops fell by 18.5% (Brookes and Barfoot 2018b).

On the downside, Bollgard II cotton in India developed resistance to pink bollworm in Western India (Fabrick et al. 2014), while Bt cotton worked without resistance in China (Qiao 2015) and USA (Carriere et al. 2003). However, resistance to American bollworm continues in India, and resistance to pink bollworm can be delayed by mixing refugia with biotech seeds (Kranthi 2015). Weeds developed resistance of Bt cotton in places where HT crops are grown and higher quantities of glyphosate are applied. NASEM (2016) has concluded that this is not because of GE crops per se and variations in applied herbicides can prolong resistance. Several technologies like Bt brinjal, HT cotton, HT maize and virus-resistant cassava are in the pipeline with documented evidence of huge benefits to farmers and to the national exchequer (Rao et al. 2018; Ashok et al. 2017). The recent application of biotech potato with bruise and late blight resistance and cold storage is found to reduce grower costs by 28%, apart from environmental benefits including a reduction of 2.5 million acre applications of pesticides, 740 million fewer pounds of carbon dioxide emitted and 84 billion gallons less of water used (Guenthner 2017).

7.4.1 Isolating Technology Effect

Higher yields and net returns in new technologies could be either due to technology effect or because better and motivated farmers self-select themselves for adoption. Therefore, isolating the technology effect by separating the confounding factors is critical in evaluating technologies, as otherwise 'farmer effect' can be wrongly attributed to technologies (Rao 2013). Several studies have applied econometric tools to separate technology effect and found higher yields in insect-resistant cotton (Kathage and Qaim 2012; Rao and Dev 2009; Stone 2011; Gruere and Sun 2012; Morse et al. 2012), herbicide-tolerant soybean (Smale et al. 2012; Fernandez-Cornejo and McBride 2002; Fernandez-Cornejo et al. 2005) and insect-resistant maize (Yorobe and Smale 2012). Meta-analysis by Witjaksono et al. (2014) found positive yield and revenue impacts after controlling for selection bias, estimation and measurement bias. Further, using panel data models, Kouser and Qaim (2011) and Krishna and Qaim (2012) have shown that there were significant pesticide reductions in Bt cotton cultivation and that these are sustainable for adopters apart from helping the non-adopters with declined pest population, resulting in a *halo effect*. This corroborates research findings, on the benefits to non-adopters, in the realm of biological science reported in *Science* by Wu et al. (2008) in China, Hutchison et al. (2010) and Carriere et al. (2003) in the USA.

7.5 Policy Framework for Harnessing Biotechnology

The current logjam in commercializing biotech crops stems for excessive and faulty regulation giving credence to uninformed and speculative fears (Adenle et al. 2018; Zaidi et al. 2019). Harnessing potential of biotechnologies is conditioned on putting in place an elaborate institutional mechanism to scrutinize technologies for biosafety, labelling, trans-boundary movement of GE foods in concurrence with Cartagena Protocol on Biosafety (CPB) and strengthening property rights through patent laws, apart from developing institutional framework for risk management and risk communication (Craig et al. 2017). This is a tall order for developing country governments, and most of them, especially those in the African continent and Caribbean region countries, are not equipped to do this, stoking fears of recurrence of the Green Revolution experience (of bypassing poor countries), though there has been some improvement in recent years (Morris 2017; Rosado and Craig 2017). The countries with relatively stronger agricultural research capabilities are moving ahead in this trajectory, and their regulatory frameworks have been analysed in this section (Table 7.5). Countries having commercial and postcolonial ties to EU in Africa, the Middle East and South and Southeast Asia adopted more precautionary approach, while those having closer ties to the USA, including most in the Western Hemisphere plus the Philippines, have generally adopted a less precautionary approach (Herring and Paarlberg 2016).

Overarching legal framework with exclusive personnel for regulation was put in place in very few countries like Brazil, S. Africa, Mexico and very recently in the Philippines, while the same has been in the process in Argentina and India, as well as in Bangladesh and Pakistan. As could be seen from Table 7.5, either Ministry of Agriculture (Argentina, China, S. Africa) or Ministry of Science and Technology (Brazil, Mexico and the Philippines) handle this except in India where Ministry of Environment, Forest and Climate Change takes a final decision. Reforms to the framework in Brazil in 2008 making National Technical Commission on Biosafety (CTNBio) as the single agency for taking decisions on approvals quickened the

Table 7.5 Policy framework in selected developing countries

Regulatory issue	Arrangement in countries					
	Brazil	Argentina	India	China	S. Africa	Mexico
Overarching law	Available	Not in place	Not in place	Not in place	Available	Available
Controlling ministry	Office of the President (CNBS) and Ministry of Science and Technology (CNBio)	Central Food Ministry	Ministry of Environment, Forest and Climate Change	Ministry of Agriculture	Ministry of Agriculture	Executive secretary nominated from Ministry of Science and Technology and approved by the president
Regulatory approach	Precautionary	Precautionary	Precautionary	Precautionary	Precautionary	Precautionary
Current stage of commercialization	Outlook very positive with quick approvals after 2008	On the whole, quite positive Approvals faster after 2012 change of policy	Moratorium from Feb 2010 on approvals. Field trials, put on hold since early 2012, are revoked in 2013	Came to a standstill amid resistance	Process of approvals moving quickly	11-year moratorium ended in 2009 Now, approval process moving quickly
Purpose of harnessing agri-biotechnology	National development and exports	National development and exports	Domestic food security and exports	Domestic food security	Domestic food security and exports	Domestic food security
Separate permissions	Not needed	Not needed	Need 'No Objection certificate'	Needed	Not needed	Not needed
Approval of staked events	Treated as new events	Allows applications for transgenic combining two approved events without full analysis	Treated as new event, though the consisting events are approved	No clear policy	Treated as new events	Evaluates them as different than the parental one
Type of labelling law	Mandatory (process based)	Voluntary	Mandatory (process based)	Mandatory (process based)	Voluntary so far (product based)	Voluntary

Labelling law	Mandatory labelling for >1%	No labelling regime. Does not differentiate GM and non-GM	Ministry of Consumer Affairs, Food and Public Distribution from 2013 for packaged form	Compulsory for soybean, maize, cotton, canola and tomato	By Ministry of Health. Only when allergens or human/animal proteins are present	No mandatory labelling. But, labelling of GM content of seeds
Enforcement of labelling	Not enforced	Not applicable	Not done presently	Enforced	Does not arise	Does not arise
UPOV Treaty, 1978	Joined in 1999	Joined in 1994	Not a member. But, enacted PPV&FR Act in consonance with UPOV '78	Joined in 1999	Joined in 1977	Joined in 1997
Patent laws	Not strong patents Plant and animals not patentable Microorganisms patentable with conditions	Strong protection to animals, plants, plant varieties, microorganisms, biological processes and genes	Microorganisms patentable	Patent law, 2008 Regulation on protection of new plant varieties, 1997	NA	Strong protection to plants, plant varieties and microorganisms Biological processes not patentable

Source: Compiled by the author from various sources process of harnessing technology and made it the leading GE crop cultivator, overtaking Argentina. To retain the edge, Argentina centralized all biotech-related decision-making by forming an exclusive Biotechnology Directorate in the Ministry of Agriculture, Fisheries and Livestock since 2009 and further reformed in 2012 to take decisions within 24 months by reducing from 42 months (USDA 2015).

Most countries take decisions on commercialization at the federal level, except in India and China. The Punjab Seed Council gave approvals to Bt cotton varieties in Pakistan until 2014, and there is uncertainty on the competent authority at the moment (Spielaman et al. 2015). In India, permissions from respective state governments are required to undertake trials since 2010 (Gupta 2011), and only eight of them have allowed trials since then. The moratorium imposed in 2010 continues in India and probably subject to the verdict of a case in the Supreme Court. Mexico came out of an 11-year moratorium in 2009 and accelerated approvals since then. Though approvals have stopped after Bt cotton in China, there was a shift in policy in 2016, which was witnessed in Chinese government acquiring biotech major company, Syngenta that aimed at allaying fears of foreign domination in technology and pushing forward transgenic crops to overcome imports and legitimize widespread illegally grown GE maize and rice crops (Economist 2016).

Development of biotechnological products in private domain is also conditioned on IPR protection either through UPOV (the Union for the Protection of New Varieties of Pulses) route or sui generis system. While Brazil, Argentina, China, S. Africa and Mexico joined UPOV 1978, India followed sui generis system and formulated Protection of Plant Varieties and Farmers Rights' Act, 2011, to enable protection to traditional knowledge by farmers. In the past few years, several African countries have joined UPOV, and several others are in consultation to do so (Jefferson and Padmanabhan 2016).

Labelling GE products has become a major issue of contention in recent times with demands for consumers' choice. While Brazil, China and India follow the mandatory process-based labelling methods, Argentina, South Africa and Mexico follow the voluntary product-based method. Though there are divergent views on which of these two methods of labelling helps consumers make an informed decision, published academic research concludes that voluntary labelling serves the purpose better than mandatory labelling (Bansal and Gruere 2012). However, a study from the USA concluded that mandatory labels led to a 19% reduction in opposition to GE food (Kolodinsky and Lusk 2018).

Most of the developing countries have signed and ratified Cartagena Protocol on Biosafety (CPB) except Argentina, though Brazil continues to have reservations about strict liability regime. The compliance to the CPB requires traceability arrangements on the source of GE product and also specific guidelines on coexistence of conventional, organic and GE crops (Bailey 2002; Wilson et al. 2008). None of the developing countries has the system for traceability and coexistence, except Brazil which has put in place rules for coexistence (Table 7.5). Stricter policies might end up with increased segregation costs for value chain actors, reduced international competitiveness (Boccaletti et al. 2017). Mexico is unique in that the argument that the places of primary source of origin of crops should be left GE free has forced them to keep GE free zones in some states. The issue of liability and compensation is another contentious matter which the developing countries will have to address in the years to come (Vigani and Olper 2012; Punt et al. 2017). Free flow of crop products from developing countries would require harmonization of GMO standards (de Faria and Wieck 2015) (Table 7.6).

7.5.1 Regulation of Gene-Edited Crops

Gene-edited crops, prima facie, seem less susceptible to stigmatization on issues of biosafety, as the technology leaves no sign of transgenics, and the ensuing products are like those from conventional plant breeding (Hefferon and Herring 2017; Adenle et al. 2018; Zaidi et al. 2019). These technologies are new, and their products might carry unintended effects like conventional plant breeding and transgenic technologies (EFSA 2012), depending on the kind of NBT used. Extensive development of NBTs over the last decade creates a situation where every country has to decide on the appropriate way to classify them for handling applications of potential trials and commercialization. The issue that arises in this regard concerns their similarity or difference to the GMOs, as they follow the latter in biological research pipeline. The first mover is Argentina by legislating to regulate NBTs on a product to product basis, using the concept of novel combination of genetic material (Srinivas 2018). The unfolding regulatory trajectories across countries show that those with product-based approach to GMOs treat NBTs like any other products of conventional plant breeding, while countries using process-based approach consider NBTs as GMOs (Seyran and Craig 2018). The former countries regulate them on a case-by-case assessment and include the USA, Canada, Argentina, Brazil, Chile, Columbia, China, Sweden and Australia (Lassoued et al. 2018). Japan also framed rules in early 2019 allowing gene-edited crops like those from conventional plant breeding. On the other hand, European Union Court of Justice decided that any organism obtained through an NBT that applies mutagenesis will be classified from now on with a retrospective effect from the day that the directive went into force as a GMO within the scope of the directive (Purnhagen et al. 2018).

NBTs are in limbo in several countries in view of the politically sensitive nature of biotechnology, difficulty of detecting NBTs from products of conventional plant breeding and wide spectrum of technologies in gene editing. These technologies range from simple refinement of conventional plant breeding without altering the genome in RNA-dependent DNA methylation (RdDM), transgene-free products with site-specific genome changes in clustered regularly interspersed short palindromic repeats (CRISPR), transcription activator-like effector nuclease (TALEN) and zinc-finger nucleases (ZFN) to gene insertions in SDN3. Therefore, the problem arises in classifying products of different NBTs either as GMOs or non-GMOs. This is a unique challenge that emanates with the advent of NBTs only. Excessive regulation as in case of GMOs can stifle investments, product development and also adversely effects consumer confidence.

Table 7.6 Policy framework in selected developing countries – *Contd*

Regulatory issue	Arrangement in countries					
	Brazil	Argentina	India	China	S. Africa	Mexico
Cartagena protocol	Ratified. But opposed to strict liability. Incorporated precautionary principle	Signed, but not ratified	Ratified and a biosafety clearing house is set up in the ministry of envt and forests	Signed and ratified	Signed and ratified. Department of Agriculture, Forestry and Fisheries (DAFF) is looking instead of DEF	Signed and ratified
GE imports	Only GE events approved for commercial production can be imported	Does not differentiate GE and non-GE	Soybean oil from Brazil, Argentina and the USA is allowed	LLP with 0% tolerance for unapproved events	1% tolerance. But, processed product allowed	Allowed under NAFTA. However, the imports should not be used for production but only for consumption. 2% level tolerance by the Secretariat of Agriculture, Livestock, Rural Development, Fisheries and Food (SAGARPA)
	0% tolerance for unapproved events		Zero-tolerance policy for unapproved events	Permitted 10 events of soybean from the USA, Brazil, Argentina and 17 events of GM corn	Only approved events allowed. 54 events in five crops – soybean, maize, cotton, canola and rice	
Coexistence	Rules exist	No policy	No specific regulation	No rules	No rules	Biosafety law provision 90 established GEO free zones by SAGARPA
Traceability	No system	No official system	No system	No system	No system	No system

Animals	GE dairy cattle produced. Recombinant proteins in pipeline. Cloning done. No GE animals so far. Same regulatory framework	Transgenics in pipeline for growth hormones. Cloning allowed. Regulation same as agriculture	In its infancy. Two buffaloes are cloned successfully. No regulations on production or marketing of cloned animals	Transgenic animals being developed, but none are approved so far	No animals so far. Regulation is same	No GE animals or products. Covered under same regulatory framework as plants

Source: Compiled by the author

7.6 Rising Investment Requirements with New Technologies and Consolidation in Seed Industry

The recently completed mergers and acquisitions in the seed industry indicate continuation of the ongoing trend in the seed industry that entails huge investments with the advent of new technologies and their convergence with information and communication technologies. However, they have raised concerns on improving small farm agriculture, especially in developing countries like India through rising seed prices (Bryant et al. 2016). To mention the top three, these are 130 billion USD merger of Dow and Dupont, 66 billion USD takeover of Monsanto by Bayer and 43 billion USD acquisition of Syngenta by China Chemical Corporation, all in the past 2 years. Even before these big ticket consolidations, 'the big six' corporations collectively controlled more than 75% of global agrochemical market, 63% of the commercial seed market and almost three-fourths of R&D expenses in the seeds and pesticides sector, and the sector has been witnessing transformation to oligopoly (Lianos et al. 2016). These recent consolidations are continuation of long-term trend in the industry of agrochemical companies taking over seed companies and likely to persist for some time to come (Rao 2004; Lianos et al. 2016; Howard 2015), if the countervailing forces discussed below do not grow strong enough to counter the trend. Besides the secular trend of agrichemical companies taking over seed companies, these corporations have been acquiring software start-ups for precision farming (Gullickson 2018). The erstwhile Monsanto established Climate Corporation as a subsidiary, and AGCO bought Precision Planting from Climate Corporation. DowDupont acquired granular to connect farmers with big data analytics. John Deere invested 305 million USD to acquire Blue River Technology that designed and integrated computer vision and machine learning technology in lettuce fields to reduce herbicide use and potential applications in other crops.

The public sector breeders quite often get stonewalled with patent hurdles in their effort to develop varieties even in orphan crops. The patent thickets create a situation referred to as 'tragedy of the anti-commons' by Heller and Eisenberg (1998), in which no one will be able to assemble a product overcoming the maze of patents and results in underuse of (or non-use) of resources. Golden rice is a classic example of this phenomenon, as its development was stalled for a long time to overcome the 40 odd patents from different owners (Jefferson and Padmanabhan 2016). The challenge of ever-rising share of the private sector in global food and agriculture R&D, which stood at 44% in 2009, is another big concern, as private sector cannot compensate for the decline of public research in view of its focus on technology development, while public universities and institutes continue to be the source of upstream research (Pardey et al. 2015). The private sector research however can have high social benefits (to farmers) relative to private benefits (to companies) (Fig. 7.2) and can be utilized for the societal gains, with a clear understanding that public research can only create agricultural public goods (Dalrymple 2008).

These disturbing developments mask another set of developments rising as countervailing forces to protect small farm agriculture. The locus of R&D expenditures in the world is now slowly shifting towards developing countries. In 2009, about

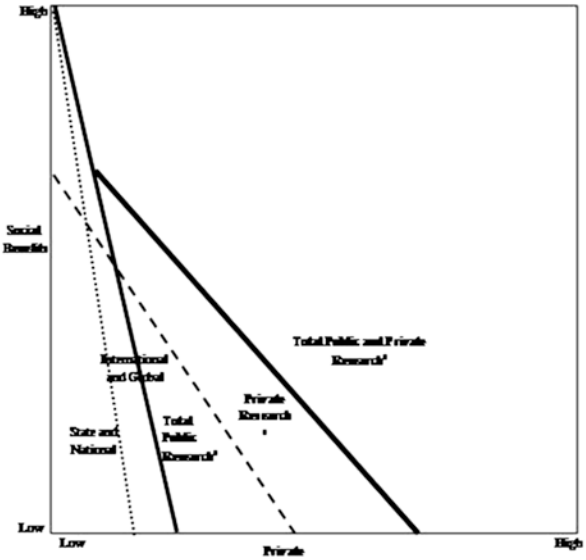

Fig. 7.2 Hypothetical relationship between the social and private benefits from public and private research. (*Source*: Dalrymple 2008)

42% of global R&D investment was done in the middle-income countries including China, Brazil and India, though low-income countries continue to have a miniscule of this total (Pardey et al. 2015). Analyses of the changing landscape of biotechnology across developing countries show that they have realized the need to be proactive to save resource-poor farmers through energizing public sector research. China, for example, acquired Switzerland-based Syngenta at a price of 43 billion USD through its National Chemical Corporation.

Several developing countries like Brazil, Argentina, China, the Philippines, Bangladesh and Pakistan have been racketing up public sector research in biotechnology and have brought out crop products in recent years. Not surprisingly, these crop products possess traits of importance to resource-poor farmers like drought tolerance, examples of which are given earlier. Another significant positive development is in the realm of legal framework of property rights, whereby gene patents have either recently been invalidated (in the USA and Australia) or likely to be done in the near future in many other countries. Also, subsequent to the Nagoya Protocol on access and benefit sharing, negotiations are underway in the Intergovernmental Committee to negotiate an international legal instrument to protect traditional knowledge and access and benefit sharing (Jefferson and Padmanabhan 2016). In India, new 2013 patent guidelines, if enforced, might change the scenario away from strong patents (Ravi 2013).

Beyond IPR protection, stringent regulations through biosafety laws dampen research and product development by the public sector as well as small investors as happened in India and Argentina, and this is referred to as 'IP-regulatory' complex

(Graff and Zilberman 2016). Despite not having patent protection, Bollgard I event of Monsanto enjoyed monopoly rights in India because of the arduous process of getting event approval leaving other companies dependent on Monsanto for seed development (Graff et al. 2015). Gene-edited crops might be less controversial on issues of bio-property as the relatively less cost, time and infrastructural requirements do not enable first-mover advantages to the developers, apart from lower chances for geographical concentration of the industry (Hefferon and Herring 2017; Lassoued et al. 2018).

7.7 Conclusions and Policy Implications

Any technology, including agricultural technologies, can in principle have both positive and negative impacts in varying degrees and only one of them in a certain magnitude. Empirical evidence in the specific socio-economic, cultural and institutional milieu is necessary to evaluate technologies. This chapter has examined the diffusion of genetically engineered crops in developing countries in a cross-country comparative perspective in regard to their nature and adoption, impacts, necessary supplementary policies and challenges associated with rising investment needs in the seed sector.

The pace of discovery in biological sciences has been rapid, and biotechnologies are moving beyond genetic engineering, and the first non-GE biotechnological crop using gene editing was released in 2016 in the form of sulphonylurea (SU)-tolerant canola (mustard) in the USA followed by bruising- and browning-resistant potato. Within the GE crops, technology has deepened to commercialize several (31) GE crops in place of just 3 crops earlier, viz. soybean, maize and cotton, and from single gene expressions like insect/herbicide resistance to second-generation products like drought tolerance and improved quality attributes. The developing countries accounted for 54% of the 189.8 million hectares of area under these crops in 2017 negating fears that resource-poor farmers in these countries would not be benefited from these technologies.

Economic and agronomic impacts of GE crops have been rigorously studied, as the controversies on their utility continue. The peer-reviewed research findings suggest higher yields, higher net income and lower chemical use with conservation tillage. The most recent meta-analysis estimated 22% yield gain associated with 39% reduction in plant protection expenditure and 68% higher net income. The longitudinal studies have shown that cultivation of these crops over the past 19 years has resulted in gains of 150 billion USD to world agriculture.

Technologies need supplementary policies to optimize social welfare. Excessive and uninformed regulation has been the bane of biotech crop adoption in the contemporary world. Very few of the developing countries could put a legal framework for biosafety, and our study reveals that this is still a work in progress with inadequate efforts to create a professional body that allays the fears of consumers and arrives at decisions based on scientific data. The countries like Brazil and Argentina have been moving fast in diffusion of these technologies, as they could put this mechanism in place. India and China are yet to navigate this process, not to speak of the many low-income developing countries, especially from the African continent. For instance, the Biotechnology Regulatory Authority of India (BRAI) bill has been in the making since 2008 in India without any end in sight. Uncertainty in regulatory approvals can have the adverse impacts of abandonment of investment and thereby innovation. A 2-year delay reduces the net present value of normal returns for a private investment into a new GM crop variety by about one-third that renders the investment loss-making (Smyth et al. 2016). Above all, several developing countries including India are yet to devise regulatory norms for regulating gene-edited crops developed using new breeding technologies (NBTs) unmindful of the ideological opposition by civil society groups as in Shiva (2018). These countries need to classify gene-edited crops as non-GMOs and regulate as those from conventional plant breeding by following the path taken by developing countries like Argentina, Brazil, China, Chile and Columbia, besides those among developed countries, viz. the USA, Canada, Australia, Sweden and Japan.

There has been a dramatic shift in the seed industry with rising investment demands with the availabilities of new technologies as well as convergence of technologies. The consolidation with the mega mergers and acquistions in recent times have to be viewed in this background. This trend is likely to continue for some time to come in view of the rising investment needs with convergence of technologies and falling margins of chemical companies. Foremost among the countervailing forces to this consolidation is the racketing up of public sector research by the national agricultural research system (NARS) in developing countries. Second is the recent trend of reversal of patent protection for DNA sequences that started with the Supreme Court verdict in *Association for Plant Pathology* vs. *Myriad Genetics* in the USA. However, it is premature to foresee the final outcome of this trend. The developing countries will gain by internalizing these technologies into their national agricultural research systems and invest more in both upstream and downstream research, besides proactively participating in the ongoing review process of negotiating international legal instruments for traditional knowledge. Enabling regulatory policies will go a long way in unleashing the huge potential created in the private sector.

The third countervailing force to overcome the asymmetric power of corporation in biotechnological research is to forge public-private partnerships like in case of drought-tolerant (DT) soybean in Argentina, DT maize in Africa and several others. Innovative platforms like Public Intellectual Property Resource for Agriculture (PIPRA) established in the University of California, Davis, and African Technology Foundation in Kenya show the way forward for the governments of developing countries to act in the interest of resource-poor farmers. It should not be forgotten that much of patented technology by companies has their origins from the upstream research done in public universities. Viewed from that angle, it becomes clear that science behind technologies and private sector domination need to be separated in taking decisions about their utilization. Excessive regulation or lack of regulatory mechanism has been stifling technologies developed by the public institutions and small companies that are of interest to developing country agriculture. The developing countries are likely to benefit more from engaging with development discourse on how to harness new opportunities arising out of rapid discoveries in biological sciences for raising incomes and welfare of rural populations with predominantly agriculture-based livelihood and thereby achieve higher national economic development.

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