Obstacles to successful commercialisation of public investments in the development of GM crops

By
Jing-wen Chiu
ORCID: 0000-0001-6994-2619

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Faculty of Veterinary and Agricultural Sciences
The University of Melbourne
Abstract

As the world’s population continues to rise and with many developing countries unable to meet the nutritional requirement of their citizens, tremendous pressure has been placed on improving the global agricultural system for future food security. Genetic modification (GM) is a key agricultural biotechnological tool that allows the direct manipulation of plant genomes, introducing novel traits that are difficult or impossible to achieve through conventional plant breeding programmes. However, the great majority of commercialised GM crops are products from multinational corporations and these cover almost all the GM crop planted area globally. Developments originating from public organisations are rarely seen in the commercial market despite substantial public investment. Little research has gone into examining the critical conditions and processes required to successfully transform proof of concept genetically modified plant material into commercial products. The purpose of this research is to identify the obstacles to successful commercialisation of GM crops developed in the public sector and to make practical recommendations to relevant stakeholders on how to overcome these.

Based on the concept of innovation uncertainty, an innovation evaluation framework is adopted to guide the overall analysis. Innovation is considered viable only when certain technological, commercial, organisational and social uncertainties have been addressed. Five specific research questions are derived: 1) technologically, to what extent are intellectual property right systems an obstacle to public GM crop developments? 2) commercially, to what extent are particular difficulties faced by public research organisations in complying with GM crop regulatory requirements? 3) organisationally, what are the barriers specific to the public sector which are preventing GM crop developments from advancing to the commercial stage? 4) to what extent does the public-private partnership model face particular difficulties or offer viable solutions in the GM crop arena? 5) socially, to what extent does the need to obtain a social licence for GM crops impact on the public sector?

A mixed method approach was applied to address the multi-disciplinary nature of the specific research questions. Five case studies of public GM crop projects at different development phases were conducted to narrow the scope of focus and identify the factors
most likely to be important in advancing a project to commercialisation. Interviews with key stakeholders from public research institutions, technology transfer offices, regulatory authorities, private seed companies, industry bodies and non-governmental organisations, in Australia, China, and India to verify and expand on the findings from the case studies. The results from the case studies and stakeholder interviews led to focussed studies on the major obstacles which were identified: 1) conducting an analysis of the global agricultural biotechnology patent landscape to examine the access of the public sector to enabling intellectual property, 2) analysing the commercial uncertainty of public GM crop projects under regulatory field trials to identify critical imperatives which drive public GM crop projects, focusing on the issues of project selection, public funding and the costs of regulation, 3) undertaking a study on the influence of national policies on GM crop developments in the public sector and clarifying organisational and financial capabilities of public sector organisations for the commercialisation of GM crops, 4) comparing a purely public sector GM project with a public-private partnership to determine whether such models address the obstacles identified in the study.

The results from the study suggest that public research institutions do not have the capability to commercialise GM crops. Technologically, the public sector is capable of creating innovative solutions that address the current agricultural problems. However, the multiple patents covering a single technology and undisclosed licensing arrangements create difficulties in establishing freedom to operate (FTO) for commercialisation. This issue is further exacerbated by the lack of resources, capability and willingness in the public sector to navigate through the patent landscape. Public sector funding has not reflected the true costs of development and remains short-term, with limited or non-existent budgets for the necessary legal/intellectual property activities. The results suggest that the regulatory cost experienced by the public sector is less than the reported industry value. However, the lack of financial continuity created by the grant-based funding model in the public sector makes advancing to the later, and more expensive, stages of the commercialisation process very difficult for most public sector organisations. This study reveals that the absence of publically available commercial and financial information on existing public and indeed private GM crop developments results in poor project planning and provides a significant barrier to successful commercialisation. The examination of national strategies in India and China provides evidence which indicates that the role of public research organisations under the
national innovation systems is to act as knowledge sources, generating human resources and intellectual property assets, and is not focussed on the production of commercial products. The absence of financial motivation for individual institutions or scientists to balance the potential liability risks, reduces the likelihood of public researchers actively participating in commercial activities. A partnership approach, drawing on the strengths of the private sector, is able to fulfil the legal rights needed for commercialisation and provides the capability and knowledge required to develop commercially acceptable products. However, the risk-averse nature of public research institutions reduces the private sector’s willingness to form partnerships and the effectiveness of those partnerships which are formed. If the commercialisation of public sector science in the GM crop area is to continue to be regarded as an appropriate activity for the expenditure of public funds then this study has practical implications for public administrators and public research scientists, clarifying the need to provide realistic, long-term, public investment, to harmonise GM regulatory requirements and to create the organisational capacity and incentives needed to commercially deliver GM crops through the public sector.
Declaration

This is to certify that:

1. The Thesis comprises only my original work towards the Ph.D.

2. Acknowledgement has been made in the text to all other materials used

3. The Thesis is less than 100,000 words in length, exclusive of tables, figures, bibliographies and references

Jing-wen Chiu
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<td>AATF</td>
<td>African Agricultural Technology Foundation</td>
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<tr>
<td>AGERI</td>
<td>Agricultural Genetic Engineering Institute</td>
</tr>
<tr>
<td>APHIS</td>
<td>Animal and Plant Health Inspection Service</td>
</tr>
<tr>
<td>ARC</td>
<td>Australian Research Council</td>
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<td>AVRDC</td>
<td>World Vegetable Centre</td>
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<td>BCIL</td>
<td>Biotech Consortium India Limited</td>
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<td>BGMV</td>
<td>Bean Golden Mosaic Virus</td>
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<td>BIPP</td>
<td>Biotechnology Industry Partnership Program</td>
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<tr>
<td>BIRAC</td>
<td>Biotechnology Industry Research Assistance Council</td>
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<tr>
<td>BMGF</td>
<td>Bill and Melinda Gates Foundation</td>
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<tr>
<td>BRAI</td>
<td>Biotechnology Regulatory Authority of India</td>
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<td>Bt</td>
<td><em>Bacillus thuringiensis</em></td>
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<tr>
<td>CAAS</td>
<td>Chinese Academy of Agricultural Sciences</td>
</tr>
<tr>
<td>CAS</td>
<td>Chinese Academy of Sciences</td>
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<tr>
<td>CAMBIA</td>
<td>Centre for the Application of Molecular Biology to International Agriculture</td>
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<td>CARiB</td>
<td>Caterpillar and Aphid Resistance in Brassicas</td>
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<td>CBD</td>
<td>Convention on Biological Diversity</td>
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<tr>
<td>CEIB</td>
<td>Centre of Excellence and Innovation in Biotechnology</td>
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<tr>
<td>CFT</td>
<td>Confined Field Trial</td>
</tr>
<tr>
<td>CGIAR</td>
<td>Consultative Group for International Agriculture</td>
</tr>
<tr>
<td>CIAT</td>
<td>International Center for Tropical Agriculture</td>
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<tr>
<td>CICR</td>
<td>Central Institute for Cotton Research</td>
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<td>CIMBAA</td>
<td>Collaboration on Insect Management for Brassicas in Asia and Africa</td>
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<td>CIMMYT</td>
<td>International Maize and Wheat Improvement Centre</td>
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<td>CNBS</td>
<td>National Biosafety Council</td>
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<td>COGEM</td>
<td>Commission on Genetic Modification</td>
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<td>Acronym</td>
<td>Full Form</td>
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<tr>
<td>CRC</td>
<td>Cooperative Research Centre</td>
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<tr>
<td>CRISPR</td>
<td>Clustered Regularly Interspaced Short Palindromic Repeats</td>
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<tr>
<td>CSIRO</td>
<td>Commonwealth Scientific and Industrial Research Organisation</td>
</tr>
<tr>
<td>CTNBio</td>
<td>Brazilian National Technical Biosafety Commission</td>
</tr>
<tr>
<td>DBM</td>
<td>Diamondback Moth</td>
</tr>
<tr>
<td>DBT</td>
<td>Department of Biotechnology</td>
</tr>
<tr>
<td>DFID</td>
<td>Department for International Development</td>
</tr>
<tr>
<td>DST</td>
<td>Department of Science and Technology</td>
</tr>
<tr>
<td>DWPI</td>
<td>Derwent World Patent Index</td>
</tr>
<tr>
<td>EC</td>
<td>European Commission</td>
</tr>
<tr>
<td>EFSA</td>
<td>European Food Safety Authority</td>
</tr>
<tr>
<td>ELISA</td>
<td>Enzyme-Linked Immunosorbent Assay</td>
</tr>
<tr>
<td>EMBRAPA</td>
<td>Brazilian Agricultural Research Corporation</td>
</tr>
<tr>
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<td>Environmental Protection Agency</td>
</tr>
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<td>European Patent Office</td>
</tr>
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<td>ETS</td>
<td>Excellence Through Stewardship</td>
</tr>
<tr>
<td>EU</td>
<td>European Union</td>
</tr>
<tr>
<td>FAO</td>
<td>Food and Agriculture Organisation of the United Nations</td>
</tr>
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<td>FDA</td>
<td>Food and Drug Administration</td>
</tr>
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<td>FSANZ</td>
<td>Food Standards Australia and New Zealand</td>
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<td>FTO</td>
<td>Freedom to Operate</td>
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<td>GEAC</td>
<td>Genetic Engineering Approval Committee</td>
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<td>GM</td>
<td>Genetically Modified</td>
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<td>Genetically Modified Organisms</td>
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<td>GRDC</td>
<td>Grains Research Development Corporation</td>
</tr>
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<td>HT</td>
<td>Herbicide Tolerance</td>
</tr>
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<td>Indian Agricultural Research Institute</td>
</tr>
<tr>
<td>ICAR</td>
<td>Indian Council of Agricultural Research</td>
</tr>
<tr>
<td>ICGEB</td>
<td>International Center for Genetic Engineering and Biotechnology</td>
</tr>
<tr>
<td>Acronym</td>
<td>Description</td>
</tr>
<tr>
<td>---------</td>
<td>-------------</td>
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<tr>
<td>ICH</td>
<td>International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use</td>
</tr>
<tr>
<td>ICRISAT</td>
<td>International Crops Research Institute for the Semi-Arid Tropics</td>
</tr>
<tr>
<td>IGMORIS</td>
<td>Indian GMO Research Information System</td>
</tr>
<tr>
<td>IP</td>
<td>Intellectual Property</td>
</tr>
<tr>
<td>IPC</td>
<td>International Patent Classification</td>
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<tr>
<td>IR</td>
<td>Insect resistance</td>
</tr>
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<td>ISAAA</td>
<td>International Service for the Acquisition of Agri-biotech Applications</td>
</tr>
<tr>
<td>LLP</td>
<td>Low Level Presence</td>
</tr>
<tr>
<td>MAHYCO</td>
<td>Maharashtra Hybrid Seed Company</td>
</tr>
<tr>
<td>MHLW</td>
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</tr>
<tr>
<td>MNC</td>
<td>Multi-National Corporation</td>
</tr>
<tr>
<td>MOA</td>
<td>Ministry of Agriculture</td>
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<td>MOEF</td>
<td>Ministry of Environment and Forests</td>
</tr>
<tr>
<td>MOST</td>
<td>Ministry of Science and Technology</td>
</tr>
<tr>
<td>MOU</td>
<td>Memorandum of Understanding</td>
</tr>
<tr>
<td>MTA</td>
<td>Material Transfer Agreement</td>
</tr>
<tr>
<td>NARS</td>
<td>National Agricultural Research System</td>
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<td>NAU</td>
<td>Nanjing Agricultural University</td>
</tr>
<tr>
<td>NBC</td>
<td>National Biosafety Committee</td>
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<tr>
<td>NBDS</td>
<td>National Biotechnology Development Strategy</td>
</tr>
<tr>
<td>NGO</td>
<td>Non-Governmental Organisation</td>
</tr>
<tr>
<td>NKL</td>
<td>National Key Laboratory</td>
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<tr>
<td>NOC</td>
<td>No Objection Certificate</td>
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<td>NRCPB</td>
<td>National Research Center on Plant Biotechnology</td>
</tr>
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<td>NRI</td>
<td>National Resources Institute</td>
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<tr>
<td>NSFC</td>
<td>National Science Foundation of China</td>
</tr>
<tr>
<td>OECD</td>
<td>Organisation for Economic Co-operation and Development</td>
</tr>
<tr>
<td>OGBEA</td>
<td>Office of the Agricultural Genetic Engineering Biosafety Administration</td>
</tr>
<tr>
<td>OGTR</td>
<td>Office of the Gene Technology Regulator</td>
</tr>
<tr>
<td>Acronym</td>
<td>Full Form</td>
</tr>
<tr>
<td>---------</td>
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</tr>
<tr>
<td>OPV</td>
<td>Open Pollinated Variety</td>
</tr>
<tr>
<td>PAC</td>
<td>Papaya Administrative Committee</td>
</tr>
<tr>
<td>PBR</td>
<td>Plant Breeder’s Right</td>
</tr>
<tr>
<td>PCT</td>
<td>Patent Cooperation Treaty</td>
</tr>
<tr>
<td>PIPRA</td>
<td>Public Intellectual Property Resources for Agriculture</td>
</tr>
<tr>
<td>PPP</td>
<td>Public-Private Partnership</td>
</tr>
<tr>
<td>PRSV</td>
<td>Papaya Ring Spot Virus</td>
</tr>
<tr>
<td>PVP</td>
<td>Plant Variety Protection</td>
</tr>
<tr>
<td>PVPFR</td>
<td>Protection of Plant Varieties and Farmer's Rights</td>
</tr>
<tr>
<td>QUT</td>
<td>Queensland University of Technology</td>
</tr>
<tr>
<td>R&amp;D</td>
<td>Research and Development</td>
</tr>
<tr>
<td>RCGM</td>
<td>Review Committee of Genetic Manipulation</td>
</tr>
<tr>
<td>RDC</td>
<td>Research Development Centre</td>
</tr>
<tr>
<td>RNAi</td>
<td>RNA interference</td>
</tr>
<tr>
<td>SCI</td>
<td>Science Citation Index</td>
</tr>
<tr>
<td>SBIRI</td>
<td>Small Business Innovation Research Initiative</td>
</tr>
<tr>
<td>SEPA</td>
<td>State Environmental Protection</td>
</tr>
<tr>
<td>SPS</td>
<td>Sanitary and Phytosanitary Measures</td>
</tr>
<tr>
<td>TALENS</td>
<td>Transcription Activator-like Effector Nucleases</td>
</tr>
<tr>
<td>TERI</td>
<td>The Energy and Resources Institute</td>
</tr>
<tr>
<td>SIPO</td>
<td>State Intellectual Property Office</td>
</tr>
<tr>
<td>TRIPS</td>
<td>Trade-Related Aspects of Intellectual Property Rights</td>
</tr>
<tr>
<td>UAS Dharwad</td>
<td>University of Agricultural Science Dharwad</td>
</tr>
<tr>
<td>UPOV</td>
<td>International Union for the Protection of Plant Varieties</td>
</tr>
<tr>
<td>USAID</td>
<td>United States Agency for International Development</td>
</tr>
<tr>
<td>USDA</td>
<td>United States Department of Agriculture</td>
</tr>
<tr>
<td>USPTO</td>
<td>United States Patent and Trademark Office</td>
</tr>
<tr>
<td>WEMA</td>
<td>Water Efficient Maize for Africa</td>
</tr>
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<td>WIPO</td>
<td>World Intellectual Property Organisation</td>
</tr>
<tr>
<td>WTO</td>
<td>World Trade Organisation</td>
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Chapter 1

Introduction

“The majority of agricultural scientists, including myself, anticipate great benefits from biotechnology in the coming decades to help meet our future needs for food and fibre. The commercial adoption by farmers of transgenic crops has been one of the most rapid cases of technology diffusion in the history of agriculture” (Borlaug, 2000)

Biotechnology has been utilised across a range of industries and is considered one of the key technologies of the 21st century. Society as a whole has benefited from the exponential growth of biotechnology industries and applications of the technology can be found across a broad spectrum of sectors. Climate change and the rapid growth of global population have driven the public investment in agricultural biotechnology. The United Nations Food and Agriculture Organisation (FAO) predicts that by 2050 the global population will reach 9 billion and overall food production will need to increase by 70%, with developing countries doubling their agricultural output, in order to meet future demands (Alexandratos & Brunisma, 2012). Increasing economic growth in some developing countries is generating a heavy demand for higher quality and more diverse food, creating tremendous pressure on primary food producers, whilst many developing countries continue to languish in food insecurity with access to a healthy diet strictly limited (Stein, 2010; Khush et al., 2012).

Concurrently, farmers are threatened by the impact of climate change, where the increase in global temperature has reduced water availability for irrigation and affected rainfall, causing drought across farmlands in many regions. The loss of arable lands due to rapid urbanisation in developing countries further challenges global agricultural production (Chen, 2007). To meet the ever increasing food demand given limited opportunities to expand agricultural land, it is expected that agricultural productivity gains need to come from an increase in yields on existing agricultural land.

Genetic modification (GM), also known as genetic engineering, is a key biotechnological tool that allows the direct acquisition of novel traits by inserting foreign DNA sequences into
target host organisms. The technology has been utilised in many different industries, predominantly in the pharmaceutical and biomedical sectors and many drug development companies have already transited from synthetic organic chemicals to recombinant proteins for therapeutic uses (Cockburn & Henderson, 2001; Ferrer-Miralles et al., 2009). In the agriculture sector, this technology offers the ability to precisely introduce useful characteristics into plants which are extremely difficult or impossible to achieve through conventional breeding programmes. The value of such technology has been observed in the capacity to protect and increase yield, enhance nutrient levels and addresses abiotic hurdles (Christou et al., 2006; Ashraf, 2010; Hokanson et al., 2010). Private seed companies are investing in GM technology, introducing novel traits, generally in major commodity crops which have the capacity to provide strong economic returns (e.g. insect resistant crops for minimising pest damage). Farmers who adopted GM crops have benefited from the technology through a reduction in labour costs, minimised yield losses to pests and better, cheaper, weed management systems. The accumulation of farm-level benefits has had a positive impact on the economy of GM cultivating countries (Qaim, 2009; Brookes & Barfoot, 2015). For example, Argentina’s adoption of GM soybean greatly contributed to the country’s recovery from the economic depression between 1998 and 2002 (Trigo & Cap, 2006) and India’s adoption of GM cotton increased average yields by 50% and turned India from a net importer to a significant exporter (Qaim et al., 2006; Qaim, 2009).

It has been suggested that the public sector\(^1\) should focus on developing GM crops to address problems faced by farmers of minor crops and to improve food security for the poor in developing countries given that these crops are of lesser interest to the multinational biotech companies (Conway & Toenniessen, 1999; Wambugu, 1999; Cohen, 2005; Qaim et al., 2013). Developments from public research can provide numerous benefits whose achievement is not necessarily a goal of commercially driven organisations involved in GM technology. However, this promising outlook for the public sector has not been realised in successful commercialisation and widespread adoption of publicly developed GM crops. Despite over 20 years of public investment, especially in developing countries such as India and China\(^2\), current public efforts are represented on the ground by only a minuscule fraction (0.005%) of the global commercialised GM cropping area (James, 2015). This thesis

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\(^1\) In this thesis, the public sector is taken as comprising government agencies, universities and non-government organisations which provide services to the general public, for the most part without any financial feedback from successful crop breeding products, GM or conventional.

\(^2\) See Section 7.3 and 7.4
identifies the obstacles to successful commercialisation of public GM initiatives and makes recommendations for addressing these obstacles.

1.1 Background to the problem

Crop improvement through plant breeding has long been a major activity of the public sector. The ‘Green Revolution’ in the 1960s, which increased agricultural production worldwide, was achieved through efforts from public research institutions (Evenson & Gollin, 2003). The literature suggests that the public sector has a very significant history of applying GM technology to introduce novel traits into plants. In fact, the world’s first GM crop originated from the public sector in 1992; a virus-resistant tobacco developed by Peking University and the Chinese Academy of Sciences (CAS). Despite the fact that the GM tobacco improved yield through disease protection (Karplus & Deng, 2008), the variety was discontinued due to foreign tobacco companies’ refusal to purchase (Macilwain, 2003). However, looking at the current commercial market for GM crops, the majority of the products have been developed and commercialised by a very limited selection of multinational seed companies.

The private sector has led in the commercial introduction of GM crops which are planted on any significant scale, with two major input traits, insect resistance and herbicide tolerance (James, 2015) (Box 1.1). Insect resistant plants expressing Bacillus thuringiensis (Bt) toxins, prevent pest damage and lead to an overall increase in yields where insect pests have been constraining it (Bates et al., 2005; Huang et al., 2005; Qaim, 2009). Herbicide tolerant crops improve the efficiency of the farming processes by enhancing flexibility in weed control, particularly in growing crops (Qaim & Traxler, 2005; Cerdeira & Duke, 2006).

These traits have been introduced into major commodity crops which are grown on very large areas and provide the highest economic returns for the trait developer i.e. maize, soybean, cotton and canola. The rapid adoption of GM crops developed by the private sector in both developed and developing countries has been largely tied to the associated socio-economic benefits. Farmers benefit from increased yield while minimising the amount of pesticide or herbicide required and reducing their application costs, with the companies either selling seeds directly at a premium or entering licensing/royalty agreements with other seed producers (Qaim & Traxler, 2005). By 2014, the global coverage of GM crops had increased to 180 million hectares, with private sector GM crops representing greater than 99.9% of the total coverage (James, 2015). There are many on-going GM crop projects in the
public sector, whose purpose is to provide benefit to local consumers, some with benefits other than producing crops with higher yields and/or lower costs of production. Yet, to date, public organisations have been largely unable to contribute directly through commercialised GM solutions to problems in minor crop industries or in developing countries (Table 1.1). China, India and Australia were selected for particular study here because, although they have very different social, scientific, economic and regulatory profiles, all three entered the GM crop commercial market early (China & Australia 1996 and India 2002) and have significant scale public section biotechnology capacity but with very limited commercial output from it.

**Box 1.1 Summary of two commonly used input traits**

**Insect resistance (IR):** *Bacillus thuringiensis* (Bt) was first identified in Japan as a pathogen of silk moth in 1901 and by 1958 it was commercially available as an insecticide. Since then, farmers have been spraying Bts for protection against bollworms and other insects. Bt sprayable insecticides have not been a major commercial success and sales are a tiny fraction of total sales of insecticide (Krimsky & Wrubel, 1996). Bts produce crystalline proteins called delta endotoxins, when ingested by insects, bind with specific receptor in their guts and damage the gut lining leading to a leakage of electrolytes into the gut, disrupting the digestive system. Since 1996 many Bt sequences have been introgressed into commodity crops with differential efficacy against various insect groups. Different companies’ products differ in the Bt sequences used e.g. Monsanto’s Bollgard™ cotton expresses Cry1Ac, Syngenta’s Agrisure™ maize expresses Cry1Ab. The current generation of Bt crops are developed with stacked traits which has reduced the potential of insects developing resistance against Bt and broadened the range of pests controlled. Current molecular technologies have allowed developers to deliver multiple trait genes on a single locus, reducing the possibility of accidental trait segregation in during subsequent breeding activities.

**Herbicide tolerance (HT):** The most common herbicide tolerant crops are either glyphosate or glufosinate resistant. Glyphosate controls a broad spectrum of plant species by inhibiting the 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) enzyme and disrupting the synthesis of aromatic amino acids. Glyphosate resistant crops expresses bacterial EPSPS (CP4-EPSPS) isolated from *Agrobacterium* sp that is insensitive to the herbicide. Glufosinate or phosphinothricin kills plants by disrupting glutamine synthetase and results in an excessive build-up of ammonia in plant cells. Crops transformed with the phosphinothricin acetyl-transferase (*pat*) or bialaphos resistance (bar) genes are able to detoxify phosphinothricin.
<table>
<thead>
<tr>
<th>Regulatory approved GM crops</th>
<th>Trait</th>
<th>Developer</th>
<th>Product name</th>
<th>Current commercial status and area coverage</th>
<th>Trait</th>
<th>Developer</th>
<th>Product name</th>
<th>Current commercial status and area coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Soybean</td>
<td>Modified product quality</td>
<td>Chinese Academy of Agricultural Sciences</td>
<td>Phytase Maize</td>
<td>Not commercialised</td>
<td>Herbicide tolerance</td>
<td>Bayer Crop Science, Dow Agrosciences, DuPont, Monsanto, Syngenta</td>
<td>e.g. Enlist™, LibertyLink™, Optum™, Roundup Ready™</td>
<td>92.1 million hectares</td>
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<tr>
<td>Maize</td>
<td>Insect resistance</td>
<td>Chinese Academy of Agricultural Sciences</td>
<td>Not available</td>
<td>Commercialised*</td>
<td>Insect resistance, Herbicide tolerance</td>
<td>Bayer Crop Science, Monsanto, Syngenta, Dow Agrosciences</td>
<td>e.g. Roundup Ready™, YieldGuard™, Viptera™, Optimum™</td>
<td>53.6 million hectares</td>
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<td>Cotton</td>
<td>Insect resistance</td>
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<td>Commercialised*</td>
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<td>Bayer Crop Science, Monsanto, Syngenta, Dow Agrosciences</td>
<td>e.g. Bollgard™, Roundup Ready™, LibertyLink™, VIPCOT™, Wildstrike™</td>
<td>24.3 million hectares</td>
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<td>Canola</td>
<td>Herbicide tolerance</td>
<td>Bayer Crop Science, Monsanto, DuPont</td>
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<td>Sugar beet</td>
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<td>Monsanto</td>
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<td>Virus resistance</td>
<td>Monsanto</td>
<td>Not available</td>
<td>2,000 hectares</td>
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<td>Eggplant*</td>
<td>Insect resistance</td>
<td>Maharashtra Hybrid Seeds Company</td>
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<td>25 hectares</td>
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<td>Modified product quality</td>
<td>OkanaganSpecialty Fruits Incorporated</td>
<td>Arctic apple™</td>
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<td>Potato</td>
<td>Modified product quality</td>
<td>BASF</td>
<td>Amflora</td>
<td>Commercially withdrawn</td>
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<td>Monsanto</td>
<td>Roundup Ready™</td>
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<td>Rice</td>
<td>Insect resistance</td>
<td>Huazhong Agricultural University, Bt Shanyou 63, Huahui-1</td>
<td>Not commercialised</td>
<td>Insect resistance</td>
<td>Bayer Crop Science</td>
<td>Liberty Link™</td>
<td>Not commercialised</td>
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<td>Regulatory approved GM crops</td>
<td>Trait</td>
<td>Developer</td>
<td>Product name</td>
<td>Current commercial status and area coverage</td>
<td>Trait</td>
<td>Developer</td>
<td>Product name</td>
<td>Current commercial status and area coverage</td>
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<td>Tomato</td>
<td>Virus resistance</td>
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<td>Not available</td>
<td>Commercialised but area coverage unknown</td>
<td>Modified product quality</td>
<td>DNA Plant Technology Corporation</td>
<td>Not available</td>
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<td>Sweet pepper</td>
<td>Virus resistance</td>
<td>Peking University</td>
<td>Not available</td>
<td>Commercialised but area coverage unknown</td>
<td></td>
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<tr>
<td>Bean</td>
<td>Virus resistance</td>
<td>EMBRAPA</td>
<td>Not available</td>
<td>Not yet commercialised</td>
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<tr>
<td>Tobacco</td>
<td>Virus resistance</td>
<td>Peking University, Chinese Academy of Sciences</td>
<td>Not available</td>
<td>Not commercially available anymore</td>
<td></td>
<td></td>
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<tr>
<td>Flax</td>
<td>Herbicide tolerance</td>
<td>University of Saskatchewan</td>
<td>CDC Triffid Flax</td>
<td>Not commercialised</td>
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<tr>
<td>Plum</td>
<td>Virus resistance</td>
<td>United States Department of Agriculture</td>
<td></td>
<td>Not commercialised</td>
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<td></td>
</tr>
<tr>
<td>Papaya</td>
<td>Virus resistance</td>
<td>Cornell University &amp; Hawaii university South China Agricultural University</td>
<td>Rainbow, SunUp, Huanong No.1</td>
<td>9,000 hectares</td>
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<td>Poplar</td>
<td>Insect resistance</td>
<td>Research Institute of Forestry, China</td>
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<td>500</td>
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<tr>
<td><strong>Total area</strong></td>
<td><strong>Public Sector</strong></td>
<td></td>
<td>~9,500 hectares</td>
<td></td>
<td><strong>Private sector</strong></td>
<td></td>
<td></td>
<td>~180 million hectares</td>
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</tbody>
</table>

Table 1.1 The commercial status of regulatory approved GM crop developments from the public and private sectors in 2015. This table was constructed base on the information extracted from an ISAAA database (http://www.isaaa.org/gmapprovaldatabase/default.asp). *The novelty of the Cry1Ac gene used by Chinese Academy of Sciences to develop Bt cotton has been debated. # The BARI Bt trait in brinjal was conventionally crossed by BARI into local varieties and has been commercialised on an experimental scale. However, it was the Maharashtra Hybrid Seeds Company (MAHYCO) in India which developed the construct using Monsanto’s *Bt Cry1Ac*, compiled the original regulatory dossier and provided Bt plants to BARI for crossing.
1.1.1 Public GM crop developments in China

China has invested heavily in GM technology since the early 1990s and is recognised as a significant player in the future of agricultural biotechnology (Huang & Wang, 2002). Five GM commodity crops developed by local public institutions have been approved by the Ministry of Agriculture (MOA) for cultivation in China (cotton, tomato, sweet pepper, poplar trees and papaya). Bt cotton was introduced into China by Monsanto in 1996, but was restricted to three provinces and without the right to breed into locally adapted cotton varieties. In the meantime, Chinese scientists led by the Chinese Academy of Agricultural Sciences (CAAS) developed locally adapted Bt cotton using a modified Cry1Ab/Cry1Ac fusion gene (Pray et al., 2001). It was the first indigenously developed major GM commodity crop, though the extent of the novelty and the indigenous contribution have been much debated subsequently. Bt cotton has been widely adopted by smallholder cotton farmers facing difficulties in effectively controlling lepidopteran insect pests, particularly pink bollworm (*Pectinophora gossypiella* Saunders) (which is practically a worldwide cotton pest) and cotton bollworm (*Helicoverpa armigera* (Hübner)) in the old world and related species in the new world. The effectiveness of chemical controls was reducing as insect pests rapidly developed resistance (Huang et al., 2002a). By 2014, China grew an estimated 3.7 million hectares of Bt cotton with an adoption rate of approximately 94% (James, 2015). It is estimated that since the adoption of Bt cotton, China has increased total farm income by $16 billion between 1997 and 2013 and by $1.58 billion in 2013 alone (Brookes & Barfoot, 2015). In terms of farm level performance, Bt cotton was able to increase yield by 10%, reduce pesticide usage by 60% and positively influence farmer health and income (Huang et al., 2002a; Huang et al., 2010). The other two GM crops which are currently commercialised in China are on a minuscule scale: virus resistant papaya (~8,000 hectares) and insect resistant poplar (~500 hectares).

Over the last 25 years, China has made rapid advances in the field of agricultural biotechnology. Multiple national schemes were established to support GM research in the public sector (See Chapter 7). For example, a national programme was initiated in 2008 with a budget of $3.5 billion, directly targeted at fostering China’s capacity to develop GM crops. The continuous and increasing support for GM research has enabled a wide array of GM developments, both plants and animals. Between 1996 and 2000, Chinese regulators

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3 All monetary values reported are in US dollars unless stated otherwise.
4 There appears to be no record of whether GM tomato and sweet pepper are still commercially available.
5 See Section 7.4.1 for details on China’s investments in agricultural biotechnology.
approved 45 applications for GM crops field trials, 65 for environmental release and 31 for commercialisation (Huang et al., 2002b). However, despite hundreds of on-going GM crop projects in China, only a very limited number of developments have obtained biosafety approval in recent years. In 2009, the MOA issued certificates for two Bt rice cultivars developed by Huazhong Agricultural University, both of which express the Cry1Ab/Cry1Ac fusion gene, and a further certificate was granted to CAAS for phytase maize. Rice is one of the most important crops in China. Approximately 20% of its arable land is under rice cultivation (Chen et al., 2011). Insect pests, particularly lepidopteran pests, cause serious damage to rice production, leading to an annual loss over $19 million (Sheng et al., 2003). Bt rice has been shown to confer resistance against major insect pests and to be able to reduce insecticide usage by 50% (Wang et al., 2010; Li et al., 2015). The high-level phytase GM maize improves the dietary utilisation of phytate in grains, reduces feed costs by eliminating the need for a microbial phytase additive and potentially reduce pollution from undigested phosphorous. This presents great potential economic value given the rising demand for livestock and the growing imports of feed (Hansen & Gale, 2014). However, it remains uncertain when these GM crops, which have passed through the regulatory process, will become commercially available.

1.1.2 Public GM crop developments in India

India is traditionally a cotton growing country with largest area of cotton in the world. Bt cotton was introduced informally into India and was planted in the western state of Gujarat in 2001 and later spread to other parts of the country. At that time, no GM crops were approved for cultivation in India. The Genetic Engineering Approval Committee (GEAC), the Indian regulatory authority of GM technology, requested the state governments to remove illegal plantings of Bt cotton. However, Indian farmers rioted in response to the government’s plan and demanded that GEAC deregulate Bt cotton for cultivation (Sadashivappa & Qaim, 2009). Challenged by the widespread adoption of illegal Bt cotton and social pressure from farmers to deregulate the material, GEAC approved three Bt cotton hybrids for commercial cultivation in 2002, for central and southern cotton growing states.

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6 The majority of approvals have been for Bt cottons to date. There are only three cultivated GM crops with Bt cotton dominating the GM seed market.

7 The biosafety certificates for Bt rice and phytase maize were originally issued in 2009 and had a validity period of 5 years, expiring in August 2014. The biosafety certificates were renewed by the MOA in December 2014.
(Qaim et al., 2006). Over the thirteen years since the initial adoption of Bt cotton, India has doubled its market share of global cotton production from 12% in 2002 to 25% in 2014 (Choudhary & Gaur, 2015). India is now the second-largest cotton producer in the world with 11.6 million hectares of Bt cotton, with an adoption rate of 96%, effectively changing India from a net cotton importer to an exporter (James, 2015). It is estimated that Bt cotton, since adoption, has increased yield by 37%, reduced insecticide use by 41% and increased farmers’ profits by 89%, with an average increase in profit of $131 per hectare (Qaim et al., 2009; Kathage & Qaim, 2012; Kranthi, 2012).

The Department of Biotechnology (DBT) was established to promote and foster agricultural, pharmaceutical and industrial biotechnology in India. In 2007, DBT drafted the National Biotechnology Development Strategy (NBDS), the first Indian policy document exclusively designed to foster biotechnology, including GM technology. Consequently, the increasing national funding and continuous government support allowed numerous public GM crop projects to make strong advances. For example, potato resistant to potato tuber moth was developed by Central Potato Research Institute; tomato resistant to fruit borers was developed by Indian Agricultural Research Institute (IARI) and rice resistant to yellow stem borer was developed by IARI (Rai & Prasanna, 2000). These have all reached the regulatory phase of the development pipeline. However, the moratorium on commercial release of GM crops put in place by the Minister of Environment in 2010 has brought the regulatory approval process to a halt8 (MOEF, 2010; Kumar et al., 2011). Despite GEAC resuming its function in 2014 (under the new name of the Genetic Engineering Advisory Committee), only one public GM crop development, from Delhi University, continues pursuing commercial approval (Pulla, 2016).

1.1.3 Public GM crop developments in Australia

Only two GM commodity crops are commercially cultivated in Australia9, insect resistant and herbicide tolerant cotton and herbicide tolerant canola. Bt cotton was introduced into Australian in 1996. The Commonwealth Scientific and Industrial Research Organisation (CSIRO) introgressed Monsanto’s Bt trait into Australian cotton germplasm. Like other Bt cotton adopting countries, the impact on farmers’ net income has been positive, with a

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8 See Section 8.2.7 for additional details.
9 GM carnation was approved by OGTR in 2002 for commercialisation in Australia for ornamental purposes but later withdrawn, significantly due to new regulatory requirements and costs.
reduction of insecticide use of 56% and an average cost savings of $72 per hectare (Fitt, 2003). At the national level, the net benefit gain from introduction to 2014 was $757 million (Brookes & Barfoot, 2015). Bt cotton varieties (single and stacked genes) now represent almost 100% of cotton grown in the country, covering 500,000 hectares.

Although herbicide tolerant (HT) canola was approved for commercialisation by the Office of the Gene Technology Regulator (OGTR) in 2003, commercial cultivation did not occur immediately. Canola growing states imposed a moratorium, due to concerns relating to co-existence and the potential for negative impacts on export markets. In 2008, moratoria on HT canola were lifted in the states of New South Wales and Victoria, followed by Western Australia in 2012 (Hudson & Richards, 2014). By 2015, the national adoption rate had reached 22%, with HT canola covering 440,000 hectares (ABCA, 2015). The national cumulative farm income gain to 2014 was $41 million with an average farm income gain of $61 per hectare (Brookes & Barfoot, 2015).

Australia does not have a national scheme supporting GM crop developments in the public sector. Nevertheless, many Australian public research organisations and researchers have undertaken GM crop research programmes, with a particular focus on major commodity crops. For example, wheat is an important grain crop for Australian agriculture industry with an annual gross production value of $7 billion AUD (25 million tonnes) and an export value of $4.7 billion AUD (www.abs.com.au). Between 2007 and 2012, 15 field trial licenses for GM wheat were issued by OGTR. All the applicants were public research organisations, including CSIRO, the University of Adelaide, the Victorian Government- Department of Environment and Primary Industries etc. The input traits under development benefit farmers by improving the agronomic performance of wheat which has greater ability to respond to abiotic stresses. The output traits are targeted directly at consumers with altered grain composition producing healthier grain for consumers. There are other on-going public GM crop developments in Australia, including the development of enhanced sugar content GM sugarcane from the University of Queensland and pro-vitamin A-enriched GM Banana developed by the Queensland University of Technology. None of these has yet reached the market.
1.1.4 Current challenges in commercialising publicly developed GM crops

To identify and understand the obstacles faced by the public sector, we need to consider the processes and activities beyond technical development which are crucial for the successful commercialisation of GM crops. Prado et al. (2014) described the product pipeline by which a GM crop is developed from initial discovery of a trait of interest to the final commercial product. In summary, the stages and principle activities are listed below\(^{10}\):

- **Discovery- Gene/Trait identification**
  Identification of potential genes of interest and model crop testing

- **Phase 1- Proof of concept**
  Optimisation of gene constructs and test on crops of interest

- **Phase 2- Early development**
  Large-scale transformations with pre-regulatory data collection

- **Phase 3- Advanced development**
  Field testings, regulatory data collection and product development

- **Phase 4- Prelaunch**
  Regulatory submission and pre-marketing strategies

McElroy (2004) categorised GM crop development activities into five general areas: technical, intellectual property/legal, breeding, regulatory compliance and marketing. The goal of the technical activities is to ensure the trait or the technology when expressed in plants confers the desired phenotypic performance under field conditions. It is well-known that the public sector has a strong research capability in creating innovative solutions, with many public GM crop projects demonstrating technical competence in developing GM crops. For example, Golden Rice was developed to alleviate vitamin A deficiency in developing countries (Ye et al., 2000; Potrykus, 2001; 2010; Beyer et al., 2002,) and the virus-resistant papaya developed by the University of Hawaii rescued the local industry from papaya ringspot virus (Gonsalves, 2014). This suggests that the public sector is technically capable of producing useful and high performance GM plant material.

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\(^{10}\) See Section 6.1 for detailed information.
Two key elements require to be in place prior to the commercial release of a novel GM crop: intellectual property protection and regulatory approval of the plants. Traditionally, plant breeding was mainly conducted in the public sector, but the rapid privatisation of plant breeding has shifted the roles of the public and private sectors. One factor which stimulated the private sector’s interest in investing in plant breeding was the changes in the intellectual property protection systems for plant varieties. More specifically, it is the extension of utility patents to include plants which are the products of human intervention\textsuperscript{11} (Fuglie et al., 1996).

Individual GM crop developments normally incorporate a broad spectrum of patented technologies and require significant legal activity to achieve successful commercial outcomes. In most cases, freedom to operate (FTO) with prior intellectual property rights needs to be obtained for the different technologies used during the development of novel crop/trait combinations. Without securing research and commercialisation license agreements, public organisations are at risk of legal liability with respect to the intellectual property holders (Rubenstein, 2003). A classic example which demonstrated the complexity of dealing with the fragmented ownership of intellectual property rights is the case of ‘Golden Rice’, which faced constraints to its commercial development during the early stages, with 70 patents from 32 patent holders all requiring negotiations (Kyrder et al., 2000; Potrykus, 2001).

The costs, complexity and the time required to comply with biosafety regulations are often considered as the key challenges for GM crop commercialisation, with countries having different attitudes and policies towards GM crops (Cohen, 2005; Paarlberg 2001; Matten et al., 2008; Davison, 2010). A recent consultancy study for Crop Life International (McDougall, 2011) found that the cost of meeting regulatory requirements for a single crop/trait combination for major industry players averaged around $35.1 million; costs well beyond the capability of individual public research institutions (Potrykus, 2010).

Furthermore, establishing FTO for intellectual property rights and complying with regulatory requirements does not guarantee a successful commercial outcome. The most basic challenge in introducing any new innovation is that of creating, capturing and maximising value for stakeholders. Even though a new innovation, such as GM crops, may create tremendous value for farmers and consumers, if the developer does not have a strategic plan to capture the value, it is unlikely that the development will be successfully

\textsuperscript{11} Plant variety protection (PVP) systems existed prior to the decisions on patenting DNA sequences. However, the low level of intellectual protection offered by PVP did not encourage the private sector to invest heavily in plant breeding (Butler & Marion, 1985; Alston & Venner, 2000).
commercialised. ‘Permission to Operate,’ is a social license granted by sharing potential value with other stakeholders in the supply chain and addressing the concerns of consumers. Both are necessary in order to gain support for the development and introduction of products. To promote the commercial uptake of GM crops, current private seed companies actively engage with stakeholders, developing acceptance plans for grain traders, local seed companies, processors, farmers, outlets and consumers.

These difficulties are not unique to public sector developments; nonetheless, they appear to be impacting more heavily on the commercial prospects for public sector developments than is the case with products from the major private sector companies. In addition, public agricultural research funding from governments in both developed and developing countries has grown slowly (Echeverria et al., 1996; Pardey et al., 1997; Thirtle et al., 2001, Pardey et al., 2013) and the world has been steadily moving towards an industry-funded research paradigm (Janssen, 1998; Kangasniemi, 2002). Consequently, public funding for utilising GM technology in crops with lesser economic value is strictly limited. It has been suggested that forming public-private partnerships may assist public GM crop in getting to market (Binebaum et al., 2001; Krishna & Qiam, 2007) and this area is explored in Chapter 8.

To conclude, the motivation for conducting this study is derived from two sources. There is a considerable research interest in understanding why the public sector has not been able to commercialise their GM crop developments. There is also a very practical interest coming from the desire to assist the poor in developing countries and to address the issue of food security, where the benefits which could be gained by the public sector applying the technology in minor crops have yet to manifest themselves. The intention is to provide advice and recommendations which may advance the prospect of eventual successful outcomes from public sector GM crop R&D.

1.2 Research question

The complexity of the various hurdles to be overcome and the interactions between them create difficulties in identifying a path for public GM crop developments. From a practical and research point of view this can be summarised in the following question:

‘What are the obstacles faced by the public sector which are preventing their GM crop developments from achieving eventual commercialisation?’
1.3 Conceptual framework

For this study, the conceptual framework builds on the idea of innovation uncertainty, where innovations can only be deemed likely to succeed when uncertainties have been minimised. This study applies Hall & Martin’s (2005) framework for managing innovation uncertainties, which builds on Freeman and Soete’s (1997) innovation management concept, stakeholder theory (Freeman, 1984) and Popper’s evolutionary learning methodology of science and its application to social affairs (Popper, 1945).

1.3.1 Innovation uncertainty

In any organisation, especially commercial firms, innovation is critical for survival and growth (e.g. Lengnick-Hall, 1992; Teece et al., 1997; Betz, 2003). A common discussion amongst scholars is the definition of innovation, whether innovation is a process leading to the product or a discrete event (Copper, 1998; Rogers, 2003; Baregheh et al., 2009). In this study, innovation is defined as an idea, process or product that is recognised as new or novel by the users. Technological innovation can be regarded as radical or incremental; radical innovations are new technologies which disrupt existing technologies, while incremental innovations are considered as improvements to existing technologies in existing industries (Ettlie et al., 1984; Garcia & Calantone, 2002; Gilsing & Nooteboom, 2006; Hoonsopon & Ruenrom, 2012). Schumpeter (1942) argued that a radical innovation provides a competitive advantage through rendering current technology and past investments obsolete. Based on the definition of innovation and radical innovation, GM technology can be considered as a radical innovation, as the technology supersedes existing conventional technological capability in crop improvement. Despite the potential for radical innovation to revolutionise the industry, the high level of uncertainty associated with the technology places doubt on its market potential. It has been suggested that the uncertainties in radical innovation are contributed to by the rate of scientific advancement, markets, industrial structures and regulatory frameworks (Freeman & Soete, 1997; Hall & Martin, 2005).

Uncertainty is a frequent study theme in the field of management and there is strong agreement amongst scholars that advances made in organisations proceed with uncertainties (Hall & Martin, 2005; Boehljie et al., 2011; Jalonen, 2011). Knight (1921) provided one of the earliest definitions and distinguished between ‘risks’ and uncertainties. He argued that risk is a measurable unknown to which we can assign probabilities based on
previous knowledge or experience. In contrast ‘uncertainty’ is a risk that lacks the information on which probabilities could be assigned and that all innovation is inherently open to uncertainties, given that new innovations disrupt the current norm. It is impossible to predict what effects the innovation will have, because these effects are dependent on unknowable actions in the future. In this thesis, Freeman & Soete’s (1997) broader definition is adopted, where innovation uncertainty is a risk that can be reduced through the acquisition of previously unknown knowledge.

Managing innovation uncertainty is a central topic of strategic management. Freeman and Soete (1997) categorise innovation into three dimensions. Firstly, general political and economic uncertainty, (which is frequently summarised as business uncertainty), affects the organisation’s capability to deliver innovations. Secondly, and more specific to the individual innovation project, market uncertainty denotes the unknown commercial viability of innovations. Lastly, technical uncertainty arises due to a lack of knowledge of the new technology or due to a lack of knowledge required to use the technology. However, technical knowledge in this context is not an understanding of whether the technology ‘works’ or not, rather it is the feasibility of the technology, taking account of commercial considerations.

Hall & Martin (2005) argued that such an approach does not address controversial technologies which influence societal third parties. Jalonen (2011) conducted a systematic review of the literature and identified eight categories of uncertainty in the process of innovation: technological, market, institutional/regulatory, social political, legitimacy/acceptance, managerial, timing and consequence. It is clear that the acceptance, timing and consequence uncertainties are social in nature, suggesting the need to manage social concerns of stakeholders for successful deployment of innovation.

1.3.2 Stakeholder theory

Freeman’s (1984) stakeholder theory moved away from the traditional thinking of strategic management12 and proposed that organisations should strategically develop plans that satisfy all stakeholders. Literature on stakeholder theory suggests that organisations which manage the interests of stakeholders are more likely to have a competitive edge in the market (e.g. Freeman, 1984; Donaldson & Preston, 1995; Jones, 1995). Freeman et al. (2010) reviewed empirical studies from other scholars and identified a positive relationship, with

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12 Traditional view was that organisations are managed in a way that maximises the return on investment the owners or stockholders of the company (Freeman, 1984).
stakeholder-focused organisations having a higher financial performance. A more important discussion which often appears in the literature is the relevance of stakeholders, where there is a need to identify stakeholders who possess power, legitimacy and urgency for the organisation (Mitchell et al., 1997). Some scholars have found that these attributes of stakeholders are dynamic and that the importance of different stakeholder groups changes over the innovation lifecycle (Elias et al., 2002; Assudani & Kloppenborg, 2010).

Freeman defined stakeholders as any group or individual who can be affected or is affected by the organisation. These may be either primary (direct impact on the organisation) or secondary (not directly involved, but able to influence primary stakeholders). Clarkson (1995) asserted that the survivability of an organisation depends on its ability to create wealth or value for the primary stakeholders (e.g. investors, employee, customers, suppliers, etc.) and to address social concerns from secondary stakeholders (e.g. interest groups, local communities). Elias et al. (2002) contended that innovation affects different stakeholders in different ways and it is important to acknowledge the influence of secondary stakeholders. They suggest that organisations should map the stakeholders who are relevant and the potentially dynamic nature of stakeholder salience. Based on Freeman and Clarkson’s distinction of stakeholder types, the primary and secondary stakeholder groups for public GM crop developments are identified here (Figure 1.1).

According to Hall and Martin (2005), radical technologies are often affected and influenced by both the primary and the secondary stakeholders and there is a need for organisations to identify, analyse and address the needs of all stakeholders. The social uncertainties of innovation can be reduced by addressing the concerns of stakeholders, both primary and secondary.
Figure 1.1 A stakeholder map of public GM crop developments with key primary and secondary stakeholders.

1.3.3 Hall and Martin’s evaluation framework

Hall & Martin (2005) argued that technological innovations, such as GM crops, can be viewed as a knowledge quest and must overcome four dimensions of innovation uncertainty:

- Technological uncertainty
- Commercial uncertainty
- Organisational uncertainty
- Social Uncertainty
Hall & Martin took Freemans (1982) and Freeman & Soete (1997) categories of innovation uncertainties and Rice et al.’s (2001) radical technology-to-organisational links and suggested that radical innovations such as GM crops need to address certain technological, commercial and organisational uncertainties. They argued that these uncertainties can be reduced where the most important variables and the interactions among them can be identified, and the probability of the outcome can be estimated. They proposed a “conjecture-refutation” approach, first described by Popper (1959), where the framework is analogous to the testing of scientific hypotheses and can be used to address the innovation technological, commercial and organisational uncertainties. Under relatively non-complex circumstances, with few stakeholders and variables, this approach is appropriate. The legitimacy of the innovation is validated based on performance criteria, i.e. whether the new technology is able to outperform an older technology on technological and/or commercial criteria.

Furthermore, they suggested that radical innovations, such as GM crops, face socio-political uncertainties, due to the presence of a greater than normal number of key variables, some of which may be difficult or infeasible to identify or quantify. The situation is complicated by the presence of secondary stakeholders who may be motivated by different values or objectives compared to those of the primary stakeholders within the value chain. Such complexity has been referred to as stakeholder ambiguity. To address the social uncertainties, Hall and colleagues proposed to apply Popper’s “Piecemeal Social Engineering” approach (Hall & Martin, 2005; Hall et al., 2011). A piecemeal approach addresses secondary stakeholder concerns regarding new invention on a case by case basis. They further argued that social uncertainties are at least as important as technical, commercial and organisational uncertainties when attempting to establish the legitimacy of innovations and indeed the very considerable socio-political influence of secondary stakeholders has already been observed in the GM crop industry. To alleviate social uncertainties, the side effects of new inventions on, and the impact from secondary stakeholders need to be recognised and addressed. Hall and colleagues propose further that social considerations can provide ‘leverage’ for furthering new inventions, by lending socio-political legitimacy, helping to justify the investment needed to address the technical, commercial and organisational uncertainties.
1.4 Research objectives

The overall objective of this study is to identify key obstacles to GM crop commercialisation, by contrasting critical elements in the public and private sectors, to determine whether the public sector’s capability to commercialise GM crops is inherently smaller. Potrykus’ (2010) experience working on pro-vitamin A fortified rice – ‘Golden rice’ - which has been in development from a successful proof of concept for some 15 years without yet reaching commercialisation in any country, is an example of the combined influences of these uncertainties on the commercial prospects for an innovation which at first look seems eminently beneficial and commercialisable. The following specific research questions are derived based on Hall and Martin’s evaluation framework and guide the present study:

**Technical barriers**

Intellectual property acquisition is an important stage in GM crop development, it determines whether the developer has the legal FTO. The licence negotiation process influences the development of the product, as there may be restrictive terms in licence agreements or patent holders refusing to license a necessary technology.

- To what extent are intellectual property right systems an obstacle to public GM crop developments?

**Commercial barriers**

The majority of public organisation GM crop developments are humanitarianly centred, targeting traits and crops which benefit poor farmers and consumers in developing countries and farmers of minor crops. The relative lack of interest in these crops by the large multinationals is an indication of the costs involved when compared to the likely financial benefits to be obtained by the seed supplier. Furthermore, current regulatory systems have requirements which are generally stated in broad terms and often it is unclear to inexperienced developers what precisely needs to be done to address these requirements and the costs of doing so.

- To what extent are particular difficulties faced by public research organisations in complying with GM crop regulatory requirements?
Organisational barriers

Historically, crop improvement research has largely been conducted in the public sector without any consideration of the need to license technologies or conduct studies to meet regulatory requirements (other than agronomic performance). This places questions on whether the public sector has built the organisational capacity needed to deliver GM crops commercially. Public-private partnerships (PPPs) are often suggested as a means to maximise the social acceptance and economic value of the product by drawing on strengths of both the public and private sectors. Over the past decade, there has been a range of PPP ventures in both developed and developing countries with limited commercial success\(^\text{13}\).

- What are the organisational barriers specific to the public sector which are preventing public sector GM crop developments from advancing to the commercial stage?

- To what extent is the public-private partnership model facing particular difficulties in offering viable solutions in the GM arena?

Social barriers

Negative public attitudes have created barriers to public GM crop developments and consumer concern has driven the current forbidding regulatory environment.

- To what extent does the need to obtain a social licence for GM crops differentially impact on the public sector?

Limitations of case studies

In the literature, the methodology for applying Hall and Martin’s framework is often based on a single case study (e.g. Jalonen, 2011; Abdullah et al., 2016). Due to the sample size, this type of analysis induces bias and limits the capacity to generalise the findings. Without

\(^{13}\) The only known example of a public-private partnership which has successfully commercialised a novel GM crop is the collaboration between the Brazilian Agricultural Research Corporation (EMBRAPA), a state-owned research corporation of Brazilian government and BASF. The herbicide tolerant soybean (Cultivance®) was approved by the Brazilian regulatory authority in 2009 and was commercially available to seed producers in the 2015/2016 season.
qualitative methods to implement control over the variables, it becomes difficult to assess whether the results reflect an actual impact in real world situations. To enhance the external validity of this study, a range of ‘successful’ and ‘not successful’ public GM crop developments were selected as case studies. A comparative set of case studies produces results which are more meaningful, more robust and can be more readily generalised (Ying, 2003). Additional studies were conducted to reaffirm the conclusions drawn from the case studies through patent landscape analysis and direct interviews with stakeholders.

### 1.5 Chapter outlines

The structure of the thesis is as follows. **Chapter 1** introduces the research question and presents the conceptual framework which guides the overall analysis. **Chapter 2** reviews the existing literature surrounding the research objectives. **Chapter 3** conducts a comparative case study on the development process of public sector GM projects and the outcome of their developments, with a particular focus on intellectual property rights, regulatory processes and public sector funding. **Chapter 4** aims to clarify the impacts of the concerns identified in Chapter 2 and 3 through semi-structured stakeholder interviews. The qualitative aspect of the study provides an in-depth understanding of the obstacles faced by the public sector in both developed and developing countries. The conclusions drawn from chapters 1-4 as to the probable obstacles to commercial success are focussed on in the subsequent chapters. **Chapter 5** addresses the commercial attributes of GM crop developments, focusing on the regulatory costs and the organisational challenges in generating the necessary regulatory dossiers. **Chapter 6** assesses the global intellectual property landscape of both the public and the private sectors, to determine whether the public sector has the freedom to operate for commercialising GM crops. **Chapter 7** examines the organisational capability to commercialise GM crops. To examine the impact of all the obstacles identified in preceding chapters, **Chapter 8** is a case study of a public-private partnership GM project contrasted against a purely public sector initiative in the same country, to show the strengths and weaknesses of the different approaches with regards to overcoming those obstacles. **Chapter 9** finishes with a discussion of the obstacles have been identified in the study as having significant impact on the prospects for commercialisation of public sector projects and concludes with what recommendations can consequently be made to stakeholders.
Chapter 2

Literature Review

To identify the research gaps and to guide the overall analysis, this chapter draws on existing literature which informs the current challenges to GM crop commercialisation, with a particular focus on developments originating from the public sector. There is insufficient space to comprehensively review all the themes surrounding the topic. To ensure relevance, selected themes build on the objectives outlined in Chapter 1.

This chapter initially reviews the actual and potential benefits of publicly developed GM crops. Secondly, it describes the current concerns with, and impacts of, intellectual property protection systems on public sector GM crop developments. Thirdly, the chapter examines the regulatory environments for GM crops. Fourthly, the chapter shows that the social objections to GM crop have not prevented the private sector from commercialisation. Lastly, the literature on the public-private partnership model and its impact on current and future public GM crop developments is examined.

2.1 Potential benefits of publicly developed GM crops

Immediately after the introduction of GM crops in the late 1990s, researchers began assessing the economic impacts of GM crops, utilising ex-post economic models to compare the changes in effective yield\textsuperscript{14} and the costs of the technology for adopters and non-adopters, concentrating on insect resistant and herbicide tolerant commodity crops in developing countries. For example, Ismael et al. (2002) surveyed the Bt cotton farmers in South Africa and identified a 24% increase in yield with an 11% increase in the gross margin a year after the introduction of Bt cotton in South Africa. Pray et al. (2002a) examined the

\textsuperscript{14} An increase in effective yield does not equate to higher genetic yield potential of the plant material. It measures the difference in yield collected as a result of prevention of yield loss to biotic and abiotic stresses. GM crops have often been introduced in improved germplasm which does have a higher genetic yield potential, confusing efforts to calculate the pure trait benefits.
benefits of Bt cotton farmers in China and concluded that a 10% higher yield was achieved by the Bt cotton varieties in comparison with non-GM varieties. Similarly, Bennett et al. (2005) surveyed Bt cotton farmers in India and identified a 45% increase in yield. These studies concluded that the GM technology was successful, due to 1) a decrease in insecticide usage, 2) an increase in yield through protection from insects and 3) a reduction in labour costs. These studies were conducted shortly after the introduction of Bt cotton within the respective countries and the results were generated under field conditions rather than from experimental field trials. Researchers continue to track the performance of GM crops in all GM cultivating countries and have observed significant long-term farm-level benefits (e.g. Fitt, 2003; Huang et al., 2003; Traxler & Godoy-Avila, 2004; Yorobe & Quicoy, 2006; Gomez-Barbero et al., 2008; Krishna & Qaim, 2008; Qaim, 2009; Carpenter, 2010). Klumper and Qaim (2014) examined the performance of Bt cotton in different regions and countries and identified an average 68% increase in farmers’ income since introduction. Brookes and Barfoot (2015) conducted a comprehensive analysis on the global farm-level effect of all commercial GM crops over the previous eighteen years and concluded that the direct global farm income benefit from GM crops was $133.5 billion at that point.

Despite significant benefits from the adoption of Bt cotton across the literature, different levels of farm benefits have been reported. Qaim (2009) argued that the variation in average farm-level effects in different countries were due to agroecological and socioeconomic factors, where the high level of gross margins identified in developing countries was contributed in part by weaker intellectual property regimes, distribution and production of GM seeds by local farmers and by government subsidy and price intervention. Falck-Zepeda et al. (2000) identified that with the strong intellectual property protection regime in the US, farmers received 59% of the technological benefits, 21% returned to the developer (in this case Monsanto) with rest of the benefits distributed across the supply chain e.g. seed breeders, distributors etc. In contrast, in countries with weaker intellectual property enforcement, such as China, Pray et al. (2001) estimated that the proportion of benefit from the technology which went to Chinese farmers was much higher, ranging from 82.5% to 87%, while the technology owner received 6%. The variation in farmer benefits depends in part on how the value is distributed amongst the stakeholders. Countries where weed and insect

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15 In Brookes & Barfoot’s meta-analysis, no economic impact data was available for minor GM crops, including virus-resistant papaya and sweet pepper in China.

16 For example, in 2006, Maharashtra state government set official retail prices for Bt cotton seeds, at much lower than the companies’ prices. This intervention transferred value from the developers to the farmers, increasing the level of farmers benefit observed in some Indian studies.
control was poor and inadequate saw yields increase from the deployment of the technologies. Improved weed and insect control also gave the farmer confidence to invest in improved germplasm, further enhancing yields. In countries where these factors did not apply, e.g. Australia, yield increases (if any) were much more modest because Australian farmers were already effectively controlling bollworm pests.

Some researchers have opposed these findings and argued that GM crops have not benefited the adopters. Studies by Qayum & Sakkhari (2003; 2005) examined the economic impact on Bt cotton farmers in Andra Pradesh, India and observed no yield differences between Bt cotton and non-Bt varieties and further argued that the high pricing of GM seeds was not offset by the reduction in pesticide use. Pschorn-Strasus (2005) observed a declining rate of GM crop adoption in Makhatini Flats, South Africa due to poor agronomic performance. However, the validity of both findings was questionable on account of the methodologies used. In the Qayum & Sakkhari study, the result indicated that there was no difference in pest control costs between Bt cotton adopters and non-adopters, implying that Bt cotton adopters continued to spray insecticide at the same rates and frequency despite the fact that Bt cotton was designed to minimise the need for chemical control. As regards the Pschorn-Strasus study, his critics suggested that farmers’ decision for not planting Bt cotton was due to consecutive drought over three planting seasons. Both studies failed to provide any evidence to suggest that the GM crops were not technologically superior to their conventional counterparts in the function for which they were developed. The material was superior in what it was intended to deliver (weed and insect control) but would only give benefits to the farmers if utilised properly and in agronomic situations where there is yield to protect. The remarkable adoption rate of GM crops in both developed and developing countries testifies the overall economic benefit of the technology (James, 2015).

Many researchers have supported the idea that the public sector should utilise the technology to generate public goods for farmers in developing countries and for the poor suffering from food insecurity and malnutrition (Wambugu, 1999; Huang et al., 2002; Cohen, 2005; Sithole-Niang et al., 2005). A general point needs to be made here. The body of literature on the value of publicly developed GM crops is very small. Most literature focuses on the impact of private sector crop varieties. This is primarily due to the limited success of the public sector in commercialising GM crops. To determine whether there is value in

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17There is speculation that the generation of Chinese Academy of Agricultural Science (CAAS)’s Bt cotton used technologies from Monsanto and infringed Monsanto’s patents despite China claiming
public research organisations pursuing GM crop developments, researchers have utilised econometric models to forecast the potential economic value of existing public GM crop projects. For example, Stein et al. (2006) conducted an ex-ante assessment of Golden Rice, contrasting the cost-effectiveness of biofortification with other intervention methods and concluded that Golden Rice is the most cost-effective method of alleviating vitamin A deficiency in developing countries. Kostandini et al. (2007) conducted an ex-ante analysis on drought-tolerant GM crops in low-income developing countries and estimated a potential annual value of $93 million, suggesting that incentives exist for public sector involvement.

The most commonly assessed public GM development crop is Hawaii’s successfully commercialised virus-resistant papaya. Sankula and Blumenthal (2004) estimated that the yield increased for GM papaya ranged from 17% to 77%18 with zero additional cost to adopters compared to non-adopters. Even though Japan, as a major market, did not initially allow GM papaya for importation and use, 75% of the Hawaii papaya area still under the GM variety.

However, the economic values reported in value proposition studies are often conducted under ‘best scenario’ settings. Hall et al.’s (2013) meta-analysis of the farm-level impact of GM crops suggested that many studies had not considered the impact of price and consumer’s willingness to pay as variables and often estimate their values without commercial considerations. Despite the potential economic value of GM crop projects presented in the literature, some researchers have identified that the current commercial environment prevents the proposed value from being commercially captured. Gonsalves (2004) personal experience with the commercialisation of virus-resistant GM papaya highlighted the fact that stakeholders within the supply chain, such as export traders and food manufacturers, were willing to pay a premium for non-transgenic varieties, as the most lucrative market was not accessible to the GM variety. As a consequence of prohibitive regulatory systems in the countries to which papaya was earlier exported, the Hawaiian papaya industry export value, which in 1996 stood at $15 million, was reduced to $1 million per annum by 2010 (USDA, 2011). Other studies have analysed consumer willingness to pay for GM foods and identified that without price incentives, many consumers would not accept products which contain GM materials (Moon & Balasubramanian, 2001; Chern et al.,

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18 The significant level of adoption of GM papaya was contributed to by the severe status of ringspot virus in the Hawaii papaya industry. The disease was threatening to destroy the industry until the GM solution was adopted.
2002; Lusk et al., 2003; Kimenju & De Grotte, 2008; Colson & Rousu, 2013). Hudson & Richards (2014) identified that the non-GM price premium for non-transgenic canola outweighed the benefit from using the GM variety, which is a function of yield gain or possible cost saving, was the reason for the non-adoption of GM canola by a substantial proportion of the farmers in Australia.

Public GM crop developers often present the ‘maximum’ potential value of their intended products to justify the funding for the work. However, in the commercial environment, there is a need to consider the influence of intellectual property systems, the time and costs required to comply with various regulations and the effects of negative consumer acceptance, on the value of GM crops. This places questions on the public sector’s capability to deliver the suite of values for GM crops which will sufficiently satisfy all the stakeholders.

2.2 Intellectual property rights for public innovation

Intellectual property rights in agricultural biotechnology are protected by a variety of patent and plant variety protection systems, with the intention of advancing scientific developments through disclosure of information while providing a return on investment to developers (WIPO, 2004). In general, intellectual property systems were designed to provide benefit inventors, at least for a significant period, and so to encourage innovation. At the same time, these systems create difficulties for others, including the public sector in the GM area (Atkinson, 2003; Graff et al., 2004; Cohen, 2005). Heller & Eisenberg (1998) introduced the phrase ‘tragedy of the anticommons’ and argued that the intellectual property system is a cause of the privatisation of biological research and has resulted in a reduction of public innovation outputs. The problem arises when individuals have the power to exclude others from using a particular technology in order to capture as much rent as possible. Thus, the time and cost needed to negotiate and maintain licenses with patent holders can create a major obstacle for public research institutions (Atkinson et al., 2003; Graff et al., 2003; 2004). Other studies argued that as the result of the global intellectual property systems, access to novel technologies for poor farmers in developing countries has been denied (Glover & Yamin, 2003; Tripathi, 2007).

The development of a GM crop requires various technological components, which are often patented with restricted access. Graff et al. (2003) demonstrated that the ownership of key technological patents, crucial for generating GM crops, are assigned to a select number of
multinational corporations (MNCs) who may have developed, bought or exclusively licensed them. Consequently, public organisations routinely need to negotiate with MNCs for access to their patented technologies. Without consents from the patent holders, the use of the technologies infringes patents and may lead to legal consequences (Rubenstein 2003). Potrykus (2010) pointed out that current public research scientists often neglect the importance of intellectual property, since their main focus, in practice, is to conduct basic research and not develop products.

Graff et al. (2004) identified numerous elements that present great difficulties for public researchers in the area of intellectual property, but the most difficult task for public researchers is the creation of a patent portfolio to establish freedom to operate. It requires searching for key patents and conducting intellectual property audits to identify patents of interest. Blakeney et al. (2007) argued that without an effective intellectual property audit, public organisations may experience delayed development processes and incur additional costs by negotiating for non-relevant patent rights.

The other major intellectual property obstacles for public organisations are the licence negotiation processes and legal transaction costs (Atkinson et al., 2003; Graff et al., 2003; 2004). Potrykus (2010) demonstrated the difficulties for the public sector in negotiating licence agreements with private companies. The construction of pro-vitamin A biofortified rice required numerous patented technologies and licenses from various private organisations. The costs required to create a patent portfolio and implement the licensing which it recommends as necessary, are very rarely costed into public sector research budgets. Furthermore, due to confidentiality agreements between private companies and the uncertainty contributed by the patent application process, during which period the invention is protected but this fact is not in the public domain, both public and private organisations have difficulties in identifying the actual patent holders which further delays the negotiation process (Graff et al. 2004).

A number of authors have pointed out the complications in relation to intellectual property and licence agreement process (Atkinson, 2003; Graff et al., 2004; Cohen, 2005; Lei et al., 2009), but very few have provided suggestions on how to overcome these hurdles. Krattiger (2007) suggested that public researchers should consistently seek non-assert covenants, which are agreements from the patent holders to not exercise the rights of their patents in particular circumstances e.g. for humanitarian uses in the developing world. This type of agreement provides the essential technological rights for public GM projects and reduces
both legal transaction costs and time. Although non-assert agreements appear to be an ideal solution for public research organisations and may often be available for the research phase of public projects, they may not always, or even usually, be available for commercialised products. This creates another layer of difficulties for public organisations, which need to consider other types of licence agreements and the licence terms within the agreements, to justify the development goal. To overcome the complex intellectual property landscape, Graff & Zilberman (2001) suggested that an intellectual property clearinghouse is needed to advance agricultural biotechnology in the public sector, enhancing the transparency of the congested intellectual property landscape. The public sector has realised the difficulties and established organisations such as the organisation Public Intellectual Property Resources for Agriculture (PIPRA) in the USA and the Centre for the Application of Molecular Biology to International Agriculture (CAMBIA) in Australia, to inform developers of the current intellectual property landscape and to provide strategies and open source constructs and technologies to help overcome these hurdles (Delmer et al., 2003). However, the success of intellectual property clearing houses in assisting public developments has not been comprehensively documented.

The international trade in GM crops generates further intellectual property complications as some countries do not accept the idea of patent protection on seeds. The Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement binds all members of the World Trade Organisation (WTO) to provide a minimum standard for intellectual property protection, whether under patent or under *sui generis* systems. The protection system adopted by many developing countries follows the laws originally in place for plant variety protection. The International Union for the Protection of Plant Varieties (UPOV) was the first agreement, signed in 1961 in Paris, to recognise the importance of implementing a protection system for plant breeders (UPOV, 2014). The rationale for introducing the Plant Varietal Protection (PVP) system was that it would encourage private investments in plant breeding. However, Kloppenburg (2004) argued that no evidence has been presented to demonstrate that PVP systems have stimulated agricultural research. Existing literature suggests that developing countries adopted the 1978 UPOV framework as it provides strong benefits for farmers (Paarlberg, 2001; Downes, 2004; Gallo & Kesan, 2006). Despite developing countries’ accession to the WTO and the TRIPS agreement to implement

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19 CAMBIA is a non-government organisation founded by Dr Richard Jefferson in 1992. The organisation focuses on open source biology, providing essential biological enabling technologies for public access.
intellectual property protection frameworks, the lack of legal enforcement remains problematic. In the absence of strict legal enforcement, pirated GM crops are illegally distributed. Ramaswami et al. (2012) demonstrated that Bt cotton in India was introduced through an informal process. Similarly, GM soybeans in Brazil were illegally planted using seeds from neighbouring Argentina (Hall et al., 2008). Paarlberg (2002) believed that developing countries need to provide a stringent intellectual property framework before private companies will invest in crops that are suited to local conditions.

The case of the Argentinean herbicide-tolerant soy industry provides an example of the dangers of neglecting the issues raised by patented technologies at an international level. After trying unsuccessfully to obtain redress in Argentina, Monsanto raised a legal case against importers in the EU for importing Argentina’s GM soy meal from its patented soy varieties without anyone paying royalties/license fees to the company. This raised conflicting issues regarding the intellectual property systems on seed patents of the countries involved (Cohen & Morgan 2008). Varella et al. (2013) analysed the case and showed that due to globalisation and international trade of commodity crops, Monsanto was able to enforce the more restrictive European intellectual property legislation against Argentinian and Brazilian exporters. This suggests that the developers of GM crops that are to be used for trade purposes need to take account of the intellectual property protection systems in different countries, regardless of the home country’s protection system, in addition of course to all the biosafety and other regulations which might be in place in the importing country. Box 2.1 provides a summary of the plant variety protection systems in the three countries being examined in detail here.

To address the growing concerns over patents and the need to comply with TRIPS, governments in developing countries have been encouraging public institutions to patent their discoveries. Liu et al. (2014) analysed China’s domestic patenting trend in agriculture biotechnology and identified an annual growth rate of 20.7% and accounting for 44.2% of total agriculture patent applications in China between 1985 and 2005. Mehta et al. (2014) focused on the patent trend in agriculture post the signing of the TRIPS agreement and found strong evidence to suggest an actively growing interest in patenting activity from the public sector. It is recognised that public organisations around the world have been improving the understanding of intellectual property of public research scientists and public institutions are actively increasing their patent contribution. However, it is unclear whether
Box 2.1 A summary of PVP systems in Australia, China and India

**Australia**

Plant variety protection in Australia started with the introduction of the *Plant Variety Rights Act 1987* which was replaced by the *Plant Breeder’s Act 1994* to align with the changes agreed under the 1991 UPOV Convention. Intellectual Property Australia started administrating the plant breeder’s right (PBR) scheme in 2004. To be protected by the PBR scheme, a new variety needs to demonstrate novelty (has not been marketed commercially) and to show distinctness (clearly distinguishable from any other variety), uniformity and stability (retain features or characteristics after propagation), also referred to as the ‘DUS’ requirement. The Australian system provides a protection term of 20 years for general species and 25 years for trees and grapevines. The Farm Saved Seed provision, outlined in Section 17 of the act, allows farmers to save seed protected under PBR for propagation for their own use. However, crops harvested from the saved seeds cannot be sold without authorisation from the owner of the rights.

**China**

In 1997, China issued the ‘*the Regulations of the People’s Republic of China on the Protection of New Varieties of Plants*’ based on the 1978 version of UPOV. China officially became a member of UPOV in 1999. Under the plant variety protection law, the Ministry of Agriculture (MOA) is the responsible authority for the examination and approval of new plant varieties. China assesses new varieties of plants using the DUS requirement and provides a protection term of 15 years for general species and 20 years for trees and vines. An important characteristic of China’s PVP system is that the right granted by MOA only provides protection for the production and commercialisation of seeds, and the ‘farmer exemptions’ system allows farmers to save seed for future propagation for own use and enables the selling of the harvested crop without approval from the owner of the rights.

**India**

*The Protection of Plant Varieties and Farmer’s Rights (PVPFR) Act* was introduced to Congress in 1999 and was passed in 2001. The aims of the act are to establish a plant protection system which encourages the development of new plant varieties while protecting traditional farmers’ rights for the use of seeds. India became a member of UPOV in 2002. Like most countries, the PVPFR authority utilises the DUS requirement for assessing new plant varieties. The length of protection in India is generally shorter than in other countries at 15 years for general species and 18 years for trees and vines from the date of registration. However, farmers are allowed to save, use, propagate, exchange and sell seeds protected under the act. The only provision is that the seeds sold or distributed by farmers must not be ‘branded’ with any association to the original breeder’s registered name.
any single public sector institution has the necessary legal freedom for commercialising publicly developed GM crops without seeking external licences.

2.3 Regulatory challenges

Regulatory systems governing the manipulation of an organism’s genome are designed primarily to protect human and environmental health, but different policy attitudes toward GM crops have resulted in the structure of regulatory systems varying across jurisdictions (Paarlberg, 2014). Some scholars observed that certain regulatory systems are more difficult to comply with and as a result have restricted GM crop developments (Paarlberg, 2001; 2014; De Greef, 2004; Matten et al., 2008; Davison 2010). McLean et al. (2012) argued that individual regulatory systems are designed based on the social, cultural and economic objectives of the particular country. The lack of agreement on the regulatory standards across international borders creates difficulties for public organisations, due to their relatively limited familiarity with, and understanding of, the different regulatory environments their products may face and the escalating costs of complying with multiple systems (Wambugu 1999; Paarlberg, 2002; Eicher et al., 2006). Potrykus (2010; 2012) demonstrated the difficulties in complying with different GM regulations based on his personal experience with Golden Rice and argued that the cause of delay in Golden Rice approval was regulations based on the precautionary principle. The intended purpose of many public developments is to provide benefits for the poor in developing countries, yet these efforts are challenged by the need to comply with current regulatory systems.

The Cartagena Protocol on Biosafety (CPB), part of the United Nation’s Convention on Biological Diversity (CBD), was ratified in 2003 in Canada. The protocol concerns the movement of GMOs across international boundaries and particularly the use of GMOs in agriculture and is structured based on the precautionary principle. The usage of the precautionary principle is explicitly stated in CPB:

Article 1 “In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.”
Principle 15 states “In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.”

Annex III of the protocol outlines the precautionary principle for risk assessment:

“Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk.”

A particularly controversial part of the precautionary principle as used in the CBD is that the absence of scientific evidence of harm does not provide an obligation on the importer to accept the product/material. Raybould & Poppy (2012) pointed out that the costs and time required to fully comply with the obligations enshrined in the precautionary principle are a major obstacle to GM development globally, despite the protocol being designed with the intention of providing a uniform regulatory framework for all countries.

Australia is one of the few major trading countries which have not signed the CPB. Instead, the country has developed its own regulatory framework governing the use and movement of GMOs. Studies have outlined the GM regulatory system in Australia, detailing the regulatory bodies, histories and political attitudes towards GM crops (e.g. Cocklin et al., 2008; Smith, 2011; Tribe, 2012). The regulatory framework is unique in the sense that the Gene Technology Act 2000 adopted the concept of the precautionary principle and interpreted the precautionary principle differently from the way it has been interpreted in the EU and has followed a science-based precautionary approach. The regulations for GMOs in Australia follow a risk assessment framework, where the Gene Technology Regulator, in the Office of the Gene Technology Regulator (OGTR), identifies the risks of a GM crop through liaison with other government agencies. Food Safety Australia and New Zealand (FSANZ) is responsible for determining the safety of GM food, and the Australian Pesticides & Veterinary Medicines Authority (APVMA) assesses the risks to human and environmental health of GM crops which contain pesticidal traits. Approval from OGTR does not guarantee approvals for commercial planting in Australia. As in many countries, agriculture is a state responsibility, where individual state governments determine the commercial release of crops (GM or otherwise) in their territories (Hudson & Richards, 2014).

After the ratification of CPB in 2003, numerous countries have signed the protocol and agreed to develop GM regulatory systems intended to be in compliance. Gupta & Falkner (2006) examined the influence of CPB in regulatory policies in Mexico, China, and South
Africa and concluded that adjustments made to the local biosafety policies since signing, to bring them into line with the intent of CPB, have been minimal and that there are still major differences between countries’ biosafety policies. This protocol has limited impact on agricultural commodity trade because the leading exporting countries of grain and oilseeds such as the US, Canada, Argentina and Australia are not signatories. To date, CPB has not been able to provide a globally uniform regulatory framework. Individual countries interpret the protocol differently and often the interpretations are based on the countries’ specific interests in GMOs.

As mentioned, public GM crop initiatives largely consist of projects that are intended to contribute to improving agriculture industries in developed countries or are humanitarian projects that are directed towards the poor in developing countries (Cohen, 2005; Hokanson et al., 2010; Potrykus, 2010). Harmonising a regulatory system for GM crops would increase the efficiency of developments and reduce the burden for the developer of deregulation in importing countries (Nap et al., 2003; Ramesser et al., 2008; 2009). Unfortunately, the regulatory systems actually adopted in developing countries have been largely based on two opposing sets of principles.

The US regulatory system puts the onus on the regulators to provide scientific evaluation and mandates compliance with efficient approval timelines (Jasanoff, 2000; Paarlberg, 2001; Davision, 2010), with the use of GM crop is considered safe until proven otherwise – Innocent until proven guilty. A number of developing countries, such as Brazil and Argentina, have adopted the relatively permissive US regulatory environment, favouring farmers as the major beneficiaries of the technology (Morris & Spillane 2008).

In contrast, some developing countries adopt the EU’s restrictive regulatory policies on the basis of ‘guilty until proved innocent’ (as, for example, enshrined in France’s criminal Code Napoleon) where currently unsubstantiated possible future health and environmental risks may be used as a reason to restrict commercialisation. To date, none of these fears has been proven in relation to current commercialised traits/crops (Domingo & Bordonaba, 2011; Nicolia et al., 2014). However, the EU’s policy enshrines the precautionary principle as outlined in the agreed Rio Declaration on Environment and Development. In Cohen &

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20 In the late 1990s, farmers in Australia and India were already cultivating GM crops prior to the regulatory systems being established. In Australia, Bt cotton was introduced in 1996 by the Commonwealth Scientific and Industrial Research (CSIRO) but the decision on a GM regulatory framework in Australia did not begin until 1998 (OGTR, 2013). Bt cotton in India was also planted prior to regulatory approval, which occurred in 2002 (Sadshivappa & Qaim, 2009).
Paarlberg’s (2002) opinion, developing countries adopting the EU regulatory policy principles are significantly influenced by international trade considerations. The fear of EU rejection of imported food and feed from GM varieties has prevented some developing countries from adopting the technology. The USA, Canada, and Argentina filed complaints to WTO based on the grounds that the EU’s policy violates the Sanitary and Phytosanitary Measures Agreement (SPS) (Disdier & Fontagne, 2010; Hanrahan, 2010; Burachik, 2013). SPS binds all members of WTO to regulate agriculture products to protect human health and the environment based on the assessment of scientific evidence and without undue delay. The outcome of the dispute favoured the US, but Disdier & Fontagne (2010) quantified the loss of export value from USA ($1.97 billion), Canada ($349.6 million), and Argentina ($52.2 million) during the moratorium process and believed the EU created a negative effect on international trading of GM crops, perhaps in particular in developing countries.

Vogel (2003) believed the stringent regulations placed on GM technology by the EU was a political response to previous regulatory failures, for example in the case of mad cow disease in the UK which resulted in the general public having doubts about the EU’s food regulatory system. Keleman & Vogel (2010) argued that the public and anti-GM campaigns pressured the EU to enforce stringent regulations on GMOs. In part, government regulations address local citizens’ concerns and represent their views, and this may be considered the case for GM technology (Jasanoff, 2000; Jaffe 2006; Hanrahan, 2010). The intention of the original precautionary principle has been subverted in the minds of many, including the developers of regulations in many developing countries, to imply that there should be no commercialisation of GM crops without certainty on all their possible impacts in the future environment and human health.

Qaim (2009) pointed out that current regulatory systems were designed only to address the first generation of GM crops (essentially herbicide tolerance and insect resistance) and may not be fully appropriate for addressing GM crops with elevated nutrients, drought tolerance or other advanced traits. More importantly, the on-going development of new breeding technologies for gene knockout and targeted insertions such as RNA interference (RNAi), Transcription Activator-like Effector Nucleases (TALENs), Clustered Regularly Interspaced Short Palindromic Repeat (CRISPR), etc. gives rise to products which are not readily amenable to what is essentially a toxicological biosafety evaluation approach which is currently in use. The European Food Safety Authority (EFSA) has been considering the need for adjustment of current regulatory systems in the EU to accommodate the next generation
of GM crops (Devos et al., 2014). It is unclear whether current the regulatory systems are well positioned to regulate the more advanced scientific techniques now used for current GM development. In a recent publication the Australia and New Zealand Food Safety Authority (FSANZ 2013) has publicly stated its position in relation to GM crops with gene knockouts using RNAi technology, rejecting the need for additional experiments to assess the safety of the transformed plant materials, as currently there is no scientific evidence suggesting any potential risks posed by the use of RNAi in plants. At the same time, OGTR has approved confined field trials of GM safflower utilising the RNAi technique. New issues raised by advanced scientific techniques such as CRISPR, TALENS and RNAi need to be debated and appropriate regulations developed as products are entering the trial process now. Existing literature has not provided knowledge on how the public sector should address the obstacles created by the current regulatory systems or specified detailed pathways towards gaining regulatory approval. As such, it is uncertain whether the public sector is fully aware of the cost and activities required to take a GM crop to commercialisation or whether public research organisations have the capability to comply with global GM regulatory systems or indeed whether such regulatory systems are appropriately adapted to the new technologies being utilised.

2.4 Environmental effects, safety concerns and risks of GM crops

Environmental effects, health considerations and the perceived risks of GM crops have driven the debate in the public domain. On one side are environmental activists who emphasis the unknown risks of GM crops and on the other are supporters who consider GM technology as a solution to many agricultural challenges and a major advance, including in terms of safety, on earlier breeding techniques such as mutagenesis. A paper published in Nature (Losey et al., 1999) sparked immediate protest from environmental activists claiming that commercial releases of GM crops would negatively affect the ecological system. This claim was based on Losey et al.’s (1999) experimental result which suggested that Bt maize was harmful to monarch butterflies. However, the scientific community strongly opposed the findings and subsequently presented counter arguments showing, in both large field trials and laboratory studies, that GM maize did not significantly affect monarch butterfly numbers (Hellmich et al., 2001; Oberhauser et al., 2001; Trewavas & Leaver, 2001).
In addition to the potential impact on wildlife, it is argued that GM crops may hybridise with wild weedy relatives, or other organisms (through horizontal gene transfer) resulting in the production of unintended new hybrid progeny which might have evolutionary advantages (Snow, 2002; Heinemann & Travvik, 2004). Riegar et al. (2002) showed that cross-pollination between GM and non-GM crops occurs at a low frequency but over a considerable distance with a number of factors contributing to the movement of pollen; the structural properties of pollen, the mechanism of movement; climatic conditions and the nature of surroundings. Hall et al. (2000) demonstrated that pollen-mediated gene flow has resulted in multiple instances of the presence of herbicide-resistant canola. It is feared that the herbicide tolerant genes or insect resistant genes from currently cultivated crops could flow into weedy relatives and cause disruption in the ecosystem (Hall et al., 2000; Orson, 2002). There is a broad consensus among the scientific community that gene flow between GM crops and wild relatives is inevitable. However, the GM Science Review Panel (2003) suggests that any concerns with potential gene flow should be examined on a case by case basis, due to the complex interactions in actual environments. Gealy et al. (2007) examined the sexual compatibility between 25 major commodity food crops and related weed species and concluded that there is a low probability that transgene flow between a GM crop and wild relatives would cause a greater environmental risk than between non-GM varieties. The author further argued that the absence of quantitative analysis of gene flow and the environmental impacts in the literature is an indication that gene flow between GM crops and conventional varieties has not caused any demonstrable environmental and health impacts.

Another key environmental issue that is repeatedly debated is the issue of resistance development. Dhrura and Gujjar (2011) sampled a population of pink bollworm in the state of Gujarat, India and identified that the sampled pink bollworms had developed resistance against Bt Cry1Ac in GM cotton. The developer of the Bt cotton (Monsanto) confirmed the results and believed that the insufficient compliance with the mandated non-Bt crop refuge zone contributed to the resistance development. It has been suggested that the evolution of resistance can be delayed with appropriate refuge strategies (Liu et al., 1999; Tabashnik et al., 2003; 2008) and this has been mandated (though not always complied with) in a number of countries.

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21 The industry’s concern is focused on the adventitious presence of GMOs in non-GM varieties irrespective of whether the presence is due to mixing of unwanted materials in planted seed or to gene flow. Even though no cases of international trade disruption have been caused by demonstrated gene flow to date, the industry has put in place criteria for farmers which are aimed at minimising the possibility of adventitious presence, as the current regulatory systems in a number of countries has placed strict liability on the developers.
of countries, although this makes a number of assumptions about the dominance of developing resistance, the mobility of the pest and other factors. An alternative method for delaying the evolution of resistance, which has already been adopted by the industry, is the stacking of more than one transgene which are each effective in conferring the desired trait but do so by a different route. The logic being that development of resistance against such transgenes is likely to require multiple simultaneous defence mutations in the target organisms, which has a much lower probability than the single mutation which may be required to defend against the effects of a single transgene (Shelton et al., 2009).

Manyangarirwa et al. (2006) have provided evidence to show that gene pyramiding is effective in delaying resistance development. However, they emphasised that stacked genes products should be co-implemented with other methods such as planting of refuge plants to effectively delay insect resistance to Bt technology.

Mannion and Morse (2012) conducted a systematic literature review on the agronomic and environmental impact of current commercialised GM crops, focusing on major crops with insect resistance and herbicide tolerance traits, and concluded that no evidence has suggested that GM crops have negatively influenced the environment. Instead, the adoption of GM crops has been positive in reducing the use of pesticides in both developed and developing countries.

Much like the issue with the monarch butterfly, the issues of human safety and risks for consumption have been a central focus of both the scientific community and consumers. A few researchers who have conducted animal feeding studies have argued that GM crops are harmful to non-targeted organisms. For example, Ewen & Pusztai (1999) conducted a rat feeding study and concluded that the consumption of GM potato reduced the growth rate and suppresses the immune system. Similarly, Seralini et al.’s (2012) long-term feeding study examined the toxicity of herbicide tolerant maize on rats and argued that the ingestion of herbicide tolerant maize induces negative health effects. However, the scientific community has objected strongly to the conclusions drawn in both studies and argues that methodologies were flawed.

The Royal Society (1999) responded to the Ewen & Pustzai experiment and criticised both the methodology and claims made by the author, and stated that:

“... the reported work from the Rowett is flawed in many aspects of design, execution and analysis and that no conclusion should be drawn from it.” (The Royal Society, 1999)
The Seralini paper was retracted by the journal publisher in 2013. The reasons were outlined by the editor in chief as follow;

“The low number of animals had been identified as a cause for concern during the initial review process, but the peer review decision ultimately weighed that the work still had merit despite this limitation. A more in-depth look at the raw data revealed that no definitive conclusions can be reached with this small sample size regarding the role of either NK603 or glyphosate in regards to overall mortality or tumour incidence. Given the known high incidence of tumours in the Sprague–Dawley rat, normal variability cannot be excluded as the cause of the higher mortality and incidence observed in the treated groups” (Food and Chemical Toxicology, 2013)

Nicolia et al. (2014) conducted a systematic review of the literature on GM safety and identified no scientific evidence to suggest that GM crops are any more hazardous than conventional varieties. The growing number of publications in relation to the environmental effects and health concerns with respect to GM crops have not provided any evidence to suggest GM crops have resulted in any serious problems. Despite the scientific evidence, debates about the safety and risks of GM crops continue in the public arena.

Lucht (2015) argued that perception of risks and value drive the behaviour of consumers and that, despite the economic benefits of GM crops for farmers, consumers have not benefitted from farmers’ adoption. Gaskell et al. (2004) conducted a Eurobarometer survey and suggested that the absence of perceptible benefits to consumers contributes to the low acceptance of GM crops in Europe. In the absence of benefits, risks perceived by consumers depend on their understanding of the subject or on the information available. However, when new innovations are introduced, very limited knowledge exists in the public domain to allow rational evaluation of the potential risks. As a result, consumers often depend on sources of information they have trusted in the past for assessing the risks of the new invention (Gaskell et al., 2004; Finucane & Holup, 2005; Costa-Font et al., 2008; Siegrist, 2008). Lang & Hallman (2005) conducted a survey examining the trust relationship between the public and institutions from different sectors and suggested that public stakeholders such as scientist and universities have the highest level of trust, with industry and corporates at the other end of the spectrum. In terms of consumer acceptance, GM crops developed in the public sector are more likely to be accepted. This is particularly the case as a significant proportion of public GM crop developments contain output traits which generate benefits directly to the consumers (Costa-Font et al., 2008; De Steur et al., 2015). Unfortunately, those individuals and organisations that had the depth of knowledge and resources to
ensure the safety of the material when GM crops were initially introduced globally, were largely in the very industry which receives minimal trust from the public. The major MNC biotechnology firms are, or were, all very heavy investors in conventional pesticide production. The strong swing of public opinion against the use of chemical pesticides has tarnished the reputation of other products developed by those companies.

GM crops remain a controversial subject even though scientific evidence has proven the safety of current products and shown no significant negative unintended effects on the environment or on human health. It is often argued by public GM crop developers that the negative public perception has prevented GM crops from achieving successful commercialisation, yet the MNCs, which are under constant criticism, continue to market new GM crops developments. Furthermore, Frewer et al.’s (2013) global meta-analysis of public acceptance of GM crops suggested that the level of consumer rejection has been declining since 2003. Therefore it is unclear why the socially favoured public research institutions are not able to commercialise their GM crops.

2.5 Public-private partnerships in agricultural biotechnology

It is widely acknowledged that public and private organisations vary in skills and expertise. Public research organisations specialise in basic research at the discovery end of commercialisation pipelines and do not have strong interests in, or knowledge of commercialisation. To facilitate the transfer of public discoveries into products, there has been strong support for the public-private partnerships (PPP) model, which is known to have value in enhancing commercial outcomes (James, 1997; Binebaum et al., 2001; Krishna & Qaim, 2007). The definition of a PPP and the role of the public sector vary across industries. The infrastructure industry often defines PPP as a partnership between government organisations and private companies with a common interest (Hawkesworth, 2011). Hartwich et al. (2008) define agricultural PPPs as a sharing of resources, risks and benefits between public and private organisations. Van der Meer (2002) observed that, with the growth of private investment and reduced public research funding, the boundary between, and the roles of, the public and private sectors in agriculture have shifted, and that crops not addressed by either sector may benefit from a PPP. He defined an agricultural PPP as pooling of resources to create value for both sectors and made the following points;
“Both parties must bring some resources to the partnership that are valuable for the other party and for the common interest. These may be information, specialised human capital, germplasm, funds or research facilities.

Both parties must have an interest that overlaps. This does not mean that goals or outputs need to be the same for each sector, the private sector may seek increased market share while the public sector may want progress in sustainable rural development.

Both parties must expect some net gain, something that they cannot achieve as cheaply, as rapidly or as effectively when they operate on their own.” (Van der Meer, 2002)

Regardless of the various definitions of PPP and the models suggested by different scholars, common reasons for partnerships are to minimise the technical, financial and legal risks and to enhance the economic outcomes (James, 1997; Hartwich et al., 2008; Byerlee & Fischer, 2002; Hawksworth, 2011).

However, some researchers have expressed concerns about the PPP model and its potential impact on public agricultural research. For example, Kloppenburg (2004) observed that PPPs tend to assign public institutions to basic discovery research, identifying novel traits, and leave the responsibility for plant breeding to the private sector. As a result, the private sector becomes the only ‘buyer’ of public sector research, allowing private companies to set the agenda for public research organisations. Hall (2006) had a different opinion and argued that rather than defining and drawing a line between public and private goods, the partnerships should be viewed in the framework of an innovation system that maximises social capital.

Krishna and Qaim (2007) estimated the potential effects of a PPP model for the development of an insect resistant brinjal (eggplant) in India and showed that a collaboration between local public research institutions and private seed companies would reduce the overall product development costs and improve the livelihood of farmers in south Asia, at the same time allowing private companies to gain benefits from their patents through profit from sales. Financial incentives remain critical for the private sector in regard to the establishment of a PPP. There are two obvious advantages to a PPP model. Firstly, it has been illustrated that a PPP model reduces the financial burden on public research organisations by providing access to private sector capital which can ensure continuous funding for developments (Mula et al., 2007). Secondly, forming partnerships with private companies minimises the time and costs needed to obtain the intellectual property rights necessary for commercialisation and draws on the private sector commercial expertise for
product development and marketing (Huang et al., 2002; Spielman et al., 2010). Spielman et al. (2010) conducted an analysis on the effects of agricultural PPPs within the Consultative Group on International Agricultural Research (CGIAR). The results supported the view that access to private sector resources enhances public innovation outputs.

Despite the apparent benefits of forming PPPs in agricultural research, the literature suggests that promoting collaborations between the public and private sectors has proved to be difficult. For example, Hodge & Greve (2007) examined a number of PPP case studies and concluded that numerous PPPs have failed due to organisational issues; in most cases a mismatch of benefits and costs lowered the incentives to deliver outcomes. Spielman & von Grebmer (2006) surveyed the partnerships between CGIAR research institutes and MNCs and identified two-tiers of constraints which limit the partnership for agricultural improvement. The primary constraints were concerned with the competition and risk associated with intellectual property rights and the secondary constraints related to incentives and the opportunity cost of partnerships. Hall (2006) identified additional challenges within PPPs, where the structure of the partnership, management process and policies in local environments are all vital factors for forming a successful PPP. Other factors may also be the high capital costs, long duration of development, technical risks and uncertain market values (Link, 2006). Essentially, the literature has highlighted that the constraints for a public-private partnership in agriculture are the difficulties in aligning incentives, the arrangement of intellectual property rights and organisational behaviour. These factors need to be analysed to determine whether it is feasible and rational for public organisations to form PPPs for any particular GM crop development.

Studies on agricultural PPPs have largely focused on policy, outlining the need to change the institutional setting to overcome the constraints (Byerlee & Fischer, 2002; Hall, 2006; Spielman & Grebmer, 2006; Hartwich, 2008). However, very few studies have suggested how to effectively structure a PPP to promote GM crop developments. Based on the existing literature, it is not clear why PPPs have not successfully delivered GM crops. This is an important knowledge gap in the public domain which merits examination.
2.6 Conclusion: the Task ahead

The above review serves two purposes. Firstly, it identifies a number of gaps in the existing literature, some of which are addressed in this study. Secondly, based on the conceptual framework outlined in Chapter 1, the literature suggests there are technical, commercial, organisational and social barriers to commercialising publicly developed GM crops.

Additionally, this review serves to address one of the research questions on ‘to what extent does the need to obtain a social licence for GM crops impact on the public sector?’ Individual public research scientists and organisations may find it an obstacle to overcome, but based on the information presented in this chapter, it is apparent that the level of challenge in terms of social acceptance faced by the public sector is equivalent to, or less than, that of the private sector, yet currently private seed companies are able to succeed in commercialising their GM products and public organisations do not. This suggests that public GM developers have failed to reduce the technical, commercial and organisational barriers which have been well-addressed by the private sector. To narrow the scope of focus, Chapter 3 will use existing public GM crop initiatives as a multiple-case study to identify key technical, commercial and organisational obstacles to the commercialisation of publicly developed GM crops.
Chapter 3

Learning lessons from existing public GM developments

3.1 Introduction

Public sector GM crop developments predominately target constraints faced by farmers and consumers in poor developing countries, which are not readily addressed by private seed companies (Rausser et al., 2000; Cohen, 2005; Pray & Naseem, 2007; Paarlberg, 2009). A well-known public research initiative, the Golden Rice project, aims to improve the health status of poor in developing countries by supplementing vitamin A in the staple diet of 400 million people. A considerable amount of time (15 years) and effort has been spent on the development of this project but to date it is uncertain when, or if, the product will be available.

Public research organisations may not have realised the existence of obstacles which reach beyond scientific proof of concept, including the need to comply with extensive regulatory requirements, intellectual property rights for commercialisation, the influence of international trade policies, the impact of consumer perception and the relative lack of commercial skills to undertake cost/benefit analyses, access to commercial market pathways and even motivation in the public sector (Paarlberg, 2002; 2009). In comparison to private companies, and despite public sector’s long history of delivering improved crop varieties, current public organisations have limited experience in the development and commercialisation of GM crops.

In an attempt to tease out the common issues surrounding commercialisation for public sector bodies this chapter takes a comparative case study approach. According to Yin (2013) a case study approach is an appropriate strategy when a) the focus of research is to answer the “how” and “why” research questions b) the researcher has no control over the variables
in the study c) the research targets a contemporary set of events. A multiple-case study can be used to examine several cases, highlighting the similarities and differences between the cases. This study explores five diverse public GM developments in an attempt to identify common experiences and messages which may give us insights into obstacles to successful development and commercialisation which will then be explored in more detail in subsequent chapters. Case studies are analysed with a focus on their development processes and their current status vis a vis commercial utilisation. The cases are:

- **Insect resistant rice**- Chinese public research institutions
- **Virus resistant common bean**- Brazilian Agricultural Research Corporation (EMBRAPA)
- **Virus-resistant papaya**- Hawaii University/Cornell University/ United States Department of Agriculture (USDA)
- **Virus-resistant plum**- USDA
- **Water Efficient Maize for Africa (WEMA)**- National Agriculture Research Systems in Kenya, Uganda, Mozambique, South Africa and Tanzania/the International Maize and Wheat Improvement Center (CIMMYT)/ the African Agriculture Technology Foundation (AATF)

### 3.2 Development of Bt Rice in China.

#### 3.2.1 Economic value of rice in China

China is the world’s largest consumer and producer of rice, with an annual production volume of 200 million tonnes harvested from 30 million hectares (FAOSTAT, 2015). It is estimated that the population in China will reach 1.4 billion by 2030, and the nation will face difficulties in achieving food security (Cui & Kattumuri, 2010). It is expected that China needs to increase its current rice yield from 6.59 to 7.85 tonnes per hectare to meet the demand of the nation’s growing population (Chen et al., 2011). Amongst the main constraints to increasing rice production, insect pests contribute to significant yield losses annually. Pest damage to rice in Asia is caused by a large diversity of insects, mainly species of Lepidoptera,
Diptera, Hemiptera and Coleoptera (Cohen et al., 2008). The stem borers are the most serious pests, resulting in a yield loss of 0.6 million tons annually (Sheng et al., 2003). A substantial amount of chemical pesticide is applied each year as the main strategy for controlling stem borers. This extensive application has resulted in environmental pollution, human health implications and the evolution of resistance to insecticides (Chen et al., 2011).

There is a long history of conventional breeding for insect resistance in rice and many genes conferring resistance to planthoppers and leafhoppers (Hemiptera) have been identified and crossed into commercial cultivars (Khush, 1995). However, native plant genes providing resistance to Lepidoptera have not been identified, despite the evaluation of thousands of sequences. Due to the importance of caterpillar pest issues, the limited current solutions for pest control and the success of Bt cotton, local Chinese research institutions have developed Bt rice varieties. Field studies on Bt rice have shown an average yield increase of 8% and an up to 80% decrease in insecticide use (Tu et al., 2000; Huang et al., 2005a). It is estimated that Bt rice offers the potential to generate a benefit of $4 billion to China annually (James, 2015).

3.2.2 Development of Bt rice in China

Bt rice has been under development in China since 1989. The first Bt rice line was developed by the Chinese Academy of Agriculture Science (CAAS). Subsequently, other public research institutions have developed their own Bt lines using locally adapted germplasm (Yang et al., 1989). Two different Bt gene constructs originating from CAAS were introgressed into local varieties, a Cry1Ab/Cry1Ac fusion gene and a construct containing Cry1Ac and a Cowpea trypsin inhibitor (CpTi) sequence. Both combinations had been used earlier in Bt cotton (Cohen et al., 2008). The initial confined field trials for transgenic Bt rice were conducted in the 1999/2000 season followed by two-years of large-scale experimental field trials. Under China’s regulatory framework, a pre-production trial is required to demonstrate commercial feasibility; a trial was completed in 2004 (Lu, 2010). By 2009, two biosafety certificates had been issued from the Ministry of Agriculture for two Bt rice strains, Huahui No. 1 and Shanyou 63 both with the Cry1Ab/Cry1Ac fusion gene (Lu 2010; Chen et al., 2011). Both Bt
rice lines were developed by public research organisations, HuaZhong Agriculture University and Zhejiang Agriculture University, and funded by national programmes (Cantrell, 2003).

3.2.3 Regulatory system in China

Like many countries, a regulatory framework has been established in China which governs the use of GM crops. The regulatory system in China can be divided into two distinct periods. The first period begins in 1993 when the Ministry of Science and Technology (MOST) issued the first biosafety regulation for GM crops. This was an initial framework of GM regulations (and at that time, GMOs were considered as a purely scientific matter with no social or ethical dimensions) which stated general principles for the need for risk assessments and identification of legal responsibilities (Li et al., 2014). However, the early Chinese regulations were not detailed, and there were growing concerns about the safety and environmental impact of GM crops. The Chinese government acknowledged the various concerns over the subject of GM crops and in May 2001, the State Council of China amended the Ministry of Agriculture (MOA)'s administrative measures and decreed a new GM regulation the ‘Regulation on Safety Administration of Agricultural GMOs’. This regulation implements rules detailing the criteria for allowable GM research & development, production, processing, marketing and import/export of GM materials (Huang & Wang, 2003). Under the national government regulation, the MOA is the primary organisation for implementing biosafety regulations and is responsible for nationwide supervision of all agricultural GMOs. In order to implement the new GM regulations, the MOA issued various guidelines to ensure governance for research and development, biosafety assessment, field trials, production, processing, importing and exporting activities (Yang, 2003). Under the MOA supervision, a National Biosafety Committee examines the regulatory dossiers and provides recommendations back to the Office of the Agricultural Genetic Engineering Biosafety Administration. Although there are other governing agencies such as the Ministry of Health and the State Environmental Protection Agency, the commercial approval decision lies within the MOA (Huang & Wang, 2003; Chen et al., 2011).

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22 All recent GM crop developments from Chinese public research institutions use public resources which are all funded under national programmes. Chapter7, Section 7.4.1 provides further detail on the Chinese national policy for GM crop developments.
3.2.4 Intellectual property issues

The Chinese intellectual property right system is often criticized for its weak legal enforcement. CAAS developed the first public Bt cotton line and formed a joint venture with Biocentury, a spun off company from CAAS, to produce and distribute Bt cotton seeds in 1999 (Huang et al., 2002b). The intellectual property right for the \textit{Cry1Ab/Cry1Ac} fusion gene in China is under a patent held by CAAS (Fang et al., 2001). However, seed companies and farmers were reproducing and distributing illicit Bt cotton seeds without consent from CAAS (Pray et al., 2002b). By 2004, the distribution of Bt cotton from CAAS accounted for only 5% of the total Bt cotton planted with the majority of marketed Bt cotton varieties developed and distributed illegally (Huang et al., 2005b; 2010).

Monsanto was only allowed to distribute into provinces which were approved by the Chinese biosafety committee, initially in Hebei and later on in Shandong, Anhui and Henan and then only in US cotton varieties. Permission was not given for introgression of the Bt trait into locally adapted germplasm, which was sometimes (though not always) better adapted to the low input systems prevalent in China at the time. In contrast, cotton varieties developed by CAAS were approved for nine provinces. Monsanto did not file a Chinese patent for \textit{Cry1Ac} in recognition of China’s weak intellectual property system. Instead, it sought protection through a partnership with JiDai, a provincial seed company in Hebei. JiDai’s monopoly power over Hebei’s seed markets allowed Monsanto to gain a technological premium from the distribution of GM cotton seeds in the province (Pray et al., 2002b). The provincial government in Hebei protected Monsanto from competitors and allowed a technological premium to be charged on the seeds. Although they were able to distribute to other provinces, absence of monopoly power in partner seed companies outside Hebei meant other seed companies were reproducing and distributing seeds illegally (Pray & Govindasamy, 2002). Trademarks provided an alternative approach for technology protection; Monsanto used the trademark name ‘Bollgard’ on their cotton varieties. The lack of intellectual property enforcement on patents or trademarks on other local seed companies meant that they were not prevented from using Monsanto’s technologies (either using seed from Monsanto varieties directly or by crossing Monsanto varieties into their proprietary germplasm).

Both public and private organisations in China have failed to enforce intellectual property rights on their Bt gene constructs. Monsanto learned from that experience and its first Bt cotton constructs in India, under a joint venture with the Maharashtra Hybrid Seed Company
(MAHYCO), were marketed only as hybrids which would not breed true and required the farmer to return to the company for seed every year. In some crops the hybrid vigour gained by this system is a strong reason for their adoption (e.g. in maize, though not markedly in cotton) but it also provides a strong intellectual property protection motivation for the seed companies. Partly for that reason, Bt rice in China is being developed in a hybrid variety based system (Huang et al., 2008).

3.2.5 Influence of consumer perceptions

China has commercialised a variety of GM crops including, cotton, papaya and poplar and generally consumers in China have been willing to purchase GM-derived products (Huang et al., 2006). However, the recent biosafety certificates granted to Bt rice received considerable attention from both the public and scientific community. On March 2010, a group of Chinese scientists and the minister of Ministry of Science and Technology (MOST) recommended the government to be cautious of GM development in staple food crops and to request additional biosafety studies (Jia, 2010). A report published in August 2012, detailing a scientific study involving feeding Chinese children with Golden Rice to determine its effectiveness as a dietary supplement, further reduced the level of public acceptance (Tang et al., 2012). According to government officials, this research did not have ethical clearance, although there has been considerable subsequent debate as to whether informed consent was indeed obtained from the parents of participants in the study (Qiu, 2012). Nevertheless, the public is taking a cautious attitude towards biotechnology-derived food, despite the government’s attempt to explain the safety of GM crops to the public and to reassure the public of their safety for consumption (Yap, 2013). With consumers wary of GM crops, the MOA appears to have slowed down field trial and commercialisation approval of all new GM crops under development (USDA, 2013a). Bt rice in China has reached the final stage of the regulatory process, with both Bt rice lines obtaining biosafety certificates in 2009. Yet to date, it is uncertain when Bt rice will be commercially available (Table 3.1 provides a summary of the case study).
3.3 EMBRAPA’s transgenic beans

3.3.1 Economic value of common beans

Common beans (*Phaseolus vulgaris* L.) are a significant source of proteins, carbohydrates, minerals and vitamins and are the main staple crop in the diet of many Central and South Americans (Broughton et al., 2003). Brazil is the largest common bean producer in the world, with a total production of 3.5 million metric tons per year. The majority of production occurs in the provinces of Parana, Rio Grande de Sul, Santa Catarina and Sao Paulo, mostly grown on small farms with an average yield of 1,000kg per hectare (Blair et al., 2013). The quantity exported from Brazil is insignificant with the great majority consumed locally (USDA, 2010). Current cultivars used for production are susceptible to Bean Golden Mosaic Virus (BGMV) transmitted by whiteflies (*Bemisia tabaci* Gennadius), resulting in an average yield loss of 20% and up to 100% under extreme circumstances (Morales & Anderson, 2001; Balsamo et al., 2015). To control the transmission of the disease, farmers spray large amounts of insecticide to prevent the spread of the insect vector (Oliveria et al., 2001).

3.3.2 Public organisation development

EMBRAPA is a public corporation, owned by the government with an organisational structure derived from the private sector. EMBRAPA was established by the Brazilian government with the goal of improving national agriculture capability and enhancing Brazilian agricultural research (Alves, 2010). Between 2000 and 2007, 90% of EMBRAPA’s funding was contributed by the Brazilian government, with the remaining budget coming from sales and external sources. For example, between 2009 and 2012 EMBRAPA received royalties of around $5 million with an additional government contribution in 2014 of around $1 billion (OECD, 2015a). Because of the social and economic importance of common beans, Brazilian researchers have been screening common genotypes which might be resistant to BGMV for many years. However, no varieties which are highly resistant to BGMV have been identified (Garrido-Ramirez et al., 2000). EMBRAPA genetically modified common beans to provide resistance against BGMV (Aragão et al., 1998). The resistance was achieved through RNA-mediated gene silencing via genetically inserting non-infective BGMV viral DNA sequences into the plant’s genome (Bonfirm et al., 2007; Aragão & Falia, 2009). The plant responds to the presence of this viral material with what is essentially a type of immunity
response. This primes the plant to trigger an immediate and strong defence response to a
genuine BGMV infection.

3.3.3 Deregulation of virus-resistant bean

The development of GM common beans started in the early 1990’s when conventional
breeding programmes failed to identify genotypes for BGMV resistance. Experimentation on
GM common beans in the greenhouse and in field trials (2007-2008) under high disease
incidence conditions provided promising results. To determine whether the GM common
beans have the same yield performance as conventional varieties, under low or no disease
conditions, three low-disease regions were chosen in which to conduct field trials. The result
from the agronomic study showed no significant difference in yield between transgenic and
conventional varieties in the low disease incidence regions (Aragão & Falia, 2009). With
promising results from the field trials and the benefits of virus resistance demonstrated,
transgenic beans were ready to be deregulated for commercialisation. For any GMO to be
commercialised in Brazil, a biosafety certificate is required from the regulatory authority.
Brazil’s first biosafety law (Law no. 8974/95) in 1995 adopted the precautionary principle
(see Section 2.3 for details of the precautionary principle), and no approvals were granted
between 1995 and 2002. However, when the federal government identified a large quantity
of GM herbicide tolerant soybean seeds which had improperly crossed into Brazil from
Argentinean borders in 2003, the federal administration was constrained to issue Provisional
Measure permits for GM soybeans which had already been planted in Brazil (de Silveria & de
Carvalho-Borges, 2007; Rhodes, 2014). Due to the wide-spread adoption and the subsequent
tremendous economic benefits, Brazil replaced the old biosafety law and took a more
permissive approach (Law No. 1110) in 2005 (USDA, 2013b; Rhodes, 2014). Under the
current regulatory framework, the decision for commercial release is regulated by two
authorities, the Brazilian National Technical Biosafety Commission (CTNBio), part of the
Ministry of Science and Technology, and National Biosafety Council (CNBS). CNBS evaluates
the social- economic component and decides whether it is in Brazil’s interest to release them
commercially and CTNBio evaluates the safety of GM crops, in regard to human health and
environmental risks (Mendonça-Hagler et al., 2008). In 2008, the council of CNBS decided
that it will only review biotech products on social and economic issues, upon administrative
appeals and otherwise decisions made by CTNBio are conclusive (USDA, 2013b). This allows
CTNBio to make the final decision on whether additional scientific experiments are required
or whether a particular GMO is safe for commercialisation (de Silveria & de Carvalho-Borges, 2007). A national biosafety certificate for transgenic beans was applied for and granted by CTNBio in 2009 and approval for commercial cultivation and consumption was granted in 2011 (Tollefson, 2011; Balsamo et al., 2015).

3.3.4 Intellectual property protection system

Intellectual property often poses difficulties in commercialising GM crops, due to component technologies/genes having been patented by other organisations and given that without proper intellectual property licensing, GM crops cannot be commercialised. However, in the case of the EMBRAPA transgenic common beans, Brazil follows a different intellectual property framework for GM crops based on two sets of laws which were enacted during 1990’s; the Industrial Patent Law (9.279/96) and the Plant Variety Protection Law (9.456/97) (Rodrigues et al., 2011). The Brazilian legal system does not recognise property rights for natural biological sequences or for the use of them. Instead, the legislation provides intellectual property rights exclusivity on products derived from technologies. A GM crop is considered a new plant variety and is protected under the Plant Variety Protection law, which was designed in accordance with the International Convention for the Protection of New varieties of Plants (UPOV) (Chamas et al., 2007). Personal communication with a scientist from EMBRAPA indicated that GM common beans are currently (2015) undergoing agronomic field trials in order to obtain plant varietal protection.

3.3.5 Rapid adoption and public sector efforts

Brazil’s rapid adoption rate for GM technology has made Brazil the second largest producer of GM soybean in the world and indeed the world’s second largest grower of GM crops (James, 2015). Brazil’s past experience with GM technology resulted in significant economic growth, and doubtless this provides a motivation to utilise GM technology in crops of importance. EMBRAPA’s development of GM common beans targeted a need of local Brazilian farmers. There appears to be no publically available information on why GM common beans have not yet reached the commercial market despite the commercial certificate having been granted in 2011 (Table 3.1 provides a summary of the case study).
3.4 Hawaii’s transgenic papaya

3.4.1 Papaya threatened by Ring Spot Virus

Papaya is an important fruit crop grown in tropical and subtropical regions. It is known for its nutrients and its richness in vitamins, antioxidants and minerals. Apart from its direct use as a food source, papain derived from papaya is used by the meat industry as a tenderiser. Brazil, India and Mexico are the largest producers of papaya, it is estimated that the global annual production of papaya has reached 11.5 million tons with India being the largest producer (4 million tons) (FAOSTAT, 2015). In the US, the largest producing region is located in Hawaii. The Hawaiian papaya industry is valued at $9.7 million, with the majority of fresh production consumed in the US, and the rest exported to Canada and Japan (USDA, 2011).

Papaya Ring Spot Virus (PRSV) is the most damaging and widespread virus infecting papaya. Trees infected during the seedling stage will not be able to produce mature fruits, while infected mature trees produce poor quality papayas with generally lower sugar content (Gonsalves, 1998). The main Hawaii papaya industry had to move from Oahu to Puna in 1950 because the main island of Oahu was severely infected with PRSV. However, PRSV was discovered in Puna in 1992 and by 1997 the entirety of Puna Island was affected by the presence of PRSV, disrupting commercial production. This risk had been foreseen and cross-breeding selection for resistance to PRSV had already started in 1979 (Gonsalves et al., 2000). With not enough progress being made by conventional breeding, in an attempt to save the Hawaiian papaya industry, resistance using a viral coat protein sequence (PRSV HA5-1) was proposed as an approach for controlling PRSV (Fitch et al., 1992). It was later identified that the mechanism of this resistance is based on RNA-mediated gene silencing (Tennant, 2001).

3.4.2 Research and development stage

The development of the virus-resistant papaya was a collaboration between Cornell University and the University of Hawaii. The project was supported by USDA, funded under the Section 406 Program (Gonsalves, 1998). The initial transformation of papaya with PRSV HA 5-1 started in 1988 by bombarding embryonic tissues with tungsten particles coated with PRSV HA 5-1. Transformed papayas were generated and kept under greenhouse conditions (Fitch et al., 1992). In 1991, the Animal Plant Health Inspection Service (APHIS) issued a
permit for small experimental field trial at the University of Hawaii’s experimental farm on Oahu Island. In the meantime, papaya in the Kapoho region of Puna was severely infected with PRSV and by 1994 the Hawaii Department of Agriculture declared that the virus was uncontrollable. The application for large field trials on Puna island was submitted in 1994 and granted in October 1995 with a given set of conditions: a) the transgenic papaya need to be isolated to minimise pollen flow b) all the trees must be monitored and c) all fruits had to be buried on site (Gonsalves, 1998). The experimental data showed impressive results with the transgenic papaya proven to be resistant to PRSV (Ferreira et al., 2002).

Prior to commercial release, transgenic papaya needed to be deregulated by three agencies; the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA) and the quarantine authority APHIS (USDA) (Belson, 2001).

EPA’s role in the regulation of GMOs is based on three different acts, the 1988 Federal Insecticide, Fungicide and Rodenticide Act, the 1954 Federal, Food, Drug and Cosmetic Act, and the 1976 Toxic Substances and Control Act. EPA regarded the viral coat protein expressed by transgenic papaya as a pesticide, due to its effect of reducing pests or diseases on papaya trees (Tripathi et al., 2007). The research team submitted a petition to exempt the transgenic papaya for regulation as a pesticide, on the grounds that the viral coat protein has been consumed by humans for many years and the fact that many papayas being sold were already infected with PRSV. Furthermore, the amounts of coat protein in transgenic papaya were lower than in PRSV infected papaya. EPA granted the exemption status on August 1997 (Gonsalves, 2014).

The objective of FDA is to ensure that the GM food developed is safe for human consumption or as an animal feed, before the product is marketed. FDA follows a consultative process where the developers provide all the safety assessment to ensure the foods are safe for consumption (FDA, 1997a). Based on the consultation note on GM papaya, the FDA concluded that the GM papaya was not materially different to the original counterpart, which had been consumed with a history of safe use. The FDA approval of GM papaya was granted on September 1997 (FDA, 1997b).

The responsibility of APHIS is to protect US agriculture from threats derived from diseases and pests. In the case of the virus-resistant papaya, the main concern of APHIS lay in the potential risk of gene flow into wild relatives. A petition document detailing reasons for exempting transgenic papaya was submitted to APHIS on Feb 1996, on the grounds that
there are no wild papaya relatives in Hawaii, nor is papaya considered as a weed anywhere in the world (Gonsalves & Manshardt, 1996). APIHS approved an exemption and deregulated transgenic papaya on September 1996 (Strating, 1996) and the commercial license was granted in 1998 (Gonsalves, 2014).

3.4.3 Intellectual property rights

The Papaya Administrative Committee (PAC) needed to obtain license agreements from patent holders for the technological components that had been used to create the virus-resistant papaya prior to commercialisation. Several conditions which favoured the PAC in obtaining licence agreements from respective patent holders: 1) The papaya industry value is relatively small in the US 2) the license holders were not working on transgenic papaya at the time 3) the papaya industry required immediate remedy and 4) the patent holders would demonstrate goodwill by assisting local papaya industry (Gonsalves, 1998). Negotiations with private companies and public organisations were completed in 1998, including Monsanto, Asgrow Seed, CAMBIA and the Massachusetts Institute of Technology (Gonsalves et al., 2007). The PAC was able to obtain all the necessary intellectual property rights required for commercialisation, but there were restrictions and terms on the license agreements including that papaya growers were restricted to planting within Hawaii, that they would only export to deregulated countries, that farmers attended information sessions on managing PRSV and a requirement that growers could only purchase seeds from the PAC (Nishina et al., 1998).

3.4.4 Difficulties associated with foreign deregulations

Exporting transgenic crops to other jurisdictions requires deregulation (the removal of restrictions on import, consumption and sometimes growing) by relevant regulatory authorities. Even the basic principles of the deregulation process in the importing country may differ radically from that of the original country of production, making it essential that the original biosafety data package produced by the developers be suited to as many relevant importing countries as is practicable, but even then further in-country laboratory and field trials may be required. It is often stated that the extension of time required for such deregulation contributes to unforeseen costs (Pray et al., 2005). In 1999, the Hawaii Papaya Industry Association submitted a regulatory dossier to Japanese regulatory
authorities for deregulation, but the event was approved for import only 13 years later (Gonsalves, 2004; USDA, 2011). During that period of time farmers wanted to maintain a share of Japan’s premium market and the Hawaiian papaya industry segmented into two different farming approaches, one group adopted the virus-resistant papaya and the other continued to use only non-GM cultivars, dedicated for export to Japan. However, the cost of producing non-GM papaya was relatively high and increasing due to the extensive testing requirement for shipping certified non-GM papaya to Japan (Gonsalves et al., 2007). The cost of producing non-GM papaya and the legal barriers for the virus-resistant papaya significantly reduced Hawaii’s market share in Japan, where the value of Hawaiian exports rapidly declined from $15 million in 1999 to $1 million in 2011 (USDA, 2012). The eventual deregulation of GM papaya in Japan in 2012 did not improve the market value of Hawaii’s GM papaya. In 2012 the weight of transgenic papaya exported to Japan was 4,630 pounds, while the non-GM varieties shipped at 1.3 million pounds (Bishop, 2013). Japanese market wholesalers remain reluctant to import GM papaya from Hawaii due to consumer concerns regarding GM food (Bishop, 2013). The Hawaiian papaya industry wishes to expand their market into China, with an aim of restoring the value of Hawaiian papaya. Scientific data collected for deregulating in Japan will hopefully minimise the time and effort required. A petition for deregulation was submitted to China’s Ministry of Agriculture in 2012 (Gonsalves, 2014) (Table 3.1 provides a summary of the case study).

3.5 Water Efficient Maize for Africa

3.5.1 WEMA project

Most countries in Africa are prone to drought conditions which are likely to be exacerbated by climate change (Jones & Thornton, 2003). A recent report compiled by FAO indicates that food insecurity remains a major issue in sub-Saharan Africa with several countries continuing to import maize to meet consumption demand (FAO, 2013). To be self-sustaining, there is a

23 Canada approved the import of GM papaya in 2003.
24 A different PRSV resistant GM papaya was developed by the South China Agricultural University in Guangzhou and was approved by the Chinese government for commercialisation in 2006 (Tecson Mendoza et al., 2008). The engineering of resistance in China’s transgenic papaya followed a similar approach to that of Gonslaves (1998) but used a viral replicase sequence instead of a viral coat protein gene. This is currently the only variety (Huanong No.1) approved for commercialisation in China with commercial planting in Guandong and Hainan Island (James, 2015).
need to increase the overall agriculture production in sub-Saharan countries. Maize is one of the major staple crops in Africa, providing a vital part of Southern Africans’ daily diet, and is commonly grown by millions of small-scale, resource-poor farmers (Banziger & Diallo, 2000). The average yield of maize in sub-Saharan Africa is 1.7 tonnes per hectare compared to the global average of 4 tonnes per hectare. Crops that are capable of withstanding drought stress without yield penalty under high rainfall conditions should enormously enhance the availability of food. The Water Efficient Maize for Africa (WEMA) project is a public-private initiative aimed at developing drought tolerant maize, using both GM technology and marker-assisted breeding, for the benefit of small-scale farmers in Africa (Kostandini et al., 2013).

3.5.2 WEMA partners and funding

The major partners within the WEMA project are National Agricultural Research Services (NARS) in the five participating countries (Kenya, Uganda, Mozambique, South Africa and Tanzania) plus Monsanto and CIMMYT (AATF, 2010). The role of the donor funded African Agricultural Technology Foundation (AATF) is to facilitate the process of technology transfer between private and public sector organisations and to provide regulatory guidance for the NARS in each country. Furthermore, AATF will assist the NARS in identifying local seed companies for distribution of drought-tolerant maize on a royalty-free basis (AATF, 2010). Monsanto, being one of the key partners in the WEMA project, donated the drought tolerant gene, the cold shock protein B (CspB)\textsuperscript{25}, under royalty-free licenses (Thomson et al., 2011; Monsanto, 2012a). CIMMYT is a non-profit organisation, with extensive knowledge and research expertise on maize and a member of the Consultative Group on International Agricultural Research (CGIAR). CIMMYT assists WEMA in identifying suitable maize germplasm and provides selection methods using conventional marker-assisted breeding techniques (Lumpkin & Armstrong, 2010). Five different NARS, the Kenya Agricultural Research Institute (Kenya), the National Agriculture Institute of Mozambique (Mozambique), the Agriculture Research Council (South Africa), the Commission of Science and Technology (Tanzania) and the National Agricultural Research Organisation (Uganda) provide research

\textsuperscript{25} Cold shock protein B (CspB) is a gene sequence from *Bacillus subtilis*. CspB is a RNA chaperone that stabilises the secondary structure of RNA and maintains its biological functions under stress conditions (Castiglioni et al., 2008). In the USA, Monsanto has gained regulatory approval for the drought tolerant trait (Mon 87460) and it is available to farmers there.
support for the development of drought-tolerant maize and select varieties which are suitable for local farmers.

The initial projection of the funding required for the development of the WEMA project was $47 million (AATF, 2008), supported by the Bill and Melinda Gates Foundation (BMGF) and Howard G. Buffett foundation. Based on the financial figures provided by BMGF, approximately $1.3 billion US dollars were granted in the area of agriculture development globally from 2009 to 2012 making WEMA one of the major projects funded. Both foundations wish to improve sustainable food production and assist in meeting the need for better quality agricultural production in Africa (Morris, 2011). The U.S. Agency for International Development (USAID) also financially assisted the WEMA project (AATF, 2012).

3.5.3 Development Stages

WEMA started in 2008, it utilises both conventional and biotechnological methods to develop drought-tolerant maize. By 2013, 15 drought-tolerant maize varieties developed through conventional methods had been commercialised in Kenya, Uganda, and Tanzania (Kitabu, 2014). Transgenic solutions for drought resistance in maize are still under development with confined field trials (CFTs) of transgenic plant material being conducted by NARS in South Africa, Kenya, and Uganda. The first CFT started in South Africa in 2009, in Kenya in 2010 and Uganda in 2011 (AATF, 2011; Thomson et al., 2011). The results from initial confined field trials have shown an increase in yield of 15% under drought condition with no reduction in yield under optimal weather conditions (Parliament Monitoring Group, 2012). The CFT results from Kenya of the drought-tolerant trait showed significant improvement over the six trials conducted and showed a minimum increase of productivity by 10% under drought conditions (Chege, 2014). One last CFT and two national performance trials are required prior to commercial release in Kenya. The expected commercialisation date of drought tolerant maize developed by WEMA is 2017, but the exact date will subject to regulatory approvals (Parliament Monitoring Group, 2012; CIMMYT, 2013; Chege, 2014). In 2011, decisions were made to incorporate insect resistance into the project and Bt maize CFTs were conducted in Kenya and Uganda in 2013 (SeedQuest, 2013). South Africa has already deregulated Bt maize and has approved commercial plantings since 1998 (James, 2015).
3.5.4 Intellectual property

The following information was extracted from WEMA’s project collaboration document (AATF, 2008) and appears to be all that is publically available. CIMMYT provided maize varieties that are suitable for local conditions and Monsanto with BASF agreed to donate their drought tolerant technology to the WEMA project. The licensing agreement from CIMMYT and Monsanto provided AATF a non-exclusive, royalty-free license and the right to sublicense to local seed companies for production and distribution. The expected outcome allows seed companies to distribute seeds to farmers without additional technology fees.

3.5.5 Regulatory challenges

To release a GM crop commercially within a country, a legal biosafety assessment system must be in place. Out of the five sub-Saharan countries targeted by the WEMA project, only South Africa and Kenya have enacted biosafety laws on the use of genetically modified organisms (GMO). Kenya recently passed a National Biosafety Act (2009) and implemented a regulatory system which allowed deregulation of GM materials for commercial release (Kingiri & Ayele, 2009). In 2000, applications for research trials for Bt cotton and Bt maize were made in Uganda. The applications were denied, based on a Uganda National Council for Science and Technology’s decision that Uganda lacked a biosafety regulatory framework that would ensure the protection of their health and environment. In 2012, a National Biotechnology and Biosafety bill was drafted which provides a regulatory framework for the development of GM crops in Uganda. The cabinet of the Republic of Uganda has approved the biosafety bill to provide a system to address the potential risks of gene technology (Parliament of the Republic of Uganda, 2013). Uganda has approved numerous field trials for WEMA’s drought-tolerant maize but no GM product has passed through the final step of regulatory approval for commercialisation. Agricultural biotechnology being relatively recent, sub-Saharan countries believe that they need to develop regulations that enable them to govern the safe commercialisation and trade of GM crops. Over the last decade, the overall momentum in Africa has moved towards becoming more involved in the use of biotechnology to provide sustainable food and fibre production (Wafula et al., 2012).

Some African countries have adopted the European concepts in regulating GMOs and essentially refuse to cultivate or import any GM crops. This presents an obstacle for public research organisations that wish to develop and commercialise a GM crop given that they
are operating under regulations enshrining such precautionary principles. It has been suggested that the EU possess highly influential power over the decision on policies in Africa. For example, many African countries require foreign assistance, and a significant proportion is contributed from European countries, either from the EU centrally, or bilaterally, with governments in Europe encouraging African countries to follow EU’s regulatory policies on GM crops (Paarlberg, 2010). Furthermore, some African countries have expressed concern about the impact of GM crops on international trade, given that they are highly reliant on countries in the EU for export markets (Bodulovic, 2005). The strict liability regime has severely impacted on the rate of development of the WEMA drought-tolerant transgenic maize. The audit report from AATF indicated that Tanzania, which has a strict liability policy on GM crops, is currently two years behind other partner countries in progress towards commercialisation (AATF, 2012) (Table 3.1 provides a summary of the case study).

3.6 Virus resistant plum in the USA

3.6.1 Plum pox virus

The US is a major consumer and exporter of plum, both fresh plums and dried prunes, with an annual export value of $160 million (FAOSTATS, 2015). Plum pox virus (PPV) is a serious threat to the stone fruit industry and has progressively spread through Europe and more recently, to Asia, Africa and North and South America, despite attempts made to control the disease by applying strict quarantine regulations (Levy et al., 2000; Scorza et al., 2013). PPV affects the fruits of commercially cultivated stone fruits such as plums, cherries, apricots, and peaches, causing fruit deformation, and premature fruit drop (Kegler & Hartmann, 1999). PPV is spread by insect vectors, most commonly through sap-sucking insects such as aphids. In 1999, PPV was detected in the state of Pennsylvania, US which led to a 10-year eradication program (essentially by tree destruction), costing more than $65 million, aimed at restoring the stone fruit industry (Scorza et al., 2013).
3.6.2 Development of virus-resistant plum

The United States Department of Agriculture- Agricultural Research Service (USDA-ARS) began the development of virus-resistant plum with the intention of selectively breeding cultivars that are highly resistant to PPV (Scorza et al., 2013). The lack of high-level resistance genes in commercially cultivated varieties has shifted the attention towards a similar approach to that of Gonsalves (1998) in developing transgenic papaya. Initial transformation with PRSV coat protein, due to its homology to PPV coat proteins, provided some limited resistance to PPV under greenhouse conditions. The PPV coat protein was then sequenced, cloned and transformed into plum varieties that could later be used to backcross into commercial cultivars. One particular event (C5) was identified as highly resistant against PPV under both greenhouse and field conditions, with collaborators in Europe confirming the effectiveness of PPV resistant plums (Malinowski et al., 2006; Scorza et al., 2013). At that time, the mechanism of resistance was not fully understood, and it was only recently revealed that the high-level resistance in the C5 event, results from the production of siRNA leading to RNA interference (Scorza et al., 2010; Scorza et al., 2013).

3.6.3 Deregulation of virus-resistant plum

The deregulation of the virus-resistant plum in the US followed a similar process to that for Hawaii’s transgenic papaya. Approvals were gained from all three US governing agencies APHIS (USDA), FDA and EPA. The deregulation process started in 2003, with initial submission to APHIS for determination of non-regulated status. In June 2007, a non-regulated status was granted from APHIS (APHIS, 2007). FDA’s consultative process requires safety analysis from developers, including nutritional composition, allergenicity and toxicology studies. A dossier was submitted to FDA in October 2006, and approval was granted in Jan 2009 (Scorza et al., 2012). ARS researchers provided relevant safety documents to EPA and exemption from regulatory requirement was approved in August 2011 (Scorza et al., 2012). The collaborators and partners in EU are working to deregulate the virus-resistant plum in Europe. Research scientists from US, France, Spain, Romania and Poland will conduct additional biosafety experiments to provide additional information required for Czech Republic scientists to complete a regulatory dossier for European Food Safety Authority (EFSA) (ARS, 2011).
3.6.4 Intellectual property negotiations

A patent for the virus-resistant plum, ‘Honeysweet’, was applied for in 2001 and was granted on September 2004 (Patent number US PP15154P2). This patent was assigned to public research organisations in US and France. The development of the virus-resistant plum required intellectual property rights from external organisations. Based on personal communication with Dr. R. Scorza, there were two factors that facilitated the successful licence negotiations with patent holders. Firstly, plum is a minor crop industry which was not of great financial interest to private organisations. Secondly, the development was a not-for-profit public project that benefited small-scale farmers. However, no information was made available on the technological components to which rights were obtained under licences or on the conditions of those licences.

3.6.5 Current status of Honeysweet plum

Despite the potential of virus-resistant plum and the availability for immediate planting, the plum industry in the US has not adopted the transgenic variety. It is apparent that the plant material will not be commercialised and distributed into the US plum industry in the near future, considering PPV is not now causing major concern in the US (Scorza, 2011). Having eradicated the disease through phytosanitary measures, current federal and state agencies in the US have in place strict quarantine programmes to prevent PPV outbreaks. Even though PPV has been eradicated in the US, all current plum trees in the US are susceptible to the virus. The current intention is to keep the virus-resistant plum as a germplasm source for future cross breeding (Scorza, 2011) (Table 3.1 provides a summary of the case study).
<table>
<thead>
<tr>
<th>Traits introduced</th>
<th>Papaya (US)</th>
<th>Beans (Brazil)</th>
<th>Plum (US)</th>
<th>Rice (China)</th>
<th>Maize (Africa)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Virus-resistance</td>
<td>Virus-resistance</td>
<td>Virus-resistance</td>
<td>Insect-resistance</td>
<td>Drought tolerance</td>
<td>National agriculture research system in Kenya, Uganda, Tanzania, South Africa and Mozambique</td>
</tr>
<tr>
<td>Developers</td>
<td>Hawaii University &amp; Cornell University</td>
<td>EMBRAPA</td>
<td>USDA-ARS</td>
<td>HuaZhong Agricultural University &amp; Zhejiang Agriculture University</td>
<td>USDA research grant</td>
</tr>
<tr>
<td>Development time</td>
<td>1988~1997 (9 years)</td>
<td>1990~2009 (19 years)</td>
<td>1989~2011 (22 years)</td>
<td>1989~2009 (20 years)</td>
<td>2008~ongoing (&gt;8 years)</td>
</tr>
<tr>
<td>Funders</td>
<td>USDA research grant</td>
<td>EMBRAPA research program</td>
<td>USDA research program</td>
<td>China’s national programmes</td>
<td>Bill and Melinda Gates Foundation, Rockefeller Foundation</td>
</tr>
<tr>
<td>Obtained intellectual property rights</td>
<td>Yes</td>
<td>None required</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Deregulation within local country</td>
<td>1998</td>
<td>2011</td>
<td>2011</td>
<td>Uncertain as MOA has slowed down all GM approval</td>
<td>Expected in 2017</td>
</tr>
<tr>
<td>Deregulation in foreign countries</td>
<td>In process</td>
<td>Unknown</td>
<td>In process</td>
<td>Unknown</td>
<td>Ongoing process (Five participating countries)</td>
</tr>
<tr>
<td>Project outcome</td>
<td>Successful and complete</td>
<td>Successful and almost complete</td>
<td>Proof successful but not commercialised</td>
<td>Proof successful but not yet commercialised</td>
<td>Ongoing process</td>
</tr>
<tr>
<td>Commercial results to date</td>
<td>450 hectares commercially planted</td>
<td>Has not yet been commercialised</td>
<td>Will only be commercialised if a PPV outbreak is detected</td>
<td>Has not been commercialised</td>
<td>Has not yet been commercialised</td>
</tr>
</tbody>
</table>

Table 3.1 Summary of all five public GM crop development case studies
3.7 Key values and issues identified

3.7.1 Value to public developments of gaining license agreements

The study confirmed that developing a GM crop normally requires numerous patented technologies and the majority of core enabling GM technologies for current developments are the property of organisations in the private sector. It is critical for public organisations to obtain licence agreements from patent holders to ensure freedom to operate (FTO). Identifying the patents of interest and negotiating licence agreements may pose difficulties, as patent holders use patents to limit and restrict competitors in order to gain competitive advantage. For that reason, many scholars believed the existence of intellectual property protection would commercially limit the ability of publicly developed GM crops to assist the poor in developing countries (Atkinson et al., 2003; Graff et al., 2003; 2004) unless novel methods can be developed within the public sector itself, although even there, the push for limiting sharing of intellectual property rights is becoming widespread. Without consents from technological owners, public researchers cannot utilise patented technologies for commercial developments; such consents are frequently forthcoming only for minor crops of no commercial interest to the patent holders.

However, analysis of the public GM crop case studies suggests that obtaining licences from patent holders may not be as prohibitive as imagined. Within the cases illustrated in the study, no projects were restricted in their development from lack of access to intellectual property rights, even for commercialisation. In fact, in the development of GM papaya, plum and maize, private organisations agreed to contribute by providing the necessary intellectual property rights under royalty-free terms. Two key critical factors ensured successful negotiation; the nature of the project and the economic size of industries involved. In comparison with the major commodity crops (e.g. cotton, soybean, maize and canola), the overall value of minor crop industries, such as papaya and plum, are minimal. As a result, private seed companies do not have any financial interest in investing in these minor crop industries, given that the costs of development and commercialisation mean that they will not generate net positive financial returns on any realistic time-frame. Secondly, the act of charity or contribution from the private sector towards public initiatives may be seen as improving the image of the donor company. It is worth stating that due to standard industry commercial-in-confidence practices, the details of the terms of the agreement between the
public and private sectors are never made publicly available. This presents as a challenge for new public GM crop developers in establishing the FTO necessary for commercialisation.

3.7.2 The need for an immediate solution

Interestingly, the virus-resistant papaya and virus-resistant plums shared many similar features during the development process, yet the outcomes are vastly different. The virus-resistant papaya began its development in 1988, and the virus-resistant plum started in 1989, with both projects transforming the plant material with viral coat proteins and achieving resistance against disease via RNA gene silencing. The issue of intellectual property rights did not pose insuperable difficulties for public organisations developing papaya and plum; the researchers were able to obtain the necessary rights for commercialisation. The regulatory environments were similar, where APHIS, EPA, and FDA determine the regulatory status of the development. However, under the same regulatory environment, with a closely similar technical mechanism for disease resistance, the regulatory approval time varied significantly. The deregulation of the virus-resistant papaya took 2 years, with first regulatory submission in 1996 and final approval in 1997. The initial dossier submission for the deregulation of virus-resistant plum began in 2003, and the plants gained approval from all three agencies in 2011 (8 years later). To date, the virus-resistant papaya has been commercialised and is deregulated for importation and use in Canada and Japan, while the commercially approved virus-resistant plum has not yet reached the market.

What contributed to the different outcomes? Firstly, it was the immediate need of a solution to farmers’ critical problems. During the development of papaya, Hawaii was already suffering from a severe PRSV outbreak and the entire papaya industry was not producing marketable products. Farmers were in dire need of a solution to combat the disease, as no other options were available. In contrast, the virus-resistant plum did not have the same urgency. Although there was an incident of PPV outbreak in the US, which consumed significant resources to eradicate using conventional methods, the current absence of PPV in the US means there is little interest within the plum farming community in converting to transgenic varieties, as it will not provide any immediate financial benefit. Secondly, by 2003 it was much more difficult to get GM approval than it had been in 1996. It has been observed that the average length of the GM deregulation process in the US has increased steadily since the first introduction in 1996 (Jaffe, 2006)
Farmers’ interests have a major impact on the adoption rate of GM crops. The level of willingness of farmers to adopt GM varieties is dependent on the additional benefit and economic value provided. Private companies invest in GM crops which create opportunities for farmers to gain substantial economic returns. In return, private companies gain a proportion of the additional value. Public GM crop developers need to consider whether their particular GM crop will produce products which provide sufficient economic value for farmers/consumers to adopt them and to justify the costs of development and deregulation and they need to convince the value chain that the product is worth actively pursuing. Even when a useful product is deregulated, there will be little uptake unless the benefits to individuals (rather than society as a whole) outweigh the perceived risks.

3.7.3 Substantial investments

Fundamentally, all the cases analysed have demonstrated scientific evidence that the GM varieties are superior to their conventional counterparts. Four public GM crop initiatives in the study have obtained regulatory approvals, but the virus-resistant papaya remains as the only commercialised publicly developed GM crop. Interestingly, the virus-resistant papaya in the US took shortest time, 11 years from basic research through to full regulatory approvals, but was, of course, the first to enter the approvals process. In contrast, the average development time for other public initiatives appears to be around 20 years. This strongly suggests that developing a GM crop is costly and time-consuming under the current regulatory environment, with a development pipeline comparable to that of pharmaceutical drug discovery. It has been estimated that the average number of years required for commercialising a new drug from initial discovery is between 9 and 12 years (Dickson & Gagnon, 2004). To conduct a 20-year project, organisations need to have agreed funding and staffing commitments. The funding sources for public organisations are mostly from research funds from governments or philanthropic organisations, which rarely have a timeline of more than 4 years. The absence of direct financial benefit for the developing organisation acts as a disincentive for public sector researchers to push a novel product through to commercialisation. As a rule of thumb companies estimate that the net present value of a product in the development pipeline is reduced by 10% for each extra year the product spends in the pipeline. Under a private company setting, companies invest the time and money to develop new traits which will increase economic output of the crop and need to see realistic prospects for financial returns for the development cost and risk.
Crops that require foreign deregulation will further add to the costs of development. The virus-resistant papaya case illustrated that the value to Hawaii’s papaya industry suffered due to restricted access to the premium market in Japan. The virus-resistant plum is currently seeking regulatory approval in Europe but the precautionary principle enshrined by the EU will create further obstacles for the developers, as the time and costs are unpredictable and indeed the investment may not lead to a favourable outcome. As for the other public initiative cases, deregulation in foreign countries may not be necessary. Common beans in Brazil are mostly consumed locally, similarly, perhaps, for rice produced in China. It may be appropriate that public efforts target crops that are consumed by local citizens to minimise regulatory work as foreign deregulation is not always necessary. Scorza (2011) suggests that public organisations need to consider methods to minimise both time and cost. The majority of resources are devoted to complying with regulations and can be minimised by consulting with regulatory agencies, reducing non-essential components within the gene construct, understanding the regulatory requirements and ensuring FTO prior to development.

3.7.4 Value of unified regulations

Government plays a vital role in determining whether a transgenic crop can be successfully developed and commercialised. In the US, China, and Brazil, local governments provide research funds to organisations for conducting GM crop research, in the hope that developments arising will greatly enhance or protect the economic status of their agriculture sector. Government regulatory control over GM crops will impact on the outcome of public efforts. Within all the cases analysed, the process of deregulation followed a systematic procedure with authorities governing the regulatory process\textsuperscript{26}. In the case of WEMA’s development of drought tolerant maize, biosafety regulations may not be clear, and the attempt to advance regulatory approval in five countries simultaneously (especially with significant heterogeneity in the principles of regulatory control amongst them) may be overly ambitious.

\textsuperscript{26} Despite China’s regulatory system approving field trials for experimental GM crops and assessing the safety of the plants, the final step for commercial approval remains politically influenced.
3.8 Conclusion

Comparative analysis of the five public GM crop case studies revealed common issues and values for public organisations developing GM crops. Public initiatives often target specialty crops or crops of particular relevance to poor developing countries and the incentive for development is very different from the private sector. The case study suggests that the challenges faced by public organisations are not predominantly technical, but more concerned with developmental, continuity, commitment, political and commercial issues.

For public organisations developing specialty crops or targeting crops in poor developing countries, the acquisition of intellectual property rights from the private sector did not restrict the developments examined. The absence of commercial conflict of interest by private companies has allowed license agreement to take place. In cases where private companies provided the key patented technologies, there may be terms outlined within the agreement that limit usage. For example, the agreement between the developers of Golden Rice and Syngenta has limited the distribution of the rice to farmers below a low-income threshold and in developing countries only, with no export of Golden Rice allowed. This will complicate issues, especially if the target crops are used for trade outside the territories in which they are developed. Public organisations conducting GM crop development need to ensure the terms of agreements fit within the scope of the initiative.

The study identified a few critical criteria which should be met to enhance the chance of successful commercialisation. Developing a GM crop is a lengthy process, and the cost may substantially increase as it progresses, especially through the regulatory phase of the development. This requires ongoing injections of financial capital in order to finance personnel and research expenses. Research funds for public organisations often have a short life cycle with limited capital, usually several grants will be required, often from a range of funders with differing interests, to meet the cost of the development. When conducting research experiments, public organisations may wish to design experiments which also contribute towards eventual regulatory dossier requirements. This may reduce the number of experimental trials required and minimise the capital needed for development. Most importantly, for any farmer or consumer to adopt new GM crops, the benefits must be apparent to them. This is crucial in determining whether the GM crop developed will actually be utilised by farmers. For example, a crop variety providing health benefits to consumers may be of little interest to seed purchasers unless there is a price premium associated with the product. Public organisations need to consider economic value and how it is to be
distributed to whom. They need to be able to assure the farmers and end-users that the product is low risk (which was not, for example, the case with the Hawaiian papaya due to marketing restrictions in its major trading partner). Without substantial economic value, the likelihood of adoption will be low, and efforts from the public organisation will quickly be obsolete.

This comparative analysis provides some common themes within public efforts in developing GM crops and has highlighted some of the specific lessons drawn from the case studies.

- Long term finance is crucial for GM crop development—why are these projects able to sustain long-term developments when hundreds of public initiatives are not able?
- Pursuing a combination of crop/trait that provides substantial economic value increases the likelihood of adoption.
- 3rd party IP is obtainable but almost by definition only for non-commercially viable crops and under restrictive conditions, reducing financial attractiveness to downstream stakeholders.
- Regulatory regimes are increasingly adding to the costs and timelines of GM crop developments.
- The negative perception of consumers affects the adoption of GM crops and influences the political environments for GM crop development.
- Public GM crop developments are often conducted by individual research groups with limited knowledge to deliver commercially acceptable products.

All these things suggest that working on really significant crops, with significantly severe problems, in countries where the product will not rely on export is probably sensible (though these are the crops of interest to industry who will restrict IP access), but even there, the influence of the regulatory regime and of politics influenced by secondary stakeholders shifts the playing field over time. Consideration of these development and commercialisation issues, including the financial commitments from public investors, the adequacy of the public current intellectual property portfolio for commercial development, the cost of regulations and the impact of developing countries’ regulatory policies are further explored in Chapter 4.
Chapter 4

Views and positions of stakeholders in Australia, China and India

4.1 Introduction

To address research questions that are difficult to conduct quantitatively, Brannen (1992) suggested a qualitative approach, allowing researchers to craft a detailed picture of the issues. Stakeholder interviews provide an effective method of gathering understanding from stakeholders across a broad spectrum, even allowing for the fact that individual stakeholders in similar positions with respect to genetically modified (GM) crop developments will have different perspectives on the subject. Some stakeholders have influence which can affect government and institutional policies and decisions (Hall & Martin, 2005). Stakeholder analysis has been utilised in the area of GM crops, for example in exploring the rationale as to why developing countries in Africa have largely rejected the adoption of GM crops (Aerni, 2005; Bett et al., 2010; Adenle et al.; 2013). As discussed in Chapter 1, the definition of ‘stakeholder’ varies across disciplines. Due to the commercial nature of the research question proposed in this thesis, the definition of stakeholder adopted in this chapter is based on Freeman’s (1984) definition of a ‘stakeholder’ as anyone that can affect or be affected by the organisation. Freeman further stated that for any organisation to succeed in the commercial world, they need to create values for the relevant primary and secondary stakeholders i.e. government agencies, companies in the supply chain, farmers, processors, consumers and the general public.

Chapter 3 identified key challenges, based on a comparative analysis of current public GM programmes that have demonstrated the technical success of their GM developments, but may or may not be able to move to successful commercialisation. The purpose of Chapter 4 is to qualitatively validate the findings identified from Chapter 3 through analysis of stakeholders’ perspectives on the obstacles to public GM crop developments in Australia,
China and India. Overall, the chapter aims to pinpoint the challenges faced by the public sector and to highlight how and why the immense public investment has not been able to deliver GM outcomes.

- Long term finance is crucial for GM crop development—why are these projects able to sustain long-term developments when hundreds of public initiatives are not able?

- Pursuing a combination of crop/trait that provides substantial economic value increases the likelihood of adoption.

- 3rd party IP is obtainable but almost by definition only for non-commercially viable crops and under restrictive conditions, reducing financial attractiveness to downstream stakeholders.

- Regulatory regimes are increasingly adding to the costs and timelines of GM crop developments.

- The negative perception of consumers affects the adoption of GM crops and influences the political environments for GM crop development.

- Public GM crop developments are often conducted by individual research groups with limited knowledge to deliver commercially acceptable product.
4.2 Methodology

Country and stakeholder selection

The study was carried out in three countries, Australia, China and India on the basis of their long history of GM cultivation and on-going GM R&D developments, where the majority of development has been conducted through public research institutions. All three countries have had considerable economic success with GM cotton and India and China have indigenously developed versions of the original private sector cottons under commercialisation. India has commercialised only GM Bt cotton (with hundreds of varieties approved) despite multiple crop/trait combinations having passed through various stages of the approvals process. Australia has commercialised GM cotton and canola, but in both cases the critical inventions/sequences were originally from the private sector outside Australia and have been conventionally bred into Australian varieties. China has commercialised at one time or another i.e. cotton, papaya, poplar, sweet pepper and tomato, but of these only cotton, papaya and poplar are still being produced and the areas involved (other than for Bt cotton) are on tiny scales. Despite the fact that all three countries have been cultivating GM crops for more than 15 years, GM crop developments originating from the public sector in these countries have yet to make a significant commercial impact. This provides a suitable context to address the research question, as to;

“What are the obstacles faced by the public sector which are preventing the public GM developments from achieving eventual commercialisation?”

Targeting primary stakeholders, 20 stakeholders were identified from India, 20 stakeholders from China and 23 stakeholders from Australia. Stakeholders were chosen based on their involvement in the industry, including key public GM developers, technology transfer officers from universities, employees of multi-national corporations (MNCs), executives from local seed companies, government regulators, members of non-governmental organisations (NGOs) and media reporters (Table 4.1). Even though secondary stakeholders can indirectly affect public GM crop developments, previous sections indicated that the social influence from secondary stakeholders has not prevented the private sector from commercialising GM crops. To identify key obstacles by contrasting elements between the public and private sectors, a broad spectrum of primary stakeholders was targeted, to ensure all the relevant themes were captured in the study.
<table>
<thead>
<tr>
<th>Name of Organisations/Institutions</th>
<th>Position</th>
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<tr>
<td><strong>Australia</strong></td>
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<td><strong>Public sector</strong></td>
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<tr>
<td>The Commonwealth Scientific and Industrial Research Organisation (CSIRO)</td>
<td>Director of Health &amp; Biosafety</td>
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<td>“</td>
<td>Director of Agriculture</td>
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<td>“</td>
<td>Principle Scientist for Bt Cowpea</td>
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<tr>
<td>“</td>
<td>Director, Business Development and Commercialisation for CSIRO Agriculture</td>
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<tr>
<td>Queensland University of Technology</td>
<td>Professor, Molecular Genetics, CTCB</td>
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<td>“</td>
<td>Professor, Institute for Future Environments, CTCB</td>
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<tr>
<td>University of Queensland</td>
<td>Director of The Australian Centre for Intellectual Property in Agriculture</td>
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<tr>
<td>“</td>
<td>Principal Scientist of GM sugarcane</td>
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<tr>
<td>AgriBio, La Trobe University</td>
<td>Research Director, Genomics and Cellular Sciences</td>
</tr>
<tr>
<td>Australian Centre for International Agricultural Research</td>
<td>Crop Improvement and Management Research Program Manager</td>
</tr>
<tr>
<td>Department of Primary Industry, Victoria</td>
<td>ex-Deputy Secretary of Agriculture Productivity and Industry Development</td>
</tr>
<tr>
<td>Australia National University (commercial wing)</td>
<td>Business Development Manager</td>
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<tr>
<td>University of Queensland (commercial wing)</td>
<td>Deputy Director, Engagement and Business Development</td>
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<tr>
<td><strong>NGOs</strong></td>
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<tr>
<td>CAMBIA</td>
<td>Founder and Director of CAMBIA</td>
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<td><strong>Regulators</strong></td>
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<td>OGTR</td>
<td>Director of Plant Evaluation</td>
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<tr>
<td>FSANZ</td>
<td>Senior Scientist, Risk Assessment</td>
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<td><strong>Industry</strong></td>
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<tr>
<td>Croplife Australia</td>
<td>Policy Manager</td>
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<td>Hexima</td>
<td>Founder and CEO of Hexima</td>
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<tr>
<td>Nufarm</td>
<td>Executive for Innovation &amp; Development</td>
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<tr>
<td>PGG Wrightson Seeds</td>
<td>General Manager</td>
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<tr>
<td>Life Sciences Queensland</td>
<td>Chief Executive Officer</td>
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<td>Dairy Future CRC</td>
<td>Chief Executive Officer</td>
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<td>Novozymes</td>
<td>General Manager</td>
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<td><strong>China</strong></td>
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<tr>
<td>Nanjing Agricultural University</td>
<td>Director, China Center for Food Security Research</td>
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<td>“</td>
<td>Deputy Director, Nanjing Biosafety Policy Center</td>
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<td>“</td>
<td>Agricultural Policy Scientist</td>
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<td>CAAS, Crop Protection</td>
<td>Director General</td>
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<td>Principal Scientist</td>
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<td>“</td>
<td>Head of insect resistance division</td>
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<tr>
<td>CAS, Center for Chinese Agricultural Policy</td>
<td>Director</td>
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<tr>
<td>CAAS, Biotechnology</td>
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<tr>
<td>Fujian Agricultural and Forestry University</td>
<td>Senior Entomologist</td>
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<td><strong>Media</strong></td>
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<tr>
<td>Caijing</td>
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<td>Beijing Technology Journal</td>
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<tr>
<td><strong>National Biosafety Committee(NBC)</strong></td>
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<tr>
<td>Chinese Academy of Agricultural Science (CAAS), Crop Protection</td>
<td>Member of NBC*</td>
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<tr>
<td>Nanjing Agricultural University</td>
<td>Member of NBC*</td>
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<tr>
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<tr>
<td>Croplife Asia</td>
<td>Communication specialist</td>
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<tr>
<td>Bayer Crop Science</td>
<td>Regulatory Affairs Manager</td>
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<td>Syngenta</td>
<td>Regulatory Affairs Manager</td>
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<td>Monsato</td>
<td>Regulatory Affairs Manager</td>
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<tr>
<td>Da Bei Nong</td>
<td>Senior Regulatory Affairs Associate</td>
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<tr>
<td><strong>Public sector</strong></td>
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<tr>
<td>Indian Council of Agricultural Research (ICAR)</td>
<td>Assistant Director General, Intellectual Property</td>
</tr>
<tr>
<td>Indian Agricultural Research Institute (IARI)</td>
<td>Joint-Director (Research)</td>
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<td>&quot;</td>
<td>Head of Genetics Division, PI Golden Rice Project in India</td>
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<td>&quot;</td>
<td>Head of Entomology Division</td>
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<tr>
<td>University of Agricultural Sciences, Bangalore</td>
<td>Professor, Department of Crop Physiology</td>
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<td>&quot;</td>
<td>Head of Genetics and Plant breeding and University Head</td>
</tr>
<tr>
<td>Indian Institute of Horticulture Research</td>
<td>Principal Scientist, Division of Biotechnology</td>
</tr>
<tr>
<td>University of Delhi-South Campus</td>
<td>Professor, Department of Genetics</td>
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<tr>
<td>&quot;</td>
<td>Ex-Vice Chancellor of University of Delhi, Head of GM Mustard Project</td>
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<tr>
<td>National Research Centre on plant Biotechnology</td>
<td>Principal Scientist, GM Brassica project</td>
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<td>Biotechnology Industry Research Assistance Council</td>
<td>Head of Investment Division</td>
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<tr>
<td>ISAAA</td>
<td>Director, ISAAA South Asia Center</td>
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<tr>
<td>Borlaug Institute of South Asia</td>
<td>Deputy Director</td>
</tr>
<tr>
<td><strong>Review Committee of Genetic Manipulation (RCGM)</strong></td>
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<tr>
<td>International Centre for Genetic Engineering and Biotechnology (ICGEB)</td>
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<td>Member of RCGM*</td>
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<tr>
<td><strong>Industry</strong></td>
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<tr>
<td>Maharashtra Hybrid Seed Company (MAHYCO)</td>
<td>Group Leader, Entomology Division</td>
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<tr>
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<td>Senior Entomologist</td>
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<tr>
<td>Bayer Crop Science</td>
<td>Regulatory Affairs Manager</td>
</tr>
<tr>
<td>RasiSeeds (HyVeg)</td>
<td>CEO-Vegetable Division</td>
</tr>
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**Table 4.1** Stakeholders in India, China and Australia who were interviewed and participating institutions and organisations. *Note that members of the regulatory bodies, RCGM in India and NBC in China, are mostly public research scientists located within public research institutions.
Data collection

Semi-structured interviews were employed, conducted in a face-to-face interaction using open-ended questions. Interviews were conducted in-country on visits made in April (India), June (China) and October (Australia) 2015. Topics of discussion centred on the themes identified in Chapter 3, targeting areas of intellectual property rights, issues with current regulatory systems, public research funding systems, organisational behaviour, consumer resistance and commercial uptake pathways. The design of the questions offered the opportunity for stakeholders to fully express their view on the difficulties of current public sector GM research and commercialisation efforts. Based on initial responses, follow-up questions were asked to get a clearer understanding of viewpoints. Appendix 1 provides a list of example questions that were discussed during the interviews. Interviews in Australia and India were conducted in English while the interviews conducted in China were in Chinese and then transcribed into English. Detailed notes were taken during the interview. An audio recording option was available to the stakeholders, but due to the sensitivity of the topic within the countries, the majority of stakeholders preferred not to be audio recorded.

Stakeholders were contacted initially via e-mail or telephone but interviews were face to face. Before conducting the interviews, consents were obtained from individuals with the purpose of the research explained. All the stakeholders agreed to express their personal viewpoint on the subject and a few individuals provided further key contacts who have also contributed to the study. This research was approved by the University of Melbourne’s ethics committee, as part of the ethics requirement for collecting information from human participants. The length of the interviews was between 25 and 60 minutes. Names and contact details of interviewees are securely deposited at the University of Melbourne but individual views have not been attached to names here as most interviewees had senior and influential positions and such ascription might have limited their willingness to speak frankly.
Analysis of data

Following the interviews, notes that were taken were transcribed electronically. The objectives of the stakeholder interviews were to establish an understanding of the current obstacles faced by public institutions in Australia, China and India and to determine whether obstacles identified were unique to the country, the particular sector, or were global issues. After reviewing the data, common themes identified were organised according to the following categories;

- Issues with public research funding systems
- The crop focus of public sector GM developments
- Intellectual property implications
- Regulatory hurdles for GM developments
- Poorly informed public attitudes creating difficulties for GM commercialisation
- The particular difficulties faced by Public-private partnership modes in the GM arena

Limitation of the Research

The choice of particular stakeholders may not fully represent the range of experience encountered by stakeholders in the three countries, despite attempts made to recruit as wide an array of stakeholders as possible. It may be possible that other individual countries possess unique challenges that have not been identified by this research.
4.3 Results

4.3.1 Issues with public research funding systems

India

In India, funding for agricultural research flows from three main sources: 1) central government 2) state government and 3) the private sector. Public agricultural biotechnology research funding is governed by the Indian Council of Agricultural Research (ICAR), the Department of Biotechnology (DBT) and the Department of Science and Technology (DST). As detailed in the national five-year plans, the Government of India has devoted enormous financial resources towards agricultural research over the last decade (Figure 4.1).

Figure 4.1 The allocation of funding from central government for agricultural R&D in India. The data for DBT and DST is based on the Union Budget of India, published by the Ministry of Finance (DST and DBT). The values for ICAR were derived from ICAR’s annual reports. 5,000 crore Rs in 2013 was approximately $US 1 billion.
Interviews with public scientists from India’s premier basic agricultural research Institute – the Indian Agricultural Research Institute (IARI) outlined that despite the significant increase in public research funds for agriculture over the last decade, the very large and growing number of institutions and departments under the ICAR system\(^{27}\) and the very substantial increase in salaries have significantly reduced the effective funding available for individual GM research and development projects. This ‘dilution’\(^{28}\) of public funding has made it difficult for public organisations to advance their GM crops to the commercialisation stage. The costs of additional activities needed for commercialisation e.g. clearing the intellectual property landscape or conducting regulatory experiments, were more or less always beyond the budget size of public sector research projects. The average budget for a GM project in India is less than $130,000 while industry estimated the cost of taking a GM crop through to commercialisation is $136 million (for details see Chapter 5).

Consequently, the long pipeline to a commercial outcome requires public developers to constantly seek for additional funding. A number of public stakeholders suggested that for Indian public organisations to successfully deliver a GM crop to the commercial market, a strategy or mandate should be put in place by the government to maximise the efficient use of public research funding, rearranging thousands of discrete scientific projects into a well-structured national programme.

Stakeholders from both the public and private sectors were in agreement that the primary focus of the Indian public research system was poorly adapted to conduct R&D for commercialisation. Discussions with public stakeholders who managed projects supported by the government, agreed that government research grants were only sufficient to cover the salary for project specific staff with limited operational expenses included and no funds for activities beyond the discovery phase. There is now commercialisation support available through a number of DBT schemes (details see Chapter 7) for a few projects only and these require collaboration with the private sector.

Stakeholders from the private sector agreed that research and commercialisation capabilities existed in the public domain, but believed that the poor communication and

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\(^{27}\) ICAR is the umbrella body responsible for co-ordinating agricultural research in India. It has four deemed universities, 60 ICAR institutions, 15 national research centres, 6 National Bureaux and 15 Directorates. Within each institutes there are many divisions and project groups. http://www.icar.org.in/en/node/325

\(^{28}\) The term dilution used by the stakeholders describes how the national research budget is divided across hundreds of institutions, and as a result, individual projects receive a very low level of funding.
project management skills in the public sector created organisational barriers for commercial developments.

China

Interviews with stakeholders in China revealed that difficulties faced by the public sector in the development of GM crops were not due to insufficient research funding. Over the last decade, China has established numerous national programmes with considerable financial capital directed towards advanced scientific techniques for crop improvement and has continued to increase the level of public research funding. Notably ‘the transgenic development scheme’, under the Mid-Long term plan, announced a budget of 20 billion RMB in 2008 (approximately $3 billion USD based on the average 2008 conversion rate), with the aim of accelerating GM developments in China. Funding for each GM crop research project under the 2014 transgenic development scheme was 3 million RMB with duration of three years (approximately $350,000 USD/year based on the 2013 conversion rate)\(^{29}\). All the stakeholders highlighted that GM related research grants have been among the largest public research grants available in China. Despite the substantial government investment and the numerous research grants established for transgenic developments, China is in a similar position to India, where the unnecessary duplication of research has led to inefficient use of government resources. Public stakeholders believed that public funding has not been well managed in China and suggested that a restructuring of the agricultural research system was necessary for commercialising public sector agricultural innovations. The Chinese government has realised the current fragmented national research system has not resulted in productive outcomes and has been considering a redesign of the Chinese public research system (Ministry of Finance, 2014).

Stakeholders from both the public and private sectors highlighted that the competitive environment within the public research system had reduced the attention given to commercialising public sector materials. It was further stated by an industry stakeholder that the allocation of national research grants has been extremely competitive, and funding agencies often measure applicants’ scientific excellence based on their publication and

\(^{29}\) The value was obtained from the Ministry of Science and Technology (MOST) website, “Application for the key topics under the National Transgenic Scheme 2014”. It calls for both public and private organisation to submit applications for the research grants. However, in recent years, the MOST has not revealed the overall size of research budget under the transgenic development plan.
patent outputs, not on commercial outcomes. Consequently, public scientists prioritise publications over the need to transform research ideas into commercial products. A couple of public stakeholders mentioned that public research institutions now provide financial rewards to research scientists for publishing in high-impact factor journal articles, further enhancing public scientists’ incentives to focus on publication. The short life cycle of government research grants further adds to the urgency to produce journal articles. A similar viewpoint was documented in a news article published by Nature (Qiu, 2010), highlighting the external drivers for Chinese scientists to publish. Indeed, many public stakeholders believed that the responsibility of public research scientists has always been to demonstrate knowledge through publications and that the responsibility for commercialising their discoveries belongs to industry.

**Australia**

Interviews with stakeholders in Australia gave insights into the current issues with the Australian public research funding system. It was emphasised by all stakeholders that the Australian government has not drafted any national policy for agricultural biotechnology development. Furthermore, the value of public agricultural research funding has been steadily declining (Sheng et al., 2010). Discussions with key GM crop developers at the University of Queensland and Queensland University of Technology revealed that federal resources in this research area, administered by the Australian Research Council (ARC), have been highly competitive with a strong focus on basic research and often not directed towards a commercial output. Consequently, public scientists need to seek other financial sources to conduct translational research. Stakeholders from both sectors further stated that the primary research funding for crop improvement is governed by the Research Development Centres (RDC) and Cooperative Research Centres (CRC). The Australian government established the RDCs and CRCs, along with the industry levy system³⁰, to encourage collaborations between public research institutions and industries. An industry stakeholder believed that the industries’ influential power over the research direction of CRCs and RDCs, and their view of consumer’s negative perception of GM crops, has meant

³⁰ Australia implemented a research system where levies are agreed by producers to contribute towards research and development. The Australian government provides matching funding based on the production value of crops. RDCs and CRCs manage the levies and invest in research with the mandate to address and resolve current industry challenges. For example the Grains Research and Development Corporation (GRDC) collects a levy of 0.99% of the farm gate value on 25 different crops and the government contributes 0.5% of the total farm gate value (GRDC, 2015).
that the willingness to invest in new GM technology has been minimal. It was stated by several public stakeholders that the current public research funding has been difficult to access and that there is no dedicated government funding scheme for GM crop development. As a result, they often seek opportunities to collaborate with MNCs.

An interesting idea resulting from discussions with industry stakeholders was that public sector funding often reflects the position of political parties. An industry stakeholder stated that public sector research had been driven by the incumbent government’s ideology, where the Australian political environment has been constantly changing directions, usually following the electoral’s quadrennial cycle. Consequently, national research directions and project funding reflect the current political stance of the leading party, resulting in a lack of financial continuity for research in the public sector. For example, the Australian Renewable Energy Agency was established by the government in 2012 to improve renewable energy technologies. After the federal election in 2013, the leading party changed their policies on renewable energy and planned to reduce the agency’s budget.

4.3.2 Crop focus of public sector GM developments

India

The current unmet need for GM technology is in minor crops and in traits other than herbicide tolerance and insect resistance, which are largely not addressed by the private sector. However, the majority of the stakeholders agreed that the public research organisations in India do not have the infrastructure or capability to deliver GM products to the market, especially for crops. Due to the diversity of type and varieties of minor and speciality crops cultivated across varying regions of the country, providing and deregulating GM versions of even a small proportion of these is seen as prohibitively expensive given that under current regulations, each variety of a particular crop would need to pass through the regulatory process even if they contained the same gene construct (this rule seems in practice to be relaxing for the multiple Bt cotton varieties approved, though field trials are still required for new Bt cotton hybrids from unapproved events\(^3\)). In addition, an industry

\(^3\) In 2008, the Ministry of Environment and Forest changed the regulatory process for GM cotton from a hybrid-based approval system to an event-based approval mechanism. Bt cotton hybrids generated from approved events only need to undertake variety trials (as do conventional varieties).
stakeholder believed that the regulatory control and stewardship of GM minor crops would be extremely difficult. Several stakeholders gave their opinions on GM minor crops and argued that it will not be economically justifiable to commercialise these, given that the potential benefits to developers and seed companies provided by minor GM crops are relatively small compared to major crops, but the costs of development and registration are comparable. On the other hand, one public stakeholder gave a slightly different perspective as to why public researchers have not deployed GM technology in minor crops. Public agricultural research in India has always been driven by the need to improve food security. As a result, research conducted in the public domain works largely on major crops with substantial economic benefits, with more than 650 scientists, for example, working on rice and 450 on wheat.

China

Discussions with stakeholders suggested that the focus of Chinese government for GM technology has shifted towards major crops with substantial economic value. Prior to 2008, policies set by the government aimed at increasing the capabilities and expertise within the nation and funding was not restricted to major crop projects. The majority of both public and private stakeholders interviewed believe that the government has made a change in direction in recent years and is now only interested in applying GM biotechnology to a selection of major crops. These stakeholders further outlined the same reasons for the current national focus; it was about ‘food security and economic value’. Under the national transgenic scheme of 2014, funding was restricted to these major crops: cotton, maize, soybean, rice and wheat.

Public and private sector stakeholders believed that the government had reduced the pace for introducing GM technology and is following a *Fibre-Feed-Food* approach ([Figure 4.2](#)), with the intention to commercialise the phytase maize as animal feed as the next major GM crop following Bt cotton, before moving onto Bt rice for human consumption. If this is indeed the approach set by the government, it would be extremely difficult to commercialise any minor GM crop in the near future.
Both public and private stakeholders took the view with respect to minor GM crop development that it was the essential for a particular GM trait/variety to have net economic benefit for stakeholders in the value chain. The development may be beneficial and valuable, but whether it was economically feasible and sensible considering all the development and regulatory costs involved and the need for appropriate post-commercialisation uptake pathways, was a different matter. In addition, an industry stakeholder commented that the development of GM crops takes a considerable amount of time but commercial varieties have a very limited market life. Thus, by the time minor GM crop varieties have passed all the regulatory requirements and were ready to be marketed, those GM varieties may have been superseded by other conventional varieties with higher performance in other agronomically important areas.

Australia.

The previous section suggested that Australia’s public sector research focus had been driven by the decisions of RDC and CRCs. The opportunity for the public sector to apply GM technology in orphan crops has been very limited, as the levies collected from minor crop industries are not able to cover the cost of developing and deregulating GM varieties. Many stakeholders believed that the privatisation of government plant breeding programmes has contributed to the current situation\textsuperscript{32}, reducing the level of public funding for improving minor crops.

\textsuperscript{32} Jarett (1990) surveyed the number of plant breeders in Australia during 1985 and reported that majority of plant breeders were located in public institutions. Lindner (2004) showed that the majority of Australian breeding programmes have been purchased by private companies. There are for example, no commercially useful canola varieties in public sector hands now despite the crop covering some two million hectares and the deployment of multiple varieties in diverse environments.
4.3.3 Intellectual property implications

India

Industry stakeholders believed that public scientists have become more aware of the difficulties associated with intellectual property protection. A public stakeholder stated that the idea of intellectual property protection using patents had been around for a period of time in India, but that Indian public institutes did not encourage their researchers to patent their discoveries or indeed to pay much attention to the patents of others. An industry stakeholder mentioned that the issue of intellectual property was exacerbated by the lack of foresight in developing novel technologies within the nation, where many research projects conducted in the Indian public research institutes have utilised internationally patented technologies without legal licences. Since accession to the World Trade Organisation (WTO) and the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement in 1995, public institutions have increased their knowledge on intellectual property and the Government of India has been encouraging public researchers to apply for patents. A public stakeholder stated that in 2001 there were 11 institutes under ICAR which between them held 30 patents, but by 2015 there were 67 institutes with 2,000 patents (applications and granted). Private stakeholders agreed that the intellectual property system in India has been improving, but the lack of legal enforcement remains problematic.

Interviews conducted in India highlighted additional issues that have generated difficulties for public organisations seeking to commercialise GM crops. Several public stakeholders stated that establishing freedom to operate (FTO) has been a very difficult task for the public sector. The lack of expertise and understanding of the intellectual property landscape has proven to be problematic for public organisations wishing to generate intellectual property free constructs. It was further stated that public research scientists do not have the time required to identify relevant technologies and negotiate licences with patent holders and that institutional intellectual property cells do not seem to have the expertise or drive to successfully negotiate intellectual property rights for their scientists. In contrast, stakeholders from the private sector disagreed with this statement and believed that public researchers ignore the need to negotiate for intellectual property rights, as there have been
no incentives for them to partake in commercialisation activities. Furthermore, it was mentioned by public and private stakeholders that it has been extremely difficult to navigate through the Indian patent database which appears to be incomplete and significantly out of date in many areas.

China

As elsewhere, China’s accession to the WTO in 2001 enforces the TRIPS agreement on the country. In order to legally commercialise a transgenic variety, intellectual property agreements with the patent holders of various technologies must be entered into. Interviews with industry stakeholders highlighted that public scientists have not fully grasped the idea of intellectual property protection and only consider whether patents have been granted for the gene that confers the novel trait e.g. truncated Cry1Ac patented by the Chinese Academy of Agricultural Sciences (CAAS). Constructs used to develop transgenic crops are always more than just the gene of interest; other technological components are required. In 2013, the Chinese government announced that local research scientists had secured all the relevant intellectual property rights for Bt rice, and that the developers have all the patents in China for development and commercialisation, but an analysis conducted by Liu and Cao (2014) examining the patent landscape of Bt rice has shown that in addition to the use of Cry1Ab/1Ac developed by CAAS, five internationally patented technologies were used to develop the Bt rice: CaMV35S, Gun-mediated transformation, the hph selectable marker, and the genes RC7 and P-ract-1. Although the patent for CaMV35S expired in 2013, the other four internationally patented technologies have ongoing patent terms covering major jurisdictions including the US, EU and Japan, though not in China. At an international level, the developers would be liable for infringing these patents if the material was to be found in jurisdictions outside of China. A survey study conducted by Hu et al. (2013) identified that even though public scientists in China have relevant intellectual property knowledge, intellectual property issues were often ignored by public scientists.

From the private industry stakeholders' perspective, intellectual property rights protection remains a major challenge in China, due to a lack of legal enforcement for illegal distribution and the unauthorised use of patented materials. Nevertheless, the majority of stakeholders believed that the Chinese government had been heavily investing in transgenic research and

\[33\] Though in fact, in many cases, licences for research and development are also required. Chapter 7 provides an example of how the patent holder can restrict public access for basic research.
improving the intellectual property protection system to ensure that China has the capability to compete globally.

**Australia**

Common concern was expressed by the public research scientists in relation to access to key technologies. It was stated by all the public stakeholders that developing GM crops requires FTO, but a significant proportion of the technologies used for construct developments are the property of the private sector. A founder of Hexima Ltd\(^\text{34}\) stated that a significant proportion of enabling technologies owned by the private sector were technologies originating in public institutions which have been licensed to commercial companies. It was further stated that although public research institutions retain the research rights and allow other institutions to freely conduct research, commercial research without agreements from the commercial companies is strictly prohibited. An example which validated this idea was the licensing arrangement between CSIRO and Bayer Crop Science. RNA interference mediated gene silencing (RNAi) was demonstrated by Dr Peter Waterhouse from the CSIRO in 1995. However, in 2004, the commercial rights in selected plant species under certain jurisdictions for this platform technology were licensed exclusively to Bayer Crop Science\(^\text{35}\).

Interviews with seed companies gave further insights into intellectual property issues and suggested that commercialising GM plant materials without the genuine assistance of the MNCs is unlikely. An industry stakeholder highlighted that the majority of traits originating from the public sector had been output traits (e.g. vitamin A precursor in Golden Rice). However, utilising input traits such as insect resistance and herbicide tolerance has become common agronomic practice for farmers of major crops. From the company perspective, the customer for the seed is the farmer, not the consumer and the immediate benefit of an input trait is more obviously beneficial to the farmer in reduced costs and increased yield volume. The industry stakeholder further stated that the intellectual property rights for input traits had been consolidated by MNCs and as a result, public sector GM crop

\(^{34}\) Hexima Ltd is a biotechnology company formed in 1998, a spin-off company from the University of Melbourne, conducting basic research to identify novel genes that confer insect and disease resistance.

\(^{35}\) The commercial right for the RNAi technology for crop developments for certain crops and jurisdictions has been licensed to Bayer Crop Science. CSIRO retained the commercial rights for cotton and canola in Australia. Personal communication with Dr Peter Waterhouse indicated that the reason that the commercial license was provided to Bayer Crop Science was the fact that Bayer Crop Science was a major funding partner with CSIRO in the research in the early 1990s.
developments need to license these from MNCs for the product to be marketable. However, a number of public stakeholders believed that accessing private companies’ intellectual property was not an obstacle. The argument provided was that industry players do not have any interest in markets which present a limited opportunity for return on investment and were consequently generous with their intellectual property in those situations. This has been true with a number of GM projects in developing countries, where MNCs have donated their trait technologies on a humanitarian basis for crops or markets of little interest to them.

4.3.4 Challenges with GM regulatory systems

India

All the stakeholders believed that the current Indian regulatory system is politically influenced. Many stakeholders outlined the story of Bt Brinjal (eggplant) which culminated in a moratorium placed by the Minister of Environment and Forests (MOEF) in 2010, which has essentially hindered agricultural biotechnological progression in India ever since. Public stakeholders stated that due to the political influences on the Indian regulatory system and the lack of political will from the government despite positive speeches from major figures, especially ex-Prime Minister Dr Manmohan Singh, the level of willingness for public scientists to pursue GM based projects has significantly reduced. The number of regulated field trials approved for public organisations has significantly reduced since the effective moratorium on progress through the GM regulatory system in 2010 and the subsequent moratorium imposed by the High Court on GM field trials from 2013 to 2016 (Figure 4.3). In addition, one of the public stakeholders highlighted that, due to the previous government’s actions and the current uncertain political environment, experts in the area of plant molecular technologies and transformation had moved away from public research institutions into the private sector. Despite the regulatory uncertainty, it was observed that private seed companies continue to conduct confined field trials. The response gathered from the private stakeholders was that for companies ‘Even though the uncertainty remains within Indian regulatory system, challenged by the possibility of losing market shares they need to actively maintain their R&D pipeline to secure their market position’.

“Agriculture is a state subject” was a key theme derived from all Indian stakeholders. In India, many matters related to agriculture have been the subject of regulation by state (not
national) governments. Despite the fact that the GM regulatory system is governed at the national level, the final decision for field trials or cultivation resides within the state governments. The ‘national vs. state’ conflict has resulted in difficulties for all GM developers, where approvals from the regulatory body for the mandatory multi-location field trials cannot proceed without a ‘No Objection Certificate’ (NOC) from individual states when a trial is planned. A number of states will not provide such certificates and it is difficult to obtain them in others.

![Figure 4.3](image) The number of approved confined field trials in India. Constructed based on the IGMORIS database 2014.

Stakeholders were asked to provide their perspective on how to overcome the current difficulties in India. A majority of stakeholders believed that the current regulatory approval agency needs to be more courageous and approve GM events based on scientific evidence. Several stakeholders noted that a new regulatory system will be established through the introduction of the Biotechnology Regulatory Authority of India (BRAI) bill in parliament and have high hopes that the new BRAI regulatory authority will provide a functional regulatory system without political interference. However, it has been before parliament in various forms since 2012 with no clear sign that it will be approved\(^\text{36}\). Even if it is approved, the complex interlocking committees, approvals processes and opportunities for vetos will not simplify or speed up the process (Figure 4.4).

\(^{36}\) The BRAI bill was introduced by the Department of Biotechnology (DBT) in 2008, to setup an independent authority for governing biotechnological products including GM crops, in an attempt to replace the current complex multi-ministerial design into a single regulatory authority. In 2013, a revised BRAI bill was submitted to the Lok Sabha (Lower of House of the Indian Parliament) but the bill was not reviewed and subsequently lapsed in 2014. The Modi government will now need to decide whether to reintroduce the bill to the parliament.
In relation to the burden of regulatory requirements, few stakeholders were concerned with
the excessive cost required to comply with regulations. A public GM developer stated that
the most difficult part of commercialising GM crops in India was not the cost but the
uncertainty within the regulatory system and the unpredictability of the time required. For
public organisations conducting work in India, the costs associated with the regulatory
experiments have been much less than would be expected from commercial companies and
can be forthcoming from government outside the research grant structure. A study reported
by Pray et al. (2005) found similar outcomes, interviewing the developers of Bt Brinjal,
revealing that the estimated cost of meeting biosafety regulations for public organisations
(as opposed to the original private sector developer the Maharashtra Hybrid Seed Company
(MAHYCO) was much lower than expected, with the government absorbing much of the
associated cost\(^37\). Private stakeholders agreed with the idea that the infrastructure and
capabilities exist in the public domain for dealing with regulatory requirements.

Figure 4.4 The organisational structure of the Biotechnology Regulatory Authority of India
(BRAI) (not yet approved by parliament).

\(^{37}\) See also Chapter 5, Section 5.2 on the public sector GM Bt cotton regulatory costs.
China

Interviews with stakeholders highlighted the difficulties and challenges created by the regulatory system, many of the stakeholders believed that the current major regulatory bottleneck for developing GM varieties had been the absence of variety registration guidelines for GM crops. Under China’s Seed Law, plant varieties need to be registered at provincial agricultural departments for commercial cultivation. However, the Ministry of Agriculture has not provided any information on how GM crops can be registered (Bt rice which obtained a biosafety certificate in 2009 is still awaiting the final clearance). Stakeholders from industry believed the administrative procedures for regulatory approval have been very unclear, unpredictable and often influenced by political decisions. The approval process fails to comply with the officially announced timelines and the lack of transparency prevents developers tracking the approval process. Several private stakeholders also noted that the Chinese government often uses regulatory policy as a barrier to control trade. An industry stakeholder emphasised that the delay in regulatory approval for Syngenta’s Agrisure Viptera® trait (MIR162) was an example of how regulatory policies were used to restrict international trade.

A public sector scientist mentioned that the cost and time required to fulfil the regulatory requirements reduces the progress of public GM development. Furthermore, an industry stakeholder claimed that there are only a handful of Chinese research scientists who have sufficient knowledge to comply with regulatory requirements to enable them to take their products through the regulatory system. However, several other industry stakeholders disagreed with this idea and believed that the regulatory burden for local developments has been negligible; once the Chinese government has decided to commercialise a local transgenic development, they will fully support the cost to comply with regulations.

Australia

There was considerable variation in the responses gathered from stakeholders with regards to the regulatory burden. It was stated by stakeholders from both the public and private sectors that a major obstacle to commercialising GM crops had been the excessive regulatory cost. An industry stakeholder stated that to deliver a GM crop into the Australian commercial market would cost the company $25 million AUD to comply with relevant

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38 See Chapter 5, Section 5.4 for details.
regulatory requirements, an investment value beyond the financial capability of the public sector and local seed companies. A number of public sector stakeholders believed that crops with lesser economic value would fail in reaching the commercial stage, due to the regulatory cost outweighing any potential benefits. Stakeholders in the regulatory authorities provided a different perspective towards the current regulatory system and claimed that although public sector scientists often criticise the system as being unreasonable, in fact they did not understand the regulatory requirements. They further emphasised that the regulatory burden observed by the public sector resulted from a lack of communication between public GM developers and regulators and suggested that if there was better communication, the public developers could do much of the regulatory experiments in the course of the developmental work.

Discussions with all stakeholders highlighted that the plant breeding industry has been concerned with the current regulatory system and its implications for the regulation of advanced scientific technologies like RNA interference (RNAi) and Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR). To date, it remains uncertain in Australia whether the current regulatory system would classify crop varieties manipulated by these technologies as GMOs. An industry stakeholder stated that ‘if the regulatory systems were to classify RNAi and CRISPR as GMOs, it would set back the agricultural biotechnology industry by 10 years.’ As elsewhere, the Australian Office of the Gene Technology Regulator (OGTR) operates under definitions enshrined in legislation and has little room to interpret legislation or respond to new technologies. Stakeholders from the regulatory agencies agreed that the current policy is based on the definition of GMOs outlined in the legislation and have not reflected the nature of new advanced breeding techniques, although both the Food Standards Australia and New Zealand (FSANZ) and OGTR have been actively seeking public and private sector input into decisions on these questions and are actively interacting with other regulatory authorities world-wide on these issues.

As in India, the issue of state vs. national interests, which presents complications for GM commercialisation, was raised by industry stakeholders. Despite approval from the federal regulatory bodies, state governments use trade and marketing considerations as a reason to reject cultivation of GM crops within particular states, enabling the Tasmania and South Australia state governments to place moratoriums on all GM cultivation and Western Australia to limit commercial cultivation of GM crops to selected areas (restrictions in Western Australia largely lifted in the last weeks of 2016). An industry stakeholder outlined
that as a result of the moratorium and the ban on GM transport through the moratorium states, the increased logistic cost for GM crops in Australia has significantly reduced the beneficial value of GM crops.

4.3.5 Difficulties created for GM commercialisation by poorly informed public attitudes

India

All the stakeholders believed that anti-GM activists and the media had brought in the negative perception of GM technology and created a fear of the unknown. After nearly twenty years of successful use of the technology, a negative atmosphere still exists in the public domain. According to public stakeholders, agricultural extension programmes have been set up by the government to educate the farmers and public about the technology, but these programmes have made little impact on the social acceptance of GM crops. One public stakeholder stated that the lack of communication in 1990’s has allowed the media and activists to generate fear amongst consumers and that it has become extremely difficult to change their current mindset. Industry stakeholders agreed with this statement that there was a lack of education from public research scientists and that this has resulted in GM technology being publically rejected.

Several public stakeholders highlighted the fact that the association between MNCs and GM technology further reduces the level of public acceptance. In India, the perception of MNCs often revolves around excessive profit and that there is a public perception that MNCs introduced the technology to take advantage of poor farmers. Activists in India constantly use this belief as a basis for rejecting the technology. Several stakeholders from both sectors mentioned that the lack of successful public developments further reduced the public’s confidence in the technology. The case of Bt cotton developed and commercialised by Indian public research institutions and withdrawn from the market after one season in 2009, due to poor performance and issues with patented material, resulted in dissatisfaction amongst farmers and has not engendered confidence (Jayaraman, 2012). Stakeholders in the public sector suggested that in order to increase public acceptance, the regulatory authorities should be transparent in their approval process to improve the negative image of GM technology. The negative public attitudes have created obstacles to GM crop development.
in India, as it politically affects the regulatory system, as demonstrated by the case of Bt brinjal which, having passed all the required tests, was not released by the MOEF in 2010, with the registration said to be pending further studies. But these supposedly required studies have never been specified to the developer- MAHYCO. Bt brinjal produced by crossing the MAHYCO material with local varieties has subsequently been released in Bangladesh (under agreements with MAHYCO) and will doubtlessly leak back across the Indian border, giving rise to the same scenario as led to the initial Indian post-hoc approval of illegally planted Bt cotton back in 2002.

China

The negative atmosphere induced by activists and the media was also considered the most challenging obstacle by all the stakeholders in China. Public stakeholders felt that the media in China had been continuously reporting negative opinions on the topic of GM technology with comments supported by famous spokesmen or celebrities. The low level of public acceptance has delayed public GM crop developments for local cultivation (apart from cotton). All of the stakeholders in China agreed that it was the lack of education and communication on the technology that allowed negative comments to spread across the country. However, a media stakeholder mentioned that there were no incentives for public researchers to visibly support the technology, as the media and the public would immediately focus on and criticise anybody who supports the technology. Several stakeholders mentioned that the lack of trust in government agencies contributed to the low acceptance of the technology. Over the last decade, there have been numerous food safety issues which have shaken public confidence, where products were declared safe by government regulatory authorities but in fact contained harmful substances. It was further emphasised by all stakeholders that the Chinese government has been well known for fabricating stories to cover up facts, which further reduces public trust in government regulators.

Australia

All stakeholders believed that the major obstacle to successful commercialisation of GM crops remains the current consumer objection towards GM crops. An industry stakeholder stated that despite Australia cultivating GM cotton and canola, the perception of a low
market acceptance for other GM crops has prevented commercialisation of any GM crops developed within the nation. Stakeholders were asked to explain their reasoning for engaging in GM projects knowing the commercialisation environment was not ideal and the response gathered was that they believed the negative consumer situation would dissipate over time, considering the time required to produce a GM crop would be more than 10 years. However, prior to advancing into the regulatory phase, many GM developers have abandoned their projects. A stakeholder from the seed industry stated that they had a GM crop project in collaboration with a public research institution, but a decision was made to terminate the project before entering into the regulatory phase. The substantial financial commitment and market uncertainty created an unmeasurable risk, which outweighed any potential economic benefits.

Another idea put forward by industry stakeholders was that the public sector was partially responsible for the current social attitude towards GM crops. A public sector stakeholder noted that despite the attempts by the public sector to present the technology more positively than had happened with the MNCs, the public sector had not commercialised any GM crops that directly benefit the consumers. This reduces the trust among the public in the capacity of public institutions to produce GM crops. Furthermore, it was stated by some stakeholders that the constant debate within the scientific community creates an additional layer of distrust towards the technology.

4.3.6 The roles of Public-Private Partnerships in the GM arena

India & China

Discussion with the stakeholders in both countries highlighted similar common themes in commercialising GM crop developments. Many stakeholders stated that the commercial pathway for public institutes in India and China has always followed a system where the newly developed varieties were licenced to local seed companies for commercialisation. These local seed companies have established the infrastructure and networks necessary for seed production and distribution. A private stakeholder claimed that most public research institutions do not understand the seed market and work on crop varieties that have no commercial value. Public research institutions have been focused on the production of open pollinated varieties (OPV), which are increasingly being replaced by the farmers with high
yielding hybrids developed by seed companies, especially in vegetable crops. Consequently, the GM crops developed by the public sector generate very limited interest amongst seed companies.

In both countries, stakeholders believed that a partnership between public organisations and MNCs would greatly enhance the prospects for successful commercialisation of public sector plant materials. However, industry stakeholders from both countries noted that both the Chinese and Indian governments have been reluctant to collaborate with foreign companies and have established policies that limit foreign companies accessing local resources. For example, the funding from Biotechnology Industry Research Assistance Council (BIRAC) in India which supports public-private partnerships (PPP) is limited to local Indian companies and will not support partnerships with foreign companies.

Private stakeholders believed that it would be extremely difficult to form partnerships (as opposed to simple licence agreements) with public researchers, due to the risk-averse nature of public organisations. A few private stakeholders suggested that the barrier for forming partnerships with the public sector is the issue of liability, as most institutions want the entire liability to fall on the commercial partners. In addition, some stakeholders stated that it would be extremely difficult to manage a large-scale project with public organisations due to the lack of co-ordination and poor management structure within the public sector.

**Australia**

The majority of stakeholders in Australia agreed to the concept that a PPP increases the probability of commercial success for the public sector. Different reasons were outlined by the stakeholders for forming a PPP including access to intellectual property rights, financial continuity and regulatory expertise; characteristics of MNCs which have successfully commercialised GM crops. This has been observed in Australia where public research institutions have formed long-term collaborations with MNCs. For example, CSIRO has established a long-term collaboration with Bayer Crop Science and AgriBios at La Trobe University conducts research in partnership with Dow Agro Sciences. Even small agricultural biotechnology companies like Hexima Ltd have long-term collaborations, in this case with DuPont Pioneer.

On the other hand, several stakeholders believed that certain constraints had limited the formation of PPPs for GM crop developments. A stakeholder from the industry had the view
that the majority of public institutions in Australia have followed the technology transfer model. However, in an industrial collaboration setting, most public institutions insist on being the patent holder but will not take any liability for commercial activities, limiting the prospects for an actual partnership. Another constraint stated by stakeholders from the commercial wing of the public sector and from NGOs was the role of cultural norms for public sector scientists. A public stakeholder described how the current public research culture had placed priority on publications, training scientists to publish rather than to solve real-world problems. Furthermore, stakeholders outside public institutions believed that public sector scientists are generally more risk-averse and not willing to actively participate in commercial activities, which are by their nature long term, uncertain, and provide no clear benefit to the participating scientist.

### 4.4 Discussion

Based on the data generated from the interviews, common themes were established (Table 4.2). Current public research funding systems, regulatory systems, intellectual property rights, and the fear of liability were seen as the major obstacles to successful commercialisation of public GM developments, not a lack of technical capability. A consensus view of stakeholders in all three countries was that the current public research funding systems had not reflected the commercial requirements needed to deliver publicly developed GM crops. Despite the significantly increased funding for GM technology in China and India over the last decade, the funding dilution outlined by Indian stakeholders resulted in the time, cost and commercial activities required for GM crop developments being well beyond the financial capability of individual public research projects. To overcome the financial burden, public sector scientists need to regularly seek additional funding from various financial sources. Comments gathered from stakeholders suggest that the allocation of public research fund is driven by the interest of investors. In China and India, the central governments have been the largest public research investors, where national policies for both countries on the use of GM technology aims at creating benefits for farmers and enhancing the economic value of agricultural production. As a result, this has placed emphasis on major crops that have substantial economic value, where strong advances have already been made by private companies, normally MNCs, often leaving out the minor crops which are commonly supposed to be the focus of public sector developments. The slow Fibre-Feed-Food approach apparently being adopted by China further hinders the
<table>
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<th>Categories of stakeholder</th>
<th>Key issues identified in stakeholder inputs</th>
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<td><strong>Australia</strong></td>
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| Public research organisations | • The reduction of national funding for agricultural development and the shift towards an industrial model creates challenges.  
                                 • Difficulties in accessing key patented technologies. |
| Industry | • Public funding is driven by government political positions and often results in a lack of financial continuity.  
                                 • The current regulatory environment prevents GM crop developments from being commercialised.  
                                 • Public research institutions are risk-averse and prioritise academic activities. |
| Government | • There is a lack of regulatory expertise in the public sector. |
| NGO | • Public research institutions are risk-averse and prioritise academic activities. |
| **China** |                                               |
| Public research organisations | • The government is concerned with the current negative atmosphere  
                                 • Unnecessary duplication of research and inefficient use of government resources  
                                 • The responsibility for commercialisation belongs to industry and not the public sector |
| Industry | • The competitive environment reduces the willingness of public scientists to participate in commercial development  
                                 • A lack of legal enforcement for the use of intellectual property rights creates concerns. |
| Government | • The focus of GM crop developments is in major crops to ensure food security. |
| NGO | • The negative atmosphere induced by activists and the media has halted the regulatory approval process. |
| **India** |                                               |
| Public research organisations | • The duplication of research and public research funding structures delays commercial developments.  
                                 • No government mandate for GM crop commercialisation. |
| Industry | • Current regulatory system is politically influenced  
                                 • The public sector does not have the capacity to develop commercially accepted plant material nor the knowledge and expertise to compile regulatory dossiers. |
| Government | • The newly proposed regulatory system will provide a functional system without political influence. |
| NGO | • Lack of incentives to participate in commercial activities and unwillingness to collaborate with foreign seed companies. |

*Table 4.2* A summary of major viewpoints from stakeholders in Australia, China and India.
probability of commercialising minor crops. Adenle (2013) conducted similar research, examining stakeholder perceptions of GM adoption in Africa and showed that numerous developing countries in Africa have also adopted the Fibre-Feed-Food approach to allow a smooth introduction of the technology (Adenle et al. 2013).

In contrast to the national public agricultural research systems in China and India, Australia has implemented a levy-based system for generating research funding from industry. It was emphasised by numerous Australian stakeholders that the industries have influential power over the CRC and RDCS and govern the direction of public research. Furthermore, it was identified that the Australian government’s contribution to agricultural research has been decreasing (Sheng et al., 2010), which further enhances industries’ decisional power directly over public sector research. The industry funding model promotes the commercialisation of public research, but it simultaneously limits the funding of public R&D projects that are not directly commercially driven. Long term transgenic crop projects with uncertain regulatory outcomes and potentially difficult export issues are generally beyond the focus of these industry-funded research bodies.

Based on the information collected, two major regulatory challenges are faced by the public sector. Firstly, a major constraint limiting public sector GM crop development is the cost of complying with current regulatory requirements. The majority of stakeholders in Australia believed that the regulatory cost often outweighs the potential economic benefit of publicly developed GM crops. However, the issue of regulatory cost was not a major concern for public GM developers in China and India. It was claimed by local stakeholders that their governments absorb the majority of the costs. Instead, the regulatory challenges faced by local public GM developers in China and India have been the uncertainty and unpredictability resulting from political influences. The lack of a functional regulatory system has prevented public GM developments from being commercialised (e.g. Bt rice in China and anything in India other than Bt cotton varieties). Secondly, the inclusion of social, economic and political considerations into the regulatory process has added further layers of difficulty which remain problematic for all GM crop developers. Numerous studies have shown that the addition of social-economic considerations without a transparently defined process to place objective values on objections to approvals, leads to a non-functional regulatory system (Raney et al., 2013; Falck-Zepeda, 2009; Cleveland & Soleri, 2005). Unfortunately India’s new BRAI structure is leading in just this direction. Furthermore, the conflict between national and state policies on GMOs has created difficulties for all GM crop developments,
where agricultural science is nationally supported in these countries, but the approval to
grow crop commercially remains a state subject. According to stakeholders in China and
India, decisions on commercialising GM crops depend on the ‘political will’ of the
government (States and Union). The direction and attitude of the governments at national
and state level decide where, when and if local GM developments will be commercially
released.

Fewer issues were observed with intellectual property rights in each country. The major
concern remained the access to key technologies owned by private companies. Both China
and India have been enhancing their national patent portfolio, partly to address the issue
and to remain competitive in the global agricultural biotechnology industry. Comments
gathered suggest that public scientists have begun to realise the importance of patents
(holding them and respecting them) and their implications for commercialisation. However,
a lack of expertise and willingness within the public institutes to construct intellectual
property landscapes and to secure licences allowing FTO remains problematic. In order to
minimise future patent infringement issues, well managed intellectual property cells need to
be in place, which focus on facilitating the development of valuable innovations. Currently,
intellectual property cells in public organisations are largely focused on reducing institutional
liabilities. It was identified as unhelpful that technologies originating from public institutions
were licensed on an exclusive basis to the private sector, limiting the public sector’s
intellectual property rights to transform their GM crop developments into commercial
products.

The commercial pathway of public GM crop development has followed the historical
pathway for the public sector germplasm system, where public organisations licence their
developments to commercial companies, allowing them to cross the genetic construct into
proprietary germplasm and to market their resulting plant materials. This system has been
used to commercialise conventional varieties but is no longer appropriate for
commercialising GM crops, as court cases regarding GM crops have demonstrated that the
liability often reflects back onto the technology developers e.g. in the Liberty Link® rice
case.39

Many studies have suggested or shown the benefits of PPPs for commercialising GM crops
(Krishna & Qaim 2007; Spielman & Grebmer 2006; Cohen 2005). Unfortunately, many
factors have limited the formation of PPPs in developing countries. For example, the

39 See Chapter 5 for the details of the Liberty Link® rice case.
competitive grant system in China has shifted the priority and drive of public scientists. The classic system of ‘Publish or Perish’ was identified as of increasing importance in China’s public research system, where the focus of public scientists has mainly been on producing publications, in order to secure future research grants and to be promoted. Consequently, there is a lack of incentive for public researchers to participate in moving toward commercialisation. Other factors include, the risks associated with intellectual property and policies that have limited foreign companies from forming partnerships with local public research institutes. These constraints need to be overcome in order to promote and construct successful public-private partnerships capable of commercialising GM crops.

The greatest challenge to the successful introduction of GM technology in any country remains the negative perception of consumers. Although China and India have set up policies aimed at utilising GM technology to enhance agricultural production, due to the low public acceptance of the technology, both governments have halted the commercial approval process for all new GM crops other than GM cotton. Stakeholders in both countries were convinced that the media and activists spread misleading information which has resulted in a negative atmosphere. Even though both countries have utilised GM crops for more than a decade with great financial benefits and no demonstrated health and safety problems, the fear of the unknown still resides within the mindset of local citizens. In China and India, the current negative perception of the technology continues to be the major obstacle to commercialising publicly developed GM crops and remains the major constraint to successful GM crop commercialisation by companies in Australia.

4.5 Conclusion

Social challenges and uncertainty within the regulatory systems are faced by both the public and private sectors, but public organisations’ GM crops have had minimal commercial success while MNCs continue to introduce GM crop varieties into the commercial market. Based on the evidence presented in this chapter, several obstacles are identified as hindering the success of public GM developments. Firstly, public research funding systems have not taken account of the additional activities needed beyond basic research to commercialise GM crops, where complying with regulatory requirements is beyond the financial, and probably the organisational, capability of a public research project. Secondly, key technological patents for GM crop development are often the property of the private
sector, even technologies originating from public institutions. Industry players are often willing to donate their technology but only if there is an absence of significant commercial interest. With growing public investor interest in applying the technology in major commodity crops, IPR remains an obstacle for the public sector. Lastly, the stakeholder interviews identified a further obstacle that was not revealed in the case studies reported in Chapter 3. Cultural norms in public organisations and the institutional fear of liability, unbalanced by any realistic prospects of large sales or royalties, have created an organisational barrier for public research scientists to participate in commercial activities.

The obstacles to commercialisation identified are multi-dimensional and need to be addressed if it is regarded as desirable for public institutions to take their research ideas forward to commercial reality. Chapter 5 explores the commercial uncertainty in public GM crop developments, focusing on the funding and commitment of public investors and the costs of complying GM regulations. Chapter 6 investigates the legal access to key enabling technologies which are relevant for commercialising GM crops through public hands. Chapter 7 examines the organisational barriers of commercialising public GM crop developments, focusing on organisational strategies, capabilities and culture. It is intended that these will lead to new insights of relevance to public sector initiatives in this area.
Chapter 5

Commercial uncertainty in public sector GM innovations

5.1 Introduction

Knowing what genetically modified (GM) crops are in the pipeline is valuable for developers, regulators, policy makers and investors in making informed decisions. It provides a landscape of current developments and opportunities for collaboration between developers and industries. Crop Life International, an industry body representing its private company members, regularly updates the plant biotechnology pipeline of the private sector. Such lists are not available for the public sector. The definition of ‘pipeline’ in this research refers to the product development process for GM crops. The different stages of GM development are normally categorised as discovery, proof of concept, development and commercialisation (Figure 5.1). Research conducted in public institutions is usually at the discovery end of the spectrum, identifying novel traits or gene sequences and providing solutions to problems that have not to date been addressed by the private sector.

Figure 5.1 A standard transgenic crop development pipeline, from discovery through to commercialisation.
• **Discovery**

The discovery or initial phase of transgenic crop development consists of basic research, exploring scientific ideas. At this stage, a gene or trait of interest is identified to take through to the next phase. In transgenesis, the gene may initially be incorporated into a construct capable of bacterial expression and the resulting protein isolated and tested for functionality e.g. by feeding to insects or spraying onto plants. The difference in approach to identify genes of interest between the public and private sectors is that public developers often start with a gene sequence and develop plant materials based on the function. The private sector usually conducts high-throughput screening to select for genes which add value to their product portfolio. The following sections outline the key activities and necessary studies in the following phases of development of a GM crop.

• **Proof of Concept**

The subsequent phase, ‘proof of concept’, uses model organisms e.g. *Arabidopsis* or easily transformed varieties of crop plants of interest, to test the expression and functionality of novel gene sequences and introduces regulatory considerations, beginning the collection of biosafety and efficacy data which many continue through the entire product development process. Most of the studies in this phase are conducted in laboratories and confined greenhouses.

A bioinformatics approach is used to determine the allergenicity and toxicity to non-targets and strictly follows the standards from the Codex of Alimentarius (Codex Alimentarius, 2003) and the World Health Organisation (WHO)’s evaluation framework (WHO, 2001). Prior to plant transformation, a plasmid vector needs to be designed that comprises suitable expression elements (i.e. promoters, upstream untranslated regions), which ensures the transgene is expressed at the desired level, in the desired tissue and at the desired time. To further enhance the usefulness of the construct, the coding sequence of the transgene is optimised to match the codon usage of the plant and unnecessary elements are removed e.g. palindromic sequences. After optimisation, bioinformatics analysis is further conducted on the construct to minimise the possibility of translating unintended peptides.

The plants are transformed in a controlled environment, in a greenhouse or laboratory to allow screening of events (which are initially individually transformed plants and later their descendants containing the same introduced sequence). For example, insect resistant GM plants will be tested for their efficacy in protection against the target pests. Thousands of
individual transformation events are normally required to select for a single event that meets all the criteria; phenotypic, bioinformatic and trait efficacy. Prior to transformation, permits/approvals need to be obtained from the responsible government agencies for growing and transporting the plant materials. Only events that meet the performance criteria will be tested in small-scale field trials, examining the agronomic performance of transgenic plants with efficacy tests to evaluate the performance of the trait. These trials are conducted under controlled conditions complying with regulatory requirements.

- **Development**

The goal of the development phase is to select for events with agronomic performance that meet commercial expectations, which will undergo further molecular characterisation. Molecular activities include full sequence of the inserts, selecting events with a single copy of the intact T-DNA without other DNA fragments and the development of a molecular assay that specifically detects the event and ensuring that the inserted sequence does not interfere with another expressed plant gene. Rigorous food, feed and environmental safety assessments are undertaken. The data collected in this phase of the development are compiled into regulatory dossiers for submission to responsible regulatory agencies.

An important part of the food and feed safety assessment is the safety of the introduced protein which was the trait-mediating factor in all older GM crop developments. How newer techniques involving gene knockout/silencing can be bioassayed for safety is an unresolved question. To ensure that the GM crop is compositionally equivalent to conventional varieties, studies are conducted on the levels of nutrients, anti-nutrients, toxins, allergen, micronutrients, minerals etc. The full amino acid sequence of the introduced peptide is analysed to ensure that there is no similarity to current known allergens or toxins. Gastrointestinal fluid and heat treatment assessments are conducted to measure the whether the material is rapidly digested. Brown Norway rat studies are conducted to screen for the potential allergenicity of the protein (gradually being replaced by bioinformatic assay), and acute oral toxicity studies are conducted to evaluate protein toxicity and other health related effects, based on factors including survival, weight, growth and pathology. Both studies are conducted with pure proteins (which are extremely expensive and difficult to produce). As part of the regulatory requirements, 90-day animal studies need to be performed to identify longer-term health implications, contrasting the effects of GM crop

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40 During the Agrobacterium-mediated transformation process, occasionally partial sequences of vector backbones and partial gene sequences are inserted into the plant genome.
and conventional varieties on nutritional balance. Rats and broiler chickens are the common animal models for feeding studies. However, the animals used are on a case by case basis.\textsuperscript{41}

Multi-location field trials are conducted to examine the agronomic performance of GM crops under different geographical and environmental conditions to ensure stable performance. At the same time, a comparative assessment is conducted between GM and conventional varieties to test the environmental risks of GM crop. The environmental studies include the persistence and invasiveness of the GM crop, the effects on non-target organisms and the fate of the novel protein under environmental conditions.

**Commercialisation**

The safety data gathered throughout the development process are compiled into regulatory dossiers for presentation to regulatory authorities. Upon the approval from the authorities the progeny of the tested Elite Event can then be commercialised (further agronomic/economic evaluation of performance against national standard varieties across the country may be required e.g. in India) (Table 5.1).

<table>
<thead>
<tr>
<th>Selection of genes/protein</th>
<th>Agronomic assessment</th>
<th>Characterisation of materials</th>
<th>Regulatory submission</th>
</tr>
</thead>
<tbody>
<tr>
<td>* Initial molecular characterisation</td>
<td>* Greenhouse trials&lt;br&gt; * Contained field trials&lt;br&gt; * Initial agronomic performance screening&lt;br&gt; * Elite Event selection</td>
<td>* Toxicity study&lt;br&gt; * Allergenicity study&lt;br&gt; * Compositional analysis&lt;br&gt; * Environmental risk assessment&lt;br&gt; * Further molecular characterisation</td>
<td>* Submission of dossiers to jurisdictions of interest</td>
</tr>
</tbody>
</table>

**Table 5.1** Summary of the key activities required for the compilation of a regulatory dossier.

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\textsuperscript{41} Regulatory authorities from different countries require different animal testing. For example, under the Indian regulatory authority, developers are required to conduct a 90 days animal feeding study on cows.
As already discussed, the majority of GM developments that have been successfully commercialised have been efforts from the private sector. Insect resistant and herbicide tolerant traits have been implemented in the four major crops, maize, soy, cotton and canola representing 99% of the current growing area of commercialised GM crops globally (James, 2015). Industry players regularly update information on their development pipeline (e.g. Monsanto, 2015) but it is unclear what the current global status of public sector GM pipeline developments is.

To attempt to gain a picture of the progress of public sector GM developments, confined field trials (CFT)\textsuperscript{42}, whose existence and sometimes location, are published in most jurisdictions, can be used as an output measurement of public GM progress, as the repetition of CFTs, with an increasing number of trials and acreage, are a strong indication of an active GM development programme which is in the process of generating regulatory data for the purpose of commercialisation. As most jurisdictions publish the existence and status of regulatory field trials, it possible to obtain a somewhat quantitative picture of current public developments. This section examines the current status of public GM crop developments, more specifically looking at the commercial attributes of the programmes, by focusing on the potential value of developments, the scale of the funding for individual projects and the costs of complying with regulatory requirements. This study focuses only on the confined field trial stage of the commercial pipeline, excluding the large number of blue sky research projects which are conducted in the public sector, as the majority of discovery projects conducted in public institutions are either not commercially driven or never get as far as field trials to generate regulatory data.

5.2 Methodology

A global public GM crop development profile was generated by identifying notifications of field trials from various regulatory agencies (Table 5.2). In many cases, due to the lack of regulatory data available, other published information was used to construct the profile. Sources include; annual reports of various public GM projects, country specific biotechnology reports from the United States Department of Agriculture (USDA) and existing literature.

\textsuperscript{42} Confined field trials (CFT) are field trials with regulatory requirements set by regulatory authorities. Although the actual requirements differ in different countries, the most common restrictions are area of planting, size of buffer zone and processes for minimising contamination.
Harmonisation of the data was required, due to the different reporting formats. Traits were categorised according to the function of transgenes inserted; insect resistant IR, product quality PQ; disease resistant DR; herbicide tolerant HT; agronomic performance AP; abiotic stress tolerant AT and others. Several other steps were taken and some reasonable assumptions made in the process of ensuring that the data represents actual public GM developments i.e.:

- Trials with plants transformed only with a selectable marker but without any other agronomic traits were excluded from the data set. The assumption taken here was that these crops will not be commercialised and were used for proof of concept.
- Unless a trait was specified, all non-trait field trials were regarded as basic research for proof of concept and were excluded from the dataset.
- In many cases, the use of phosphinothricin acetyl transferase (PAT) was considered as the presence of a herbicide tolerance trait by many regulatory agencies. Manual screening of notifications and permits revealed that the insertion and expression of PAT were mainly used as a selectable marker rather than an agronomic trait.

<table>
<thead>
<tr>
<th>Country</th>
<th>Sources of information</th>
</tr>
</thead>
<tbody>
<tr>
<td>South Africa</td>
<td>Department of Agriculture, Forestry and Fisheries, Republic of South Africa. <a href="http://www.daff.gov.za/daffweb3/Branches/Agricultural-Production-Health-Food-Safety/Genetic-Resources/Biosafety/Information/Permits-Issued">www.daff.gov.za/daffweb3/Branches/Agricultural-Production-Health-Food-Safety/Genetic-Resources/Biosafety/Information/Permits-Issued</a></td>
</tr>
<tr>
<td>Country</td>
<td>Sources of information</td>
</tr>
<tr>
<td>----------------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>India</td>
<td>Indian GMO Research Information System. <a href="http://igmoris.nic.in">igmoris.nic.in</a></td>
</tr>
<tr>
<td>Malaysia</td>
<td>Malaysia Biosafety Clearing House, Department of Biosafety, Ministry of Natural Resources and Environment, Malaysia. <a href="http://www.biosafety.nre.gov.my/country_decision.shtml">www.biosafety.nre.gov.my/country_decision.shtml</a></td>
</tr>
<tr>
<td>Europe</td>
<td>Deliberate release and placing on the EU market of GMOs, Joint Research Centre, European Commission. Gmoinfo.jrc.ec.europa.eu/gmp_browse.aspx#</td>
</tr>
</tbody>
</table>

Table 5.2. Sources of information used to generate the CFT database.
The time under development for individual public GM projects was determined by examining the organisations/crops/traits and counting years of CFTs that were approved. A key assumption in calculating the time under the regulatory phase was that notifications having exactly the same organisations, crops, and traits in different years were indications of consecutive field trials of the same event. For example, the Commonwealth Scientific and Industrial Research Organisation (CSIRO) has two licenses for conducting CFTs of high oleic acid safflower with exactly the same gene sequences inserted (fragment of FATB, FAD2 and fatty acid biosynthesis gene) during the periods between 2013 to 2015 and 2015 to 2019. Therefore, it was assumed that they were trialling the same event. However, due to the lack of full regulatory information availability, it is possible that different plasmids or promoters were used in subsequent field trials, resulting in a new event being tested rather than being of consecutive CFTs of identical constructs.

**Methodological challenges and limitations**

1. Many countries do not publicly report and provide outlines for regulated field trials. For example, Argentina does not publish any information on past and on-going CFTs. This presents challenges for this research in determining public involvement in those countries. Therefore, it is difficult to generate a full global landscape of public GM developments and the report here is limited to countries with publically available adequate regulatory information.

2. Challenges with information gap such as:
   - **Trialling year unknown (only approval year is given)**
     Where there were cases where the regulatory authority does not state the length of CFT, additional sources of information were used to determine the total length of time under the regulatory phase.
   - **Commercial confidential information**
     In many cases, notifications do not provide the gene sequences that were inserted.
5.3 Results and analysis

5.3.1. Growth of public sector GM crop developments

The trend of public GM crop developments was analysed by identifying the initial year of CFT of all public GM developments based on a total of 1,263 events identified. Examining the total number of public GM events over time, the first peak period of growth commenced shortly after the commercial introduction of GM crops in 1996 and the number of field trials approved every year increased dramatically by over seven-fold, with trials of 61 events approved in 1998 (Figure 5.2). The second peak of developments in 2005-2007 is contributed very largely by the geographic expansion of existing traits which have been commercialised earlier. The majority of recorded public GM crop developments reaching CFTs originated from developed countries (US, Europe, Canada, Australia and Japan), accounting for 93.3% (1,178 events) of global public sector GM developments, while developing countries (India, Bangladesh, Pakistan, Philippines, Indonesia, Thailand, Malaysia, Mexico, Brazil, Ghana, Burkina Faso, Nigeria, Kenya, Uganda, South Africa) represent only a small proportion of 6.7% (85 events). However, the trend observed and the proportion of developing countries and their trials contributing to it are most likely to be underestimated, due to the lack of quantitative information on regulatory field trials in many developing countries. China has invested heavily in GM developments since the year 2000 (Huang et al., 2004; 2005b), with two GM crops, insect-resistant rice and phytase maize obtaining biosafety approval from the Ministry of Agriculture (MOA) and will have many more CFT approvals than are publically available. It is safe to assume that the number of public GM trials will continue to increase.

![Figure 5.2](image)

**Figure 5.2.** The global trend in public GM crop developments under CFT between 1993 and 2015.
5.3.2. Focus of public sector GM crop developments in developed and developing countries

To identify the focus of the public sector work, an analysis of crop distribution was conducted. Public GM initiatives cover a large diversity of crops. Maize, potato, other fruits, tomato and soybean account for more than 50% of all public GM developments (Figure 5.3). Public sector developments target areas that are to a significant extent not occupied by the private sector for GM solutions, though there is a great deal of private advanced biotechnology going into improvements in, for example, vegetables. The relatively low interest in major crops such as wheat (6%), and rice (3%) is likely to reflect the political environment as these are key staple food crops for which there is significant consumer sensitivity/opposition to the use of GM technology.

Figure 5.3 Global distribution of public GM crops under confined field trials between 1993 and 2015. The total number of GM unique CFTs identified was 1,26343.

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43 Other fruits include apple, avocado, banana, blueberry, orange, grape, grapefruit, melon, lemon, lime, papaya, pear, persimmon, pineapple, plum, raspberry, strawberry and watermelon. Other field crops include cassava, cowpea, common bean, chickpea, dry bean, lentil, lupin, oat, pea, peanut, sugar beet and sweet potato. Trees include aspen, poplar, walnut, American chestnut, black cottonwood, eastern cottonwood and eucalyptus tree. Vegetable includes cabbage, cauliflower, brinjal and lettuce.
Exploring public GM crop developments in developing countries (both in Asia and Africa)\textsuperscript{44}, a reduction of crop diversity and a shift of focus were identified. Instead of focusing on the four internationally traded major crops, maize, soy, cotton and oilseeds, the crops of focus are largely sugarcane, sorghum, brinjal, papaya and rice (Figure 5.4). As mentioned, however, only 6.7\% of all public sector CFTs are in developing countries.

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{distribution_of_public_gm_crops_in_developing_countries_under_cfts_between_1993_and_2015.png}
\caption{Distribution of public GM crops in developing countries under CFTs between 1993 and 2015. Total number of GM crop developments identified was 85.}
\end{figure}

Further analysis was conducted by examining the production value of these crops in countries in which they are currently under CFTs. Production values and the total agricultural production value of the various developing countries were gathered from the Food and Agriculture Organisation (FAO) of the United Nations. What was identified was that the majority of crops under public sector development in a particular country represent a significant proportion of total agricultural production in that country (Table 5.3). For example, banana production in Uganda was 28.6\% of total Uganda agricultural production.

\textsuperscript{44} For all the countries under the United Nations Country Classification (United Nations, 2015, page 135) for which CFTs were found, developed economies examined here are Australia, Canada, Japan, United States and Countries in the European Union. The developing countries are Bangladesh, Brazil, Burkina Faso, Ghana, India, Indonesia, Kenya, Malaysia, Mexico, Nigeria, Philippines, South Africa and Uganda.
Only two cases were identified where a crop which entered regulatory field trials had less than 2% of the relevant national agricultural production value. These are virus-resistant papayas and insect resistant brinjal. Upon examining the papaya events that entered regulatory field trials, the majority of the events (four out of six) have Papaya Ring Spot Virus-Coat Protein (PRSV-CP) inserted. These events entered regulatory field trials after the first commercialisation of GM papaya in Hawaii. As for the brinjal, most of the CFTs are insect resistant expressing cry1Ac (five out of six). The Bt brinjal which entered the regulatory phase was developed from an elite event45 (EE-1), donated by the Maharashtra Hybrid Seeds Company (MAHYCO) to public institutions in Bangladesh, India and Philippines, under the Agricultural Biotechnology Support project funded by USAID. Local scientists introgressed the EE-1 into local varieties and their agronomic properties were evaluated under CFTs (Choudhary et al., 2014a). Although both virus resistant papaya and Bt brinjal represent a small proportion of total agricultural production value, both crops are of importance to poor local farmers. For example, Brinjal is an important cash crop for resource-poor farmers in India but is prone to insect damage which causes enormous yield loss. It is estimated that fruit and shoot borer causes a yield loss of 60% to 70% and is difficult to control with chemical insecticides (Choudhary et al., 2014a). It was estimated that the Bt brinjal would produce a net benefit of $330 to $397 per acre, with national benefits exceeding $400 million a year in India alone (Krishna & Qaim, 2008). Public sector institutions in developing countries are targeting crops of importance to individual countries. In many cases, public GM developments utilise technologies developed by other organisations and implement these developments in local crop and varieties, because of the perceived economic and social benefits.

45 The Elite-Event 1 contains gene sequences of Cry1Ac, nptII, the CaMV35s promoter and the aad gene in pMON10518 plasmid vector.
<table>
<thead>
<tr>
<th>Crop and % of CFTs in developing countries</th>
<th>Country of relevance</th>
<th>Production (tonnes)</th>
<th>Production (values $1,000)</th>
<th>% of country’s total agricultural production</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sugarcane (12%)</td>
<td>Brazil</td>
<td>768,090,444</td>
<td>24,995,210</td>
<td>27.6</td>
</tr>
<tr>
<td></td>
<td>South Africa</td>
<td>18,000,000</td>
<td>591,066</td>
<td>8.5</td>
</tr>
<tr>
<td></td>
<td>India</td>
<td>341,200,000</td>
<td>10,419,705</td>
<td>5.5</td>
</tr>
<tr>
<td>Sorghum (8%)</td>
<td>Burkina Faso</td>
<td>1,880,465</td>
<td>284,221</td>
<td>13.8</td>
</tr>
<tr>
<td>Brinjal (7%)</td>
<td>India</td>
<td>13,444,000</td>
<td>2,874,354</td>
<td>1.5</td>
</tr>
<tr>
<td>Papaya (7%)</td>
<td>Philippines</td>
<td>166,261</td>
<td>47,185</td>
<td>0.3</td>
</tr>
<tr>
<td>Rice (7%)</td>
<td>Bangladesh</td>
<td>51,500,000</td>
<td>13,591,020</td>
<td>68.6</td>
</tr>
<tr>
<td></td>
<td>Indonesia</td>
<td>71,279,712</td>
<td>19,296,706</td>
<td>32.9</td>
</tr>
<tr>
<td></td>
<td>Philippines</td>
<td>18,439,406</td>
<td>4,905,365</td>
<td>30.0</td>
</tr>
<tr>
<td></td>
<td>India</td>
<td>159,200,000</td>
<td>42,568,380</td>
<td>22.3</td>
</tr>
<tr>
<td>Cassava (6%)</td>
<td>Nigeria</td>
<td>47,406,770</td>
<td>5,536,539</td>
<td>16.1</td>
</tr>
<tr>
<td></td>
<td>Uganda</td>
<td>2,979,000</td>
<td>546,135</td>
<td>11.3</td>
</tr>
<tr>
<td>Maize (6%)</td>
<td>South Africa</td>
<td>12,486,000</td>
<td>1,026,505</td>
<td>14.8</td>
</tr>
<tr>
<td></td>
<td>Burkina Faso</td>
<td>1,585,418</td>
<td>222,269</td>
<td>10.8</td>
</tr>
<tr>
<td></td>
<td>Uganda</td>
<td>2,748,000</td>
<td>346,091</td>
<td>7.2</td>
</tr>
<tr>
<td>Potato (6%)</td>
<td>Bangladesh</td>
<td>8,603,000</td>
<td>1,377,095</td>
<td>7.0</td>
</tr>
<tr>
<td></td>
<td>South Africa</td>
<td>2,252,000</td>
<td>328,717</td>
<td>4.7</td>
</tr>
<tr>
<td></td>
<td>Indonesia</td>
<td>8,603,000</td>
<td>1,377,095</td>
<td>2.4</td>
</tr>
<tr>
<td>Soybean (6%)</td>
<td>Brazil</td>
<td>81,724,477</td>
<td>21,902,731</td>
<td>24.2</td>
</tr>
<tr>
<td>Banana (5%)</td>
<td>Uganda</td>
<td>8,926,308</td>
<td>1,382,170</td>
<td>28.6</td>
</tr>
</tbody>
</table>

Table 5.3 The production value of selected crops under CFT in developing countries and their value in tonnes and international dollars and as a percentage of the value of the total national crop value. Source FAOSTAT, 2015.

The International dollar is a currency used by FAO, for aggregating global production values of commodities by minimising the implication of exchange rates, facilitating comparison of productivity between countries. The ‘International prices or dollars’ are based on the Geary-Khamis formula,
5.3.3. Distribution of traits in public sector led regulated field trials

![Figure 5.5 Global distribution of traits in public sector led CFTs between 1993 and 2015. IR: Insect Resistance, PQ: Product Quality (e.g. biofortification), DR: Disease resistance, HT: Herbicide Tolerance, AP: Agronomic Performance, AT: Abiotic stress Tolerant, Other traits include crops producing pharmacological products, enzyme production, colour alteration and altered secondary metabolism.

The types of trait identified under development between 1993 and 2015 are presented in Figure 5.5. Traits of GM crops can be categorised as input and output traits. Input traits have direct benefits to farmers in either reducing labour cost or minimising loss to various stresses. Output traits modify crops to benefit consumers, such as producing enhanced nutrient content or improved taste. Of all single trait crops developed by the public sector, input traits dominated (77%), with a focus on disease resistance (33.4%), agronomic performance (14.5%) and abiotic stress tolerance (12.1%). Rather little focus is aimed at generating insect resistant and herbicide tolerant crops (a combined total of 12.8%). The result contrast with the Netherlands Commission on Genetic Modification (COGEM) survey (COGEM, 2014), where 73.1% of all trials (both in the public and the private sectors) were of which assigns a single ‘price’ to every individual commodity crop, regardless of the location of production system.
herbicide tolerance and/or insect resistance traits, the most common amongst all biotic stress related traits. This further supports the idea identified in the previous section, that public sector developments target areas which are not addressed by the private sector. The private sector has tended to develop crops with herbicide tolerance to complement their existing agricultural chemicals or insect resistant traits for major commodity crops (and stacks of both together).

Product quality traits like nutrient modification, production of health-related compounds and reduction of allergenistic responses account for 23% of all single trait crops under CFTs by the public sector. This significant proportion indicates that the public sector is highly focused on generating output traits. However, the value of output traits is likely to be difficult to capture due to current consumer resistance against the use of GM crops.

![Figure 5.6](image.png)

**Figure 5.6** Initial public sector CFTs of GM crops with stacked traits between 1993 and 2015.

Several traits can be stacked into a GM plant by genetic engineering or crossing through conventional breeding methods. The advantage of using genetic engineering is that it allows targeted gene insertion and the ability to include more than one trait at a locus (making the accidental separation by subsequent breeding much less likely), minimising time and costs.

Based on the results presented in **Figure 5.6**, it is apparent that the public sector is developing GM crops with stacked traits. The dominant crop with stacked traits is maize, and

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47 Similar to the constraints acknowledged here, the author of the survey report identified that many herbicide tolerance genes are used as selectable markers rather than as input traits. Therefore, the number of herbicide tolerant crops identified in the COGEM report may be overestimated.
12 out of 14 public maize events are stacked with herbicide tolerant traits. However, this finding may be an exaggeration, due to the fact that the notification provided by the applicants does not always indicate whether they are testing GM crops with stacked traits or whether they refer to independent GM events with different traits.

Overall, this section of the analysis has highlighted the fact that substantial investments are still being made in the public sector for developing GM crops. Based on the evidence of crops and trait distributions within the public sector portfolio, it is reasonable to conclude that the public sector largely focuses on developments not addressed by industry.

5.3.4. Distribution of field trial lengths of public GM developments

The number of years a particular GM crop has been under regulatory field trials can be used as an indicator to predict which public GM crop developments may be likely to be commercialised. The lengths of field trials were determined based on the number of years specified in the notifications/permits. However, developers may not utilise the full duration of a permit. An assumption that is crucial to this part of the analysis is that all public regulated field trials were conducted for all the seasons allowed by the permits/notifications.

Figure 5.7 Number of public sector GM projects with particular continuous years of CFTs. A total of 1,263 CFTs occurred between 1993 and 2015.
In total, three-quarters (75%) of public GM developments have conducted 3 or fewer years of regulated field trials. More than half have conducted only one year of CFT (52.8%), 12.3% conducted 2 years of trials and 10.5% conducted 3 years (Figure 5.7). To take into consideration CFTs which started in 2012, 2013 and 2014 which could only have a maximum of one to three years of CFTs by 2015, an analysis was conducted on public GM crop developments with one, two or three years of CFT across the timeline. It is evident from Figure 5.8 that only a small proportion of public GM crop development CFTs continue after one year. For example, in 2006 there were 66 developments which had conducted one year of CFT, but by 2007 and 2008, the number of CFTs that had two and three years of CFTS had reduced down to 22 and 12 respectively. This suggests that only 12 out of 66 public GM developments continued conducting CFTs after 2006 and provides confidence to argue that the figures for public GM developments that had less than three years of CFTs identified in Figure 5.7 was not significantly affected by trials that started late in the timeline.

An article by Prado et al. (2014) indicated that the average total time under field trials for private sector GM developments is approximately 6 years. This suggests that the majority of public sector developments are in the early phases of development and that most have never reached the late development phase of conducting regulatory experiments.

![Figure 5.8](image-url) The initial year of CFTs for public GM project with one, two or three years under CFTs.
Further examination of public GM programmes which have conducted four or more years of CFTs, reveals that developing countries have 27 publically developed GM crops reaching this stage - 31.8% (27 out of 85) of all crops commencing trials. This contrasts with the position in developed countries where 17.0% (200 out of 1,178) of public GM crop developments that have entered CFTs are still under trial after 4 years. This may suggest that developments in developing countries are more likely to be eventually commercialised.

5.3.5. Funding bodies of on-going GM projects in Africa

This section explores the commercial attributes of public GM crop projects that have conducted more than 3 years of CFTs, by examining the funding bodies and the size of funding in an attempt to understand what drives so many developing countries’ public GM projects forward. This section uses current African public initiatives as illustrations, as results from preceding sections suggest that public GM projects in developing countries are more likely to be commercialised. Information was gathered from project websites, annual reports and databases from philanthropic foundations and aid agencies.

Based on Table 5.4, all the African projects with more than three years of CFTs are supported by philanthropic foundations. The amount of external funding per project ranged between $1.5 million and $95.95 million. All the projects except one have budgets over $10 million. The project with the largest fund available is the Water Efficient Maize for Africa (WEMA) project with funding over $95 million, targeting multiple countries. However, not all the funding is directed towards the development of GM maize specifically, as opposed to the utilisation of other biotechnologies[^48]. This result suggests that significant external financial contributions are required from investors to bring public GM crops close to commercialisation. It is worth noting that all philanthropic inputs have ‘matching’ inputs from the national agriculture research systems (NARS) or universities in the countries involved. These are difficult to quantify but clearly add greatly to the overall cost. In addition, most of the African public GM projects have been on-going for close to 10 years, indicating a strong commitment from the investors to pursue commercialisation.

[^48]: WEMA uses three different breeding approaches; conventional, marker-assisted and genetic modification, but the distribution of funding between these different approaches is not publically available.
<table>
<thead>
<tr>
<th>Crop under development</th>
<th>Trait</th>
<th>Research Partners</th>
<th>Funding bodies</th>
<th>Funding $US</th>
<th>Number of years from the start of the project</th>
<th>Current Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Banana</td>
<td>Bacterial wilt resistance</td>
<td>AATF, Academia Sinica, IITA, NARO-Uganda</td>
<td>Gatsby Charitable Foundation and USAID</td>
<td>USAID-$1.5 million</td>
<td>11 years</td>
<td>Confined field trials in Uganda</td>
</tr>
<tr>
<td>Banana</td>
<td>Enhanced with vitamin A and iron</td>
<td>NARO-Uganda and Queensland University of Technology</td>
<td>BMGF</td>
<td>BMGF $12,426,000</td>
<td>10 years</td>
<td>Confined field trials in Uganda</td>
</tr>
<tr>
<td>Cassava</td>
<td>Disease resistance</td>
<td>Danforth Center, ETH Zurich, KARI and NaCRRI</td>
<td>BMGF, Howard G. Buffett Foundation, Monsanto Fund, USAID</td>
<td>BMGF $5,549,000, Monsanto Fund $5,300,000, Buffett $860,000, USAID $2,694,000, Total $14,403,000</td>
<td>9 years</td>
<td>Confined field trials in Uganda and Kenya</td>
</tr>
<tr>
<td>Cassava</td>
<td>Enhanced with vitamin A, iron and protein.</td>
<td>Danforth Center, ETH Zurich, NARS (Kenya and Nigeria)</td>
<td>Bill and Melinda Gates Foundation</td>
<td>BMGF $15,663,000</td>
<td>10 years</td>
<td>Confined field trials in Kenya and Nigeria</td>
</tr>
<tr>
<td>Cowpea</td>
<td>Insect resistance</td>
<td>AATF, CSIRO, IITA, Kirkhouse, Monsanto, NARS (Nigeria, Ghana, Burkina Faso)</td>
<td>Rockefeller foundation and USAID</td>
<td>No information publicly available.</td>
<td>12 years</td>
<td>Confined field trial in Ghana, Nigeria and Burkina Faso</td>
</tr>
<tr>
<td>Maize</td>
<td>Insect resistance</td>
<td>CIMMYT, KARI</td>
<td>Syngenta Foundation</td>
<td>No information publicly available.</td>
<td>15 years</td>
<td>Confined field trial in Kenya</td>
</tr>
<tr>
<td>Maize</td>
<td>Drought tolerance</td>
<td>AATF, CIMMYT, Monsanto, NARS (Uganda, Kenya, South Africa, Tanzania and Mozambique) and University of Cape Town</td>
<td>Bill and Melinda Gates Foundation and Howard G. Buffett Foundation</td>
<td>Phase I- BMGF and Buffett - $47,000,000, Phase II- BMGF- $48,951,000, Total $95,951,000</td>
<td>7 years</td>
<td>Confined field trial in Uganda, Kenya and South Africa.</td>
</tr>
<tr>
<td>Sorghum</td>
<td>Enhanced with vitamin A, iron and zinc</td>
<td>AATF, Africa Harvest, CORAF/WECARD, CSIR (South Africa), Danforth Center, ICRI SAT, NARS (Kenya, Nigeria, Burkina Faso and South Africa) Pioneer, University of California (Berkley), University of Pretoria</td>
<td>Bill and Melinda Gates Foundation and the Howard Buffett Foundation</td>
<td>Phase I- BMGF $21,047,000, Phase II- Buffett $5,215,000, Total $26,262,000</td>
<td>10 years</td>
<td>Confined field trial in Kenya and Nigeria</td>
</tr>
</tbody>
</table>

Table 5.4 Current funding status of public GM crop developments in Africa.
It was stated by the developer of the vitamin A bananas from the Queensland University of Technology that the philanthropic foundations provide funds that are often beyond the scale of government funding and that they are committed to translating scientific discovery into products. In addition, philanthropic organisations such as the Bill and Melinda Gates Foundation (BMGF) provide the necessary expertise for commercialisation i.e. regulatory affairs, which is largely absent in the public sector.

5.3.6. Distribution of government investments

It was seen from the national policies of developing countries, especially China and India, that countries have invested heavily in agricultural biotechnology. According to the recent USDA (2013a) report, although the exact government expenditure on agricultural biotechnology is unknown, it is believed that the Chinese total public investment in agricultural biotechnology outweighs that of any other country in the world. In late 2008, China initiated a 26 billion RMB project (approximately US$3.75 billion, based on the exchange rates in 2008), an initiative to promote GM crop developments in China (Chen et al., 2011). In 2015, the Chinese government outlined the need for GM crops in the No1. Central Document of China. However, investments made by governments have generated very little in the way of commercial outcomes so far. Despite the apparently heavy government financial commitment, many stakeholders believe that public developments are confronted by the lack of financial commitment from governments to take initiatives through to market. An initial review of Chinese public GM project funding provided very limited information. For example, the Ministry of Science and Technology outlines only the maximum funding available for each topic under the ‘Transgenic Breeding Policy’. In 2013, research projects on techniques on transgenic cloning could receive a maximum contribution of 2 million RMB (US$323,000 based on the 2013 exchange rate) covering a period of two years (MOST, 2013). However, it is uncertain how many GM development projects were sanctioned by the central government. Discussions with two magazine editors from Caijin and the Beijing Technology Journal in China, revealed that a challenge faced by the public sector is not the thinly distributed public funding, rather it is that much of the

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49 The No1 Central Document is the first document published by the Chinese government every year and outlines national concerns. The No1 Central Documents between 2004 and 2013 have focused on agricultural developments. For the first time ever, the 2015 No1. Central Document emphasised the need for GM technology, a strong indication that China is now aiming to commercialise its GM developments.
funds are diverted into biosafety research. This may be driven by a well-known quote from the deputy minister of MOA that “转基因研发要积极，推广要慎重”, ‘we should be bold in researching transgenics but be cautious in commercialisation’ (MOA, 2014), which probably represents the current Chinese government’s funding attitude. The lack of quantitative information on the number of projects granted and total funding allocated creates difficulties in determining the funding attributes of public sector GM developments in China.

In order to test the idea that government funding is thinly distributed across a large number of projects and to provide a contrast to the funding for individual projects supported by philanthropic foundation/aid agencies, the funding of public GM developments in India was examined, with a special focus on projects sanctioned by the Department of Biotechnology (DBT) under the Ministry of Science and Technology. DBT was created in 1986 to promote biotechnology in four sectors of the Indian economy, agriculture, industry, healthcare and the environment. In 2005, DBT drafted a National Biotechnology Development Strategy (NBDS) for applying biotechnology in agriculture, a long-term commitment from the government of India. The DBT budget went up from 6,215 million rupees ($15 million) in the Ninth Five-Year Plan to 50,000 million rupees ($180 million) in the Eleventh Five-Year Plan. However, it is uncertain how much funding has been directed towards agricultural biotechnology and for the development of GM crops. Annual reports of projects sanctioned by DBT were reviewed to determine the amount of funding directed towards GM crops. Classification of projects into GM or non-GM was based on a personal analysis. In many cases, there were projects which examine the characteristics of novel gene sequences which might later be utilised to develop GM crops, those projects are considered here as basic research and classified as non-GM (Table 5.5).

The proportion of total funding directed towards GM crop developments ranged between 5.2% and 29.7% and on an average it only accounted for 14.6%, a modest fraction of the total budget allocated for biotechnology as a whole. Aggregating the total amount of DBT funding directed towards the development of GM crops over the period of six years for 31 projects gives a value of $3,913,640. That value is less than any single philanthropically funded GM project in Africa. Furthermore, a significant decrease in funding has occurred between 2011 and 2014. The budget allocated to GM crop projects in 2014 was only 13.6% of the 2011 budget. It is uncertain what factors contributed to the decline in DBT investment in GM crop developments, but it is speculated that the moratorium on the commercialisation of Bt Brinjal from 2010 might have contributed to the observed trend.
<table>
<thead>
<tr>
<th>Year</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total amount sanctioned by DBT to biotechnology projects (Rupees)</td>
<td>435,130,978</td>
<td>699,292,740</td>
<td>224,258,988</td>
<td>274,390,707</td>
<td>79,747,528</td>
<td>187,300,868</td>
</tr>
<tr>
<td>Total amount sanctioned by DBT to GM projects (Rupees)</td>
<td>25,576,328</td>
<td>36,482,128</td>
<td>59,049,654</td>
<td>41,672,899</td>
<td>23,681,454</td>
<td>10,244,400</td>
</tr>
<tr>
<td>USD equivalent for GM projects</td>
<td>542,611</td>
<td>800,454</td>
<td>1,232,180</td>
<td>765,918</td>
<td>404,652</td>
<td>167,825</td>
</tr>
<tr>
<td>Percentage of total DBT funding directed to Ag Biotech</td>
<td>5.9%</td>
<td>5.2%</td>
<td>26.3%</td>
<td>15.2%</td>
<td>29.7%</td>
<td>5.5%</td>
</tr>
</tbody>
</table>

**Table 5.5** The annual amount of DBT funding directed towards biotechnology and GM crop developments. The annual budget of DBT is based on the figures provided by the Union Budget of India ([http://www.indiabudget.nic.in](http://www.indiabudget.nic.in)). Conversion of Rupees to USD is based on the average exchange rate in the respective years.

As mentioned earlier, the funding received by individual projects averaged less than $130,000 ([Appendix 2](#)). Putting the scale of funding into context, the Department of Science and Technology (DST) in India has recently revised the salary for scientific research fellows and research associates (who would be the main researchers paid from the projects as opposed to by the institutions). The cost of hiring a junior research fellow is Rs 25,000 ($380) per month and a level one research associate is Rs 36,000 ($550) per month (DST, 2014). For a laboratory group that hires one of each, it would cost the project Rs 732,000 ($11,000) for research staff per year or $33,000 over the average three year life of a project. An average grant of $130,000 may just be sufficient to cover staff salary, minor equipment and consumable costs, but is utterly insufficient to pay for activities related to commercial development. Depending on the magnitude of the research, projects funded by government agencies have a standard lifetime between two and five years. However, preceding sections have indicated that the successful development of GM crop takes a considerable amount of time and money. Therefore, given the funding level identified in Table 5.5, the majority of the projects aiming for commercialisation will need very considerable further assistance or to raise multiple projects to cover the cost of development to commercialisation. India government research funding is thinly distributed across multiple projects, with short term
structures, insufficient to commercialise GM crops, and this is probably true of government grant support elsewhere in the developing world, including China.

5.3.7. Cost of regulatory requirements for GM crop developments

In many countries outside of the USA, the public sector has been the main contributor to the generation of new crop varieties. The public sector conducted the R&D and new varieties were given to seed companies for production and distribution under various terms and conditions. However, the development and commercialisation of GM crops has added additional requirements; in particular the need to conduct regulatory experiments. Comparing the costs of developing a conventional variety against the cost of development of a GM crop, the additional cost is largely caused by the need to generate regulatory data to gain approval. It has been estimated by the industry that the regulatory phase of development costs an average of $35.1 million with a time frame of 10 years (McDougall, 2011), though clearly this is country, trait, crop and date specific.

Globally, every jurisdiction has different requirements for gaining regulatory approval. The debate between EU and US about the safety of GM crops has created two extremes in the underlying philosophy of regulatory systems. The precautionary principle adopted by the EU has been constantly debated and it has proven very difficult to deregulate any GM crops under such conditions (Miller & Bradford, 2010; Raybould & Poppy, 2012). In Australia, the Office of Gene Technology Regulator (OGTR) assesses the safety and approves the commercial release of GM crops. The decision to grant commercial release is based on the method outlined in the Risk Analysis Framework- 2013 (OGTR, 2013). The risk assessment considers whether the GM variety is substantially different to the parent organism, the introduced gene encodes for products which are toxic or allergenic to humans and other non-target organisms and whether it poses environmental risks such as weediness potential or effects on wildlife. Many developing countries have also established their own regulatory systems and methods of assessing GM crops. For example, the Genetic Engineering Approval Committee (GEAC), the regulatory authority in India, has produced national guidelines for the safety assessment of GM crops and similarly, MOA of China has

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50 Choudhary et al. (2014b) provides a comprehensive review of the current Indian regulatory system. The Ministry of Environment, Forest and Climate Change publishes all the guidelines and protocols for the assessment of GM crops which can be accessed via the following link
implemented a series of regulations, covering all aspects of work with GMOs, from laboratory research through to commercialisation\textsuperscript{51}.

Despite all the differences in the regulatory systems, the questions asked by the regulatory authorities, to be answered in the applicant’s submission, are generally alike. Table 5.6 presents a summary of the regulatory requirements for GM crops. However, it needs to be clearly stated here that the current regulatory requirements for the commercial release of GM crops do not clearly outline the exact studies required to meet the regulatory requirements. Instead the regulatory authorities require applicants to demonstrate safety in the various areas. This creates uncertainty and has allowed the industry to set the standard for compiling regulatory dossiers. Furthermore, the political interference in the final approval process adds another level of uncertainty\textsuperscript{52}.

The lack of a harmonised global regulatory framework for GM crops has created serious issues for GM developers and often results in asynchronous approval. This refers to a situation in which a GM crop is approved for commercialisation in one country before it has received approval (possibly only for import as food or feed and not for growing) in another. Consequently, developers may find themselves liable for any trade disruption resulting from not securing regulatory approvals in major growing and export jurisdictions. Two classic examples of asynchronous approval of GM crops which resulted in major lawsuits are the cases of Liberty Link rice from Bayer Crop Science and of MIR162 maize from Syngenta. Liberty Link® rice was found in a rice shipment imported into EU without regulatory approval and resulted in a $750 million settlement to compensate the US farmers when subsequent shipments to the EU were blocked. Similarly, the MIR162 maize incident in China resulted in a trade disruption with an economic loss estimated to be in the range of $1 billion to $2.9 billion (National Grain and Feed Association, 2014). It is apparent that GM crop developers need to ensure they have obtained approvals from regulatory authorities in jurisdictions of interest prior to commercialisation. These approvals may not be necessarily be cultivating approvals but may be biosafety and import-only approvals. For example, all but two of the Australian GM crop approvals (canola and cotton) are for import only, not for growing e.g. GM maize, soybean, sugarbeet, etc. (www.foodstandards.gov.au).

\textsuperscript{51} Li et al. (2014) outlines the GM regulatory system in China and the biosafety data needed to enter each developmental stage for a novel GM crop.

\textsuperscript{52} See section 5.3.8

\begin{footnotesize}
\begin{itemize}
\end{itemize}
\end{footnotesize}
Table 5.6 A summary of the major regulatory requirements for GM crop biosafety approval.

<table>
<thead>
<tr>
<th>Regulatory requirements</th>
<th>Characterisation of materials</th>
<th>Food/feed safety</th>
<th>Environmental safety</th>
</tr>
</thead>
</table>
| Information on crop of interest/parent crop | • Reproduction characteristics  
• Known toxins/allergens  
• History of safe use | • Nutritional composition | • Existence of wild relatives  
• Geographic distribution of plants |
| Information on the process of transformation | • Full sequence of construct  
• Origin of genetic elements  
• Method of transformation | • Existence of markers  
• Safety of markers |  
| Information on gene product | • Homology to known toxins/allergens  
• Protein’s mode of action  
• Target specificity  
• History of safe use | • Protein characterisation  
• Acute toxicity study  
• Allergenicity study | • Gene flow |
| Information on GM plants | • Full sequence of the insert in the genome  
• Phenotypic stability  
• Expression data  
• Compositional assessment (Protein and amino acid profile)  
• Event-specific detection method  
• Agronomic advantage | • Nutritional equivalence  
• 90 day animal studies (animal models depend on jurisdiction)  
• Digestibility assay  
• Heat stability study | • Effect on non-target organisms  
• Effects on biodiversity  
• Persistence and invasiveness of the plant  
• Soil fate of protein  
• Crossing potential |

The private sector invests heavily in obtaining global regulatory approvals, despite the cost and time needed to comply with different regulatory requirements (though the agricultural biotechnology major players have all moved their major research facilities outside Europe). This is logical when we consider that the majority of currently commercialised GM crops are global commodity crops used in international trade. For example, the cabbage and cauliflower market in India is the largest in the world and there are GM solutions available for major biotic stresses, but the total national seed market (all varieties) in these minor crops is worth c.$2 million per year. Since this is where a seed company’s financial return would have to come from, it would make no sense for a company to embark on a GM project in these crops if the regulatory cost for a single GM variety was going to be many millions of dollars.
However, there is great variability between countries and uncertainty about the cost of complying with regulatory requirements. In an attempt to identify the actual regulatory cost for developing a GM crop, detailed cost information was identified from the literature. Very little data appears to be publically available. In addition, the regulatory cost of developing insect resistant Bt cabbage and cauliflower from the CIMBAA PPP project and the Bt cotton developed by Central Institute for Cotton Research (CICR) (both in India- see Section 8.3) are added for comparison. Detailed figures of the regulatory costs for each project were provided by the principal investigators.

The regulatory costs identified in Table 5.7 vary enormously, from $53,000 to $12.5 million. The information collected on the regulatory cost of public GM projects is partial and no projects seem ever to have reported detailed compliance costs publicly. The only comprehensive cost information is from the CIMBAA project, based on actual costs and agreements made with laboratories plus estimated field trial costs. Nevertheless, the data suggests that US costs are higher than in India and China, with China having the lowest compliance cost. The lower cost reported in China is a result of the Chinese government absorbing the majority of the costs, as most GM developments in China are conducted by local public institutions where salaries and infrastructure costs are not factored into compliance costs. India shares a similar system, where the regulatory cost of the public sector ($134,548 for novel Bt cotton from the Central Institute for Cotton Research (CICR)) being significantly lower than the expected costs for the private sector ($1,990,000 for Bt cotton from MAHYCO). Interestingly the ICAR Bt cotton and the CIMBAA PPP both utilised the same Indian government approved biosafety test laboratories under contract (as required by regulations) but the prices charged to MNC/international PPP were many times higher than those charged to CICR as an Indian government organisation. This was a result of a formal, tiered government regulated fee structure. Pray et al. (2005) observed that the apparently relatively high cost for the private sector is contributed to by the way research project budgets are calculated in the public sector, where salary costs of principal scientists were not included and the biosafety assessments were conducted by other public research institutions which charged minimal fees. This suggests that both China and India may be promoting local public sector developments in part by minimising the costs of regulatory requirements and creating a cost barrier for foreign companies.
<table>
<thead>
<tr>
<th>Regulatory requirements</th>
<th>Bt (Cry1Ab) Brinjal, India (IARI) (Pray et al., 2005)</th>
<th>China (Public sector) (Pray et al., 2006)</th>
<th>Bt cotton India, (Public sector) (pers. comm.)</th>
<th>Bt (Cry1Ac) Cotton, India (MAHYCO) (Pray et al., 2006)</th>
<th>Hybrid mustard India (Bayer) (Pray et al., 2005)</th>
<th>Bt (Cry1C+Cry1B) Cabbage/cauliflower, India (Public-Private Partnership) (pers. comm.)</th>
<th>US (Private sector) (Kalaitzandonakes et al., 2007)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Food Safety Studies</td>
<td>33,000</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Molecular Characterisation</td>
<td>1,500,000.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>300,000 – 1,200,000</td>
<td></td>
</tr>
<tr>
<td>Gene Product Production</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>160,000 – 1,700,000</td>
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</tr>
<tr>
<td>Gene Product Characterisation</td>
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<td></td>
<td></td>
<td>121,690</td>
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</tr>
<tr>
<td>Allergenicity (Brown Norway rat)</td>
<td>22,038 150,000</td>
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<td>410,265</td>
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<td>Event Characterisation</td>
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<td>Plant phenotypic studies</td>
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<td>42,888</td>
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<tr>
<td>Animal studies</td>
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<td></td>
<td>1,500,000.00</td>
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<td></td>
<td>300,000 – 840,000</td>
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<tr>
<td>Crop Production</td>
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<tr>
<td>Palatability/range finding studies</td>
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<td></td>
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<td>293,353</td>
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</tr>
<tr>
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<td></td>
<td></td>
<td>69,571</td>
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</tr>
<tr>
<td>Fish studies</td>
<td>6,624 5,000</td>
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<td>270,571</td>
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<tr>
<td>90 days rat</td>
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<td>250,000 – 300,000</td>
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<tr>
<td>90 days on chicken</td>
<td>3,312 5,000</td>
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<td>90 days in goats</td>
<td>9,937 55,000</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>90 days on cows</td>
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<td></td>
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<td>163,440</td>
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<tr>
<td>Water buffalo</td>
<td>10,000 33,000</td>
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<td>Compositional Assessment</td>
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<td>271,604</td>
<td>750,000 – 1,500,000</td>
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<td>14,353 1,000,000.00</td>
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<td>130,000 – 460,000</td>
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<td>Persistence, invasiveness and dormancy</td>
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<td></td>
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<td>122,936</td>
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<td>Non-target study</td>
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<td>100,000 – 600,000</td>
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<tr>
<td>Soil fate of protein</td>
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<td>50,747</td>
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<td>China (Public sector) (Pray et al., 2006)</td>
<td>Bt cotton India, (Public sector) (pers. comm.)</td>
<td>Bt (Cry1Ac) Cotton, India (MAHYCO) (Pray et al., 2006)</td>
<td>Hybrid mustard India (Bayer) (Pray et al., 2005)</td>
<td>Bt (Cry1c+Cry18) Cabbage/cauliflower, India (Public-Private Partnership) (pers. comm.)</td>
<td>US (Private sector) (Kalaitzandonakes et al., 2007)</td>
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<tr>
<td>Resistance management</td>
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<tr>
<td>Confined field trial</td>
<td>1.162</td>
<td>3.864</td>
<td>40,000</td>
<td>9,000</td>
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<tr>
<td>Multi-location field trial</td>
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<td>6,780</td>
<td>9,937</td>
<td>255,000</td>
<td>57,180</td>
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<td>Large Scale field trial</td>
<td>5,688</td>
<td>9,937</td>
<td>300,000</td>
<td>17,000</td>
<td>88,625</td>
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<td><strong>International regulatory requirements</strong></td>
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<td>600,000 – 4,500,000</td>
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<tr>
<td>Registration for dossier submission</td>
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<td></td>
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<td></td>
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<td>264,773</td>
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<tr>
<td>Biosafety approval globally</td>
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<td></td>
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<td>224,908</td>
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<td>Legal support for regulatory dossiers</td>
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<td>140,478</td>
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<td>Farmer and consumer socio-economic studies</td>
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<td>15,000 – 82,910</td>
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<td>Pro-poor economic study of dissemination options</td>
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<td></td>
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<td></td>
<td>30,000 – 142,979</td>
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<tr>
<td>Salary and expenses</td>
<td>1,095,000</td>
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<td></td>
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<td></td>
</tr>
<tr>
<td><strong>Total expected cost (US dollars)</strong></td>
<td>53,556</td>
<td>61,050</td>
<td>134,548</td>
<td>1,990,000</td>
<td>4,603,000</td>
<td>5,338,540</td>
<td>3,180,000 – 12,550,000</td>
</tr>
</tbody>
</table>

**Table 5.7** Costs of regulatory compliance in US dollars. Constructed based on the data from CIMBAA project manager for Bt cabbage and cauliflower (based on 2009 exchange rate), Pray et al. (2005) for Bt Brinjal and Hybrid Mustard, Pray et al. (2006) for Bt cotton from MAHYCO-Monsanto and China, and data from the BN Bt cotton project in India (based on the 2006 exchange rate).
5.3.8. Uncertainty due to political influences

Despite individual countries establishing national regulatory frameworks which are intended to ensure the safety of GM crops, decisions on GM crop cultivation are driven by political agendas, impacting directly on the regulatory approval systems and/or causing conflicts between national and states positions. As a result, political influence frequently reduces the potential value of GM crops either by limiting the areas of cultivation or preventing the commercial approval of GM crops.

5.3.8.1 Australia

Under the federal Gene Technology Act 2000, the OGTR is responsible for authorising the release of GMOs in Australia. However, states have implemented legislation based on ‘marketing concerns’ to block the commercial release of GM crops, creating an unclear path to market. Despite the OGTR having approved two herbicide tolerant canola events for commercial release in 2003, governments of canola-growing states decided to impose moratoria on all GM canola cultivation. For example, the New South Wale Government enacted the Gene Technology Act 2003 and ordered two moratoria under the act which have prevented the commercial cultivation of GM canola. Similarly, the Victorian, South and West Australian, and Tasmanian governments have all imposed moratoria on the cultivation of GM canola at various times. The arguments for the moratorium orders were to ensure and maintain access for Australian crops in both international and domestic markets. In addition, the moratoria were intended to allow farmers of non-GM varieties to capture premiums in the international market and to minimise the costs of segregation in post-harvest processing and handling for canola farmers. The South Australia state government introduced the moratorium in 2008 and banned all transport of GM crops through the state, stating that road transport of GM materials could potentially contaminate local farms. Consequently, the movement of GM canola in Australia has had to avoid South Australia.

It has been suggested that the decision on the moratorium of GM canola is politically influenced by special interest groups (Dowie, 2004; Cocklin, 2008). At the time of the debate, the adoption of GM canola in Victoria was strongly supported by the Victorian Farmers Federation, private seed companies (i.e. Monsanto and Bayer Crop Science) and industry support groups, while the opponents, the Organic Federation of Australia, Greenpeace etc., expressed serious concerns about the potential risks associated with the adoption of GM
canola. However, the decision to ban GM canola for four years from 2004 in Victoria was a result of lobbying from two export-oriented dairy companies, which expressed concerns about the prospect of contamination (Dowie, 2004). The dairy industry had political influence on the decision regarding GM canola moratoria, taking into consideration that the industry is the third largest rural industry in Australia, with 68% of the dairy farms located in Victoria, representing an export value of $2.3 billion (DEDJTR, 2014). The states of New South Wales and Victoria lifted the moratorium in 2008, and Western Australia approved the cultivation of GM canola in selected growing regions in 2010 and has now lifted all bans, but active debates and lobbying continue.

5.3.8.2 China

China presents a unique case. Despite the national interest in fostering the GM industry and the establishment of a regulatory framework which has already approved many Bt cotton varieties, the political stance on foreign entities greatly limits the use of GM crops. In addition to securing a biosafety certificate from the MOA for the cultivation of GM crop, under China’s seed law all plant varieties must be registered at either provincial or national level before commercial production. In general, the use of GM crops for cultivation is approved on a province by province basis, involving field trials, some of which duplicate the results generated for the national review. Not all varieties can be registered at the national level. The provincial agriculture committee, under the MOA, decides whether varieties can undergo the national registration process, which allows varieties to be planted in any province. Bt cotton in China was introduced by Monsanto through a partnership with JiDai, a local seed company in Hebei. As discussed in Section 3.2.4, Monsanto’s Bt cotton was limited by its licence to Hubei, Anhui and Shandong without access to local germplasm. In contrast, when CAAS Bt cotton was released in 1997, it was allowed for cultivation in Anhui, Shanxi, Shandong, and Hubei provinces using locally adapted varieties, while Monsanto’s Bt cotton remained restricted to germplasm from outside China (and so not locally adapted). By 2004, CAAS’s Bt cotton expanded to Henan, Liaoning, Jiangsu, Xinjiang, Shaanxi, Jiangxi, Hunan, Sichuan and Zhejiang, a total of 13 provinces, essentially all the regions where cotton is cultivated (Wang et al., 2015). Due to such restrictions from the Ministry of Agriculture, Monsanto’s share of Bt cotton rapidly declined. It was reported that in 1998, Monsanto’s share of Bt cotton stood at 72% but it steadily declined to 7% in 2006 (Fok & Xu, 2011).
In recent times, Zhangye City in Gansu Province issued a ban on GM crops, including cultivation, selling and the use of any GM materials. An official document was released in October, 2013 stating that no organisations or companies are allowed to use GM crops within the city. However, this is in conflict with the national regulations established by the MOA, which assert that once a GM crop is approved and registered nationally, users are allowed to cultivate the materials in any provinces.

5.3.8.3 India

A major political influence brought to a halt the functioning of the Indian GM regulatory system; the moratorium imposed by the Minister of Environment and Forests on Bt Brinjal in 2010. In early 2009, GEAC concluded that Bt Brinjal was safe for environmental release and recommended it to the MOEF for approval. Upon receiving the recommendation, the Minister conducted public consultations across India and decided to impose a moratorium on the commercialisation of Bt Brinjal. According to the Rule of 1989, GEAC is the statutory committee for approval of GM crops for environmental release and the approval of the Minister of Environment should not have been necessary;

‘This committee shall function as a body under the Department of Environment, Forest and Wildlife for approval of activities involving large scale use of hazardous microorganisms and recombinants in research and industrial production from the environmental angle. The Committee shall also be responsible for approval of proposals relating to release of genetically engineered organisms and products into the environment including experimental field trials.’ (Environment Protection Act, 1989)

Later, a notification was issued by MOEF which changed the name of the Genetic Engineering ‘Approval’ Committee to Genetic Engineering ‘Appraisal’ Committee (Gazette of India, 2010). With the change of name, the mandate for GEAC in the regulatory system became uncertain and the Indian GM regulatory system ceased to function. In addition, MOEF now requires a ‘no objection certificate’ (NOC) from state governments for developers to conduct field trials within each state. This has empowered the state governments in deciding whether to adopt GM crops and has resulted in a division amongst the states which further increases the uncertainties in the regulatory system. Only Punjab, Haryana, Gujarat and Andhra Pradesh have issued NOCs for GM field trials (Singh, 2014).
The Biotechnology Regulatory Authority of India (BRAI) bill prepared by DBT was introduced in 2008, to replace the current regulatory system for biotechnological innovations. According to the BRAI bill, the purpose of forwarding this bill was

‘to promote the safe use of modern biotechnology by enhancing the effectiveness and efficiency of regulatory procedures and provide for establishment of the Biotechnology Regulatory Authority of India to regulate the research, transport, import, manufacture and use of organisms and products of modern biotechnology and for matters connected therewith or incidental thereto’ (BRAI, 2013)

BRAI was designed to function as autonomous authority to provide a solid legal foundation for regulating research, manufacture and transport products of biotechnological technology. It was proposed that the authority appoints a chairperson, four chair members (two full-time and two-part time) and two advisory bodies (Inter-Ministerial Governing Board and Biotech Advisory Council). The next tier consists of a risk assessment and enforcement units with three separate divisions responsible for Agriculture, Forestry and Fisheries; Human Health and Veterinary; and Industrial and Environmental applications. There have been many objections to this Bill, and one of the main points argued by those who oppose it was that the BRAI Act has an overriding effect on the State-level Act (outlined in Clause 81 of the BRAI bill) (Greenpeace, 2012)

‘Clause 81. — This clause lays down the provisions for overriding effect of the proposed legislation. It provides that the provisions of the proposed legislation shall have overriding effect, notwithstanding anything inconsistent therewith contained, in any other law for the time being in force or in any instrument having effect by virtue of any law other than the proposed legislation.’ (BRAI, 2013)

Clause 81 within the BRAI bill essentially empowers the BRAI Act over the constitutional power of state governments. But, according to the Constitution of India, agriculture is a subject that is governed by state governments. This created a conflict between union and state governments over the subject of GM crops.

‘14- Agriculture, including agricultural education and research, protection against pests and prevention of plant diseases’ (List II-State List, Seventh Schedule (Article 246), The Constitution of India.)
The BRAI Act attempts to unify the regulatory framework within the nation by aligning the union and state policies for GM crops. Many state governments have not allowed GM trials to take place within their states and have been heavily opposing the Bill, as they believe agriculture related matters should remain governed by individual states (The Hindu, 2010). In the meantime, although GEAC has once again been authorising field trials, there have been no new GM approvals for a new crop species since cotton was approved in 2002.

5.4 Conclusion

This chapter analyses the commercial attributes of public sector GM crop developments under regulatory field trials; examining the focus of public sector initiatives, the funding and commitment of public investors and attempts to identify the cost of generating a GM crop. The global landscape of public GM developments indicates that public funders continue to invest in GM technology for a variety of crops and traits. The fundamental reason for public R&D appears to be a focus on providing innovations which the private sector would not undertake. These niche opportunities for public involvement have different levels of importance. In developing countries, the focus of GM developments still surrounds major or staple crops with substantial economic value, providing evidence that public sector developments are still driven by the potential value of the developments. However, successful commercialisation of innovation is not purely driven by the overall economic value it provides. It requires a detailed value capturing and sharing strategy with all the stakeholders within the value chain. Yet no commercial information for public sector developments was identified in this study, despite the fact that, the public sector, in theory, should be transparent about their operations. This results in a gap in knowledge which, if filled, could have been utilised to generate commercial models for public sector developments. It makes the total pipeline cost difficult to estimate, even to the developers and funders. Consequently, most GM initiatives in the public sector run out of funding well before entering the regulatory phase.

The second section of the chapter analysed the funding attributes of public sector GM developments, by contrasting the project funding from various public investors. Many current GM projects that are moving forward are supported by philanthropic foundations and aid agencies. These foundations provide the financial commitment needed to take account of the long development pipeline. In contrast, although enormous capital has been
invested by governments around the world, much of the governmental public sector funding is thinly distributed and too short-term to be realistically expected to lead to product commercialisation. Examining the size of government funding allocated to projects revealed that individual project funding is frequently only sufficient to cover the basic salary of research staff and discovery phase experimental costs. The short duration of government grant funding creates further financial challenges for public developers. This provides a strong indication that current government research funding systems are not reflecting the finance needed for commercial developments. Lacking long-term financial commitments from government investors, public GM developers will need to seek additional financial support from other sources.

The last section of the chapter aimed at identifying the costs of development, more specifically the costs of complying with regulatory requirements. The cost the public sector has encountered, at least in China and India, is much less than the value reported by industry. It is possible that the lesser costs observed are partly due to the lack of any attempt to seek global regulatory approval and concealed government and institutional subsidies. In developing countries which promote public sector GM developments, much of the costs are absorbed by the government and not reported publicly. However, the development of GM crops is often affected by political influence on the regulatory approval system, which has significantly delayed public access to the benefits of GM crops. The uncertainty as to the integrity of the approval process, generated by political interference, has slowed public sector moves towards crop approvals.

Current gene editing technology allows the removal of selectable marker from the gene construct to deliver marker-free GM crops e.g. CRISPR, zinc finger nuclease etc. However, the potential impact of gene editing technology on the cost structure of regulatory compliance would be minimal. This is a result of the fact that the majority of GM crop developments have relied on using selectable markers which have been approved by regulatory authorities worldwide for commercialisation. In most cases, no additional biosafety data needs to be collected unless GM crop developers use a novel marker gene which has not been assessed by regulatory authorities. For example, OGTR has conducted risk assessments of antibiotic resistance selectable marker genes and reporter genes used in GM crops and identified that these markers do not pose a risk to human health or to the environment.
Information gathered for this chapter is limited and most information available revolves around India. Attempts have been made to find the cost figures for other public GM developments around the world. However, no detailed published commercial information was identified, resulting in the absence of crucial information which could greatly benefit future public GM developers.

Overall, based on Hall and Martin’s framework, the commercial uncertainty encountered by the public sector is added to by the lack of financial information on existing public GM developments and on the data for generating regulatory dossiers. If information was available it could be utilised to inform public investors about the funding requirements and likely time lines required and used to develop strategic plans to effectively capture the value of GM crops. Without the support of information from existing public sector GM projects to reflect back to public investors, most public sector GM developments will be confronted by uncertainties of funding, time and cost and are ultimately unlikely to be successful in producing a commercial product, even if the uncertainties of politically influenced approvals processes can be resolved.

**Key obstacles identified in this chapter:**

- Substantial public investment is still being made in the public sector for the development of GM crops without a true understanding of the processes, time and costs needed to comply with the global regulatory requirements.

- The potential liability due to asynchronous approval and the uncertainty created by political influences, particularly in developing countries, have significantly reduced the likelihood of capture of the value of public developments which generally target minor crops with limited economic benefits.
Chapter 6

Access of the public sector to enabling intellectual property

6.1 Introduction

A patent is an exclusive right granted by governments to inventors, to prevent others from manufacturing, using or selling the invention without permission. Individual countries have developed intellectual property systems based on two distinctive patent regimes. Most developed countries have followed the product patent regime which provides a stronger intellectual property protection. The process patent system, providing a weaker protection system, is favoured by developing countries. The rights in process patents are for the manufacturing process and not for the product itself, creating an opportunity for others to produce the same product through different processes without infringement. This weaker patent regime has contributed to the widespread growth of the generic pharmaceutical industry in developing countries, providing medicines at a very low cost. However, under the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, members of the World Trade Organisation (WTO) have enforced product patents for agrochemical and pharmaceutical products (Chowdhury et al., 2014). Furthermore, gene sequences isolated from their natural state and with utility demonstrated, are product patentable (Worrall, 2001). This has created an environment where accessing technologies, including gene sequences, requires the authorisation of patent holders.

The negotiation process, time, transaction costs, and the possibility of patent holders refusing to license proprietary intellectual property, creates implications for public agricultural research (Lei et al., 2009). The ‘tragedy of the anti-commons’ describes the current situation where exclusivity, created by intellectual property systems and multiple ownership of technology, leads to underuse of resources and socially unfavourable
outcomes. This has been observed in biomedical research, where organisations constantly compete for patent rights and multiple owners each have a right to exclude others from accessing the technology (Heller, 1998). Research conducted more than 10 years ago (Graff et al., 2003), demonstrated that the majority of agricultural biotechnological patents were held by the private sector, with the public sector accounting for only a quarter of the total. However, in recent years, public research organisations have become more aware of the implications of intellectual property for research and have gradually increased active patenting of their innovations (Barham et al., 2002; Heisey et al., 2005; Chen & Guan, 2011).

The first section of this chapter uses the Caterpillar and Aphid Resistance in Brassicas (CARiB) project, a public GM crop initiative, as a platform to illustrate the process of identifying relevant patents required for commercialisation (i.e. clarifying the relevant patent landscape). This is a necessary step for R&D projects (public or private) before licence negotiations between developers and patent holders which should eventually lead to the developer having freedom to operate (FTO). Appreciating the difficulties and potential costs of obtaining licences, many projects such as CARiB use patent landscape analysis to design construct structures that use alternative enabling technologies which were either not patented or for which the patent has expired, attempting to minimise the need to seek licences. Failure to at least be clear on the requirements in different regulatory areas round the world on the need for relevant licences for research as well as for commercialisation has led to many (probably most) public sector GM projects being in the end uncommercialisable.

Certain traits are well and clearly known to be proprietary to particular companies or organisations, but the much larger suite of patents relating to enabling technologies (see below) is much less well understood in the public sector. Without legal access to these (not only for commercialisation but also for the research leading to commercialisation in many jurisdictions), many projects develop interesting and functional modified plants but have no way to take the innovation further. To gain a fuller understanding of these issues Section 6.2 describes in detail the intellectual property considerations surrounding the CARiB collaborative public sector GM crop project between Australia and India, which was led by the University of Melbourne and for which I provided the intellectual property strategy advice based on a patent landscape analysis undertaken by a consultant from the Public Intellectual Property Resource for Agriculture (PIPRA) at the University of California, Davis.

Patent analyses can be used as an output measurement for R&D and are useful indicators of innovation, providing an overview and ownership landscape for current R&D technologies.
and highlighting areas of active research (Griliches, 1990). Against this background, Section 6.3 contrasts innovations which have led to proprietary intellectual property in agricultural biotechnology held in the public and private sectors. More specifically this section examines agricultural biotechnological patents to assess i) the concentration of relevant trait and enabling patents in public and private hands, ii) the ownership of relevant intellectual property for GM crop developments and iii) the role of third party IP in the freedom of public bodies to commercialise GM developments.

6.2 The Caterpillar and Aphid Resistance in Brassica project (CARiB)

After the public-private partnership, the *Collaboration on Insect Management for Brassicas in Asia and Africa* (CIMBAA) ended in 2010 (see Chapter 8), a fully public sector project, CARiB, continued and extended the work from 2012, with the aim of providing pre-breeding plant material to the seed sector which would control caterpillar and aphid pests of cabbage and cauliflower in India and of canola in Australia. The project was funded under the Australia-India Strategic Research Fund initiative of the Indian and Australian governments, with a number of partners led from the University of Melbourne (in Australia) and from the International Centre for Genetic Engineering and Biotechnology (ICGEB) (in India). The main strategy was to develop dual-gene Bt cabbage and cauliflower lines for India for caterpillar control and to utilise RNA interference (RNAi) as a method of aphid control when stacked with the Bt, for cabbage and cauliflower in India and for canola in Australia. As the efficacy of the particular Bt combination to be used was not in doubt but considerable preliminary work needed to be carried out before an aphicidal RNAi sequence could be inserted in plants, the project carried out the Bt insertions and plant selection first with the intention of later stacking the RNAi sequence for aphid control directly adjacent to the Bt sequence, using a somewhat novel targeted gene insertion system. All these components and technologies had potential third party intellectual property implications. These are explored here as a not atypical example of the intellectual property minefield requiring to be negotiated by public sector projects.
6.2.1. Bt Cry1B/1C for caterpillar control

Plant transformation mediated by Agrobacterium tumefaciens has become the most commonly used method to deliver novel traits into targeted plants. The transformation process consists of a number of key steps:

a) the creation of a functional construct including the gene of interest and transcriptional regulatory elements
b) insertion of the construct into a T-DNA backbone and
c) introduction of the T-DNA into Agrobacterium to allow transfer into the plant chromosome.

TDNA backbone:
The pPIPRA560 plasmid from PIPRA at the University of California-Davis was selected as the T-DNA backbone for cloning all the constructs designed by CARiB precisely because it was available under royalty-free terms for humanitarian use in developing countries and under modest fee-based terms for developed countries. The license agreement for the commercial use of pPIPRA560 was obtained from the University of California-Davis.

Bt sequence:
The Bt Cry1B/1C combination was originally developed and shown to be effective under the CIMBAA project (2002-2010) and the patents were intended to be held by the public sector at the point of commercialisation (never realised). The project closed just months before the granting of the patent which the project had sought and it remained in the ownership of the private partner, Bayer Crop Science. To avoid infringing that patent, the Cry1B/1C sequence was redesigned for CARiB (although this redesign also addressed some minor issues which had arisen during the previous CIMBAA project). Although the functional Bt protein molecules were the same as those used in the CIMBAA project, the DNA sequences were changed sufficiently for the sequence to fall outside the ambit of the CIMBAA patent. A ‘Bt-only’ construct was designed to demonstrate the efficacy of the new Cry1B/1C sequence in cabbage and cauliflower (Figure 6.1) and for use without the RNAi sequence as an additional product in Indian cabbage and cauliflower.

Regulatory elements:
A number of gene regulatory elements were included in the construct to control the expression of the Bt Cry1B/1C. The 5’Untranslated Region (UTR) of the tapetum specific E1 gene (GE1) of Oryza sativa (rice) acted as a leader sequence with the expression of Cry1B
and Cry1C operating under the control of subterranean clover stunt virus (SCSV) S4S4 and SCSV S7S7 promoters respectively. The 3’UTR of the pea Rubisco E9 and the 3’ UTR sequence from the Flaveria bidentis malic enzyme (ME3) were used as transcription terminators. To prevent bacterial expression of Cry1C, a potato intron sequence was inserted within the Cry1C sequence.

**Selection marker:**
The neomycin phosphotransferase II (NptII) gene is a component of the pPIPRA560 plasmid obtained under the UC Davis license agreement. It is widely used as a selectable marker for plant transformation, conferring resistance to the antibiotics kanamycin and neomycin. The constitutive expression of NptII was designed to be regulated by the figwort mosaic virus M3 strain (FMV34S) promoter and the 3’ UTR of mannopine synthase (MAS). However, the presence of selectable markers in commercial GM plants has raised public concern. A heavy burden is placed on GM crop developers by the costs of additional biosafety studies for the selection marker sequences remaining in products, needed in order to comply with strict regulatory requirements. The CARiB strategy was to generate marker-free GM plants by employing the site-specific Cre-lox recombination system for the removal of selectable markers. The NptII gene and regulatory elements were placed between two lox sites, which were recognized by the Cre recombinase allowing for the removal of the lox-flanked selectable marker. This construct was successfully transformed into Arabidopsis thaliana and its efficacy against insect pests was demonstrated. It is now being transformed into cabbage and cauliflower lines in India.

![Figure 6.1](image)

**Figure 6.1** The CARiB’ Bt only’ construct for cabbage and cauliflower for India. Source: Dr J. Golz, Department of Genetics, the University of Melbourne.

### 6.2.2. RNAi donor construct

Homologous recombination is a DNA metabolic process that functions in the repair of DNA double-stranded breaks in all forms of life. A system has been demonstrated which allows precise insertion or deletion of gene sequences in plants (Puchta, 2005). To stack RNAi
sequences into Bt transformed plants via homologous recombination, the CARiB project designed a staged crossing system with transformed plants containing different constructs. The RNAi donor construct was structured with gene sequences which express double-stranded RNA (dsRNA) which targets specific insect genes and inhibits transcription and translation. At the time of writing, the efficacy of RNAi for inhibition of a number of selected aphid housekeeper genes is being demonstrated. To generate the flanking sequences needed for homologous recombination, the RNAi cassette was placed between two selectable markers, VENUS (encoding for a fluorescent protein) and the Beta-glucuronidase (GUS) reporter system. Sequences for both selectable markers were designed to be partial, VENUS with 3’ end and GUS with 5’ end, with I-SceI recognition sites attached. The strategy is to excise the RNAi cassette and the selectable markers with the I-SceI meganuclease by creating double-stranded DNA (dsDNA) breaks at the recognition sites and to use the partial VENUS and GUS sequences for homologous recombination. *lox5171* and *loxP* recognition sites were included in the construct for the excision of selectable markers in the final construct (Figure 6.2).

**Figure 6.2** The CARiB RNAi donor construct for delivering RNAi into Bt transformed plants.

*Source: Dr J. Golz, Department of Genetics, the University of Melbourne.*

Selection marker:

An antibiotic resistance marker cassette was incorporated into the RNAi donor construct for selection of transformed plants. The *Bar* gene, isolated from *Streptomyces*, expresses phosphinothricin acetyl transferase which allows the use of a phosphinothricin based herbicide for selection. The constitutive expression of *Bar* is controlled under the nopaline synthase (NOS) promoter and regulated by octopine synthase (OCS).
6.2.3. Bt with ‘landing site’

The ‘Bt with landing site’ target construct was structured to carry the dual Bt cassette and a ‘landing site’ for the insertion of the RNAi donor cassette described above (Figure 6.3). The space needed for the landing site was designed by placing the selectable marker cassette (with the same design as the selectable marker cassette of the ‘Bt-only’ construct) between two I-SceI sites. The I-SceI meganuclease will cut at the recognition sites and create 5’ VENUS and 3’ GUS flanking sequences, which share sufficient length and homology with the 3’ VENUS and 5’ GUS flanking sequences from the RNAi donor for homologous recombination to occur and an insertion to result.

Figure 6.3 CARiB construct with a dual Bt gene cassette and a ‘landing site’ for homologous recombination. Source: Dr J. Golz, Department of Genetics, the University of Melbourne.

6.2.4. Constructs for recombination

Two additional constructs were designed for the expression of the I-SceI meganuclease and the Cre recombinase to be temporarily crossed in and crossed out again once gene targeting and the removal of selectable markers has been achieved. Both constructs have marker genes under the control of the cauliflower mosaic virus (CaMV) 35S promoter. The aacC1 gene encodes for gentamicin acetyltransferase which provides resistance against antibiotic gentamicin and the Bar gene provides resistance against phosphinothricin based herbicides. The parsley ubiquitin promoter (Ubi4-2) was used to drive the expression of I-SceI meganuclease and the CLAVATA3 (CLV3) promoter controls the expression of Cre recombinase (Figure 6.4).
6.2.5. The homologous recombination gene stacking process

Several crossings between transformed plants are needed to stack RNAi with the dual Bt genes and to generate marker-free GM crops. The initial cross between the RNAi donor (P1) and I-SceI meganuclease plants generates descendants which have the capability of excising the RNAi cassette through site-directed dsDNA breaks (F1A). The F1A plant carrying both Bar and aacC1 selectable marker genes confers resistance to gentamicin and phosphinocitrin based herbicides and are used for selection. Similarly, a cross between the ‘Bt with landing site’ (P2) and I-SceI meganuclease plants produces descendants that are capable of excising the selectable marker cassette and ‘opening-up’ the landing site for insertion (F1A’). The selection of F1A’ is based on antibiotic resistance against gentamicin and kanamycin (Figure 6.5).
Figure 6.5 Crossing system designed to stack RNAi with dual Bt genes via homologous recombination and to generate maker-free plants using site-specific Cre-lox recombination system.
Due to the shared homology of flanking sequences of VENUS and GUS induced by the I-Scel meganuclease, crossing F1A and F1A’ allows homologous recombination to occur and leads to the insertion of the RNAi cassette, generating descendants with full RNAi and dual Bt gene sequences (F2), with active VENUS and GUS marker genes for visual and quantitative selections. The constitutive expression of VENUS is regulated by CAMV35S promoter and the GUS reporter system is driven by the ribosomal protein 5A (RPS5A) promoter (Figure 6.5).

As outlined in the preceding sections, the constructs were designed with different lox recognition sites to enable the Cre-lox recombination system to be used for the removal of the selectable marker cassettes. Upon recombination, the VENUS expression cassette and the GUS reporter system are flanked by two lox5171 and loxP sites respectively. Crossing F2 plants with a Cre recombinase line induces cleavage on the lox sites and removes the selectable markers, creating marker-free GM plants (Figure 6.5).

These constructs were designed to require as little 3rd party intellectual property as possible, with the co-operation of Dr Cecilia Chi-ham, a patent attorney at PIPRA organisation at the University of California- Davis, who subsequently prepared an intellectual property portfolio highlighting enabling and trait technologies for which research and commercialisation licenses might be required for FTO (Table 6.1). Although a particular piece of development work may be carried out in, say, Australia, if it is to be commercialised outside the country in which it was developed (and even if products eventually arising are to be exported -for example pickled cabbage ex India) then the intellectual property status of all sequences and technologies needs to be examined and clarified in all of the relevant intellectual property jurisdictions. This is not as simple as it may sound, as not only do many countries and regions of the world not have clear intellectual property policies on these issues, most do not have publically searchable intellectual property data bases, and the information in those that do is not only frequently incomplete, but will not show patent applications under consideration but not yet granted (a process which can take years). Consequently one can only provide at best a partial landscape analysis for some regions. Table 6.1 only covers patents in India Australia and the US, as the final products need the legal FTO in India and Australia and the examination of the US patent landscape assists the project in identifying relevant patent holders for licence negotiations.
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<td><strong>Cry1B cassette</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SCSV-5454</td>
<td>Promoter</td>
<td>Evaluate CSIRO/Bayer</td>
</tr>
<tr>
<td>Tapetum E1 Leader</td>
<td>Transcription regulation, 5'UTR</td>
<td>None</td>
</tr>
<tr>
<td>Cry1B</td>
<td>Insect resistance</td>
<td>Evaluate CSIRO/Bayer</td>
</tr>
<tr>
<td>Pea Rubisco E9</td>
<td>Promoter</td>
<td>None</td>
</tr>
<tr>
<td>Technology Inventory</td>
<td>Type of Technology</td>
<td>IPR Status by Jurisdiction</td>
</tr>
<tr>
<td>----------------------</td>
<td>--------------------</td>
<td>---------------------------</td>
</tr>
<tr>
<td>SC SV-5757</td>
<td>Promoter</td>
<td>Evaluate CSIRO/Bayer</td>
</tr>
<tr>
<td>Tapetum E1 Leader</td>
<td>Transcription regulation, 5’UTR</td>
<td>None</td>
</tr>
<tr>
<td>Cry1C</td>
<td>Insect resistance</td>
<td>Evaluate CSIRO/Bayer</td>
</tr>
<tr>
<td>Potato intron</td>
<td>Transcription regulation intron</td>
<td>None</td>
</tr>
<tr>
<td>ME3’UTR</td>
<td>Transcription regulation, 3’UTR</td>
<td>Evaluate CSIRO/Bayer</td>
</tr>
</tbody>
</table>

**RNAi construct**

<table>
<thead>
<tr>
<th>Plant selectable marker gene cassette</th>
<th>NOS</th>
<th>Promoter</th>
<th>None</th>
<th>None</th>
<th>None</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>PAT</td>
<td>Promoter</td>
<td>Evaluate Bayer</td>
<td>Expired</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td>OCS</td>
<td>Promoter</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Fluorescent marker gene cassette</th>
<th>CaMV35S</th>
<th>Promoter</th>
<th>None</th>
<th>None</th>
<th>None</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>VENUS</td>
<td>Fluorescent protein</td>
<td>Patent Pool Portfolio managed Life Technologies corporation</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>CaMV19S</td>
<td>Transcription regulation 3’UTR of VENUS 5’ end</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td>CaMV35S</td>
<td>Transcription regulation 3’UTR of VENUS 3’ end</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Scoreable marker gene cassette</th>
<th>RP55A</th>
<th>Promoter</th>
<th>None</th>
<th>None</th>
<th>None</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>GUS</td>
<td>Scoreable marker</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td>NOS</td>
<td>Transcription regulation 3’UTR of GUS 5’ end</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td>OCS</td>
<td>Transcription regulation 3’UTR of GUS 3’ end</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

Table 6.1 Intellectual property portfolio of the CARiB constructs (Modified after a report to CARiB by Dr Cecilia Chi-Ham of PIPRA, University of California- Davis)
A patent audit was conducted on the technologies listed in the portfolio to identify active patents and determine whether the scope of claims and jurisdictions had the potential to be relevant to FTO for CARiB. I undertook searches using Patent Lens, an open source patent database developed by the Centre for the Application of Molecular Biology to International Agriculture (CAMBIA). The initial search only identified EU and US patents, as free public databases do not cover patents from all jurisdictions. Country specific patent databases were accessed to identify key patents in Australia and India, but searching for Indian patents poses great practical difficulties, as the official database is notoriously difficult to navigate and is incomplete and significantly out of date. Discussions were undertaken with patent holders to establish whether license agreements were necessary, (though there are often differing opinions as to whether a particular piece of work falls under the purview of a particular patent). For example, Cellectis revealed that they do not hold relevant patents for I-Scel in the jurisdictions of interest and as such license agreements will not be required. The intellectual property audit enabled CARiB to redesign constructs and avoid unnecessary license negotiations and narrowed the number of technologies requiring license agreements down to four (Table 6.2). 18 months have been spent in perfectly amicable negotiations over these four technologies but, at the time of writing, those licenses were still not actually agreed. Persuading major international companies to focus on the licence requirements for a minor project is not always easy, nor has it been easy to persuade all the CARiB project members of the necessity of such licences or to agree to the provision of the costs required to maintain them.

As can be seen here, the construct components for which FTO needed to be clarified were mostly enabling technologies (not traits); promotors, meganuclease, recombination systems etc. The CARiB project team took great pains to reduce the number of technologies for which licences were required to an absolute minimum (The Commonwealth Scientific and Industrial Research Organisation (CSIRO) is a project partner in CARiB and access to the generic patent suite for the use of RNAi in insects is under negotiation with them).
<table>
<thead>
<tr>
<th>Technology</th>
<th>Type of technology</th>
<th>Assignee</th>
<th>Patent Number</th>
<th>Country of relevance</th>
<th>License required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cry1B/Cry1C</td>
<td>Insect resistance</td>
<td>Bayer Crop Science</td>
<td>US2010023551, AU2007228981</td>
<td>AU</td>
<td>Not required</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>IN</td>
<td>As sequence changed</td>
</tr>
<tr>
<td>UBI4-2</td>
<td>Promoter</td>
<td>BASF</td>
<td>US8030539B, US2008013451, AU2005287547</td>
<td></td>
<td>Negotiation in process</td>
</tr>
<tr>
<td>recombination</td>
<td>system</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>system</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lox1571</td>
<td>Recombination</td>
<td>Dainippon Sumitomo</td>
<td>US6465254B1, AU74145B2, EP1035208B1</td>
<td></td>
<td>Negotiation in process</td>
</tr>
<tr>
<td></td>
<td>system</td>
<td>Pharma</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 6.2 Summary of unexpired patents in India and Australia relevant to CARiB.

Despite the large number of technologies involved in developing a GM crop and the complexity in navigating through the patent landscape, achieving FTO for commercial development is not as forbidding as suggested by some GM crop developers. The outcome of this particular audit suggested that key enabling technologies for developing GM crops are largely controlled by the private sector and only good project design enabled most (but not all) of the need for licences to be avoided. However, most public research projects do not conduct patent landscape analyses and lack the skills to establish patent portfolios for identifying patents of interest. Furthermore, public projects are not generally designed with any budget for legal advice or for the continuing licence payments. The licence payments
increase significantly after the research phase, with licence terms based on the licencsee’s estimate of commercial prospects of the crop plant developed. This chapter goes on to examine the extent to which current public patent ownership allows public research organisations to conduct GM crop developments without needing to negotiate licences with other public organisations or with the private sector.

6.3 Patent landscape analysis

To assess the extent to which public sector GM crop developers have ready access to critical patents needed for the successful development and commercialisation of GM crops, this part of the study followed a patent searching strategy outlined in an Organisation for Economic Co-operation and Development (OECD) report (OECD 2011a). The methodology applied in this study consists of four fundamental steps: 1. selecting a patent database, 2. constructing relevant keywords, 3. applying International Patent Classification (IPC) codes and 4. analysing selected patents. The analysis section examines the global patent landscape of the public and private sectors, more specifically looking at the origin and distribution of the public sector patents. Further analyses were conducted to determine whether the public sector has access to key enabling technologies. Overall, the analysis section aims to identify the intellectual property obstacles for commercialising public GM developments.

Step 1: Selecting a patent database

There are many patent databases, both free and subscription based, providing access to worldwide collections of patents. For the purpose of this research, the Thomson Innovation® database (a product from Thomson Reuters®) was used to identify relevant patents. Thomson Innovation® is an extensive worldwide database which contains patents from the Patent Cooperation Treaty (PCT), the European Patent Office (EPO), the United States Patent and Trademark Office (USPTO), and with Asia-Pacific coverage including the State Intellectual Property Office (SIPO) in China. This database is specifically designed for intellectual property professionals who routinely conduct patent searches. Although it is possible to locate patents from individual national patent offices, it is time-consuming and many are difficult to navigate. An advantage of using Thomson Innovation® is the accessibility of non-English patents e.g. French, German, Japanese and Chinese. This database provides fully English translated patents from other foreign languages while free databases are often limited to patents in English. This additional feature suited the scope of
this research, as the objective is to determine the global agricultural biotechnology intellectual property positions of the public and private sectors. The Thomson Innovation Database® utilises the Derwent World Patent Index (DWPI), clustering individual patents into families based on the interpretations of intellectual property experts.

**Step 2. Developing keywords which provide broad coverage**

This study aims to identify technologies that are essential for developing GM crops. It is possible that many relevant patents would not be identified by only using keywords such as ‘genetic modification’ or ‘genetic engineering’. To ensure maximum coverage of applicable patents within the search, it was crucial to utilise relevant keywords which would reveal patents of interest. After reviewing a number of key relevant technological patents for developing transgenic plants, keywords were selected based on the frequency of appearance and relevance in the titles, abstracts, and claims. Table 6.3 has the list of keywords selected for the search strategy in order to generate a comprehensive database of relevant patents.

<table>
<thead>
<tr>
<th>Key words</th>
<th>Genetically + Modified + Engineered Improvement</th>
<th>Abiotic stress Abiotic stress</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transformation</td>
<td>Yield</td>
<td>Drought resistance</td>
</tr>
<tr>
<td>Generating</td>
<td>Enhanced</td>
<td>Drought resistant</td>
</tr>
<tr>
<td>Plants</td>
<td>Biofortification</td>
<td>Drought tolerance</td>
</tr>
<tr>
<td>Transgene</td>
<td>Nutrient</td>
<td>Drought tolerant</td>
</tr>
<tr>
<td>Recombinant</td>
<td>Insect resistance</td>
<td>Water efficient</td>
</tr>
<tr>
<td>Agrobacterium</td>
<td>Insect resistant</td>
<td>Salt resistance</td>
</tr>
<tr>
<td>Gene regulating</td>
<td>Insect tolerance</td>
<td>Salt resistant</td>
</tr>
<tr>
<td>Plant expression</td>
<td>Insect tolerant</td>
<td>Salt tolerance</td>
</tr>
<tr>
<td>Improved + traits + characteristics + growth Insect resistant</td>
<td>Herbicide resistant</td>
<td>Salt tolerant</td>
</tr>
<tr>
<td>Promoter</td>
<td>Herbicide resistant</td>
<td>Herbicide tolerant</td>
</tr>
<tr>
<td>Plasmid</td>
<td>Herbicide tolerance</td>
<td></td>
</tr>
</tbody>
</table>
Step 3. Using IPC codes to filter relevant patents

Following the first step of identification, the initial collection of patents needs to be organised with the corresponding International Patent Classification (IPC) codes. IPC codes were developed by the World Intellectual Property Organisation (WIPO); it is a hierarchical system for classifying individual patents into technological clusters. After reviewing the WIPO classification, the IPC codes A01H and various sub-classes of C12N 15 were identified as relevant for clustering patents of interest:

<table>
<thead>
<tr>
<th>IPC Classification</th>
<th>IPC Descriptions</th>
</tr>
</thead>
<tbody>
<tr>
<td>A01H</td>
<td>New plants or processes for obtaining them; plant reproduction by tissue culture techniques</td>
</tr>
<tr>
<td>A01H 4/00</td>
<td>Plant reproduction by tissue culture techniques</td>
</tr>
<tr>
<td>A61K 48/00</td>
<td>Use of medicinal preparations containing genetic material which is inserted into cells of the living body to treat genetic diseases, gene therapy</td>
</tr>
<tr>
<td>C12N15</td>
<td>Mutation or genetic engineering; DNA or RNA concerning genetic engineering, vectors, e.g. plasmids, or their isolation, preparation or purification</td>
</tr>
<tr>
<td>C12N15/05</td>
<td>Plant cells</td>
</tr>
<tr>
<td>C12N15/29</td>
<td>Genes encoding plant proteins</td>
</tr>
<tr>
<td>C12N15/32</td>
<td>Bacillus crystal proteins</td>
</tr>
<tr>
<td>C12N15/33</td>
<td>Genes encoding viral proteins</td>
</tr>
</tbody>
</table>

Table 6.4 A detailed description of relevant IPC codes for refining patents of interest.

**Final search parameter:**

The final search parameter string, generated based on Steps 2 and 3 is listed below:

\[
\text{SSTO=\{(Plant) AND CL=(Genetic* OR Transgene OR Recombinant OR Yield OR Drought OR Stress OR insect OR Transformation OR Promoter OR Plasmid OR Heat OR Biofortification OR Generating OR Expression OR Nutrient OR Improve OR Salt OR Toleran* OR Resistan* OR Plant) AND IC=((A01H) OR (C12N001500)) NOT IC=((C12N000500)) AND DP>=(19950101) NOT TI=(Cultivar OR Hybrid OR CV* OR Inbred OR Variet* OR Line* OR Name*) NOT PN=(USPP*)\}
\]
The time frame for this study was set between 1996 and 2015, considering that a standard patent term is usually twenty years from the initial application (it varies across jurisdictions), as the scope of this analysis is examining technologies with active patents. Therefore, any patent families that were granted before 1996 were excluded from the dataset. In addition to the limitation of time-frame, plant variety patents were also removed from the dataset. Under the US patent system, plants derived from GM technologies can be patented and registered with USPTO. This research focuses on technologies which have active patents and are crucial for developing GM crops, rather than particular GM varieties. The final dataset after the various filtering processes, resulted in 76,145 individual patents from 19,608 patent families globally.

Although the combination of keywords and IPC codes provides a solid searching strategy for identifying patents of interest, there are some limitations to this methodology. It is possible that patents that are not related to this study are included in the data set (false positives). Manual screening of the dataset removed the false positives. In addition, it is possible that patents of interest are not identified due to the restriction of search parameters used (false negatives).

6.4 Analysis and discussion

6.4.1. Increasing growth of agricultural biotechnology patents

To assess the current status of agricultural biotechnological innovations and the relative positions of the public and private sectors, an annual count of patent families granted by patent offices in different jurisdictions was compiled, (e.g. USPTO, EPO, SIPO, PCT and the Australian Patent Office (AusPat)). The analysis of intellectual property capacity was measured by the number of patent families rather than individual patents, minimising replicate data, since individual inventions may have been granted patents in multiple jurisdictions.

53 Patent families are created by patent databases and can greatly vary from different patent databases. The Thomson Innovation database uses the Derwent World Patents Index (DWPI) by drawing patents involving the same invention into a family around the first published incidence of the invention.
For nearly 20 years following the commercial introduction of GM crops in 1996, innovation in agricultural biotechnology has continued to grow (Figure 6.6). The initial growth period occurred between 1996 and 2000, to a point where 770 patents families were granted in 2000. Latterly, the number of patents families has escalated dramatically by over three-fold over the five years to 2015. By 2014, there were more than 2,700 patent families granted globally. With the advances in genomics and sequencing technologies, the costs and time required to identify new traits have significantly reduced. It is evident that GM technology has not reached maturity and is likely to further expand.

Not all patent families within the dataset have global intellectual property protection, and many of the patent families are limited to protection within certain countries, due to the jurisdictions of interest of the patent holder, the cost of maintaining active patents and other legal considerations. To assess patenting activities in different jurisdictions, country-specific profiles were generated by locating country specific patents within each individual patent family (Figure 6.7). All jurisdictions including global PCT applications indicated an increasing trend in patent families granted annually. However, the rate of increase varied across different jurisdictions. China has the most significant rate of increase, and in 2014 SIPO granted more than 1,500 patents in this area. Another key finding is that the number of patent outputs outside the US and China is only increasing at a marginal rate with minor
fluctuations. The US and China are certainly important jurisdictions for transgenic developments. The relative drop in patent family approval observed in 2015 was due to the time when the research was conducted, when many 2015 patents had not yet been published.

**Figure 6.7** Annual trends in agricultural biotechnology patents granted from 1996-2015 in different jurisdictions. Data for 2015 is incomplete.
6.4.2. Ownership of patented technologies

In order to assess the ownership of technologies, individual patent families were categorised based on the assignee/s of the patents. General information about the ownership can be easily located within the patents. The following categories have been applied in categorising the patent families; multi-national corporations (MNC), other private firms, independent inventors, universities and public research organisations. In cases where there are multiple assignees (including both public and private organisations), the classification of jointly assigned patent families is based on the organisational type of the first assignee.

<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Private sector</td>
<td></td>
</tr>
<tr>
<td>MNC</td>
<td>4,966</td>
</tr>
<tr>
<td>Other private organisations</td>
<td>4,926</td>
</tr>
<tr>
<td>Independent inventors</td>
<td>1,034</td>
</tr>
<tr>
<td>Subtotal</td>
<td>10,926</td>
</tr>
<tr>
<td>Public Sector</td>
<td></td>
</tr>
<tr>
<td>Universities</td>
<td>4,314</td>
</tr>
<tr>
<td>Public research organisations</td>
<td>4,236</td>
</tr>
<tr>
<td>Subtotal</td>
<td>8,550</td>
</tr>
<tr>
<td>Undetermined</td>
<td>132</td>
</tr>
<tr>
<td>Total</td>
<td>19,608</td>
</tr>
</tbody>
</table>

Table 6.5. Number of patent families assigned to different categories of organisations.

On the basis of the parameters and the data obtained, universities around the world contributed 22.0% of approved patents and public research organisations 21.6% with a combined total of 43.6% between 1996 and 2015 (Table 6.5). The public sector has a strong contribution in agricultural biotechnology. Essentially for every two patents granted one is assigned to a public institution. The MNC intellectual property portfolio, however, represents a significant proportion of the global patent outputs (25.2%), considering there are only six entities, DuPont, Monsanto, Bayer, Syngenta, DowAgro Sciences and BASF. The remainder of the patents (25.1%) are scattered amongst other private commercial firms and
not-for-profit private organisations, with companies such as Ceres Inc. (0.74%) and Mendel Biotechnology Inc. (0.44%).

<table>
<thead>
<tr>
<th>Top 10 public sector assignees</th>
<th>Number of patents</th>
<th>% of all patents</th>
</tr>
</thead>
<tbody>
<tr>
<td>University of California, USA</td>
<td>234</td>
<td>1.2%</td>
</tr>
<tr>
<td>The National Institute of Agrobiological Sciences, Japan</td>
<td>211</td>
<td>1.1%</td>
</tr>
<tr>
<td>Institute of Crop Science CAAS, China</td>
<td>191</td>
<td>1.0%</td>
</tr>
<tr>
<td>Institutes of Genetics and Developmental Biology CAAS, China</td>
<td>183</td>
<td>0.9%</td>
</tr>
<tr>
<td>China Agricultural University, China</td>
<td>175</td>
<td>0.9%</td>
</tr>
<tr>
<td>CSIRO, Australia</td>
<td>130</td>
<td>0.7%</td>
</tr>
<tr>
<td>Huazhong Agricultural University, China</td>
<td>116</td>
<td>0.6%</td>
</tr>
<tr>
<td>University of Zhejiang, China</td>
<td>99</td>
<td>0.5%</td>
</tr>
<tr>
<td>Nanjing Agricultural University, China</td>
<td>98</td>
<td>0.5%</td>
</tr>
<tr>
<td>Rural Development Administration, Korea</td>
<td>97</td>
<td>0.5%</td>
</tr>
<tr>
<td>USDA, USA</td>
<td>90</td>
<td>0.5%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>1,624</strong></td>
<td><strong>8.4%</strong></td>
</tr>
</tbody>
</table>

| Major AgBiotech firms                                                                          |                   |                 |
| Du Pont Pioneer                                                                               | 1,497             | 7.6%            |
| Monsanto                                                                                    | 968               | 4.9%            |
| BASF                                                                                        | 847               | 4.3%            |
| Syngenta                                                                                    | 734               | 3.7%            |
| Bayer                                                                                       | 583               | 3.0%            |
| Dow Agro Sciences                                                                            | 315               | 1.6%            |
| **Total**                                                                                    | **4,944**         | **25.1%**       |

*Table 6.6* Patents assigned to the top public sector assignees within the patent dataset compared with those assigned to the MNCs.
The distribution of intellectual property ownership between top assignees from the public sector and the six largest agricultural biotechnology companies is listed in Table 6.6. Du Pont and Monsanto hold the largest share of corporate intellectual property portfolios. By contrast, among public organisations, the University of California in the USA, the top public sector organisation, holds only 1.2% of relevant global patent families. The remaining public research organisations each have less than 0.5% of global AgBiotech patents. It appears that public AgBiotech patent ownership is highly fragmented across hundreds of public institutions.

However, the data does not tell us whether these organisations retained the intellectual property rights to these patents, nor does it give any indication of whether the rights have been transferred to other organisations through various licensing agreements. Licensing arrangements are relatively common in many industries, and public organisations often adopt licensing strategies to generate a return on their investments. In most cases public organisations licensed their developments under either exclusive terms (complete intellectual property rights for the use) or partial exclusive terms (limiting the intellectual property rights for example by geographical region or types of crops) or on a non-exclusive basis (sharing technologies among many organisations). These licensing transactions are confidential in nature. Therefore, it is difficult to assess whether the rights under patents have been transferred to other organisations. Knowing that the private sector licenses many key technologies from the public sector, it is safe to assume that the status of private sector utilisation of public sector intellectual property is not captured in the preceding analysis.

6.4.3. Public-Private research collaborations

Many researchers have supported the idea of public-private partnership for developments in agricultural biotechnology, combining research expertise from both the public and the private sectors (Chrispeels, 2000; Lewis et al., 2000; Krishna & Qaim, 2007). Jointly assigned patents generally represent technologies which have resulted from collaborations between different organisations. It is possible to indicate the level and type of collaborations, by examining jointly assigned patents. All the jointly assigned patent families within the dataset were classified either as ‘private-private’, ‘public-private’ or ‘public-public’ based on the organisational type listed on the patent families.
Table 6.7 Ownership of singly and jointly assigned patent families and the status of public-private partnerships between 1996 and 2015.

Table 6.7 shows that 7.0% of the total patent families are assigned to more than one organisation. Out of all the private sector patents within the dataset, only 8.7% are jointly assigned. In contrast, 14.6% of total public sector patents are jointly assigned, perhaps demonstrating a stronger likelihood for public researchers to collaborate and form partnerships for developing new technologies, or it could be that much public research is paid for by multiple bodies including the private sector. Furthermore, out of all the jointly assigned patents involving private organisations, 74.6% are public-private partnerships and for all the joint assigned patents involving public research organisations, 59.3% are public-private partnerships. This provides strong evidence that the majority of collaborations in agricultural biotechnology are in the form of public-private partnerships and that private companies are more than willing to collaborate with public research organisations.

### 6.4.4. Increasing trend of private sector patents through acquisition

For the MNCs, in addition to their in-house R&D, a common strategy for consolidating their technological capabilities is through mergers or acquisition of smaller entities. Acquisition of small entities ensures the companies have the necessary technologies to further produce novel products, minimising restrictions from competitors. Many of these small companies are spin-offs from universities or public research organisation, offering novel technologies that provide competitive advantages. A number of important MNC acquisitions are listed in Table 6.8 For example, Syngenta acquired Devgen for its RNAi technology for pest control and hybrid rice technology (Syngenta, 2012), Bayer acquired Athenix Corp. for their insect resistance and herbicide tolerance technologies, and Monsanto purchased Alellyx for sugarcane breeding technologies (Monsanto, 2008). These acquisitions consolidate either
their existing technological capabilities or provide opportunities for expanding into different markets.

<table>
<thead>
<tr>
<th>Parent organisation</th>
<th>Acquired organisations</th>
<th>Number of patent families acquired</th>
<th>Time of acquisition</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BASF</strong></td>
<td>Verenium Corporation</td>
<td>22</td>
<td>2013</td>
<td>(BASF, 2013)</td>
</tr>
<tr>
<td></td>
<td>Sungene</td>
<td>51</td>
<td>2002</td>
<td>(Sungene, 2015)</td>
</tr>
<tr>
<td></td>
<td>CropDesign</td>
<td>144</td>
<td>2006</td>
<td>(BASF, 2006)</td>
</tr>
<tr>
<td><strong>Bayer Crop Science</strong></td>
<td>Nunhems</td>
<td>24</td>
<td>2002</td>
<td>(Nunhems, 2015)</td>
</tr>
<tr>
<td></td>
<td>Athenix Corp</td>
<td>62</td>
<td>2009</td>
<td>(Bayer Crop Science, 2015)</td>
</tr>
<tr>
<td><strong>Dow AgroSciences</strong></td>
<td>Agrigenetics</td>
<td>31</td>
<td>1998</td>
<td>(Fatka, 2007)</td>
</tr>
<tr>
<td></td>
<td>Mycogen</td>
<td>47</td>
<td>1998</td>
<td>(Fatka, 2007)</td>
</tr>
<tr>
<td><strong>DuPont Pioneer</strong></td>
<td>Danisco</td>
<td>29</td>
<td>2011</td>
<td>(DuPont, 2011)</td>
</tr>
<tr>
<td><strong>Syngenta</strong></td>
<td>Devgen</td>
<td>16</td>
<td>2012</td>
<td>(Syngenta, 2012)</td>
</tr>
<tr>
<td></td>
<td>Delta and Pine Land</td>
<td>2</td>
<td>1998</td>
<td>(Feder, 1998)</td>
</tr>
<tr>
<td></td>
<td>De Ruiter</td>
<td>3</td>
<td>2008</td>
<td>(Monsanto, 2008a)</td>
</tr>
<tr>
<td></td>
<td>Allelyx</td>
<td>6</td>
<td>2008</td>
<td>(Monsanto, 2008b)</td>
</tr>
<tr>
<td></td>
<td>Divergence inc.</td>
<td>6</td>
<td>2011</td>
<td>(Monsanto, 2011)</td>
</tr>
<tr>
<td></td>
<td>Dekalb</td>
<td>31</td>
<td>1998</td>
<td>(Feder, 1998)</td>
</tr>
<tr>
<td></td>
<td>Seminis</td>
<td>66</td>
<td>2005</td>
<td>(Monsanto, 2005a)</td>
</tr>
</tbody>
</table>

Table 6.8 Acquisitions by the top six AgBiotech corporations and the number of patent families obtained from smaller entities identified within the data.

### 6.4.5. Origin of public sector patent families

Previous sections have illustrated that there has been a significant increase in agricultural biotechnological patent outputs from the public sector. The origin of technologies developed by the public sector can be determined by the residency of priority patents. Residency of a patent is based on the country code assigned to the priority patent (US for United States of American)
America, EU for Europe, CN for China, etc.), based on this method, the origins of public sector patents are illustrated in Figure 6.8. Public sector patents predominantly originated from China (40%) and US (27%), followed by Japan with 10%, Korea with 7% and with other countries around the world holding 3% or less (India 0.4%). This patent output from China strongly reflects recent Chinese government policy and investment in agricultural biotechnology (Huang et al., 2002).


6.4.6. Technological composition of patent families

Previous sections indicate that the patent portfolios held in the public sector (Universities and public research organisations) represent a significant proportion of the global agricultural biotechnological patent families. Collectively, the public sector patent portfolio has more patents than the MNC portfolio. However, the ownership of public patents is scattered across hundreds of public institutions. It is reasonable to assume that no single public organisation has ownership of an intellectual property package sufficient to commercialise a transgenic crop globally. Essentially, all public R&D for transgenic plant developments will need some form of licensing agreement, either in the form of public-public or public-private intellectual property licences. This section of the analysis aims to
provide insights on technologies originating from the public sector, including areas of weakness. Themescape™ is a patent mapping tool based on an algorithmic function which clusters patents into ‘mountains’ based on the similarity of patents (key technical words). The distance between families, in any direction, indicates their thematic proximity, the closer the distance, the more closely related. There are no X and Y-axis implications associated with the spatial concept mapping (Trippe, 2015). Areas shown in white represent a high density of closely related patents followed by brown, green and blue in that order.

Contrasting the patent landscapes of the public and private sectors shown in Figure 6.9, it appears that MNCs are strongly focused on selected technological areas (large areas of white and brown regions). In the public sector, even though there are regions of strong public focus, there is a greater proportion of blue and green regions, indicating a more diverse range of research. To examine the different type of technologies patented by the public and private sectors, two distinct areas of platform technologies are highlighted; the regions circled in blue are enabling technologies and regions in red are trait technologies. These clusters are further explored to examine technologies that are available to the public sector (Table 6.9).

MNCs have heavily invested in trait technologies especially in sequences that translate into insecticidal proteins and confer herbicide tolerance, with a combined total of 384 patent families in this area (Table 6.9). Another key area of a strong focus is oil enhancement traits, comprising 150 patents. This finding strongly reflects the business model of these companies, focusing on first-generation traits that enhance yield or that minimise yield loss. In addition to the novel traits, MNCs have numerous patents on enabling technologies which are crucial for developing transgenic plants i.e. regulating gene expression through constitutive promoters and terminators, selectable markers for identifying transgenic plants and methods of removing selectable markers, thus minimising regulatory hurdles. Overall, Table 6.9 demonstrates that MNCs have consolidated the necessary technologies and created intellectual property packages allowing their development and commercialisation of transgenic crops, although frequently requiring company to company sharing of patent rights.
Figure 6.9 Topographically mapped patents families. Figure A indicates the focus of MNCs R&D and Figure B reflects the developments in the public sector. Areas circled in blue represent areas of enabling technologies and areas circled in red represent trait technologies. Where there is no cluster identified, patents in those areas are low in number.
<table>
<thead>
<tr>
<th>Enabling Technologies</th>
<th>MNC</th>
<th>Public</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transformation and Recombination methods (Dominated by the private sector on <em>Agrobacterium</em> transformation)</td>
<td>94</td>
<td>no cluster</td>
</tr>
<tr>
<td>Selectable Markers and Removal Methods (Dominated by the private sector on antibiotic based selectable markers and various methods for removing markers from the constructs)</td>
<td>25</td>
<td>no cluster</td>
</tr>
<tr>
<td>Promoters (Centred on constitutive promoters and tissue specific promoters)</td>
<td>240</td>
<td>172</td>
</tr>
<tr>
<td>Tissue Culture Regeneration (Dominated by public sector research with various methods for regenerating transgenic plants)</td>
<td>no cluster</td>
<td>49</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Trait Technologies</th>
<th>MNC</th>
<th>Public</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pathogen/Disease Resistance (Various viral coat proteins with a strong focus on rice)</td>
<td>105</td>
<td>418</td>
</tr>
<tr>
<td>Male Sterility (Production of hybrid seeds and prevention of self-pollination)</td>
<td>22</td>
<td>no cluster</td>
</tr>
<tr>
<td>Plant Enzymes (Various plant metabolic enzymes)</td>
<td>166</td>
<td>42</td>
</tr>
<tr>
<td>Drought &amp; Salt Tolerance (Dominated by public sector with novel traits that confer tolerance to abiotic stress)</td>
<td>40</td>
<td>362</td>
</tr>
<tr>
<td>Herbicide Resistance (A trait heavily dominated by MNC with many patents covering glyphosate and other herbicide tolerant genes)</td>
<td>186</td>
<td>15</td>
</tr>
<tr>
<td>Insect Resistance (Majority of patents families are centred on <em>Bt</em> genes and various <em>Cry</em> proteins)</td>
<td>162</td>
<td>34</td>
</tr>
<tr>
<td>Agronomic Enhancement Traits (Quality traits such as enhanced biomass, oil content, vitamin, fruit ripening. MNCs primary focus is on improving oil content)</td>
<td>150</td>
<td>357</td>
</tr>
</tbody>
</table>

Table 6.9 Technological landscape of key patent families for MNCs and the public sector, by categorised contour clusters (Figure 6.9)
In contrast, the public sector has a large intellectual property portfolio of techniques relevant to producing transgenic plants which are valuable in a wide range of key technologies, and has devoted a lot of resources to identifying new traits which confer resistance against diseases (418 patent families) and tolerance to abiotic stresses (362 patent families). However, there is a lack of ownership of enabling technologies for transformation and selectable markers assigned to the public sector, with only a few selected patents on the use of Agrobacterium transformation by public institutions. This relative lack of ownership of enabling technologies pushes the public sector into collaboration or licensing agreement with the private sector. This analysis provides a generalised view of public and private sector R&D, it does not represent a detailed analysis of FTO.

### 6.5 Exclusivity of enabling technologies

Previous sections have shown that the public sector maintains a large portfolio of patents relevant to developing transgenic crops. As discussed, the majority of public sector patents are novel gene sequences which confer traits such as drought tolerance, salt tolerance, disease resistance, etc. Transgenic developments require more than these novel traits. The development process needs access to fundamental technologies for inserting foreign DNAs (DNA transformation methods), selecting transformed events (selectable markers) and providing regulatory elements to drive the expression of novel gene sequences (constitutive promoters). Access to these enabling technologies is so important for the public sector that some space is given here to explaining the complexity faced when seeking the use of transformation technology, gene promoters, selectable markers, co-transformation, site-specific transformation and homologous recombination, though there are many other enabling technologies.

#### 6.5.1. *Agrobacterium* transformation

In current research practice, the most common mode of plant transformation is mediated by *Agrobacterium tumefaciens*. Despite the long history of use, the current intellectual property landscape of *Agrobacterium* transformation still poses intellectual property challenges for public research organisations conducting commercial transgenic research, even though
there are other transformation methods available and although many improved methods for transformation originated from the public sector. Transformation technologies are most likely to be dominated by private sector patents with broad claims or licensed from the public sector exclusively to companies e.g. biolistics developed by Stanford University has been licensed exclusively to DuPont.

Navigating even just the patent landscape for Agrobacterium transformation is a challenging task, due to a large number of patents on this technology. Table 6.10 illustrates part of the patent landscape of Agrobacterium transformation, based on the analysis of Nottenburg and Rodriguez (2008). Both the public and the private sector have worked on Agrobacterium transformation and applied for patents on their innovations. However, many patents originating from the public sector have been licensed exclusively to private companies. For example, the Max Plank Society licensed exclusively to Bayer Crop Science, and Washington University has licensed exclusively to Syngenta.

<table>
<thead>
<tr>
<th>Assignee</th>
<th>Technique</th>
<th>Patent Number</th>
<th>Date of Expiry</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leiden University</td>
<td>Agrobacterium binary vector limited to families of Amaryllidaceae and Liliaceae</td>
<td>US5149615</td>
<td>04 Dec 2009</td>
</tr>
<tr>
<td>Japan Tobacco</td>
<td>Agrobacterium-mediated method for transforming monocotyledons</td>
<td>US5591616</td>
<td>07 Jan 2014</td>
</tr>
<tr>
<td>Washington University (Licensed exclusively to Syngenta)</td>
<td>Agrobacterium transformation of dicotyledons- strain that lacks functional tumour gene</td>
<td>US6051757</td>
<td>18 Apr 2017</td>
</tr>
<tr>
<td>Monsanto</td>
<td>Agrobacterium co-transformation method</td>
<td>US8273954</td>
<td>25 Sep 2029</td>
</tr>
</tbody>
</table>

Table 6.10 Major patents that have broad coverage for the use of Agrobacterium-mediated transformation. (Adapted from Nottenburg and Rodriguez, 2008).

In 2002, Syngenta filed a lawsuit against Monsanto for infringing their Agrobacterium transformation patent and requested that Monsanto pay royalties based on the value of
their commercial GM crops. By 2005, that dispute resulted in a cross license agreement where Monsanto and Syngenta provided each other with royalty-free, non-exclusive licenses for their *Agrobacterium* transformation technologies. The legal battle over the ownership of *Agrobacterium* transformation was not only between corporates. There was a patent interference dispute at the USPTO in 1993, between Monsanto and the Max Planck Society, over the ownership of the technology. Both Monsanto and the Max Planck Society claimed to be the inventor of this technology (limited to dicots). The Max Planck obtained an EU patent in October 2003 and Monsanto had a PCT application in 1984. Prior to the dispute being resolved by USPTO, Monsanto announced an agreement with Bayer and Max Planck Society that ended the interference and provided royalty free research licences for the Max Planck Society and Bayer with non-exclusive licences in the US (Monsanto, 2005b). Although the eventual USPTO decision was made in favour of Monsanto, the US patent for this technology was only issued recently. On September 2012, the USPTO published a patent (US 8273954 B1) granting Monsanto exclusive rights on the use of *Agrobacterium* transformation for generating transgenic plants with a patent term of 17 years from the publication date (expected expiry date is the 25th September 2029).

Prior to 1995, patents granted by USPTO either had a patent term of 17 years from the date of issue or 20 years from the application date (longest patent term applied). However, in 1995, the USPTO changed their patent system in order to align it with the TRIPS agreement, in an attempt to minimise the negative impacts of submarine patents. Under the new US patent system, exclusive rights to patented materials are provided for 20 years from the filing date, regardless when patents are granted. However, patent applications filed before 8th of June 1995 fall under the previous system. Because Monsanto filed the application prior to the change of system, this resulted in an extended exclusive right for Monsanto’s *Agrobacterium* transformation and has significantly impacted the patent landscape of plant transformation. Monsanto has publicly announced that they will provide royalty free research licenses for public and non-profit research institutions in the US (Monsanto, 2012b). Public research institutions that wish to commercialise their transgenic developments using *Agrobacterium* transformation within the US will need to seek commercial licences from

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54 A submarine patent is a patent that emerges after extended prosecution period, intentionally delayed by the patent applicant.
Monsanto (other members of this patent family in different jurisdictions have already expired).

### 6.5.2. Promoters

The second group of enabling technologies is the constitutive promoters, regulatory elements essential to drive the expression of transgenes and selectable markers. The most commonly used constitutive promoter in transgenic constructs is the cauliflower mosaic virus (CaMV) 35S promoter. Intellectual property ownership of this promoter belonged to Monsanto. However, since patent US5352605 expired on the 4th of Oct 2011 and US5530196 expired on the 25th of June 2013, there is no restriction on access to the CaMV35S promoter. In addition, there are publicly owned constitutive promoters which have similar promoter expression profiles to CaMV35S. For example, the figwort mosaic virus 34S (FMV34S) promoter, patented by the University of California, Davis (US6051753), is capable of replacing CaMV35S as a constitutive promoter for many uses (Table 6.11).

<table>
<thead>
<tr>
<th>Assignee</th>
<th>Technique</th>
<th>Patent Number</th>
<th>Date of Expiry</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monsanto</td>
<td>Chimeric genes for transforming plant cells using viral promoters (CaMV35S)</td>
<td>US5352605</td>
<td>04 Oct 2011</td>
</tr>
<tr>
<td></td>
<td></td>
<td>US5530196</td>
<td>25 Jun 2013</td>
</tr>
<tr>
<td>Dow Agro Sciences</td>
<td>Plant ubiquitin promoter system (Ubi-1)</td>
<td>US5510474</td>
<td>23 Apr 2013</td>
</tr>
<tr>
<td>Monsanto</td>
<td>Modified ubiquitin regulatory system (Ubi-1)</td>
<td>US6878818</td>
<td>09 Sep 2019</td>
</tr>
<tr>
<td>CSIRO</td>
<td>Recombinant promoter for gene expression in monocotyledonous plants (Adh-1)</td>
<td>US5290924</td>
<td>20 Apr 2013</td>
</tr>
<tr>
<td>UC Davis &amp; Monsanto</td>
<td>Figwort mosaic virus promoter and uses (FMV34S)</td>
<td>US6051753</td>
<td>18 Apr 2017</td>
</tr>
</tbody>
</table>

Table 6.11 Major patents that have broad coverage on the use of promoters for driving expression of transgenes.
6.5.3. Selectable markers

In many transgenic developments, a selection method for identifying successfully transformed plants is necessary, due to the low frequency of successful transformation. The most common strategy for selecting transformed events is via negative selection, eliminating events that have not been properly transformed. This strategy consists of the inclusion in the construct of a suitable selectable marker and most often in the form of genes conferring antibiotic or herbicide resistance. The most commonly used antibiotic selectable markers are \textit{NptII} for kanamycin resistance and hygromycin phosphotransferase (\textit{hpt}) for hygromycin resistance. Both \textit{NptII} and \textit{hpt} offer regulatory advantages for developers who plan to commercialise transgenic crops, as both of these antibiotic resistance genes have been approved by various regulatory agencies around the world, minimising additional biosafety data required for regulatory approvals.

<table>
<thead>
<tr>
<th>Assignee</th>
<th>Technique</th>
<th>Patent Number</th>
<th>Date of Expiry</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monsanto</td>
<td>Antibiotic Resistance to select transformed plant cells</td>
<td>US6174724</td>
<td>23 Jul 2008*</td>
</tr>
<tr>
<td>Monsanto</td>
<td>Kanamycin resistance (\textit{NptII} gene) with \textit{CaMV35S}</td>
<td>US5034322</td>
<td>23 Jul 2008</td>
</tr>
<tr>
<td>Syngenta</td>
<td>Hygromycin resistance (\textit{hpt} gene)</td>
<td>US5668298, US6048730</td>
<td>16 Sep 2014, 11 Apr 2017</td>
</tr>
</tbody>
</table>

Table 6.12 Major patents that have broad coverage on the use of antibiotic resistance markers for selecting transgenic plants (Adapted from Chi-Ham et al., 2012, Pray & Naseem 2005, and Roa-Rodriguez & Nottenburg, 2003)\textsuperscript{55}.

\textsuperscript{55} Although the US6174724 patent was granted on 16\textsuperscript{th} of Jan 2001, due to the terminal disclaimer statement on the patent, the length of patent protection of this patent does not extend beyond that of the US 5034322 patent. A terminal disclaimer bounds the patent term of the later patent to the patent term of an earlier granted patent, designed to prevent double patenting of similar disclosures from the same assignee.
Examining the patent landscape of NptII and hpt has revealed that broad claim patents covering the use of NptII are owned by Monsanto and broad claim patents on the hpt gene belong to Syngenta. Monsanto’s NptII patents have already expired and Syngenta’s hpt protection will soon expire (Table 6.12). However, European Union pressure for regulatory requirements on all genetic sequences introduced into plants presents great difficulties for all developers. Challenged by the strict regulatory regime, removing selectable markers from transgenic plants would significantly reduce the burden of regulatory requirements. Based on a review compiled by Breyer et al. (2015) the following technologies, which have been applied in delivering marker-free transgenic plants are described below;

6.5.4. Co-transformation

There are many approaches to this strategy which relies on the gene of interest and selectable marker integrating at different loci within the plant, making it possible to remove the selection marker through segregation. Differing approaches include using: 1) two strains of Agrobacterium, simultaneously, each with a single T-DNA. 2) a single Agrobacterium strain with two plasmids or 3) a single bacterium strain with a single plasmid carrying both T-DNA regions. This strategy has been applied by numerous researchers and was used to remove the selectable marker for the development of Golden Rice (Miki & McHugh, 2004; Al-Babili & Beyer, 2005).

6.5.4.1 Site-specific recombination

Utilising the genetic recombination occurring between two defined DNA sites allows a marker-removal strategy to be implemented. The most common site-specific recombination system used is the Cre-lox system from bacteriophage P1. By flanking the selectable marker with the recognition sites (lox), this allows the recombinase (Cre) to excise the targeted region. However, this strategy also requires crossing between two transgenic plants to generate progeny that is marker-free and re-insertion of the excised sequence does occur at low frequency (Chong-Pérez & Angeno, 2013).
6.5.4.2 Homologous recombination

The basis of this mechanism relies on the DNA repair mechanism of plant cells, using two directly repeated sequences flanking the marker sequences. Creating double-stranded breaks on the repeated sequences allow cells to repair through homologous recombination and the removal of the selectable marker. The challenge with this system is the low frequency of recombination and the requirement for extensive labour to generate marker-free transgenic plants (Puchta, 2005).

<table>
<thead>
<tr>
<th>Assignee</th>
<th>Technique</th>
<th>Patent Number</th>
<th>Date of Expiry</th>
</tr>
</thead>
<tbody>
<tr>
<td>Du Pont</td>
<td>Site-specific recombination of DNA in eukaryotic cells</td>
<td>US4959317</td>
<td>25 Sep 2007</td>
</tr>
<tr>
<td>Sungene (acquired by BASF)</td>
<td>Recombination cassette and methods for sequence excision in eukaryotes</td>
<td>US7736886</td>
<td>05 Jan 2024</td>
</tr>
<tr>
<td>Monsanto</td>
<td>Methods for obtaining marker-free transgenic plants</td>
<td>US8829275</td>
<td>11 May 2027</td>
</tr>
</tbody>
</table>

Table 6.13 Patents that provide broad coverage on methods of removing selectable markers from plants.

Table 6.13 shows that the private sector has control of intellectual property access to selectable marker removal technologies and most of the key patents will remain active for many more years. DuPont holds one the earliest developed site-specific excision technologies, the Cre-lox recombination system. It was developed in the 1990s and at that time public access to this technology was highly restricted. Biomedical researchers were restricted from accessing Cre-lox mice unless license agreements were made with DuPont. In 1998, the National Institute of Health in the US (NIH) signed a memorandum of understanding (MOU) with DuPont, in order to provide public access to this technology to conduct basic research (NIH, 1998). However, the MOU limited the public sector to conducting basic research in the medical field and commercial research was not covered by the MOU. In addition, the MOU specifically excludes any use of the Cre-lox system in plants or any agricultural applications;
“(1) DuPont agrees that PHS can use without cost the DuPont Patent Rights for its non-commercial biomedical research purposes, provided, however, that such research purposes specifically excludes: (a) use of cre DNA and/or lox DNA in higher plants or agricultural applications.”

As demonstrated with the Cre-lox example, the challenges for public institutions in accessing patented technologies are not unique to the agricultural biotechnological industry and it remains problematic for public application researchers in a range of biological disciplines. Although patents covering the most common selectable markers have already expired, there are many more key enabling technologies which have the potential to restrict public GM developments.

6.6 Conclusions

This chapter provides an examination of the innovation capability for GM crop development in the public and private sectors, more specifically looking at the intellectual assets of the public sector which are relevant for commercialising transgenic developments. Results suggest that the public sector is significantly enhancing its global patent portfolio. The ownership gap between the public and private sector has greatly narrowed, with more public organisations encouraging researchers to file patent applications. The major contributors of public sector patents are from public institutions in China, accounting for 40% of total public sector patents. This strongly reflects the Chinese government’s attitude towards, and investment in, GM technology. Public sector patents are spread across hundreds of organisations in multiple countries. In contrast, the private sector, accounting for 50.3% of global patents, has a majority of patents aggregated into the portfolios of MNCs, with the top six AgBiotech firms controlling 25.1% of all AgBiotech patents. Even this level of consolidation of intellectual property rights within the private sector is likely to be underestimated, due to private investments in public research and to various non-disclosure licensing agreements.

Cluster analysis of patent families through categorisation of enabling and trait technologies has shown a distinction between the focus of the public and private sectors. The MNCs remain focused on first-generation traits such as insect resistance, herbicide tolerance and oil enhancement, maximising farmers’ yields through current agronomic practices. This arises from the fact that return on investment for MNCs come from seed sales to farmers.
and not directly from enhancement to quality traits of more significance to consumers. Developments of particular importance to small-scale farmers are less of a priority to MNCs, than they are (in principle) to publically funded organisations. Public sector research is scattered across a wider spectrum, including basic plant developmental research with a strong focus on disease and stress related traits. This trend is most likely to continue, as it already has for the last twenty years, where the focus of private sector is driven by major crops with substantial economic value, while public sector projects are, for the most part, more blue-sky research.

A key challenge for public GM crop development and commercialisation is the fragmentation of public sector intellectual property, where individual institutions lack the essential intellectual property package for commercialisation. There are many publicly owned enabling technologies, for example from PIPRA and CAMBIA, which aim to address this issue but their impact to date is modest.

This Chapter has illustrated that developing an intellectual property strategy enables the developer to identify non-proprietary technologies which minimise the need to negotiate licences from the private sector. However, public research scientists have continued to rely on enabling technologies such as Agrobacterium transformation, NptII, and other patented technologies owned by the private sector. Although the majority of private patent holders have not restricted public access for research purposes, without securing commercialisation licences public institutions remain liable for potential patent infringement.

Based on Hall and Martin’s framework, the analysis suggests that the public sector has become more aware of intellectual property and of the implications it holds for commercialisation but individual public research scientists have insufficiently addressed the legal information and requirements associated with technologies which is critical in reducing the technical uncertainty for commercialisation.
Key obstacles identified in this chapter:

- No single public research organisation has all the necessary IP rights to commercially deliver GM crops. As a result, public developers need to seek licenses with patent holders, from both public and private organisations. But the costs of negotiating multiple licences and the on-going licence payments generally fall outside the budget scope of public research projects. Even accessing technologies from the public sector can be prohibitive.

- A well-conducted patent landscape analysis allows public GM crop developers to design genetic constructs which minimise the number of IP licences required from third parties. However, the majority of public GM crop developers do not conduct such analyses, or lack the expertise, to do so and generally have not considered the need to establish FTO prior to commencing any development.

- Public research organisations have strongly focused on novel trait developments and have heavily relied on enabling technologies from the private sector. The need to access private sector technologies is exacerbated by the exclusive license agreements from public sector discoveries to other public and private organisations.
Chapter 7

Organisational barriers to the commercialisation of publicly developed GM crops

7.1 Introduction

The incentives for the private sector to invest in innovation revolve around capturing market share, gaining competitive advantages and generating profits (e.g. Schumpter, 1942; Kim & Mauborgne, 1999; Ferreira et al., 2014), while the imperative for the public sector is to provide services and products of value to economies and particularly addressing areas of public importance neglected by industry (Jordan, 2014). However, public sector innovations seem to be developed with less urgency and to be more difficult to adopt. The introduction of agricultural biotechnology in the 1990s has remodelled the innovation process for agricultural development, more specifically the utilisation of genetic modification (GM) technology for generating new varieties of crops. Developers may encounter organisational challenges while exploiting the technology, as existing organisational capabilities may not complement the introduction and development of radical innovations. Simultaneously, organisations may find it difficult to change their processes and behaviours to accommodate changing technological needs. Studies have been conducted which have resulted in theories addressing organisational uncertainties for innovation, suggesting that organisational uncertainties arise when the innovation process is not consistent with organisational capabilities and strategies (Miles et al., 1978; Teece, 1986; Han et al., 1998).

7.2 Conceptual Framework

To examine the organisational challenges to the commercialisation of public GM crop developments, the conceptual framework adopted in this chapter builds on the
organisational barriers to public sector innovation outlined in a recent Australian government report (Katsigiannis et al., 2014). The report categorised and divided public organisational barriers across three distinct areas; Innovation strategy, Innovation processes and Organisational culture.

Innovation strategy is the creation of paths and the defining of goals for an organisation (Anthony et al., 2006). Pisano (2015) states that institutions often fail to produce innovative outcomes, simply due to the lack of an innovative strategy, which in this context is merely a set of policies aligning resources and capabilities within the organisation to achieve a particular goal. Katsigiannis et al. (2014) outlined that public institutions rarely establish strategies for transforming knowledge to move towards an outcome. Consequently, resources are not allocated to activities outside basic research and development.

Furthermore, Katsigiannis et al. (2014) identified that most Australian public institutions have not developed the capacity to facilitate innovation, nor implemented management processes for it. Innovation processes are more than the discovery of a technology or of knowledge. They involve a broad spectrum of activities and stakeholders. Among the elements of innovation processes, organisational learning plays a vital role. Stata & Almond (1989) stated that in order for organisations to be more innovative, they need to learn from past experience and to modify behaviour and actions accordingly. However, due to the risk-averse nature of the public sector, most public institutions are reluctant to change. The public sector is built on risk minimising behaviour, providing services that are reliable and consistent. As a result, public management processes have been established to ensure these objectives are met. Bellante and Link (1981) suggested that the risk-averse culture of the public sector is due to the greater proportion of risk-averse individuals who seek stable careers within the public sector. Furthermore, the unwillingness of the public sector to change and innovate is contributed to by the lack of incentives for change and the fear of the consequences of failures (Buuge et al., 2011).

This framework helps to conceptualise organisational challenges to public sector innovation and can be tested against public GM crop developments. Public sector innovations in this area are mainly driven by governmental policies, driving the direction of research through strategic allocation of resources as grants. The first section of the chapter examines innovation strategies in the public sector by analysing India’s and China’s policies on agricultural biotechnology, establishing the role of public institutions for GM crop development and commercialisation. An attempt was made to include Australia’s
agricultural biotechnology policy as a comparative case study to provide a contrast of approaches between developed and developing countries. However, only a single Australian biotechnology policy document was identified: ‘Australian Biotechnology-a National Strategy’ (Biotechnology Australia, 2000). This document did not outline any policies or strategies for investment in the public sector for GM crop developments. Instead, the strategy promotes research through the rural Research and Development Corporations (RDCs) with the objective of maximising the national economic benefits. Moreover, it highlighted the need to counteract the negative perception of consumers in order to increase the acceptance level of GM crops in Australia. Nor are there any Australian Government dedicated funding streams directed at agricultural biotechnology in the public sector. Even though there are a number of GM crop projects currently conducted by Australian public sector scientists in India and elsewhere, these projects are not driven by any Australian policy in place.

The subsequent section of the chapter explores the innovation process for GM crop developments, more specifically looking at the industrial standards for GM commercialisation. Discussions with stakeholders (Chapter 4) suggest that there is a lack of incentives for public research scientists to pursue commercialisation. The final section of the chapter identifies concerns with the public research culture and its impact on GM innovation, through the examination of the competitive grant system in China and the implications of such systems on the culture of public sector scientists.

7.3 India’s policy and strategy for agricultural biotechnology

In the early 1980s, the Government of India realised the potential of biotechnology in assisting India’s economy and established the National Biotechnology Board to stimulate biotechnological research in India. The initial objectives of the board were to create awareness and promote research in the pharmaceutical, manufacturing and agricultural industries. The board rapidly expanded and became the Department of Biotechnology (DBT) in 1986, an apex body designed to oversee, plan and facilitate the growth of India’s biotechnology industry. To foster the growth of biotechnology in India, DBT was responsible for developing a national policy to accelerate the uptake of the technology. In 2007, the Government of India approved the National Biotechnology Development Strategy (NBDS)
drafted by DBT, and this document was the first policy document exclusively designed to foster biotechnology in India.

7.3.1. Capacity building

An essential element to the NBDS has been to create infrastructure and to develop human resources for both the private and the public sectors. R&D in biotechnology has been relatively costly compared to other industries. The long developmental pipeline and substantial resources required to conduct clinical trials (pharmaceutical) or regulated field trials (agricultural) often discourage small and medium enterprises from entering into the industry. To promote research in the private sector, DBT has established biotechnology incubation centres in Hyderabad, Lucknow and Chennai, providing access to world-class research facilities. The Government of India absorbs the infrastructure cost in order to promote R&D in the private sector. Another important element is the talent pool for advancing the industry. Several new government initiatives have been launched to increase the number of skilled personnel for the biotechnology industry. The Biotech Industrial Training Programme coordinated by the Biotech Consortium of India Ltd (BCIL) facilitates the transfer of graduate students into industries by providing industrial training for Bachelor and Master of Science graduates. Financial incentives are given to both parties, accelerating the process of transferring students to the industry; a one-off grant of Rs 10,000 to each student and Rs 50,000 to each training company participating in the programme. During 2014, 701 student candidates were chosen from a pool of 2,420 applications. This is a popular programme amongst students for transiting from universities into the workforce (DBT, 2014).

To facilitate biotechnological research within the public sector, DBT started a programme to develop Centres of Excellence and Innovation in Biotechnology (CEIB), to support and strengthen institutional capacity for biotechnological innovation. An example that illustrates the scheme for research in agricultural biotechnology is the partnership between DBT and the International Crops Research Institute for the Semi-Arid Tropics (ICRISAT) in establishing the Center of Excellence in Genomics. The financial support from DBT strengthened the breeding facilities in ICRISAT and provided research training fellowships for students and scientists. To increase the research capability in the public sector, DBT offers 250 fellowships per year for students to join Ph.D. programmes in institutes of their choice. Between the year 2007 and 2014, 700 students completed Ph.Ds. under this fellowship scheme. DBT further deepens the research capability of public scientists by providing opportunities for
advanced training overseas. Forty six national experts were selected under this scheme in 2013-2014 and were sent to laboratories and institutions around the world (DBT, 2014). Further initiatives and training programmes funded by the Government of India and DBT are directed at developing manpower for biotechnology. To date, the Government of India continues to be proactive and supportive in assisting the growth of all areas of biotechnology.

7.3.2. Strategic directions for agricultural biotechnology

Coupled with the emphasis placed on developing human resources and infrastructure for all biotechnology sectors, the NBDS document further outlines the strategic direction for commercialising agricultural biotechnology.

(i) Accelerating the pace of product development

In our quest for better products, strong and sustained support should be given to encourage indigenous discovery of new genes and promoters in both public and privately owned institutions. Nevertheless, wherever there be an urgent need for a product to achieve food or nutritional security, creative commercial and academic international partnerships should be explored in national interest for sourcing important genes and promoters through licensing arrangements on exclusive/non-exclusive basis. The cost effectiveness should be carefully assessed on a case-to-case basis (p. 24, NBDS, DBT, 2007).

DBT’s first strategic priority for agricultural biotechnology has highlighted an important key challenge for India in developing and commercialising transgenic crops, intellectual property ownership of novel technologies. Prior to the amendment of the Indian patent act in 2005, patents were granted on processes rather than products and several areas were not patentable, including new varieties of plants and pharmaceuticals. Local Indian firms took advantage of the system and replicated many developed countries’ products (mainly pharmaceutical products) by investing in alternative low-cost production methods. Consequently, global market share in a range of products were lost to imitators in India. Governments from developed countries have received complaints from the private sector which has pressured India to comply with World Trade Organisation (WTO) regulations (Simonettiet et al., 2007). India being a member of the WTO, has to comply with the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement. This has gradually resulted in a new legal protection structure comparable to those of developed countries. To
ensure that India remained competitive at a global level under the TRIPS agreement, DBT has emphasised the need to develop an efficient intellectual property management system within the public sector and to encourage scientists and young graduates to have a better understanding of intellectual property issues and implications. Shortly after the amendment of the patent act, the Indian Council of Agricultural Research (ICAR), the apex body for co-ordinating agricultural research in India, released a guideline for intellectual property management and commercialisation of public sector research (ICAR, 2006).

Section 1.5.6 Patenting versus Publishing

ICAR scientists/innovators may publish such research results of academic or public significance as do not impinging ICAR’s interest in the protection of IP. They will not reveal inventive steps, if applicable, in such publications. They shall defer any publication of inventive steps/potential IP with commercial or strategic implication until an application for their IPR protection has been filed and recorded.

Section 1.5.7 Public Domain Knowledge

Wherever ICAR decides not to apply for IPR protection, efforts will be made quickly publish the research results and thereby bring the information/knowledge into public domain. This will also be done by digitalisation of the publications creating widely accessible prior art so that any unacknowledged use of the public domain information generated in ICAR is forestalled. (p. 5, ICAR, 2006)

Section 1.5.6 outlined above, potentially shifted the priorities of research outputs for public research institutions in India. ICAR has been pushing the public researchers to file for patents, especially technologies that are of national interest. A review by Suman & Pandey (2014) has shown that ICAR has been rapidly increasing the rate of granted patent applications in recent years; from 2008 (35), to 2010 (54 patents) to 2011 (94 patents). Overall, ICAR is aiming to generate an intellectual property asset base that will allow the country to compete on a global scale.

7.3.3. Pathway to commercialisation

One framework established by DBT to support public GM developments is the Platform for Translational Research on Transgenic Crops (PTTC), a clearing house for GM discoveries in
the public sector. This platform was introduced in collaboration with ICRISAT, providing a physical infrastructure that is capable of conducting large-scale transgenic research, identifying patents of relevance and preparing dossiers for deregulation. Essentially, the PTTC identifies technologies or traits with substantial value and conducts activities required for commercialisation (Figure 7.1).

**Figure 7.1** The PTTC model for supporting transgenic developments in India.

*Source: Sharma et al., 2009.*

Despite the substantial amount of public sector time and resources committed to setting up this platform, under the model, the commercial uptake pathway for publicly developed GM crops requires industry partners. As was stated within the NBDS document, facilitating the growth of biotechnology in India is likely to need to use public-private partnerships (PPP) as the core model for translational research.

**(ii) Public-Private Partnership**

There is an urgent need to promote and improve the levels of horizontal integration between public-public and public-private laboratories. Institutes that generate knowledge and those that specialise in late stage field trials are currently compartmentalised. While support to public-funded innovation must continue to be strengthened, it is proposed that at least 30% of government-funded programmes must have a commercial partner who will be responsible for directing R&D towards commercialisation. Public investment should also be encouraged in small and medium companies, especially for late stage trials of transgenic crops.
Partnership between public-funded organisations and industry is crucial in the science-to-product chain. (p. 24, DBT, 2007).

A PPP should provide a platform that combines strengths of both sectors and improves the likelihood of commercialisation. DBT has proposed that 30% of the annual budget will be reserved for assisting collaborations between the private and public sectors (Singh, 2009). Two PPP initiatives were developed to support this platform, the Small Business Innovation Research Initiative (SBIRI) started in 2005, and the Biotechnology Industry Partnership Program (BIPP) launched in 2008. Both initiatives aimed to facilitate translational research in India through PPPs. By 2011, the SBIRI initiative had provided $5 million in grants and $31 million in loans, with a total sum of $36 million in government investment. The public funding has attracted an additional investment of $33 million from the private sector (Vijayaraghavan & Dutz, 2012). Despite the fact that the agriculture sector only accounts for 25% (9 out of 37) of total approved applications, five of those projects are currently developing transgenic crops (Appendix 3). From 2005 to 2011, there were 791 applications and 86 projects selected and funded. The average success rate between 2005 and 2011 was 15.6% (Vijayaraghavan & Dutz, 2012). The second PPP initiative, the BIPP initiative aims to fund high-risk technologies that are of national interest on a cost-sharing basis. This scheme was designed to assist well-established companies in conducting high-risk research, with a typical research project timeline of 6 to 8 years. This initiative has been managed by the Biotechnology Industry Research Assistance Council (BIRAC) and supported by two industry bodies, the Association of Biotech Led Enterprises and BCIL. By 2011, BIPP had provided $36 million USD with $13 million as grants and $23 million as loans and attracted an additional investment of $66 million from the private sector (Vijayaraghavan & Dutz, 2012). To date, 11 GM crop projects have been supported by the BIPP. However, both the SBIRI and BIPP scheme have put in place stringent criteria (Appendix 4) as the programmes were designed to assist the biotechnology industry in India. The applicants must be Indian registered and majority-owned entities. Secondly, the research project must have a significant socio-economic relevance. Lastly, the company must have the infrastructure and human capital for conducting relevant research. These criteria were set to accelerate the R&D process and to ensure the investment and outputs remain the property of India. The intellectual property rights belong to the recipient of funds with specific conditions, where the rights need to be available and accessible and affordable to people in developing countries. The company would need to pay a 5% royalty of net sales to BIRAC, beginning with the first sale of product (BIRAC, 2014).
7.4 China’s policy for innovation of GM crops

With a growing population of more than 1.36 billion people and threatened by decreasing arable land area due to urbanisation, China’s ability to feed its citizens in the future presents a significant challenge for the Chinese government. Furthermore, China’s growing economy has raised people’s living standard and changed the structure of food consumption. Despite the substantial improvement in agricultural production, agricultural imports continue to increase. The Chinese government has placed great emphasis on investment in improving the value of overall agricultural production. The majority of agricultural investment has been made in the public sector. China has the world’s largest public agricultural research system, employing more than 43,000 full-time employees in over 1,000 research institutes at the national and provincial levels (Chen & Zhang, 2011).

7.4.1. Investments in agricultural biotechnology

Government investment in agricultural biotechnology in China started in the early 1980s with a pioneer programme, known as the 863 programme, for accelerating science and technology. The establishment of this programme was based on a proposal from four prominent scientists. The 863 programme has been implemented in China’s five-year plans with an initial policy focus on promoting basic research at a national level. Between the years 1986 and 2001, the programme has invested a total budget of 15 billion RMB ($1.9 billion) in seven distinct areas: biotechnology, space, information technology, laser technology, automation, energy and materials science. It has been estimated that 1.5 billion RMB ($190 million) was spent on biotechnology, with 750 million RMB ($95 million) in agricultural biotechnology (Huang & Wang, 2003). However, by the current five-year plan, the direction had shifted towards an output oriented policy. A recent statement from the Ministry of Science and Technology (MOST) outlined below describes the current government direction (MOST, 2016).

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56 Five-year plans are strategic central government documents which outline various initiatives for economic development over the next five years. Agricultural development has been an area of focus since the 1980s.

57 This calculation uses the average exchange rate in 20001, where 1 USD= 8.01 RMB.
“..., the program will greatly enhance China’s high-tech innovation capacity in selected fields and improve the international competitiveness of major industries. It will master a number of technologies with industrial potential and proprietary IPR. It will nurture a number of high-tech industrial growth sources which will optimize and upgrade China’s industrial structure as a way of fostering both the individual and the overall strength of high-tech industries. It will also develop innovative and enterprising talents for high-tech R&D and industrialization” (MOST, 2016)

China’s goal has been to create a modern and innovative nation which can compete internationally. Despite China’s great enthusiasm for accelerating applied research for transforming industries, developmental research requires the knowledge generated from basic research. A decade after the 863 programme commenced, a complementary programme ‘973’ was initiated in 1997. Again, agriculture and biotechnology remained a focus of the programme. For the year 2015, the funding allocated for agricultural development under the 973 programme was 31.2 million Euros ($ 35.5 million) with a total programme budget of 325 million Euros ($370 million) (European Commission, 2015).

Part of the underlying reason for investing in basic research was to address the need for a robust intellectual property portfolio. The Chinese patent law was enacted in 1984 and at that time many biological and chemical inventions were not patentable (Lin et al., 2004). Pressure was applied by the US government, attempting to block trade from China, particularly in items which the US believed were developed using intellectual property which had not been licensed to China. In order to resolve the conflict between the US and China, a memorandum of understanding (MOU) was signed between the Government of the US and the Government of People’s Republic of China. An amendment to the patent act (1992) was made in accordance with the terms of the MOU. It expanded patentable subjects, including chemicals and pharmaceuticals and extended the patent terms from 15 to 20 years. Overall, this strengthened the rights of foreign intellectual property asset holders. A second amendment occurred shortly after (in 2000), due to China’s accession to the WTO and the need to comply with the TRIPS agreement. China realised the disadvantages which would occur without China holding a correspondingly strong intellectual property asset portfolio and began investing in patentable basic research. This resulted in the increasing trend of patenting activities in China observed in Chapter 6.

As mentioned, China continued to invest in biotechnology and the funding available tripled from $238 million in the ninth five-year plan to $795 million in the tenth five-year plan (2001-2005) (Cao, 2013). During the 10th five year plan, a greater focus was placed on GM
technology. Support for this funding increase was contributed to by the successful introduction of Bt cotton in China in 1997. By the 11th Five year plan (2006-2010), China had become one of the top nations investing in biotechnology. Furthermore, the State Council produced additional policy guidelines, the Medium and Long-term Plan (MLTP) for the Development of Science and Technology (2006-2020), a central policy document that provided further funds for research and development in biotechnology. In 2008, a mega-project the “National GMO variety development project” was announced under the MLTP plan. This project has allocated funding of $3.5 billion USD for 2008 to 2020 (Jia et al., 2010). The continuous investment from the government reinforces the notion that China wants to become a leading innovative country, including in biotechnology. However, the two indigenous GM crops that had obtained biosafety certificates from the Ministry of Agriculture in 2009, the Bt rice from Hua Zhong University and the phytase maize from the Chinese Academy of Agricultural Sciences (CAAS), have not been commercialised to date.

7.4.2. Infrastructure and human capability

Creating a globally competitive public research R&D system requires investments in infrastructure and human resources. The investment made by the Chinese government not only directs funding towards scientific research, it simultaneously enhances education and training, considering that the majority of agricultural R&D in China has been conducted in public institutions. Over time, the quality of human capital to conduct biotechnology research has greatly improved. The number of researchers with PhDs gained in any area of biotechnology increased significantly, with more than 2,000 Ph.D. students graduating annually in the field of biotechnology (Chen et al., 2007). In the 15 years, 1986 to 2000, the number of staff working in agricultural biotechnology tripled from 740 to 2,128 (Huang&Wang, 2003) and this trend will have accelerated. CAAS has promoted numerous programmes to attract and retain talent for agricultural developments. The CAAS Elite Youth Program, started in 2013, aims to attract young and talented researchers by providing a substantial start-up research fund per researcher of no less than 1 million RMB ($161,000) during the first year. After completing the first year, the researcher receives 2 million RMB ($322,000) for operational costs for research and 1 million RMB for laboratory equipment (Qi, 2013). This scale of investment suggests a strong commitment from the government to attract the best talent for agricultural development and the growing number of education
programmes at national, states and institutional level indicates that China is committed to agricultural biotechnology.

The National Key Laboratory (NKL) system, started under the MOST in 1986, provides dedicated resources to enhance the capability to conduct basic research in the public sector. By 2001, 30 NKLs were established for agricultural research and 12 of these were dedicated to agricultural biotechnology (Huang et al., 2002b). Other than through NKL system, many laboratories and programmes funded by ministries and provincial governments have been conducting agricultural biotechnological research (Huang et al., 2004). Although NKLs are equipped with the most advanced technologies for conducting basic scientific research, these laboratories do not have the capacity to carry out development activities at a commercial standard (Zhang, 2000). Despite the number of PhD graduates and the considerable number of national research laboratories being established, the only successful public GM development that continues to be cultivated on any scale has been Bt cotton.

7.4.3. Industry as the commercial pathway

The first indigenously developed major commodity crop was the CAAS Bt cotton, although, as mentioned earlier, the novelty and indigenous contribution have been much debated subsequently. CAAS conducted the R&D and generated the biosafety data for regulatory approval and licensed the Bt technology to provincial seed companies for marketing and distribution. Minimal regulatory consideration was given to requirements of other jurisdictions, as China remains the largest consumer (>30%) and importer (35%) of cotton in the world (OECD, 2015b). Almost all the cotton grown in China was supplied to local textile companies. However, recent government policies have redirected the focus of GM developments onto other major crops including maize, soybean, rice and wheat. The commercialisation pathway for these major crops has been very different to that for cotton, as these crops are internationally traded. China has appreciated the need for the commercialisation process for major GM crops to take potential international liabilities into consideration.

The government became cognisant of the issues surrounding liability for the public sector and have actively adopted a public-private partnership model. The Special Foundation for Transgenic Plants Research & Commercialisation programme was established by MOST in 1999, providing financial support for transgenic research and commercialisation. To be
eligible for funding under this scheme, local public institutions need to form partnerships with private companies. Concurrently, the company needs to show financial commitment by investing in the programme. A substantial budget was allocated under this scheme between 1999 and 2003, a total of $60 million USD (Huang et al., 2002b). This system shares many similarities with the Indian PPP model, with both governments engaging the private sector to conduct agricultural biotechnological R&D, actively promoting the industry.

Examining recent categories of grants under the ‘National GMO Variety Development Scheme’ suggests that the current focus is to enhance industrial capabilities. Five categories were listed under the 2104-5 grant document, 1) Transgenic developments, 2) Genetic cloning, 3) Biosafety evaluation, 4) Transgenic related policy and strategic development and 5) Transgenic development in industry. It is noteworthy that category 3 and category 4 of the transgenic megaproject are not directed towards transgenic developments. Instead, they focus on biosafety related issues and on developing communication strategies to overcome current negative public opinions in China. It was suggested from the discussions with stakeholders in Chapter 4 that policymakers in the Chinese government are concerned that the current social environment will prevent the industry from advancing. Consequently, research funding from programme 863, 973 and the National GMO Variety Development Scheme have put a major emphasis on biosafety research and directed a substantial amount of funding towards it (Huang et al., 2005b). The commercial focus is clear from the wording of the rules for applications for grants under category 5.

“Category 5

Research direction: Utilising herbicide tolerant and insect resistant genes to develop new herbicide tolerant and insect resistant materials; in conjunction with a conventional breeding programmes to generate varieties of herbicide tolerant and insect resistant maize and soybeans. The outcome must have an industrial application.

Expected outcome: Generate 6 to 8 new herbicide tolerant or insect resistant varieties that are in environmental field trials, with a minimum of 2 varieties at the biosafety evaluation stage. Demonstrate the agronomic benefit in terms of herbicide tolerance or insect resistance of 3 to 5 varieties through multi-location trials or have applied for/been granted at least 5 patents.

Criteria: The applicant must be a commercial company, with the capability to conduct transgenic R&D. This includes both human resources and physical infrastructure that are suitable for transgenic development and must have a product that is currently at biosafety
evaluation. The company must have the financial assets that are needed to commercialise GM crops, including the cost of a biosafety monitoring team.

**Budget size:** The state council grant for an individual project will not exceed 10 million RMB, with the applicant having a financial commitment in the ratio of 1:5”. (MOST, 2013)

Analysing the category 5 selection criteria and the desired outcome, highlights the current thinking of the Chinese government. It is apparent that the government is targeting crops and traits with the highest immediate economic value. China wants to build an agricultural biotechnology industry that is comparable to the MNCs in western countries, such as Monsanto, Syngenta or Bayer Crop Science. The government has been assisting local agricultural biotechnology companies in creating the physical infrastructure and capabilities needed for commercialising GM crops. Category 5 provides the largest grants, up to 10 million RMB ($1.5 million) under the new transgenic megaproject, at the same time encouraging investments from private companies. Personal communication with foreign seed companies in China revealed that only two local companies, Da Bei Nong and Origin Ltd, were selected for grants under category 5. They are currently the largest indigenous agricultural biotechnology seed companies in China. The intention of the Chinese government to commercialise GM crops through the private sector is reflected in the recent licencing deal between Origin Ltd. and CAAS.

“For the life of the patent, Origin will possess exclusive rights to sell and develop field crop products that contain these technology traits worldwide, Origin will also receive exclusive rights to sub-license to any third parties to develop seed products that contain these traits. Origin Agritech will also receive the rights to improve and further develop enhancements of this Bt-gene” (Origin, 2010)

In September 2010, Origin Ltd. made an agreement with CAAS to jointly own the rights to the CAAS Bt gene and have been incorporating the gene into commercial germplasm. Furthermore, Origin has taken over the phytase maize programme from CAAS for commercialisation. The exclusivity of the Bt licence can be seen as an indication that the Chinese government is not intending to promote major GM crops through public institutions.

**7.4.4. Summary of the agricultural biotechnology capacity in China and India**

The agricultural biotechnology policies in China and India reflect the national strategy for GM development and depict the intended role of public research institutions. Both countries
have recognised the value of biotechnology as a tool for assisting the growth of the agricultural, industrial and medical industries and have heavily invested in the public sector to promote the technology. India wants to enhance economy’s growth, with the aim of converting the country into a global manufacturing centre for advanced technologies. The “Make in India” programme, launched by Prime Minister Modi in 2014, has continued emphasising the need for biotechnology. China shares a similar rationale for investing in biotechnology, as part of reforming into an innovative and globally competitive country.

Government investments have strengthened the public sector’s capacity to conduct basic R&D. A considerable number of skilled professionals have been generated in both countries. Furthermore, the investments have provided infrastructure with world-class laboratory equipment. India has created many Centres of Excellence while China has established National Key Laboratories for agricultural biotechnology. However, it is apparent that the governments’ investments in the public sector are directed towards knowledge generation by fundamental research and they have not allocated significant resources to commercial activities in the public sector. The knowledge and scientific discoveries generated in the public domain are increasingly converted into patents, as the accession of China and India to the WTO further demands the generation of robust national intellectual property portfolios.

The challenge in commercialising a product with multiple technological components is further compounded by the need to comply with the TRIPS agreement. This is shifting the consciousness of national research systems, which can no longer neglect intellectual property implications and has resulted in a substantial number of patent applications from both countries over the last decade.

Despite the Platform for Translational Research on Transgenic Crops being established for advancing public sector GM developments in India, evidence suggests that the current innovation strategy in place is not aiming to further develop commercial capabilities within public institutions. Instead, the Indian government has been focusing on a public-private partnership model. China’s interest is on crops with significant economic value, rice, soybean, maize and wheat, but commercialisation of the main commodity crops needs to take international trade into consideration. China wants to accelerate the growth of the industry and has realised that public institutions are incapable of delivering novel products at a global scale. Consequently, investments have been directed towards corporations that possess the capability to conduct the necessary commercial activities, limiting public research organisations to basic underpinning research and the generation of exploitable patents.
Overall, the driver for these governments to invest in GM technology is not to address the issue of minor crops or gaps created by the industry. Instead, the national strategies are primarily targeting this technology to generate a local industry that is globally competitive. Consequently, the role of the public sector has been designed to build the capacity and basic knowledge needed to support the growth of the industry.

7.5 The industrial standard for commercialising GM crops

Challenged by public’s negative perceptions and fear of GMOs, governments around the world have set in place various regulations and policies which tightly monitor the movement and the use of GMOs. The pathways to commercialisation used for the products of conventional agricultural developments can no longer hope to satisfy government regulations for GM crop developments. To meet the legal requirement and minimise liabilities, the global agricultural biotechnology industry has established an industrial standard for commercialising GM crops, the ‘Excellence Through Stewardship’ (ETS) programme. This section of the chapter analyses the guidelines implemented by ETS and identifies key processes and industry criteria for commercialising GM crops. Overall, this highlights that the great majority of public organisations lack the capability to comply with such requirements.

7.5.1. History of 'Excellence Through Stewardship'

ETS is a not-for-profit organisation funded in 2008 by agricultural biotechnology industry which facilitates the management processes of GM crop developments. The majority of the members are seed producers and biotechnology companies from the private sector (e.g. Monsanto, Syngenta, Bayer Crop Science, DuPont Pioneer etc.) with three public organisations; the International Maize and Wheat Improvement Center (CIMMYT), the International Center for Tropical Agriculture (CIAT) and the African Agriculture Technology Foundation (AATF).

The purpose of ETS is to act as an industry certification system, providing legal assurance to grain traders and food manufacturers, essentially an industry response to the number of GM crop incidents that have reflected negatively on the developers. The StarLink® maize case provides a classic example of poor stewardship that resulted in very significant costs to the
developer and was the first major GM crop contamination incident which caused international trade disruptions. Under the US regulatory system, StarLink® maize was approved by the USA Environmental Protection Agency (EPA) for animal use but not for human consumption, due to a potential allergenicity concern regards to Bt Cry9C. In 2000, traces of StarLink® maize were discovered in human food supply chains, and this began a series of product recalls which resulted in $60 million compensation being paid by Bayer Crop Science to the food manufacturers and retailers for the loss of sales (Taylor & Tick, 2001). In addition to the loss due to domestic contamination, international trade disruption occurred when US export shipments tested positive for StarLink® maize. Japan and Korea, which had not approved the use of Cry9C refused to import any maize shipments from the US (Lin et al., 2003)\textsuperscript{58}. The concerns as to Cry9C’s potential allergenicity have since been allevied but considerable financial damage was done and confidence in the capacity of developers to manage GM products in the food chain was harmed.

### 7.5.2. ETS guidelines and criteria

The primary objective of the programme is to preserve the identity of the genetic material throughout the entire product lifecycle, allowing developers to track their products through the supply chain. The principal document ‘Guide for stewardship of biotechnology-derived plant products’, assists members in implementing stewardship processes and quality management systems. The guideline has the following key objectives:

- A commitment to thorough testing for food, feed and environmental safety
- Full compliance with applicable regulatory requirements
- Continual active engagement with the value chain to evaluate and promote appropriate stewardship approaches

Firstly, ETS requires all members to develop and implement a stewardship and quality management system by maintaining and tracking construct and plant integrity from research through to commercialisation and eventual withdrawal, with strong regulatory

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\textsuperscript{58} This case was different from other international commodity trade disruptions. The incident originated domestically due to poor identity preservation which led to contamination of the human food supply. The two cases of international trade disruption outlined in Chapter 5 were due to asynchronous regulatory approval. Nevertheless, to minimise potential liability, industry now actively pursues both food and feed approvals in jurisdictions of interest.
considerations, to ensure legal requirements are met for the purpose of commercialisation. Figure 7.2 outlines the ETS stewardship process at different stages of the development pipeline. Right from the construct development stage, industry has adopted preventive measures to track the identity and integrity of technological components. Considerable and onerous documentation procedures are recommended, including the bar-coding of all transformed plant material samples and commercial seed packets to ensure traceability of the development from the first laboratory experiment, through the development and commercialisation cycle to the final stage of product recall. It is evident that the industry has set a robust quality monitoring system for the development of GM crops but it is safe to assume that no public institution has the organisational capabilities or resources to comply with such rigorous standards.

In addition to ensuring that the regulatory requirements in jurisdictions of relevance are met prior to commercialisation, a key activity enforced by ETS is the market assessment of products prior to launch, advising GM crop developers to conduct full market and trade evaluations in order to develop commercialisation strategies. Suggested activities include economic studies on the market segment, volume of exports and the value of development. Further suggestions are provided for the developer to consult relevant stakeholders such as farmers, government regulators, and stakeholders within the supply chain, enabling an overall analysis of the feasibility of the product and its likelihood of success.

To date, many commercialised GM crops contain an insect resistant trait (generally one or more of the Bts), but it has been identified that some insects have gradually developed resistance against the trait (Tabashnik & Carriere, 2010). As a result, ETS advises the developers to establish resistance manage strategies for minimising insect resistance development. The privatisation of agricultural services and the reduction of government spending in agricultural extension have reduced public sector’s role in this area (Farrington, 1995; Marsh & Pannell, 1998). This magnitude of difficulty further increases in developing countries, due to the large numbers of small-scale farmers and the high level of illiteracy. In addition, a monitoring programme is required by ETS, to measure the baseline susceptibility of target pests and to sample and monitor performance on a regular basis. Based on the criteria in this guideline, the additional activities remain the responsibility of the developer, even beyond product commercialisation, suggesting that GM developers are responsible throughout the entire product life cycle.
Figure 7.2 Key activities and processes for addressing plant product integrity from initial lifecycle of the product. Adapted from ETS (2014).
The most challenging aspect of ETS is the need to actively withdraw plant material at the end of the product life cycle by destroying all seed stocks while maintaining appropriate regulatory approvals throughout the discontinuation phase until an acceptable low-level of presence (LLP)\textsuperscript{59} is achieved. Public research organisations do not have the mechanisms to withdraw products from the market, which implies that legal licences need to be maintained indefinitely to minimise potential liability. Furthermore, there remain concerns when countries such as China adopt a zero-tolerance threshold for unapproved GM events which causes a major problem for all agricultural commodity trading. Even when a GM event has been discontinued, developers need to maintain regulatory approvals to minimise their legal liability.

In summary, ETS is structured to preserve and track the identity of GM crops throughout the product’s lifecycle. Guidelines developed by ETS implement management process in both the pre and post-commercialisation stages, reflecting the current challenges faced by the industry. The absence of international regulatory harmonisation has the potential to place strict liability on the developers, due to the risk of asynchronous approval, leading to international trade disruptions. For this reason, much emphasis has been placed by ETS on incorporating regulatory elements into the development process. Secondly, the current negative opinions of many consumers have generated wariness amongst traders and food manufacturers in utilising GM crops. In order for the developers to reassure industries and consumers the safety of the product, investments have been directed towards post-commercialisation processes, to ensure the continuing quality and integrity of the products.

The additional processes and activities enforced by ETS will increase the overall development cost of GM crops. Not only is compliance with ETS onerous and very expensive, it requires the authority to enforce excellent record keeping right from the laboratory to the consumer product. Only a limited number of large companies have this level of authority right through the value chain. ETS as an industry standard thus provides a major barrier to direct public sector commercialisation of GM crop advances. Furthermore, traceability

\textsuperscript{59}The term ‘low level presence’ is adopted to describe the accidental presence of small amounts of biotech events that have undergone full safety assessment and have receive regulatory approval for all possible uses in one or more countries but are still unauthorized in others due do regulatory asynchronicity or expiration of their approvals” (Kalaitzandonakes, 2011)
requires labelling at all steps and implementing ETS rules out the production and sale of unlabelled GM seeds and crops for local markets in the developing world\(^6\).

### 7.6 Public sector culture and behaviour

It is generally accepted that public research scientists have a responsibility to facilitate the innovation process through knowledge generation and to support the application of knowledge leading to innovative outcomes. Challenged by the limited resources and a diversity of issues, many governments have adopted a competitive funding approach, allowing the funders to focus on areas of priority and to maximise resource efficiency. This section examines the adoption of a competitive research funding system in China, and the public research culture that has resulted from it. This serves to illuminate the incentives and risks for public scientists engaging in commercial activities.

#### 7.6.1. Introduction of competitive grant system in China

Competitive granting is a mechanism designed for governments and organisations wishing to focus research funding priorities and to improve the relevance of research. The fundamental rationale of competitive grant systems is to induce competition amongst applicants, allowing funders to prioritise issues of concern and to focus funding on the ‘best’ laboratories and ideas. In the 1980s, special funding programmes were implemented by the Chinese government’s National Science Foundation of China (NSFC) including the 863 programmes for developing technology in areas of national interest. To accelerate science and technology research in China, a competitive granting system was introduced along with these funding schemes. Shortly after, in the year 1988, 33\% of the funding had transited from block funding into competitive funding (Rozelle et al., 1997). Over time, the competitiveness of national funding for science and technology development continued to increase and between 1985 and 1994, provincial and prefectural funding for research decreased rapidly by 43\% and 77\% respectively (Rozelle et al., 1997). Provincial funding was becoming more competitive, and Prefectural funding was seen as less competitive but suffered the largest decline. The combination of increasingly competitive national and provincial grants and the declining level of prefectural funding has resulted in a competitive environment for local

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\(^6\) Chapter 8 measures public GM crop projects based on the industrial standards illustrated in this section.
research institutions. Reputable national institutes and NKLs received a higher share of funding from national programmes. Between 1985 and 1994, the proportion of national competitive grants going to NKLs increased from 38% to 45% (Rozelle et al., 1997). At present, the majority of national research resources can only be accessed through the competitive grant system. The purpose of the reform is to create elite scientists in each field who have an abundance of resources, enabling them to generate quality outputs. Governments around the world have adopted the competitive granting system\textsuperscript{61}. Despite many benefits of a competitive research funding system, there are implications for the current culture for the public research system.

7.6.2. Access to competitive grants

Responsibility for governing the distribution of research funds is usually given to the relevant ministry/agencies, which implement processes for reviewing proposals and awarding grants. The funding allocation system is often criticised by local scientists, as the selection process is often vague and questionable. Furthermore, when the responsible agencies are calling for project proposals, the selection criteria for national projects are often ambiguous. Consequently, scientists may apply for funding from different agencies using the same project.

“In China, however, scientists could use almost the same idea to apply for grants from different government agencies and have almost identical projects funded. Government agencies, eager to show the central government that their programmes are worth the investment, are willing to fund a small number of well-established researchers with the expectation that their achievements would later be used to justify the funding and even become the sponsor’s own credentials.” (Cao et al., 2013)

The point being established here is that researchers who are well-known in their respective areas can more easily obtain competitive funding through multiple agencies. Furthermore, with the establishment of NKLs, there is a strong tendency for agencies to fund researchers within NKLs. As a result, senior researchers who have established a successful early career will continue to get financial support from the government. This results in different

\textsuperscript{61} The adoption of competitive funding systems is not unique to China, DBT from India has adopted a system with exactly the same notion of accelerating research in areas of interest. In Australia, the Australian Research Council administers two public research programmes, the Discovery Programme and the Linkage Programme and under both national grants are allocated based on a competitive system.
viewpoints on the competitive granting system, where successful grant applicants view the system as a success while the less fortunate believe the system is corrupt.

‘One CAAS research director, who was herself quite successful, frankly admitted that it was difficult for outsiders and newcomers to become a part of established “old boys’ networks”’. (Rozelle et al., 1997)

This has created a culture in China’s public research system, where the assessment of a scientific proposal is not purely on the quality of the proposal, but has a strong focus on the people involved in the project and the relationship between the scientists and bureaucrats. A hidden competitive advantage is always given to senior scientists who have maintained a long-term relationship with government officials (Shi & Rao, 2010). However, it is appreciated at the centre of government that clear transparent processes should be in place which clearly define the selection criteria and the objectives and chose successful applicants against those criteria. Consequently in 2014, as part of the Chinese anti-corruption campaign, the Chinese government arrested public research scientists who had misused public research funds. A government report identified that the well-funded national transgenic project was a target of the corruption (Qiu, 2014). It was further criticised by local scientists who felt the transgenic project had concentrated too much funding on a select few people who have strong political connections (Xin, 2014).

7.6.3. Incentives for public sector scientists

The only method to obtain national funding for young scientists who are not situated in a well-established laboratory is to climb up the hierarchical system. In China, there has been a deliberate national push towards ‘publish or perish’, with an emphasis for scientists to publish in Science Citation Index (SCI) or high Impact-Factor journals (Ding, 2001; Qiu, 2010). The need to publish is imposed by research institutes, as the national ranking of institutions is conducted by the Institute of Scientific and Technical Information of China with scorings base on the number of SCI papers and total impact factors produced. In order to advance their scientific careers, scientists need to regularly publish journal articles. The constant publishing and the competitive culture are not uniquely at the senior level, in fact, this culture norm has spread to graduate students. Ph.D. students are required to produce several SCI publications before being allowed to graduate; a mandate imposed by Chinese research institutions. Consequently, many graduate students publish information or findings,
merely to fulfil the criteria in order to gain the academic merit. The tremendous pressure applied by public institutions has resulted in students and scientists purchasing authorships for publications (Hvistendahl, 2013). The argument from institutions was that they need to use publications to track the performance of public scientists as there is no other evaluation system in place and that the only independent and verifiable key differentiator was peer reviewed publication.

Incentives go beyond securing research grants and progression in academia. A National Knowledge Innovation Program implemented by the Chinese Academy of Sciences (CAS) in 1998, aimed to accelerate scientific breakthroughs. Only a limited number of scientists were selected to partake in the programme. The benefit of being in the programme is the salary. Scientists under this programme can earn three to four times more than a colleague who is conducting similar work but not in the programme. Furthermore, there are monetary rewards for publishing in respected journals, ranging from $240 to $1,200 per article (Ding, 2001). The Chinese government has made financial incentives available either for personal gain or for enhancing laboratory capabilities. Again, to be selected, a good track record of publications is the minimum selection criteria. Of course not all scientists work in the public sector for financial benefits; some chose the career out of passion. But, in order to retain their positions within the research institutions, there is a need to regularly publish journal articles.

7.6.4. Risks outweigh the gains

It has been established that public research scientists have a risk-averse attitude towards commercialisation, even when financial incentives are provided (Bugge et al., 2011). Although profits generated from publicly developed technologies in China can flow back to the research institutions, the benefits are distributed amongst all staff as bonuses (Rozelle et al., 1997). The individual public researcher receives very little benefit from participating in commercial activities. The public sector has built a cautious attitude towards risks and the political consequences of failure (Potts & Kastelle, 2010). Often, taking personal cost and value into consideration, the risks of failures are seen to outweigh the probable benefits of success. Consequently, it is safer for public scientists to maintain the current state of affairs (Townsend, 2013). This lack of motivation and incentive creates barriers to public sector innovation (Casebourne, 2014). Private companies, on the other hand, are motivated to
innovate, even when confronted by the risk of failing, as their survival depends on their ability to compete within the market (Utterback, 1994; Cefis & Marsili, 2006).

Developers of GM crops face a further risk, that of social non-acceptance. The level of GM acceptance in China has significantly decreased in recent times due to a number of food safety issues and the Golden Rice incident where the GM rice was fed to local Chinese children purportedly without full authority approval or parental permission. Subsequently, to alleviate the fear of the technology, the Chinese government has wanted their public scientists to engage and communicate with the public, eradicating the current irrational fear. Numerous attempts have been made by public scientists to convince the public of the safety of GM, but in many cases the scientists have become the victims of GM antagonists. Members of public use online media as a form of cyber bullying, criticising their national researchers, branding scientists that advocate for GM as ‘national traitors.’ Professor Zhang Qi Fa, the principal scientist for the development of Bt rice in China, suffered attacks and accusations from the general public after delivering a lecture at the China Agricultural University (Stone, 2011). Incidents of activists raging against developers of GM crops have been observed outside China. In fact, it’s a global phenomenon. For example, field trials of Golden Rice in the Philippines were destroyed by activists in January 2016, claiming that the Golden Rice would contaminate local crops. The risk-averse nature of the public sector, coupled with the additional social risk, has resulted in most public institutions shying away for commercialising their GM developments. Of those that do advance into the commercialisation process very few succeed.

Overall, the competitive grant system started off with the intention of allocating resources to the best talents to ensure rapid and quality outcomes. In the early years of the system, scientists published journal articles to show competency for conducting national research. This has resulted in a group of elite scientists who have maintained a long-term relationship between themselves and with friends which presents a significant challenge for other scientists. The competitive system has generated a cultural norm, where researchers need to regularly publish in order to secure future grants. The very heavy administrative and organisational burden imposed in moving towards commercialisation does not result in additional high-quality publications and does not promote co-operative teamwork on national priorities. However, despite the competitive culture generated and the fact that the incentives motivating researchers have shifted towards career advancement and financial
incentives, there have been considerable scientific achievements from the competitive grant system.

7.7 Conclusion

This chapter analysed the organisational barriers to public GM crop developments, examining the current innovation strategy, innovation process and organisational culture of the public sector. Examining national strategies in India and China has revealed that no explicit innovation strategy has been put in place which would drive the commercialisation of publicly developed GM crops within the public sector itself. The analysis of agricultural biotechnology policies in both countries suggests that both governments have been focusing on promoting industrial growth through the private sector. The role of the public sector under the national innovation system is to act as a knowledge source, generating human resources and intellectual property assets. Consequently, few resources have been allocated for commercial activities in individual public institutions. Private companies have established industrial standards for the commercialisation of GM crops. However, the costs of regulatory compliance are beyond the capability of relatively resource-poor public sector projects, nor do the public organisations have the skills or long-term interest needed to meet those standards. Furthermore, the lack of incentives for public researchers to advance developments into commercial products creates additional barriers. Innovation strategy, innovation processes and organisational culture barriers do not appear to be independent. It has been often stated that an organisation’s culture drives the innovation process and development, but this chapter has clearly shown that national policy determines the direction and capacity of the public sector in working towards commercialisation of GM crops.

Key obstacles identified in this chapter:

- National policies of developing countries have outlined the need to invest in GM technology but no mandate has been given governments to make the public sector responsible for delivering GM crops to the market. In fact, current policy directions have limited the role of public research organisations to basic R&D and to facilitating the transfer of technology to the private sector. Consequently, investments made in the public sector have not allocated sufficient fund for building the organisational capabilities necessary to commercialise GM crops.
The regulatory environment has allowed the private sector to establish an industrial standard for all activities throughout the lifecycle of GM crops. Public research organisations do not have the organisational capacity and resources to deliver materials under such standard and the costs of ensuring traceability throughout the value chain reduces the benefits generated by the GM technology, potentially to a point where many public developments, especially minor crops, are no longer commercially viable.

The competitive grant system has created an environment which does not support collaborations between public research organisations for innovation commercialisation. Public research scientists compete against each other and are focused on generating journal publications for securing future research grants. The lack of financial and career incentives for public research scientists to engage in commercial activities, suggests that the majority of public GM crop developments are not conducted in a manner conducive to the delivery of a commercial product e.g. absence of FTO, lack of identification of uptake pathways, using marketable germplasm to transform etc.
Chapter 8

Public private partnership models - can they advance public GM crop developments

8.1 Introduction

Preceding chapters have indicated that the fragmentation of the public sector’s intellectual property rights, the unpredictable development costs and the cultural norms of public research organisations are obstacles to the successful commercialisation of publicly developed GM crops. To advance public GM crop developments, scholars from different disciplines have suggested a public-private partnership (PPP) approach, combining the strengths of the public and private sectors (Lewis, et al., 2000; Binebaum. 2001; Krattiger, 2002; Hartwhich et al., 2008). This model is extensively utilised in the infrastructure industry and has delivered public goods across a broad spectrum of industries. In the agricultural biotechnology industry, multi-national corporations (MNCs) have the resources, which are often absent in the public sector, to successfully commercialise GM developments i.e. the considerable financial capital, intellectual property rights to key technologies and a well-established pathway to market etc. (Kowalski et al., 2002). On the other hand, public research institutions have the knowledge of local markets, locally adapted germplasm, very often have developed the novel invention and performed proof of concept testing and can assist in improving the image of GM technology. Individual agricultural biotechnology PPPs are unique and can take a variety of forms. Byerlee and Fischer (2000) have described different types of potential partnership and observed the success of different PPP models in facilitating the development of GM crops in the public sector. The most common types of PPP collaborations have been:

- Donation of technology from private companies to public research institutions - The Commonwealth Scientific and Industrial Research Organisation (CSIRO) Bt cowpea programme in Nigeria followed this model, where Monsanto donated the Bt Cry1Ac technology under a royalty-free license.
- **Exchange of knowledge and information:** An example of this type of partnership is the collaboration between the Agricultural Genetic Engineering Institute (AGERI) in Egypt and DuPont Pioneer. AGERI licenced the patented Bt gene to Pioneer and, in return, Pioneer trained AGERI scientists on molecular characterisations techniques and processes for evaluating transgenic plants (Lewis et al., 2000).

- **A cost-sharing joint venture:** For example, Syngenta was responsible for obtaining the freedom to operate (FTO) and generating regulatory data for the Golden Rice project and the company retains the commercial rights outside humanitarian uses (Potrykus, 2001).

Syngenta negotiated with patent holders and provided an intellectual property package for the Golden Rice researchers. It was agreed that the public sector retains the rights to sublicense Golden Rice to public research institutions and to provide for poor farmers in developing countries. Syngenta initially planned to commercialise Golden Rice in developed countries but abandoned the commercial plan in 2005. Looking across current GM crop PPPs, the level of private sector participation in the partnerships has been minimal, mostly in the form of technological donation with no expectation of financial returns. Many agricultural biotechnology companies have donated their technologies to support public initiatives. For example, Monsanto donated their drought resistant gene to the Water Efficient Maize for Africa (WEMA) project, managed by the African Agricultural Technology Foundation (AATF).

To explore whether a PPP has advantages in driving public GM developments forward towards commercialisation and to address the challenges identified in preceding chapters, this chapter is a comparative case study of the publicly developed Indian Council of Agricultural Research (ICAR) Bt cotton, contrasted against the Collaboration on Insect Management for Brassicas in Asia and Africa (CIMBAA), a PPP for Bt cabbage and cauliflower in India. Both developments were targeting poor Indian farmers and operated under the same regulatory environment at much the same time.

**8.2 Case study on the process of a publicly developed GM crop**

To analyse the innovation processes of public GM crop developments, this section builds a case study on the ICAR Bt cotton, illustrating the developmental challenges faced by public institutions. No private companies were involved from R&D through to production and commercialisation.
8.2.1. A publicly developed GM crop- ICAR’s Bt cotton

India is the world’s second largest cotton producer with an annual production of over 6 million metric tonnes of cotton lint. According to the most recent International Service for the Acquisition of Agri-biotech Applications (ISAAA) report, the adoption rate of Bt cotton in India has increased from almost none in 2002 to 95% in 2015, covering 11 million hectares of land (James, 2015). The rapid adoption rate implies that the Bt technology is an effective tool in protecting farmers’ yields and/or reducing production costs. Bt cotton was officially introduced into India as hybrids (Mon531) in 2002 by the Maharashtra Hybrid Seed Company (MAHYCO), in partnership with Monsanto and was rapidly adopted by local farmers. A further event also developed by MAHYCO-Monsanto and containing the dual Bt genes Cry1Ac and Cry2Ab (MON-15985) was later introduced into India. 951 hybrids (87% of the total Bt cotton hybrids commercialised in India) have been generated from the MON-531 and MON-15985 events (Choudhary & Gaur, 2011; 2015). Several Indian seed companies realised the market potential for Bt cotton and obtained licences for Bt genes for their hybrid varieties. For example JK Agri-Genetics licensed the Bt in their varieties from Monsanto but there are other approved Bt genes. Nath Seeds licensed a Cry1Ab/1Ac fusion gene from the Chinese Academy of Sciences (CAS) (Table 8.1).

<table>
<thead>
<tr>
<th>Event</th>
<th>Gene</th>
<th>Developer</th>
</tr>
</thead>
<tbody>
<tr>
<td>MON-531</td>
<td>Cry1Ac</td>
<td>MAHYCO-Monsanto</td>
</tr>
<tr>
<td>MON-15985</td>
<td>Cry1Ac and Cry2Ab2</td>
<td>MAHYCO-Monsanto</td>
</tr>
<tr>
<td>Event-1</td>
<td>Cry1Ac</td>
<td>JK Agri-Genetics</td>
</tr>
<tr>
<td>GFM Event</td>
<td>Cry1Ab and Cry1Ac fusion</td>
<td>Nath Seeds</td>
</tr>
<tr>
<td>BNLA-106</td>
<td>Cry1Ac</td>
<td>CICR and UAS Dharwad</td>
</tr>
<tr>
<td>MLS-9124</td>
<td>Cry1C (synthetic)</td>
<td>Metahelix Life Sciences</td>
</tr>
</tbody>
</table>

*Table 8.1. Bt cotton events approved for commercialisation in India. Source: IGMORIS, 2012.*

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62 While the regulatory system was still assessing the Bt cotton forwarded by MAHYCO-Monsanto, illegal Bt cotton seeds were discovered in the state of Gujarat in 1999 and were officially reported in 2001. The illegal seed was marketed as NavBharat seed but contained the Bt Cry1Ac developed by Monsanto. This event had not gone through the regulatory system mandated by the Genetic Engineering Approval Committee (GEAC), but local entrepreneurs had already managed to cross it into the local seed supply, with more than 11,000 hectares of illegal Bt cotton growing in 2000 (Jayaraman, 2001). It has been argued that the approval of MMB’s Cry1Ac cotton in 2002 was effectively forced on the Indian government by this unofficial, but highly successfully, growing of Bt cotton by thousands of farmers.
Before 2006, the price for hybrid Bt cotton seeds was c.Rs 1,600 for a packet of 450 grams, sufficient for one acre of land. The pricing of Bt cotton seeds generated outcries from local farmers and eventually led to government interventions. In 2006, the Maharashtra state government in India set the maximum price of Bt cotton at Rs 750 per packet (Sadashivappa & Qaim, 2009). Intense pressure from the Government of India was applied to local institutions for a publicly developed Bt cotton, in an attempt to maximise the trait value to cotton farmers 63.

In 2008, the BNLA-106 event was approved and commercialised. This was the first public Bt cotton event developed indigenously in India. Three public Indian research institutions contributed to this project; the National Research Center on Plant Biotechnology (NRCPB), the University of Agricultural Sciences (UAS) Dharwad and the Central Institute for Cotton Research (CICR), all under the ICAR system. Unfortunately, due to poor agronomic performance, the Bt NHH 44 hybrid (generated from BNLA-106) was withdrawn from the commercial market after one season in 2009. Furthermore, it was reported that the Bt NHH44 (BNBt) contained Monsanto’s Cry1Ac instead of the intended BNLA-106 Cry1Ac. This incident led to an investigation by ICAR into the development process of BNLA-106.

8.2.2. Integrity of BNLA106 event

The BNBt project was divided between the three public research institutions. The role of NRCPB was to provide the gene construct for transformation and to generate molecular information for regulatory approval. A Cry1Ac gene developed by researchers at the University of Ottawa was used to develop the construct. UAS, Dharwad was in charge of plant transformation, screening of plant materials, and producing seeds for biosafety studies. CICR was responsible for conducting confined and multi-location field trials and producing breeders’ seed. The role of marketing and distribution was given to the Maharashtra state seed corporation. However, according to the ICAR report, at a certain point during the development process, contamination occurred, resulting in Monsanto’s Cry1Ac being present in the commercialised seed.

To determine whether this incident was a case of contamination or due to other factors, steps were taken by ICAR to examine the development process and confirm the validity of

63 The conventional varieties were sold at 450 Rs per packet and at that time MAHYCO was charging Rs 1,250 as the ‘trait value’ (Sadashivappa & Qaim, 2009). The price intervention reduced the value captured by the developers and provided additional value for Bt cotton to the farmers.
BNLA-106’s Cry1Ac. The initial validation of the construct was based on results generated from a Southern hybridisation analysis published in Current Science (Katageri et al., 2007). However, the validity of the conclusion reached was questionable, as the detection method was based on utilising Cry1Ac as a probe, with the method not able to differentiate between BNLA-106 and MON531’s Cry1Ac. After the identification of the substitution of Monsanto’s Cry1Ac for NRCBP’s Cry1Ac, further results were provided using a ‘purified’ BNBt construct. The ICAR report stated that:

“4.0.3 During the visit of the committee to NRCPB, Dr Kumar presented Southern hybridisation analysis data which indicates that when the Cry1Ac gene is used as a probe, and plant genomic DNA is digested with HindIII, a ~7kb fragment is detected in ‘purified’ BNBt, and an 8kb fragment is detected in MON531. Dr Kumar also presented data from flanking sequence information of the event in “purified” BNBt, and event specific markers for the same which have now been developed. Furthermore, PCR primers that are directed against NOS promoter (a unique feature of pBinBt3) and the vector backbone amplify a product of 1.4kb from the “purified” BNBt that is different from MON531.” (ICAR, 2012)

However, it was stated in the report that the results of a third party testing of BNBt seeds concluded that the MON531 event was the only event present in all the seeds tested. This further generated questions regarding how the ‘purified’ BNBt was collected and whether NRCPB’s Cry1Ac was actually different from Monsanto’s Cry1Ac. Despite ICAR claiming that NRCPB’s Cry1Ac was indeed different from Monsanto’s Cry1Ac, full molecular characterisation of the event was never achieved during development of BLNA-106. No event-specific primers were designed for detecting the construct nor was the complete sequence of the event provided64. To date, the identity of the construct remains questionable. Furthermore, construct validation in the subsequent development phases did not occur. Scientists at UAS, Dharwad used enzyme-linked immunosorbent assays (ELISA) and insect bioassays to identify transformed plants. Again, both methods were conducted to test the expression of Cry1Ac and the killing power of the construct and were not able to assess the construct’s unique identity. Reflecting back to industry’s procedures under the Excellence Through Stewardship (ETS), outlined in Chapter 7, prior to transformation the identity of the construct should be established. This requires a full sequence analysis of the construct, restriction endonuclease mapping, PCR using specific event primers, Southern hybridisation with event specific probes and other applicable methods (ETS, 2014) as was

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64 Full sequence analysis of the event and event specific primers are regulatory requirements for approval in all jurisdictions. Approval with absence of critical requirements suggests serious issues with the Indian regulatory system at the time.
done for the CIMBAA elite event brassicas (see below). However, the only validation information on BNLA-106 present in cotton was based on testing for the presence of Cry1Ac.

It is common practice during product development for organisations to repeatedly apply identity tests in order to ensure the quality of the development, helping to ensure the calibre and purity of their product and so to maximise their eventual market share. As there are extensive regulatory requirements for commercialising GM crops, many of the experiments which need to be undertaken can serve both purposes. It is an essential step in ensuring a high-quality GM crops that the developer generates and identifies events with the highest agronomic performance, not simply verifying the efficacy of the trait in the plant. This requires accounting for adaptation to soil and climate with the output being yield and field quality and ensuring that the trait insertion has not compromised the agronomic performance of the plant transformed. Large numbers of independent transformations need to be generated for subsequent selection of the elite event(s) which are to be taken forward to commercialisation. However, this was not the case for the BNBt project. The BNLA-106 event was selected from just two independently created events.

“5.03 Only two Southern positive transformants were obtained in the development of BNBt; one of which was single copy and the other was multi-copy. As the multi-copy line was not used further, it meant that only one event was available. This is grossly inadequate, as a large number of events need to be screened in the event selection trials to identify the best performing line having commercial potential. It may be added that it is not impossible to get an agronomically desirable strain from a single transgenic event. However, its probability is extremely low.” (ICAR, 2012)

The choice of germplasm to transform was poor and furthermore, in the commercial seed production process, it was later identified that inadequate backcrossing had been done and the traits were still segregating, resulting in a mix of seed with and without the Bt trait, resulting in the overall poor performance of BNBt cotton, exacerbating the problem.

“5.0.8 Commercial seed production procedures were not followed, even though there is a well-established procedure in this regard. For example, had the breeders/seed production scientists been more careful in monitoring, the segregation/admixture for morphological traits like petal and pollen colour could have been easily identified and red flags raised.

5.0.6 There seemed to be an extreme hurry to come up with a public sector Bt cotton. Agronomic evaluation is normally started when strain(s) are nearly homozygous and
homogeneous. But in the present case, BNBt was put under field evaluation before the homogeneity was achieved”. (ICAR, 2012)

It is not clear at what stage the substitution of the Monsanto’s Cry1Ac for the public NRCPB’s Cry1Ac took place and who was responsible, but it must have been before the material was provided to CICR for selection and seed production. Many of the validation processes required to ensure the quality of the developed varieties were not implemented during the development of BNBt cotton. The overall quality of this public sector GM crop was poor and resulted in a commercial failure in a single field season. The lack of commercial consideration from the public sector throughout the whole process strongly contributed to the poor performance of BNBt. Even ignoring the issue of which Bt was present in the commercialised plant material, the development process was conducted in a manner similar to a small-scale scientific project. The developers seemed to believe that the product from a proof of concept was sufficient to deliver quality plant material capable of meeting regulatory requirements and satisfying the agronomic needs of the market.

8.2.3. Poor implementation of the management practices

The foundation of the ETS guidelines builds on process management, implementing procedures to ensure steps are carried out accordingly, whether it is quality, identity preservation or meeting regulatory requirements65. In the ICAR Bt cotton case, the absence of guidance and of a structured programme management system was a major factor in the lack of validation or quality checks during the development process. This was deficient coordination at the management level.

“7.0.6 Dr Katageri says that he is a conventional breeder and did not have competence and facilities to discriminate MON531 and BNLA106 events. It is pertinent to note that, in the NATP proposal, Dr Katageri is listed as the person responsible for molecular analysis of the transgenics. If he had no requisite expertise, he should have had the necessary correction made in the project proposal…” (ICAR, 2012)

Paragraph 7.06 clearly highlights the inadequate planning of the project. The responsibility allocated to Dr Katageri was to carry out the transformation and ensure the integrity of the plant at the molecular level; one would expect that the allocation of tasks would match the skills and expertise of the responsible person in charge. This issue was never resolved during

65 For details, see Chapter 7, Section 7.5
the development process, implying a poor oversight from ICAR. Even the report from the investigation committee was unable to identify the exact point at which the \textit{Cry1Ac} substitution was made.

Another element suggesting poor management structure was that the project never had the freedom to operate (FTO). NRCPB’s \textit{Cry1Ac} gene used for the development of BNBt was given by Dr Altsosaar from the University of Ottawa, under a material transfer agreement (MTA) signed in 1996, by Dr Sharma, the former Director of NRCPB. In order to secure the intellectual property rights for commercialisation, Dr Ananda Kumar (Principal Investigator at the NRCPB) negotiated with the University of Ottawa for a FTO agreement on the \textit{Cry1Ac}. In response, the University of Ottawa requested an intellectual property due diligence (Annexure IV-B, 57-58, ICAR, 2006). In a meeting held on during October 2006, this issue was raised and discussed. However, ICAR felt the FTO agreement was not necessary. Below is part of ICAR’s comments from the minutes of the meeting:

\begin{quote}
“It was decided that we should continue with R&D and bio-safety related work for the release of indigenously developed Bt cotton varieties/hybrids. If any difficulty is encountered in future, that will be handled at that time in future. For the same, it was also decided that the ‘Freedom to Operate’ analysis as desired by the University of Ottawa in its e-mail correspondence with Dr P. Ananda Kumar is not required at this stage.” (Annexure-XIII, Page 127, ICAR, 2012)
\end{quote}

The investigation committee concluded that the ICAR’s stance on intellectual property considerations meant that the project had violated the MTA agreement between the NRCPB and the University of Ottawa. Suggestions were given to ICAR for taking legal opinions on the infringement of intellectual property right and recommendation was made to immediately establish FTO for genes obtained from Dr Altsosaar and other sources. Interestingly, the FTO discussion occurred after the promulgation of the newly amended patent law due to the TRIPS agreement and the new intellectual property guideline published by ICAR in September, 2006. Yet, a critical step in minimising legal liability was simply and deliberately ignored by the Indian public research system at a very senior level.

This case study examining ICAR’s Bt cotton, illustrates common problems in the innovation process in public sector institutions developing GM crops. The inappropriate scale of transformation and lack of validation and quality processes resulted in a commercial failure. At the point of commercialisation, Monsanto’s \textit{Cry1Ac} was identified, instead of NRCPB’s \textit{Cry1Ac}. As such, all biosafety studies conducted were deemed invalid by the investigation.
committee. It is interesting to note that the lack of molecular characterisation of the event did not prevent the Genetic Engineering Approval Committee (GEAC) granting commercial approval for it, reflecting a serious issue with the Indian regulatory system at the time. The management structure of the project further hindered the development, producing potential liabilities for the developer. From the case study, it appears that the public research institutions were either not aware of the processes required to successfully commercialise a GM crop or chose to ignore them.

This example remains the only Indian GM crop from a public developer to achieve regulatory approval and commercialisation (briefly). Although this development may not represent all public sector developments, it does highlight some of the inadequacies of public sector science in the commercial arena. The industry’s implementation of additional post-commercialisation processes and management systems under the ETS system present further challenges for the public sector as described in Chapter 7.

8.3 A public-private partnership model- CIMBAA

Cabbage and cauliflower are major vegetables produced and consumed in India. According to the most recent published FAOSTATS (2015), India was the world’s second largest producer with an annual production of 8,534,000 tonnes of cabbage and other brassicas and 7,887,000 tonnes of cauliflower and broccoli. Both crops are cultivated for the most part on small-scale plots and are of considerable economic importance to local farmers. As cultivation intensifies, pest infestation causes losses in yield which have proven difficult to reduce. Among the insect pests, Diamondback moth (DBM) *Plutella zylostella* (L.) poses the most serious threat and frequently causes a yield loss of greater than 30% in vegetable brassicas (Lingappa et al., 2004). Globally, it is estimated that the economic cost of lost production and of insect control of DBM is between $4 and 5 billion, where the cost of cabbage and cauliflower protection in India alone has reached more than $228 million per year (Zalucki et al., 2012). Due to the immediate effects and the ease of application of chemical insecticides, excessive insecticide spray regimes have negatively impacted farmers’ health (Weinberger & Sirnivasan, 2009). To make matter worse, DBM can develop resistance to newly introduced insecticides after only one or two cropping seasons (Sandur, 2004). Other Lepidopteran pests are also a major problem in brassica production in India, notably cabbage webworm (*Hellula undalis* (F)), cabbagehead worm (*Crocidolomia binotalis* (Zeller)),...
cotton bollworm (*Helicoverpa armigera* (Hübner)) etc. Conventional breeding programs have not developed any commercial varieties that are resistant to DBM and other pest-management strategies have not been successfully adopted into farmer’s agronomic practice on any considerable scale.

CIMBAA was established to address these challenges. The main strategy adopted in the collaboration was to provide a sustainable solution by developing cabbages and cauliflowers which constitutively express Bt proteins within the plants. By introducing a self-defence mechanism into the plant, the input cost for farmers would be reduced and the cycle of reliance on insecticides and the resulting insect resistance development would be broken. CIMBAA intended to license the technology to any breeding company, public or private, which had the capacity to handle the material appropriately in terms of adherence to quality control standards, regulatory compliance and record keeping. India was the first targeted country, primarily because of the scale of production and the severity of the pest issue, but also as having a biosafety regulatory system which had previously approved GM crop (Bt cotton) for cultivation. It was believed that the public-private nature of this collaboration enhanced the transparency of GM crop developments and it was specifically designed to benefit the poor.

CIMBAA consisted of five partners and was formed at an initial meeting held in 2000. The public sector partners involved were:

- The Natural Resources Institute (NRI) of the University of Greenwich, UK
- The Entomology Department and the Office of International Programmes, Cornell University, USA
- The University of Melbourne, Australia
- The World Vegetable Center (AVRDC), Taiwan

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66 It is inevitable that insects will develop resistance against insecticides, including the Bt proteins. However, Zhao et al. had shown that stacking Bt proteins, which had separate binding sites in the insect gut, was effective in delaying resistance development (Zhao et al., 2003). CIMBAA’s strategy was to stack Bt *Cry1B* and *Cry1C* (which have separate binding sites) and to promote their use with other complementary insect resistance management strategies for delaying resistance development.

67 At that time, CIMBAA believed that India had a well-developed biosafety regulatory system for approvals of GM crops.
The private partner was Nunhems Pvt., which was soon to become the vegetable seed division of Bayer Crop Science. In addition to the mentioned partners, several public research institutions were involved in parts of the collaboration:

- Indian Agricultural Research Institute (IARI), India
- The Energy and Resources Institute (TERI) University, India
- Central Institute for Cotton Research (CICR), India
- Bogor University, Indonesia
- FAL, Switzerland
- Wageningen University, Netherlands
- Commonwealth Scientific and Industrial Research Organisation (CSIRO), Australia
- Max Plank Institute for Chemical Ecology, Germany
- Nanjing Agricultural University (NAU), China

8.3.1. Advisory and management of the collaboration

After the identification of the technological problems and market opportunities, there was a need to define and align common goals and incentives for all participating partners and to lay out activities and responsibilities of each partner involved in the collaboration. CIMBAA was built on a management committee model, where each partner designated a committee member. The Steering Committee comprised the directors from partner institutions and was responsible for ensuring that CIMBAA’s activities were appropriate, scientifically based, efficient and in the best public interest. The private sector appointed Nunhems’ Director of Research. Members of Steering Committee met at least twice a year to review CIMBAA’s progress and provide direction and advice to the project coordinators. The project management team implemented advice from the Steering Committee and discussed the progress on a monthly basis by conference call. CIMBAA had an effective communication system, which is critical for any public-private partnership project hoping to succeed (Pinto & Slevin, 1987; Belout & Gauvreau. 2004). In addition, CIMBAA established an International Advisory panel to oversee the progress of the project, ensure that it was operating to international ‘best practice’ standards and to act as ambassadors for the project in

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68 When CIMBAA was in the early stages of formation the intention was to move away from the MNC image and at that time Nunhems was an independent Dutch vegetable seed company operating in India. However, in 2002, Nunhems was acquired by Bayer Crop Science.
international circles. The panel consisted of current and past Directors General of international agricultural research centres and institutions, including of Consultative Group on International Agricultural Research (CGIAR) organisations, CSIRO and various institutes under ICAR. Members of the International Advisory panel were motivated to see whether CIMBAA could be utilised as a model for future public GM crop developments which were becoming a preferred commercialisation route for public sector developments at that time.

It was crucial for CIMBAA to engage with government officials and local research institutions in India. An Indian Advisory panel was established to assist CIMBAA to be clear on the evidence which would be required to allow the developed plant material to address all the concerns of the Indian regulatory systems. The panel provided a route for the project to receive technical guidance for studies to be conducted in India and to ensure that the work and data were understood by senior Indian government scientists. The panel was chaired by the Vice-Chancellor of TERI University, which led the communication aspects of CIMBAA. The committee members were directors and senior scientists from ICAR, NRCPB, IARI, the Department of Biotechnology (DBT), the National Bureau of Plant Genetic Resources (NBPGR) and included members of the Indian government apex GM approval body at the time, GEAC. **Figure 8.1** provides a detailed overview of CIMBAA structure and the name and position of original committee and panel members, though there were some changes over time.
Additional Research Partners

IARI, India
TERI University, India
CICR, India
Bogor University, Indonesia
FAL, Switzerland
Wageningen University, Netherlands
CSIRO, Australia
Max Planck Inst. Chem. Ecol. Germany
NAU, China

IARI, India
TERI University, India
CICR, India
Bogor University, Indonesia
FAL, Switzerland
Wageningen University, Netherlands
CSIRO, Australia
Max Planck Inst. Chem. Ecol. Germany
NAU, China

Figure 8.1 The CIMBAA structure.
8.3.2. The role and activities of CIMBAA partners

Despite the common goal of developing caterpillar-resistant plant and providing them to Indian and then global brassica farmers, partners of the collaboration had different emphases on activities they wished to pursue, partly in response to donor objectives (see next section). NRI’s interest was to undertake research for the benefit of developing countries. The University of Melbourne and associated public research partners had a major focus on basic research. Cornell University has a long history in GM crop developments and supporting their commercialisation. For example, the Agricultural Biotechnology Support Project, led by Cornell University, assisted a number of GM projects in developing countries, including the Bt brinjal for South Asia and the virus resistant papaya for the Philippines. A number of public research partners were interested in the socio-economic aspects or the environmental impact of GM insect resistant cabbage and cauliflowers. Only two partners within the collaboration agreed to take on commercial activities—AVRDC and Nunhems.

CIMBAA’s intention was to reduce the opportunities for monopoly profits and, to guarantee that the materials were accessible to public and private sector breeders on a ‘level playing field’ basis and to research institutions for further development, by holding the licensing rights in the public sector. AVRDC agreed to hold the CIMBAA licences and the regulatory dossier and to license the plant materials to breeders, as they believed that GM was the next platform technology in improving vegetable varieties and that they should be at the forefront of that development. Nunhems decision to join the collaboration was partly due to their interest in seeing whether the public sector was able to successfully introduce GM food crops which are directly consumed by the public. They believed that the public orientation of the collaboration would assist in reducing the negative perception of GM crops. They wished to see a ‘public sector pull’ rather than a ‘private sector push’ for a GM crop in the developing world. From the start, they appreciated that the project on its own was not likely to return a commercial profit, as the cost of development and regulation were much more than the value of the annual Indian brassica seed market, but it was to be a potential ‘door opener’ for other developments. Nunhems assisted strongly in the GM construct, design, insertion, plant transformation and breeding. The agreed division of activities between the public and private sector partners is outlined in Table 8.2.
The activities conducted were designed in four different phases (Russell & Uijtewaal, 2008). Phase I (2002-2004) conducted country need assessments, technical feasibility studies, identified genes of interest and engaged with partners and stakeholders. By the end of Phase II (2005-2007), the partnership was formally established and had demonstrated the need for an ‘in-seed’ solution. Transgenic plant materials were developed and preliminary studies of plant materials under field conditions were undertaken. Phase III (2007-2010) focused on the efficacy of the Bt plant against a range of key pests, the selection of plants for commercialisation and developing an integrated pest management context for the material. Phase IV (2011-) was to conduct formal regulatory studies in India, followed by submission of the regulatory dossier for cultivation approval in India and for biosafety import approval in other regulatory regions.

In addition to key developmental activities, CIMBAA structured a stewardship programme, prior to the establishment of ETS in 2008, ensuring that the product would make a long-term contribution to sustainable agriculture with optimal yields and the least possible environmental interference. The benefits of the technology could only be realised on a long term scale if the product was properly managed. Three major areas were targeted by the programme: 1) integrated pest management, 2) resistance development management and 3) an on-going quality and resistance monitoring programme. Post-commercial monitoring teams were to be established to maintain the quality of the plant material by regularly
assessing the level of Bt expression in plants and monitoring resistance development in the target insects. It was proposed that the modest licensing fees generated from seed companies would cover the cost of the stewardship programme which would be run by public sector organisations in India.

8.3.3. Nunhems’ contribution to the commercial development

It was appreciated from the start that to have a good chance of commercial success, an optimal gene candidate would need to be put into commercial grade plant lines. The consortium selected the Cry1B and Cry1C genes, both of which were known to be effective against DBM and FTO was available. Cry1C was proprietary to Bayer Crop Science and Cry1B was publically available. Initial efficacy studies of the Cry proteins used lab produced pure proteins and were conducted in China, India, Indonesia, US and Australia (Shelton et al., 2009). These studies provided confidence in the broad usefulness of the Cry1B/1C combination. Studies at the University of Melbourne and IARI showed, over 20 generations of selection, that the Cry1B/1C combination was practically immune to resistance in DBM, giving the expectation of long term field efficacy. The public sector conducted molecular characterisation activities and all the entomology studies. Furthermore, a consumer study was undertaken in 2006-2007 by the public sector. This demonstrated the market feasibility and probable public acceptability of the product (Krishna & Qaim, 2008; Weinburger & Srinivasan, 2009).

Nunhems, which became part of Bayer Crop Science in 2002, was responsible for activities including plant transformation, contained and confined field trials, and final elite event selection assisted by the other partners. In addition to the capability to conduct large-scale development and trials on its proprietary field sites in India, Bayer Crop Science had the necessary regulatory and commercial understanding to ensure the final materials would meet all the regulatory requirements and have the desired agronomic characteristics. In the plant transformation phase, Bayer Crop Science stacked the Cry1C and Cry1B sequences next to each other in a single genetic construct on a single chromosome, minimising the chance of accidental segregation by breeders in the future. Given that there is a broad spectrum of cabbage and cauliflower varieties, Nunhems targeted germplasm that had the largest share of the market for transformation, providing 550 cabbage transformation events and 600

69 An Elite Event is the name given to plants derived from a single transformation which will be used for further breeding for the purpose of commercialisation.
cauliflower events for selection, with the first molecular characterisation and line selection conducted at the Nunhems headquarters in the Netherlands. As required under Indian Government regulations Nunhems setup an Institutional Biosafety Committee in 2005. Members include Indian scientists from the DBT, the quarantine service and other relevant organisations. The committee applied for import licenses from the Review Committee of Genetic Manipulation (RCGM). Approval was received in 2006 and 85 lines were imported. As the first regulatory step was to demonstrate the usefulness of the plant in a contained trial (i.e. under strict quarantine and not in the open air), a polyhouse was built on the Nunhems field sites at Bilaspur near Delhi to test the performance of the plants and to demonstrate proof of concept and satisfy the regulator, allowing for large scale field trials in the following seasons. After the preliminary testing and selection of a small number of well-performing lines, large scale screenhouse trials were conducted in the 2008 and 2009 seasons, on Nunhems sites at Murthal in Haryana in North India and Bengaluru in the South.

Molecular assessments of events were based on gene copy numbers, segregation and, ELISA tests for the presence of the Bt proteins. The public sector partners (TERI University under contract to NRI) assessed the efficacy of the plant against a range of major and minor lepidopteran pests. Entomology was scored based on the performance against DBM, cabbage webworm (*Hellula undalis* (F)), cabbage cluster caterpillar (*Crocidolomia binotalis* (Zeller)), cabbage white butterfly (*Pieris brassicae* (L) / *P. rapae* (L)), cotton bollworm (*Helicoverpa armigera* (Hübner)), and cabbage leaf worm (*Spodoptera litura* (F)). Nunhems plant breeders assessed the agronomic performance of the trial events based on 15 different characteristics, including, firmness, size, colour, field standing capacity, etc. Four years of studies and selection from the initial 1,150 transformations produced in 2005, resulted in a single elite event cabbage and a single cauliflower determined as the most suitable for further development to registration with two backups of each (Figure 8.2). Highly detailed molecular characterisation of these three events for cabbage and three for cauliflower were carried out at the University of Melbourne to ensure that the events were single copy, had no residual molecular backbone, had the full length of *Cry1B/1C* insert and were expressing appropriately. The Melbourne team had earlier produced an unambiguous molecular screening test for the CIMBAA sequences as required by the regulators. Once approved, these events were used as parents for generating commercial hybrids. It is worth mentioning

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70 Field sites for GM crop testing require approval from the RCGM and, of the partners, only Nunhems had the approved properties for testing GM crops. Although CIMBAA could have approached ICAR and accessed their RCGM approved sites for testing, considering the potential liability of accidental release which would have stayed with Nunhems, this option was not pursued.

71 Events were kept as ‘back-up’ in case of any later problem with the elite events.
that usually only one event progresses through to the next phase, as the regulatory costs makes it impractical for developers to take multiple events through to registration.

![Diagram of Elite Event selection process for Bt cabbage](image)

**Figure 8.2** A summary of the Elite Event selection process for Bt cabbage.

### 8.3.4. Public sector funding arrangement

It was estimated that the completion of the project with regulatory dossier submissions would cost the project a total of 15 million Euros (approximately $22 million\(^{72}\)). The CIMBAA agreement had the private sector funding its own activities and the public sector covering its own costs, partly to minimise any suggestion that the public partners were ‘in the pockets’ of the private sector. The public sector responsibilities included the efficacy and biosafety of the material. This was felt to be important for the development of public trust. It was clear that no single donor was going to be prepared to fund what was potentially a 10 to 15 year, multimillion dollar project. CIMBAA followed a multi-donor approach, as donors proved to be more willing to support individual projects, rather than to contribute to the originally suggested central CIMBAA investment fund. An advantage was that the funds for particular activities allowed the leading partner of individual projects to work efficiently and on time. However, the potential drawback of such a strategy was that particular areas of study might

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\(^{72}\) Based on the average 2010 exchange rate.
have difficulties in gaining financial support at the necessary time. CIMBAA was fortunate to obtain funding from different sources for the scientific development and social-economic studies. The United States Agency for International Development (USAID)’s Program for Biosafety Systems funded the Phase I development- including technical feasibility studies and gene selection. The Eislen Foundation funded the socio-economic impact assessment in India. A Taiwanese government grant supported AVRDC’s insect resistance management research. An Indo/Dutch programme funded some social aspects of the study, including stakeholder engagement. The UK Department for International Development (DFID) provided support to NRI for studies on public-private partnership structures, the advisory panel costs, the overall project management and most of the technical work of the public sector, through a series of grant from 2002 to 2010. The prime intent for DFID was to ascertain whether a PPP model could deliver a ‘poor friendly’ GM crop into the developing world. A DFID representative attended the CIMBAA Steering Committee meetings ex officio. By 2010, CIMBAA had utilised 4 million Euro (approximately $5.2 million USD) in public partner contributions and the private partner had contributed at least an equal amount in funding its own costs (Table 8.3). Appendix 5 provides a detailed overview of CIMBAA’s funding arrangement for key activities.

<table>
<thead>
<tr>
<th>Country</th>
<th>Donor</th>
<th>Time</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>USA</td>
<td>Programme for Biosafety System- USAID</td>
<td>2005-2008</td>
<td>$300,000</td>
</tr>
<tr>
<td>UK</td>
<td>Department for International Development</td>
<td>2006-2010</td>
<td>$4,500,000</td>
</tr>
<tr>
<td>Germany</td>
<td>Eislen foundation</td>
<td>2006-2008</td>
<td>$180,000</td>
</tr>
<tr>
<td>Holland</td>
<td>Indo-Dutch tailor-made biotech programme</td>
<td>2007-2010</td>
<td>$275,000</td>
</tr>
<tr>
<td>Taiwan</td>
<td>Taiwanese government grant</td>
<td>2007-2008</td>
<td>$75,000</td>
</tr>
<tr>
<td>Australia/India</td>
<td>Australia/India Strategic Research Fund-Department of Industry Innovation and Scientific Research, Australia/ DBT, India</td>
<td>2008-2011</td>
<td>$758,000</td>
</tr>
</tbody>
</table>

Table 8.3 Public sector donors for CIMBAA. Note: All financial figures are converted to USD based on the average exchange rates at the start of the funding.

8.3.5. Arrangement of intellectual property rights and issues of liability

It was briefly mentioned in Chapter 4 and demonstrated in Chapter 5 that the development of a GM crop consists more than just the insertion of a gene of interest. Plant transformation
requires plasmids, constitutive promoters, terminators, selectable markers and methods of transformation, technologies that are often protected by intellectual property systems. Consequently, developments that are commercially focused need agreements from respective patent holders to prevent potential infringement. CIMBAA benefited from their partnership with Nunhems, as their parent company Bayer Crop Science assembled all the necessary intellectual property rights for GM crop commercialisation. Table 8.4 outlines all the technological components supplied by the private partner to construct the CIMBAA materials, including the use of *Agrobacterium* transformation. Due to commercial confidentiality, Nunhems never provided a list of patents or documents proving that they had the rights to respective technologies. Instead a letter was provided to the public sector stating that Nunhems had all the commercial rights for the technological components listed which were sufficient to provide FTO for the project.

<table>
<thead>
<tr>
<th>Name of the technology</th>
<th>Definition</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>pTDL008 derived from pGSC1700</td>
<td>Plasmid vector</td>
<td>For transformation into targeted material</td>
</tr>
<tr>
<td>LB</td>
<td>Left Border repeat</td>
<td>Cis-acting element for T-DNA transfer</td>
</tr>
<tr>
<td>3’me 1</td>
<td>Terminating signal for <em>Cry1B</em> and <em>Cry1C</em></td>
<td>Stop signal</td>
</tr>
<tr>
<td><em>Cry1B</em></td>
<td>Insect resistance gene</td>
<td>Insect resistance</td>
</tr>
<tr>
<td><em>Cry1C</em></td>
<td>Insect resistance gene</td>
<td>Insect resistance</td>
</tr>
<tr>
<td>Ps7s7</td>
<td>Promoter for <em>Cry1C</em></td>
<td>High-level constitutive expression</td>
</tr>
<tr>
<td>Ps4s4</td>
<td>Promoter for <em>Cry1B</em></td>
<td>High-level constitutive expression</td>
</tr>
<tr>
<td>P35S3</td>
<td>Promoter for <em>bar</em></td>
<td>High-level constitutive expression</td>
</tr>
<tr>
<td><em>Bar</em></td>
<td>Glufosinate ammonium-tolerance gene</td>
<td>Herbicide tolerance selectable marker</td>
</tr>
<tr>
<td>3’ nos</td>
<td>Terminating signal of <em>bar</em> gene</td>
<td>Signal terminator</td>
</tr>
<tr>
<td>RB</td>
<td>Right border repeat</td>
<td>Cis-acting element for T-DNA transfer</td>
</tr>
</tbody>
</table>

**Table 8.4** Technologies required for the genetic modification of the CIMBAA plant material.
The Government of India placed a strict liability on the developer for any harm caused by the GM materials, at least prior to commercial approval from the regulatory authorities. CIMBAA was concerned with the possibility of unauthorised release of materials during field trials, leading to movement of seeds outside the trials sites and potentially into countries which had no approvals. In addition to seeking biosafety and cultivation approval in India, CIMBAA planned to obtain import approvals (non-cultivation) from the major regulatory jurisdictions; US, Canada, Europe and Japan and to seek cultivation approvals in the countries with the highest potential for exploitation of the particular sub-tropical brassica germplasm containing the CIMBAA gene e.g. Bangladesh and Philippines. A molecular kit for detecting the CIMBAA construct was developed at the University of Melbourne and a patent application was submitted by Bayer Crop Science in 2007 with the agreement that the ownership of the patent would pass to the public sector (AVRDC) at the point of commercialisation approval in India. The patent was granted in 2010.

The original proposal was for the public sector to disseminate the materials to plant breeders and growers in developing countries. However in 2009, following a change of Director General, AVRDC withdrew from CIMBAA, citing doubts over AVRDC’s capacity to manage the licensing of plant materials to public and private breeders and concerns over AVRDC’s ‘green’ image. AVRDC believed that it was inappropriate for them to continue their commercial role in CIMBAA. Cornell also withdrew, stating that they do not have any role in the commercialisation process. In a Steering Committee meeting in 2009, no other willing or capable public institutions were found leaving Nunhems as the only potential licensor for the CIMBAA material. The shift of licensing and commercial responsibility from the public sector institutions to the private partner meant that the post commercialisation liability was also transferred onto Nunhems. A financial incentive was needed to justify those risks and was agreed that Nunhems had to be free to commercialise the plants that would generate a return on their investment. However, this potentially changed the very nature of CIMBAA’s intention to benefit poor farmers and concerns were expressed that substantial public funding had been used for sole benefit of a single private company.

8.3.6. Commercial pathway

To create a win-win situation for both the public and private sectors, DFID supported a stakeholder study, with a strong focus in India, on a mechanism that would allow the commercialisation process to continue while protecting farmer’s benefits. The outcome of
the study proposed that DFID should support the difference between full commercial costs in India and a price that small farmers could reasonably afford, by purchasing seeds from Nunhems at a full commercial rate and reselling them to State Seed Corporations for distribution at a lower cost. This would maintain Nunhems interest in the collaboration while acting to safeguard the benefit to poor farmers. However, a concern of side selling between farmers was raised, given that seeds delivered to subsidised farmers would be at a discount, creating an opportunity for subsidy farmers to profit by reselling seeds to commercial farmers. Nevertheless, whether or not trades occurred at the farmers’ level, Nunhems potential revenue would not be jeopardised.

However, Indian government stakeholders felt that in order to increase acceptance of any GM food crops, the product should not be introduced as a monopoly by a MNC. Sharing of the plant materials at a relative early breeding stage with Indian seed companies and public seed breeders and allowing them to enter the market shortly after Nunhems, was requested as necessary to ensure public confidence (and hence regulatory approval) in India. It was proposed by CIMBAA that constructs or plant material would be licensed to Indian public and private sectors breeders to cross into their own varieties only after commercial approval was granted by the Indian regulators, as then the burden of liability on CIMBAA partners would be reduced. This strategy served two functions; it protected Nunhems interest by providing a two-year early market advantage given that plant transformation and selection of Elite Events take considerable time and expense. Secondly, it would prevent accidental release of material prior to regulatory approval, as Nunhems was the holder of the material and under the Indian strict liability regime, all liability would fall on to Nunhems.

8.3.7. Outcome

By mid-2009, CIMBAA was ready for the final phase. Field trials had successfully demonstrated the viability of the plant materials and Elite Events were chosen. Full protocols and quotations had been obtained for all the regulatory studies required (including chicken, goat, cattle feeding trials) and integrated pest management studies had been carried out and recommendations drawn up. However, the political decision of the Indian regulatory system on MAHYCO’s Cry1Ac brinjal in February 2010 resulted in an uncertain regulatory environment. This material had obtained all the regulatory requirements for approval and completed nation-wide agronomic testing by mid 2009. In late 2009, the final decision for the release of the material was passed on to the Minister of Environment and
Forests. The minister called for public consultation over the following months and eventually decided to delay any GM crop release pending further ‘safety’ studies which were never specified. In consequence, Bayer Crop Science recommended the discontinuation of the project early in 2010 for the following reasons; the pressure to share plant materials with competitors before commercialisation approval, the potential liability from asynchronous approvals globally and most importantly, the political decision putting the regulatory system into abeyance. Given the uncertain regulatory environment, the fact that no GM vegetable crops had been released where the plant is to be consumed raw and the unknown delay in time to regulatory approval, the company could not justify the continued investment. As earlier mentioned, as a rule of thumb, a one year delay to market was estimated to reduce the net present value of products to the company by 10%.

In 2010, members of the Steering Committee unanimously agreed to Nunhems decision that under the current uncertain environment, there was no clear path forward and CIMBAA was discontinued in May 2010. During the discontinuation phase, steps were taken to ensure full documentation showing that all growing plants and live seeds were destroyed, with relevant stakeholders and regulators informed. Small quantities of seed were held by Bayer Crop Science in Europe in case of subsequent regulatory challenges.

CIMBAA had been a great technical success with no insurmountable scientific obstacles. However, the political environment in India (still continuing in 2016) and the public sector’s lack of courage to follow through in taking the patent and licensing responsibility, prevented CIMBAA from succeeding.

This case study complements preceding section by contrasting a public sector development and a public-private partnership model. It provides evidence to support the view that currently at least some public institutions are not implementing the critical processes necessary for successful commercialisation of a GM crop but also make clear the dominating influence of political and regulatory issues, including liability regimes, in the prospects for successful commercialisation (Table 8.5).
### Areas of concern

<table>
<thead>
<tr>
<th>Technical Level</th>
<th>CIMBAA</th>
<th>ICAR’s Bt cotton</th>
</tr>
</thead>
<tbody>
<tr>
<td>Efficacy of the plant material</td>
<td>Demonstrated the efficacy of Cry1B and Cry1C</td>
<td>Demonstrated the efficacy of Cry1Ac</td>
</tr>
<tr>
<td>Freedom to Operate</td>
<td>Nunhems supplied the necessary IPR</td>
<td>FTO was never achieved prior to the development</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Commercial Level</th>
<th>CIMBAA</th>
<th>ICAR’s Bt cotton</th>
</tr>
</thead>
<tbody>
<tr>
<td>Funding</td>
<td>A cost-sharing basis with a multi-donor approach for the public sector</td>
<td>Funded by the ICAR system</td>
</tr>
<tr>
<td>Cost of development</td>
<td>Approximately $22 million had it gone to completion</td>
<td>Estimated to be $500,000 based on the regulatory costs ($135,000)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Commercial pathway</th>
<th>CIMBAA</th>
<th>ICAR’s Bt cotton</th>
</tr>
</thead>
<tbody>
<tr>
<td>Original plan was that AVRDC would hold the patents for licensing. However, AVRDC’s withdrawal shifted the responsibility to Nunhems to distribute and license at full commercial rates, with DFID subsidising for small-scale farmers</td>
<td></td>
<td>Distribution through State Seed Corporations</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Commercial outcome</th>
<th>CIMBAA</th>
<th>ICAR’s Bt cotton</th>
</tr>
</thead>
<tbody>
<tr>
<td>The development was prevented from moving forward due to political influence on the regulatory system and liability concerns with movement of plant materials</td>
<td>The development was politically supported despite the lack of regulatory data.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Organisational Level</th>
<th>CIMBAA</th>
<th>ICAR’s Bt cotton</th>
</tr>
</thead>
<tbody>
<tr>
<td>Management structure</td>
<td>A well-structured management panels with commercial expertise and political connections</td>
<td>Poor oversight from ICAR and absence of project management</td>
</tr>
<tr>
<td>Commercial understanding</td>
<td>CIMBAA had tight control and monitored the development of the plant material at an industrial level</td>
<td>Poorly implemented. Material unsuitable for commercial purposes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Outcome</th>
<th>CIMBAA</th>
<th>ICAR’s Bt cotton</th>
</tr>
</thead>
<tbody>
<tr>
<td>Successfully selected commercial material, but discontinued due to political climate</td>
<td>Obtained approval but was withdrawn due to poor performance and likely IP infringement</td>
<td></td>
</tr>
</tbody>
</table>

**Table 8.5** Comparison of the PPP CIMBAA brassicas and public sector cotton project case studies.
8.4 Discussion

What lessons can be learned from these two case studies which shed light on the commercialisation of publicly developed GM crops? From the scientific point of view, the plant materials produced by both projects succeeded in demonstrating the efficacy of their insect resistant crops. However, technical success of the trait does not guarantee a commercial outcome, as GM crop developments are constituted of patented technologies and successful agronomic qualities are also required. Commercial developments require due diligence on the intellectual property landscape with agreements from technology owners. A strong contrast between developers’ attitudes and approaches toward intellectual property right were identified in the case studies. The FTO was not achieved for ICAR’s Bt cotton and in fact, ICAR deliberately neglected the need to obtain license agreements from patent holders, even upon the request of the key technology developer, Dr Altossar. This suggests that public research institutions often do not recognise the importance of intellectual property right for commercial developments. In addition, the absence of licensing agreements implies that the intellectual property cell under the ICAR system did not enforce the need for developers to seek licenses from patent holders. In contrast, CIMBAA had a different attitude and approach towards IPR. CIMBAA did not directly engage with patent holders for licensing agreements, as past experience from the Golden Rice project suggested that the process of identifying and obtaining licenses from patent holders is beyond the capability of the public sector. Instead, CIMBAA sought intellectual property support from Nunhems, as the private partner had the capacity to provide the necessary FTO for commercialisation. This did, however, result in the public sector partners having no definite understanding of the underlying intellectual property /FTO status of the construct they were using. The issue faced here by the public sector was not the technical proof of concept but rather the commercial availability of the technologies. Forming a partnership with companies which have the necessary intellectual property package for delivering GM crops can greatly reduce the challenges in obtaining the FTO.

The comparison of case studies draws two interesting points regarding the financial aspect of public GM crop developments. Firstly, the ICAR’s Bt cotton case study indicates that no financial challenges were encountered that prevented the development from moving forward. In fact, comparing the regulatory cost between ICAR’s Bt and CIMBAA’s estimates suggests that the cost of ICAR’s development was only a small portion of CIMBAA’s total.
CIMBAA’s estimated regulatory cost was $5.4 million (25% of total cost) with an expected total cost of $22 million. Similarly, Philip McDougall (2011) identified for CropLife that the regulatory cost for a private sector development was around $35.1 million (26%) out of a total development cost of $136 million. Based on the assumption that the regulatory cost is equivalent to 25% of the total cost of development, the estimated cost of developing ICAR’s Bt cotton was only $540,000 (based on the actual costs of the regulatory studies of $135,000). However, this value might be seen as an underestimate given that the development of Bt cotton had been well established in India, the regulatory requirement for fibre crops was less demanding than food crops and the majority of the development cost was absorbed by the government through its staffing support for institutions. Despite CIMBAA being a public initiative that shared the same purpose as ICAR’s Bt cotton, the collaboration received no direct financial support for the operating costs from the local government (though there were indirect benefits from Indian joint partner e.g. salaries for senior scientists).

CIMBAA also illustrated that public donors were more willing to fund individual research activities (social, biosafety, scientific) rather than directly investing in developments with the aim of leading to commercial developments. The absence of block funding for commercial development meant that public GM developers need to align the donors’ interests with the activities which were crucial for technological development prior to commercialisation. In the CIMBAA case study, Nunhems alleviated the financial burden of the public partners through an at least equal private partner contribution. A cost-sharing PPP can assist the issues with public funding system by allocating activities to the private partners that are of less interest to public donors and more in line with the private partners’ skills and interests.

Quality is an important attribute for successful commercialisation of any product. It is critical for developers to implement activities to ensure their products meet consumer needs. However, the ICAR’s Bt cotton case study clearly demonstrated the public sectors’ lack of commercial understanding. For example, non-commercial grade germplasm was transformed and little or no agronomic assessment of the transformed plant material was conducted. Insufficient back crossing was undertaken and the commercialised plant material was still segregating for the trait. Irrespective of the debate on the potential patent infringement, the material was not favoured by the farmers (poor germplasm for yield and the plants were still segregating) and would not out-compete existing Bt products. In

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[73] Detailed regulatory costs of both case studies are outlined in Chapter 5.
contrast, CIMBAA benefited from their partnership with Nunhems. The private partner had the knowledge of regulatory requirements, the infrastructure to carry out field trials and the market awareness, attributes that are often absent in the public sector and had quality germplasm available for transformation. Nunhems transformed 550 events of cabbages from which the project selected over several years a single elite event based on numerous molecular, efficacy and agronomic criteria to ensure the marketability of the final plant materials.

Measuring the case studies against the industry’s standard for commercialising GM crops outlined in Chapter 7, and even though both case studies started their development prior to the establishment of ETS, CIMBAA was conducting activities at the industry level (Table 8.6). CIMBAA placed a strong emphasis on the stewardship of the materials and was cautious in activities with potential liability. This was contributed to by the fact that in 2006 Bayer Crop Science, the mother company of Nunhems, made a $750 million compensation for the adventitious presence of a (then) unapproved herbicide tolerant rice in the US. All the processes, including the final discontinuation activities, were conducted in a manner that minimised the risk of adventitious presence and all potential liability.

Examining the case studies at the organisational level suggests that the management structure and project coordination are critical for the success of public GM crop developments. CIMBAA had a well-structured management system with local and international advisory panels and a Steering Committee providing scientific and commercial advice to the technical development and commercialisation team. Furthermore, committee members of the international advisory and Indian advisory panels comprised of Director Generals or senior executives with a strong understanding of Indian government processes and regulations. In the CIMBAA collaboration, both the public and private sector coordinators were key factors driving the development process forward. For example, the multi-donor approach for funding public sector activities was achieved by CIMBAA’s public sector coordinator having a major focus on the organisation of funding for the programme, taking responsibility beyond the individual organisational interest. On the other hand, the management of ICAR’s Bt cotton programme was criticized by the investigation committee which stated that the whole project was poorly planned with inappropriate distribution and oversight of the work. This suggests that organisational management plays a vital role in successful public GM crop developments.
CIMBAA conducted a full market and farmer needs assessments, stakeholder agreements, including consumers’ willingness to pay (e.g. Krishna & Qaim, 2008; Weinberger & Sirinivasan, 2009 etc.). A full commercial strategy was developed prior to commencement. There were no insect resistant brassicas commercialised anywhere in the world.

Bt cotton was already well established in India and it had been demonstrated that >80% of the trait value (from commercial seeds) was already going back to the farmers. This places questions on whether any further benefits were worth the public investment.

Extensive trials showed excellent insect control, agronomic performance and trait stability.

GM protein efficacy against insects was demonstrated but trait stability was not ensured.

Nunhems was responsible for maintaining the quality and integrity of the plant materials from transformation through to the final event selection.

It was clear that activities which should have been crucial for gaining regulatory approvals were not carried out by the developers.

CIMBAA developed a stewardship plan and a monitoring program that ensured the quality of commercial plants.

No information is publicly available

To ensure no unauthorised movement of plant materials, all growing Bt plants in India were destroyed, with regulators and stakeholders informed immediately afterwards. Small quantities of seed were kept in Bayer Crop Science in Europe.

ICAR stopped the seed multiplication and suspended commercialisation. However, no programmes were targeted at recalling the product materials. The plant material might still be present in the environment.

Table 8.6 Comparison of CIMBAA and ICAR’s Bt cotton against ETS criteria.

The foundation of a PPP builds on the sharing of benefits, resources and risks. CIMBAA was able to advance after AVRDC’s decision to withdraw from the project by passing the licensing responsibility onto Nunhems. To balance the increase in risk, an equivalent incentive was required, where Nunhems had to be free to commercialise the plant materials to justify the investment and risks. However, with the pressure from Indian stakeholders to share the materials early in the development phase and the uncertain regulatory environment due to the political decision on Bt brinjal, the private partner could not justify the investment and risks where the public partners could have continued. Despite the benefits of a PPP in assisting public GM crop developments, the risk-averse nature of public research institutions creates a tremendous challenge to developing a pro-poor GM crop. In fact, most public research institutions do not participate in commercial activities simply due to the potential for liability. To be fair, the private sector takes on the risk only with the expectation of future
balancing financial benefits. The public sector is not set up to organise or appreciate that financial compensation. This does not mean, however, that public sector organisations are not appropriate commercial partners in a well-designed and managed PPP.

8.5 Conclusion

This chapter demonstrates that a public-private partnership approach is able to address the obstacles identified in preceding chapters and improves the likelihood of commercial success for public GM crop developments. The private partner is able to fulfil activities that are poorly conducted by the public sector and has the capability and knowledge to develop commercially acceptable materials. The partnership can make an uneconomic proposition for industry (due in large part to regulatory costs) into a viable programme for public benefit. However, the CIMBAA case study illuminates the risk-averse nature of public research institutions which reduces the private sector’s willingness to participate in the partnership. Although CIMBAA succeeded in addressing the developmental issues through private sector support, the collaboration was ultimately challenged by both the public project partners’ fear of reputational damage and liability and by the political decision which resulted in an uncertain regulatory environment in India. The poorly executed Bt cotton was politically favoured and approved by the regulatory authority, even in the absence of regulatory data. This suggests that in developing countries such as India, the political environment dictates the outcome of GM crop approvals, but may not produce a commercially (or legally) viable product.

Key obstacles identified in this chapter:

- Public research funding generally has a short life cycle with limited capital and the need to seek and orchestrate multiple research grants in meeting the costs of development are obstacles to sustaining long term developments. Furthermore, the differing research interests of public funders create funding gaps for non-research related activities which are crucial for delivering commercial outcomes e.g. intellectual property license arrangements.
Public research organisations are generally risk-averse and the potential liability and consumer sensitivity associated with GM crops have resulted in most public research organisations shying away from participating in commercial developments. Consequently, the private sector becomes the only uptake pathway of public innovations and without financial interest, or perceived benefits for the commercialising organisation, most public developments will not advance to the commercial stage.

Public GM crop developments are often conducted by individual research groups with limited knowledge with regard to the critical activities required for delivering GM crops. Without guidance and support from well-structured panels of scientific and commercial experts most developments would fail to meet regulatory requirements or achieve market acceptance.
Chapter 9

Conclusions and Recommendations

9.1 Introduction

This study explores the obstacles to the successful commercialisation of publicly developed GM crops and the implications of these obstacles for future commercial success. The study has also sought to identify whether a public-private partnership model can address the obstacles identified in the study and can drive a successful public GM crop commercialisation. The concept of innovation uncertainty and Hall and Martins’ (2005) innovation evaluation framework for radical innovation were applied to guide the overall analysis, addressing the research question:

“What are the obstacles faced by the public sector which are preventing public GM crop developments from achieving eventual commercialisation?”

As described earlier, under Hall & Martin’s framework, an innovation can be considered viable when technological, commercial, organisational and social uncertainties have been satisfactorily addressed. For technological uncertainties to be overcome, the innovation must be feasible in practice. Commercial uncertainties relate to whether the innovation can successfully compete in the market. Organisational uncertainties are concerned with whether the organisation’s strategy, capability and complementary assets are capable of delivering the innovation. Lastly, social uncertainty refers to the impact of the innovation on, primary and secondary stakeholders and their impact on the innovation. The widespread concern of stakeholders resulting from the societal uncertainties on the use of GM crops has created controversies which adversely affect the innovation of GM crops.
The social activism against GM crops has been very influential in the decision-making processes in public administrations and national GM-related authorities, making direct public funding for long-term GM crop development difficult and creating negative political influences on regulatory approval systems. Additionally, the social risk associated with GM crop developments has resulted in most public sector developers shying away from engaging in commercial developments. Despite the importance of addressing social uncertainties in the GM area, the negative perceptions of consumers have not prevented the commercialisation of a substantial number of GM crops from the private sector, many of them are highly successful. The literature review in Chapter 2 suggests that the levels of public concern about health and environmental issues have steadily declined, yet, the socially trusted public sector has not been able to successfully deliver its GM crops into farmers’ hands. Applying Hall & Martin’s framework to the research question, this suggests that the public sector faces particular difficulties in minimising technological, commercial and organisational challenges.

9.2 Evaluation based on Hall and Martin’s framework

The main empirical findings are chapter specific and were summarised within the respective chapters. This section will synthesise the findings from preceding chapters and draw conclusions under Hall and Martin’s framework.

9.2.1. Technical barriers

Hall and Martin suggested that to overcome technological uncertainty, the innovation in question must be demonstrably feasible, based upon technological and corporate scientific competencies. They suggest that the technological uncertainty of innovation has a low level of stakeholder complexity and the uncertainty is localised within the state of the scientific paradigm. From a purely scientific perspective, no evidence has arisen from this study to suggest that the public sector has failed to produce technically feasible GM plant materials at least to the proof of concept stage. Instead, technological uncertainty is introduced by the need to secure patent rights to comply with global intellectual property systems. This has changed the agricultural innovation process by requiring GM crop developers to establish the freedom to operate (FTO) for commercialisation.
In addressing the research question ‘To what extent are intellectual property right systems an obstacle to public GM crop developments?’ the results from the patent landscape analysis showed that seed companies, particularly multinational corporations (MNC), actively patent and acquire intellectual property rights to key enabling technologies to ensure the legal freedom for commercialisation. In contrast, public research institutions often place a strong focus on novel trait discoveries with limited interest in enabling technologies. Consequently, such enabling technologies, even those originating from the public sector, are often the effective property of private companies. Despite accusations from the public sector that the private sector’s technologies are very difficult to access, no evidence has been found to support these claims. In fact, the majority of public GM crop projects which have taken IP issues seriously have been utilising patented technologies from the private sector made available under a range of licence agreements. These are frequently provided pro bono by industry although with caveats concerning the scope of their utilisation. Governments and public research organisations continue to promote patenting in the public sector and the gap in patent ownership in agricultural biotechnology between the public and private sectors has greatly narrowed over the last decade. However, the significant growth of public sector patents is divided across thousands of public research institutions and no single public research institution is likely to have the legal freedom to commercialise a novel GM crop without negotiating licence agreements with both public and private patent holders.

The study demonstrated that the need for proprietary technologies can be minimised by conducting patent landscape analyses which enable the public research scientists to design constructs in such a way that most of the necessary component technologies are accessible freely or are out of patent. However, such careful consideration for future FTO issues is rarely undertaken in the public sector. This study argues that the intellectual property barriers faced by the public sector are not due to restrictive access to patented enabling technologies. Instead, it is predominantly the result of public research scientists failing to adequately address the need to establish the FTO for commercialisation, or indeed completely ignoring it until far too late in the commercialisation process. A number of reasons are suggested as to why the majority of public research organisations have not successfully managed intellectual property rights needed for commercial developments.

Firstly, discussions with stakeholders highlighted that investments and promotions made at both national and organisational levels are largely directed towards the generation of peer reviewed publications and at enhancing the public ownership of patents, rather than to assisting public research scientists in establishing the FTO for commercial developments. As
a result, public researchers generally do not have the expertise to compile patent portfolios or the experience to negotiate licences with respective patent holders. Secondly, the study showed that public research funding generally does not allocate resources for external support (e.g. private patent attorneys) or for the continuing payment of commercial licences, creating difficulties for public developers in establishing and maintaining FTO. Lastly, many public researchers, even at senior levels, have relied on using patented enabling technologies but have not considered the need to seek authorisation from patent holders, which has result in many research outputs being uncommercialisable. Organisationally, the public sector has not dedicated the necessary resources or built the capacity to sufficiently address the complex legal information required to sufficiently reduce the impact of technical uncertainty on commercialisation.

Under Hall and Martin’s innovation framework, this study argues that the public sector has only addressed the scientific aspect and failed to sufficiently acknowledge the legal aspects of the technology which are relevant for commercialisation. The Conjecture-Refutation approach, underlying the Scientific Method which is commonly the basis of advances in research communities, is able to effectively address the scientific aspect of innovation because there are relatively few stakeholders and little stakeholder ambiguity. Multiple patents covering a single technology and the undisclosed licensing arrangements between players create a high level of stakeholder ambiguity over the ownership of technologies. The Conjecture-Refutation approach is only valid if error elimination criteria are identifiable, which becomes unlikely under high degrees of stakeholder complexity and ambiguity.

9.2.2. Commercial barriers

Commercial information is critical in determining whether an innovation is able to survive and compete in the marketplace. Hall and Martin suggested that commercial uncertainty has a low level of stakeholder ambiguity, as decisions are largely made based on economic merits, and can be minimised by acquiring knowledge about existing competitive products, identifying the costs of development and devising a commercial strategy. This level of analysis is routinely undertaken by private sector developers but generally only in the most simplistic and sketchy way by public sector developers, with little or no involvement of the downstream supply chain in the consideration of which trait/crop/variety combinations to pursue. In addition, the need to comply with global regulatory requirements addressing real
or hypothetical safety and environmental concerns, has created a further layer of commercial knowledge which is foreign to the public sector.

To answer the question ‘to what extent are particular difficulties faced by public research organisations in complying with GM crop regulatory requirements’, the qualitative result from discussions with primary stakeholders suggests that that the costs of regulatory compliance and the political influence on the regulatory systems have greatly reduced the value of GM technology and has limited its application to all but a few internationally traded major crops. To demystify the regulatory burden of public GM crop developments, the study compiled a list of detailed regulatory cost figures from the public/private project CIMBAA (the Collaboration on Insect Management for Brassicas in Asia and Africa) project and illustrated the costs of conducting the biosafety work necessary for generating an acceptable regulatory dossier. These costs are not as forbidding as described by some public and private developers, although still well beyond the budget of almost all public sector projects. In fact, in developing countries which promote GM crop developments, much of the costs have been non-explicitly subsidised by governments.

The difference between the public sector regulatory costs reported in this study and the estimates of private industry is partly due to the need to gain social licences from supply chain stakeholders. Farmers, grain traders and food manufacturers, confronted by the possibility of losing market share require assurance from the GM crop developers that their products have the necessary legal freedom for commercialisation. The potential liability due to unintended trans-boundary movement of plant materials and the possibility of asynchronous approvals have resulted in the private sector conducting biosafety studies in a manner that provides much more data than is strictly necessary for the regulatory dossiers and indeed has self-imposed very high traceability and safety standards on the industry. At the same time, the ‘case by case’ regulatory assessment, without explicit data requirements from regulators, has created uncertainty as to the type and magnitude of experiments needed to demonstrate safety. This has allowed the industry to set the current very high data requirement standard for approvals, which has significantly increased the costs of meeting global regulatory requirements. Furthermore, multi-national corporations (MNCs) have established global offices with professional staff who liaise with regulatory authorities to ensure simultaneous deregulation of their products in all jurisdictions of interest. Clearly, this scale of operation is beyond the financial capability of individual public research
institutions. Any attempt to comply with such standard would render many priority ‘public good’ crops commercially unviable.

The commercial uncertainty of public GM crops can be reduced through a Conjecture-Refutation approach, as commercial and development cost information can be gathered to assist the developers in determining whether the product will be likely to succeed in the market. Such analysis is not generally undertaken in sufficient detail by the public sector nor allowed to determine the research and developments actually undertaken. However, the opaqueness of available financial information on the development costs and the commercial strategies of existing public GM crop projects has also contributed significantly to the commercial challenges faced by the public sector. This has held back other public GM crop developers and public administrators from effectively responding to the commercial challenges. Consequently, the capacity within the public sector to comply with commercial requirements is rendered uncertain. This has allowed public research scientists to undertake GM crop development work without identifying the impact of key market nuances and industry dynamics, resulting in developed technologies being left sitting on the shelf. The information required to reduce commercial uncertainty is restricted by the current organisational behaviour of the public sector in not seeking the necessary economic rationale for their work nor understanding the costs of it, and by both the public and the private sector in keeping almost all such information ‘commercial in confidence’.

9.2.3. Organisational barriers

The question was: What are the organisational barriers specific to the public sector which are preventing public sector GM crop developments from advancing to the commercial stage? Organisationally, the public sector has the capacity and capability to conduct basic research and discovery. However, the shift from conventional breeding to GM technology (incremental to radical) for crop improvement has created a disruptive effect on the organisational capability to address the technical and commercial hurdles identified in the study.

The organisational strategy for commercialising public research and the incentives for public research scientists to engage in commercial activities are largely dependent on national policies which have shaped the structure and culture of public research organisations. Analysis of the national GM crop policies of China and India suggests that national
investments in the public sector have been primarily targeted at building human capacity to conduct basic research and at facilitating national innovation systems through technology transfer models, although this is nowhere explicitly stated. The role of the public sector is seen to be to act as a knowledge source for generating human resources and intellectual property assets rather than commercial products. Consequently, governments have not seriously attempted to build the necessary commercial capabilities in the public sector to take discovery through to commercialisation.

It is broadly accepted that the costs and time to develop a GM crop, from the initial discovery phase through to final commercial approval, greatly exceeds the funding required for conventional plant breeding programmes. Despite strong interest and substantial investments from governments in developing countries, particularly China and India, the study shows that public research funding systems have not reflected the costs of GM development through to commercialisation. The excessive division of national biotechnology budgets into multiple, short-term, projects with limited allowance for the costs of commercial activities has created difficulties in sustaining developments long-term. Public developers working under national government funding need to secure multiple research grants to financially support the development process of a single GM variety. In contrast, the study demonstrates that projects supported by international philanthropic foundations, which often provide on-going bulk funding, are able to advance further in the development process. This suggests that organisationally, the allocation of public funding for GM crop developments have not met the realistic commercial need.

The lack of incentives and rewards for public research scientists to participate in commercial activities is derived from how public research systems are designed. Public sector funding is largely based on competitive grant systems, and academic performance is evaluated on the quality and quantity of scholarly publications and research grant incomes, not on commercial outcomes. The CIMBAA case study demonstrated that public research organisations are strongly focused on reducing institutional liability. The absence of an offsetting income stream from the commercialisation of minor GM crops to set against the potential risks and liability of holding the intellectual property, prevents public sector organisations from actively advancing products towards commercialisation. This ‘Catch 22’ is generated by the natural assumption that organisations developing products using only public sector finance will not be expected to benefit financially from those products. This attitude is changing only slowly, though some organisations such as the Commonwealth
Scientific and Industrial Research Organisation (CSIRO) and the Brazilian Agricultural Research Corporation (EMBRAPA) have commercial concerns explicitly in their mandates now. Organisationally, the absence of profit motivation to balance potential liability prevents ideas from advancing into development after initial discovery.

### 9.2.4 Social barriers

Negative perceptions of consumers has created obstacles for the public sector to deliver GM solutions to farmers in need. The social risk associated with developing GM crops have adversely impacted on the willingness of the public sector to move into the commercialisation area and politically influenced regulatory approval systems.

**Table 9.1** summarises the innovation barriers identified above.
| Primary driver for public GM crop developments | • Humanitarian |
| Technological obstacles | • Public researchers are capable of demonstrating proof of concept and have effectively addressed the scientific concerns of the technology  
• The lack of resources, capability and willingness to navigate through the patent thicket have resulted in many public GM crop developments not establishing the FTO for commercialisation |
| Commercial obstacles | • The costs of complying with regulatory requirements renders many minor GM crops commercially unviable  
• Public developers have not considered the need for, and the costs to, gain social licenses/permission to operate from supply chain stakeholders  
• The capacity of the public sector to comply with regulatory requirements is rendered uncertain by the lack of commercial and economic information on existing public and private GM crop projects. |
| Organisational obstacles | • National policies have limited the role of the public sector to being a knowledge source and have not built commercial capability in public research organisations  
• The excessive dilution of public funding into multiple short-term projects has created difficulties in sustaining long-term developments  
• No financial or career incentives exist for public research scientists to engage in commercial activities |
| Social obstacles | • The public sector faces the same challenge as the private sector due to opposition to GM technology but has been less willing to face down those objections |

Table 9.1 Summary of the innovation barriers for public GM crops based on Hall and Martin’s Innovation Evaluation Framework.
9.3 A public-private partnership model for future public GM crops

The study illustrated the potential benefits of a public-private partnership (PPP) model and clearly shows that PPPs are capable of addressing the technical and commercial challenges faced by the public sector. As illustrated in the CIMBAA case study, forming a partnership with a MNC which has critical parts of the required intellectual property package, obviates the need for much of the legal activity and cost for the public sector partner. Moreover, the core enabling technologies supplied by the private partners provide regulatory advantages, as many of these technologies are embedded in current commercial products which have been approved by regulatory authorities, and all or part of the earlier approval dossiers can be referenced in the new approval request.

Developing a GM crop is an onerous exercise, often beyond the knowledge and capability of public research organisations. Private companies have invested heavily and built the in-house expertise and infrastructure necessary to ensure the integrity and quality of plant materials from initial discovery through to commercialisation. Furthermore, they have acquired the requisite regulatory knowledge and understand the market environment, attributes that are often absent in the public sector.

The study suggests that a PPP is able to address some of the organisational barriers identified in the study. For example, a cost-sharing PPP alleviates the financial burden of the public sector by allocating activities that are of less interest to public funders to the private partners. However, the public-private partnership discussed in Chapter 8 is paradoxical in that the public sector wanted to benefit from commercialisation without taking any risk or liability. The risk-averse nature of public research institutions creates a tremendous organisational challenge to facilitating PPPs for commercialising GM crops. Despite efforts to utilise public-private models to assist the commercial process for publicly developed GM crops, the political environment, driven in large part by unsubstantiated negative public perceptions of risk, limits public sector commitment to the commercial outcome of the developed technologies. No PPP which was a genuine partnership, rather than a technology donation, has yet succeeded in commercialising a GM crop.
9.4 Practical implications

Real effort is needed to improve the likelihood of commercialising publicly developed GM crops. This is particularly required at the early stages of development. Based on the barriers identified, the study suggests that the following aspects are critical to the success of commercialising GM crops in the public sector. Public administrators genuinely wish to see public sector developments commercialised by public sector organisations they should consider building these aspects into public research funding schemes and public researchers wishing to engage in GM crop developments should consider these as guidelines:

1. **Demonstrate legal freedom for commercialisation**
   Public GM crop developers need to have all the necessary research and commercialisation licences with explicitly agreed commercial terms from third parties prior to commencing development. In addition, traits discovered in the public sector need to be patented to protect the public interest and to ensure that the new intellectual property does not infringe any established patents.

2. **A commercialisation strategy**
   Public GM crop developers need a commercial strategy that includes: a value proposition which accurately reflects the dynamics of the particular industry, a supply chain stakeholder/consumer acceptance plan and a product development strategy, which includes variety development and selection, a realistic seed distribution pathway and a pathway to meet farmer support requirements.

3. **Financial commitment/continuity for commercialisation**
   Technological innovations such as GM crop development typically require large capital outlays which must be foreseen. A financial strategy needs to be designed that accurately reflects the magnitude and timing of expenditure along the pathway to market.

4. **Incentives to engage in commercial activities**
   There is a need to generate a body of public researchers/ managers/ administrators / legal advisors/ technology transfer specialists who genuinely have a willingness to engage in commercial activities and this may require financial and career incentives.
As preceding sections have pointed out, the majority of public research organisations do not have the organisational structures and capability required to meet these criteria. The following recommendations to modify organisational characteristics if GM crop commercialisation is genuinely sought from the public sector are largely directed at public administrators and public funding bodies with advice applicable to public research scientists.

9.4.1. Addressing the investment gaps

To optimise national investment in delivering GM crops through the public sector, there is a need to clearly differentiate public research funding which is intended to result in new basic knowledge from that which is aimed at applied research, and to identify public projects that have a realistic commercial potential in the market. Despite many countries around the world establishing long-term national science and research policies, a great deal of the resources have not been allocated in a way which is capable of sustaining long-term developments.

The current environment for GM crop developments requires extensive intellectual property studies and legal activities which traditional public funding systems are not geared up to support. In an Organisation for Economic Cooperation and Development (OECD) review on public sector funding, it is suggested that stable, predictable funding over the long term is important for public innovation and it is being recognised around the world that public funding structures need to improve in order to enhance public performance (OECD, 2011b). The current study recommends a targeted public funding system that genuinely supports the pursuit of commercial outcomes and appreciates the long-term costs of such programmes. However, due to the absence of commercial information on existing public sector GM crop developments, it is difficult for public funders to structure a funding system that accurately reflects the costs of developing a GM crop in the public sector. This study further recommends that there is a need for transparency on the true costs of existing public (and private) GM projects, to deliver the financial information required by public administrators for utilisation in developing commercial models for future work.

Industry investors claim that, even with the best management practices, as a rule of thumb, for every 100 research projects scanned for commercial potential, only ten may justify the further investment for commercial development. Of the ten identified, perhaps only one or two projects will have true potential to achieve strong commercial outcomes (Department of
Industry, 2013). This is a key challenge for investment in public sector programmes. One funded and commenced, there is no mechanism to stop expenditure on programmes which have shown themselves to be unviable. To optimise public investment and minimise duplication of research, the study recommends that public funding bodies and public research organisations should establish commercial units that assess the potential of public discoveries. Clear commercial pathways to the delivery of humanitarian benefits need to be established e.g. commercial value, FTO, uptake pathways. Public funders should implement stronger long-term monitoring/reporting criteria which would genuinely stop projects if the advances fail to meet key milestones.

9.4.2. Improving current regulatory environments

New GM crop varieties are primarily developed where supply chain stakeholders and developers are rewarded for their efforts, most often in financial form. But such incentives for commercialising minor GM crops in both developed and developing countries are inadequate. It was illustrated in the study that the core underlying problem is that the costs of complying with the global regulatory requirement are prohibitive and seed sales to minor crop farmers do not provide large enough revenue streams to offset those costs. The need to comply with various regulatory authorities simultaneously has created operational costs beyond the reach of the public sector under current national government funding models. Existing literature has outlined the importance of harmonising GMO approval systems and has suggested the harmonisation of GMO-related policies and decision-making approaches through international instruments e.g. the Cartagena Protocol on Biosafety (CPB), the Codex Alimentarius, the Application of Sanitary and Phytosanitary (SPS) Measures (e.g. Ramessar et al., 2008; 2009; Davison, 2010). The CPB attempts to establish regulatory systems for GMOs around the world, but the principles outlined within the document leave significant room for flexibility of interpretation resulting in a multiplicity of specific regulatory requirements across the globe.

The current GM crop industry is facing essentially the same regulatory obstacles as the pharmaceutical industry faced in the late 1980s, where the inconsistencies between national regulatory requirements significantly increased the costs of development and created barriers to trade (Abraham & Reed, 2003). At that time, the pharmaceutical industry persuaded the major regulatory agencies around the world to harmonise their regulatory standards for drug testing. Consequently, the International Council for Harmonisation of
Technical Requirements for Pharmaceuticals for Human Use (ICH) was established in 1990, with, as founding regulatory members, the European Commission (EC), the US Food and Drug Administration (FDA) and the Ministry of Health, Labour and Welfare of Japan (MHLW). The ICH established a group of experts, comprising scientists from industry and the regulatory authorities, in various technical areas and developed a consensus that reconciled the differences between the world’s three major regulatory regions and established technical guidelines for regulating the safety of new drug developments.

It has been suggested that the most important aspect of harmonisation for biotechnology products is to standardise the regulatory requirements across regions and allow data generated in one country to be recognised in other countries (Romeis et al., 2008). The Working Group on Harmonisation of Regulatory Oversight in Biotechnology from the OECD was established in 1995 with the primary goal of promoting international regulatory harmonisation. The working group focused on generating consensus documents on two specific categories: the biology of the host crops and the biosafety information of novel traits used in commercialised crops. The aim was to encourage the sharing of information and to avoid the need to repeatedly address common issues which involve the same organism or trait (Macdonald & Yarrow, 2006). An international initiative launched by the International Organisation for Biological and Integrated Control of Noxious Animals and Plants (IOBC) has gathered together scientists from public organisations, private companies, regulatory authorities and commercial testing laboratories. The group developed a scientific approach for evaluating the potential risks to non-target insects with the intention of providing guidance to regulatory authorities and harmonising global regulatory requirements (Romeis et al., 2008). However, neither of these initiatives has yet succeeded in harmonising regulatory requirements across different countries and are in need of wider support. Based on the example of the ICH, the current study recommends that public administrators, regulatory authorities, public and industry research scientists should work together to create an organisation that develops internationally recognised regulatory guidelines with explicit requirements that are transparent, predictable, and purely scientifically based. This would allow developers to better predict the costs of regulatory requirements and would minimise duplication of regulatory experiments. Although there are significant differences in the underlying philosophies of major regulatory regimes, in practice

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74 These consensus documents are accessible through the following link http://www.oecd.org/science/biotrack/consensusdocumentsfortheworkonharmonisationofregulatoryoversightinbiotechnology.htm
the specific studies required to demonstrate safety are largely similar. We are at a point in
time when public administrators and regulatory authorities globally, by developing a unified
system, could take advantage of the current situation where many developing countries
have yet to establish functioning regulatory principles and processes.

9.4.3. Building commercial capacity and capability

The public sector needs to better understand the business requirements for commercialising
GM crops, to enable public research organisations to be able to move from discovery to
development stages and to be accepting of the level of resources and expertise required for
commercial activities in this area. There is a need to motivate public researchers to promote
engagement in commercial activities outside of basic research.

Firstly, the study has highlighted the importance of commercial understanding and it is
recommended that the public sector should improve its commercialisation skills, if indeed it
is considered desirable for public bodies to enter the commercial arena in this area. This
would require the development of staff with both scientific and business skills backgrounds.
For example, to build commercial awareness within the research community, public
research organisations could offer short introductory businesses courses for staff and for
Master and Ph.D. students and could promote greater mobility between industry and
researchers through exchange programs.

Secondly, the intellectual property cells of public research organisations, which currently
function largely to identify liability issues for their parent organisation, should function
beyond the scope of simple technology transfer and actively assist public researchers to
establish FTO and to exploit their intellectual property through commercialisation and not
solely by licensing.

Thirdly, the academic cultural environment strongly discourages public researcher scientists
from engaging in commercial activities, where they risk financial and career security and do
not gain recognition for their commercial achievements. To improve incentives and to
ensure that researchers can gain clear benefits from pursuing commercialisation, the
following options could be considered:

Financial incentives: Increase opportunities for researchers to directly and personally
benefit from the commercialisation of their work, through a share of royalties or by other
means. This approach is spreading. For example, the University of Melbourne seeks to foster an environment which supports knowledge transfer and entrepreneurial activity and concedes that public research scientists should be financially rewarded for their valuable intellectual property. The public research scientist(s) or the ‘creator’ is entitled to 40% of the royalties from the licensing partner, with the university and the researcher’s faculty receiving 20% and 40% respectively (University of Melbourne, 2016). In China, Fudan University promotes patenting activity by offering cash rewards; 1,000 RMB for a patent application and 3,000 RMB for an approved domestic patent (Wu, 2010).

**Non-financial incentives** - A greater professional recognition of commercialisation activities in tandem with traditional academic indicators e.g. journal articles and grant funding. For example, many universities in the US and Canada have included patents and commercialisation in their tenure and career advancement decisions (Sandberg et al., 2014). Public research funders and organisations often include research ‘impact’ in their criteria of researcher success, but as the actual commercial impact of a GM crop development is likely to be at least 10 years from the original development and as teams of researchers, support staff, administrators and others are likely to have been involved positively in the intervening years, some clearer formula needs to be developed if ‘impact assessment’ is to have any effect on the behaviour of public scientists.

The study also emphasises that it is not enough to invest the resources in building organisational capacity and capability in the public sector. There is a need to improve the current public policy on commercialising public discoveries which are generating public ‘goods’, whose benefits may not be readily monetised by the developing organisation. Many public research organisations have established technology transfer offices and are in the business of intellectual property licensing as the central commercial pathway of their discoveries. For example, the Australian *Science and Industry Research Act 1949* sets the primary functions of CSIRO, as carrying out scientific research which assists Australian industry and the community. CSIRO’s commercial model is based on patent generation and technology transfer, through licensing, contract research, and industry collaboration. However, products with high societal value but little economic value, such as minor GM crops, are still uneconomical under a technology transfer model which relies on the uptake of discoveries by private companies. This study recommends that public administrators and directors of public research organisations add provisions to existing public commercial
policies which would allow the public sector to either directly deliver or to support the private sector delivery of public goods.

9.5 Should the public sector take on a commercial role?

The very considerable resources and time needed to implement the recommendations outlined in preceding sections and the industry experience of the low proportion of initiated research programmes which eventually result in a commercialisable product, place questions on whether it is rational for public research organisations to enter the commercial arena. The public sector has traditionally produced ‘public goods’ (e.g. minor crop varieties) for smallholders by directly transferring seed to farmers or by licensing to local seed companies for production and distribution. However, there is a need to go beyond this traditional public delivery model, especially for traits/crops derived from advance technologies, because of the commercial obstacles identified in the study.

‘Are intellectual property policies encouraging or deterring innovations from the public sector?’

Intellectual property systems were established to encourage private sector R&D investments by providing exclusive legal rights for commercialisation. Following the legislation of Bayh-Dole Act in the USA, which allows public research organisations to patent discoveries from government funded research, many national and public policies have been redesigned, promoting public research organisations to patent their research discoveries. From a national perspective, intellectual property policies are designed to increase commercial outputs through technology transfer, to improve the effectiveness and utilisation of government funding and to act as an additional revenue stream by allowing the private sector to acquire and retain partial or complete property rights.

Many countries have recognised the need to balance the accessibility of patents for public research against the rights of patent holders and provisions have been implemented within legislation, allowing public scientists to conduct research without negotiating research licences from patent holders e.g. China and India. However, such provisions do not exempt the public sector from the need to gain FTO for commercialisation. Moreover, the technology transfer model which allows private companies to retain complete property rights has made it much more difficult for the public sector to address market failures.
Current public policies have resulted in a situation where public research organisations are limited to basic R&D with no realistic mechanisms to overcome the intellectual property barriers for accessing rights for almost any crop/trait combination that was seriously viable. This restricts the public sector to working with crop/trait combinations which, almost by definition, are going to struggle to find a commercial place in trading systems. The private sector will only acquire public sector technologies when there are opportunities to generate profits. Innovations with only societal values may have no sensible pathway to market for the private sector, unless the full development and regulatory costs are covered by the public sector, then the development may well be economic for private sector marketers. Government administrators should reconsider the trade-offs between innovations created through technology transfer and the need to access enabling technologies for delivering public goods. There is a need to weigh the socioeconomic importance of delivering public goods and to consider provisions to legislation which would provide mandatory public access to key patented technologies in certain defined circumstances.

'Are current public research funding systems designed to facilitate radical innovation in the public sector?'

Public research funding systems have moved toward selective and competitive models with the expectation of obtaining higher returns in terms of knowledge creation and research output. The increasing reliance on competitive project funding at the expense of block grant and long-term institutional funding, has pressured public research into short-term, low-risk projects and away from long-term development research. Furthermore, the distribution of public research funding is often based on a peer review system, where a panel of experts assess the quality of the proposal according to predefined criteria, mainly based on scientific merits and not on the commercial feasibility of the project. This creates competition and prevents collaboration between public research groups and re-directs the focus of public research scientists to publications for securing future grants. In many countries, the intermediary bodies which are responsible for co-ordinating government research funding have made changes in their mode of operation with the aim of evaluating research projects for their commercial potential and funding those with genuine commercial prospects but the impact of such changes on addressing market failures remains uncertain.

Public research policies continue to promote industry collaborations with the idea that industries should invest in public R&D to develop solutions to their challenges. However, the growing level of industry funded research spurs concerns regarding the potential long-term
effects on public sector innovation. From a private sector perspective, the collaboration with the public sector is undoubtedly positive but it is unclear whether such collaboration drives public research away from the traditional incentives of knowledge sharing and the delivery of public goods.

Overall, the design of current public research funding systems does not support the public sector to deliver radical innovations, such as GM crops, and essentially the private sector becomes the only buyer of public research discoveries. There is a need to consider a flexible public funding mechanism which addresses specific priority areas, if it is regarded as desirable for the public sector to continue addressing market failures and delivering social benefits.

‘Should governments continue to invest in the public sector for the commercial development of GM crops or should the focus be on facilitating technology transfer?’

As already discussed, evidence from this study suggests that public research organisations do not have the capability or commercial understanding to deliver GM crops to the market. Furthermore, public research funding systems have been designed in such a way as to encourage public research scientists to deliver commercial outcomes, or put in place any consequences for failure to deliver. This has resulted in substantial public investments not being directly utilised to deliver public goods.

It maybe that we need to come to the realisation that the commercial delivery of GM crops is not a role of the public sector, as we do for radical innovations in many other fields e.g. chemicals, robotics, medical science, and to be accepting of the fact that public research organisations do not have the capacity to commercialise GM crops, nor is it necessarily logical that they should have.

Technology transfer is now an integral part of many countries’ innovation systems, used to achieve economic development and to capitalise on public investment. In recent decades, many universities and public research organisations have established technology transfer offices, responsible for commercialising their intellectual property. Moreover, many public policies in place, nationally and organisationally, aim to encourage stronger public-private research collaboration and technology transfer. This study suggests that different technology transfer models can be utilised to deliver economically valuable traits discovered in the public sector by licensing to private companies while PPP models may be a valuable mechanism for the delivery of minor GM crops to the poor, though only if the public sector
provides funding and other resources sufficient to generate mutual interest from the private sector.

9.6 Limitations of the study and future research needs

This study has offered an evaluative perspective on the obstacles to public GM crop commercialisation. Given the multi-disciplinary nature of the study, there are limitations which should be appreciated. Firstly, a factor that was not considered in the study is the relationship between regulatory requirements and the date at which particular projects were undertaken. Industry stakeholders believe that the time and costs of complying with global GM regulatory requirements have significantly increased since the first commercial GM crop introductions in the mid 1990s. It is uncertain whether the successes of earlier public GM crops were partly a result of more accessible regulatory environments. Future research should conduct a longitudinal study on the regulatory requirements and the costs of complying with them.

There are limitations on the data collected within the study. The study had a national focus on Australia, China, and India for the analysis for the reasons given in the introduction. It is possible that the conclusions drawn from the study are country specific and cannot be generalised across the public sector globally. To validate the conclusions of this study, further studies should be conducted in other countries which have on-going public GM crop development programmes e.g. Nigeria, Uganda, Kenya, Philippines and Indonesia.

The present study lacks quantitative validation of the financial side of public GM developments. Future research should analyse the value of public GM crop developments and identify value distribution systems which can allow the stakeholders to adopt the technology (e.g. a value chain analysis/cost-benefit analysis). This study attempted to construct a value chain analysis by seeking detailed financial information from public GM crop developers to conduct a quantitative analysis. However, there is no published information in this area from past or on-going public GM crop projects and all existing public GM developers contacted for this study were unable/ unwilling to share financial data, citing ‘commercial in confidence’ reasons, even when the project was purely public sector funded. This adoption by public organisations of one of the less desirable aspects of private sector initiatives is regrettable and arguably improper, given that the initiatives are funded from the public purse. In any event, other ways need to be found to routinely construct
transparent value chain analyses if appropriate public support for GM crop developments is to be justified, generated and maintained.

The present study focused on agricultural biotechnology within the public sector, but it is unknown whether the conclusions drawn from the study were particular to the technology studied or have a wider general applicability across the public sector. The conclusions drawn have similarities with results in the literature, particularly for pharmaceutical developments in the public sector. For example, Uecke (2012) concluded that public pharmaceutical development should follow a technology transfer model, given that there is a lack of motivation for public researchers to push for commercialisation, issues with permanent access to financial resources and an absence of expertise in drug development. Uecke argued that in order to enhance public sector output, an evaluation system is needed which takes into account the commercial activities of researchers and does not solely focus on publication performance. It would be valuable for an analysis to be conducted as to whether the conclusions of the current study could be generalised and applied other areas of public sector research which share similar profiles (i.e. a long development process, requirements for significant capital for delivery and stringent regulatory environments).
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Appendix 1. Interview topics for stakeholder in Australia, China and India

Issues with public funding for GM crop development

What do you see as the main challenges of public research funding system? (Generalised questions about public research funding systems and outcome expectations)

- How is public research funding allocated?
- Do the funding bodies expect a commercial product by the end of the project? If not what are the expected outcomes?
- Do the scientists expect a commercial product by the end of the project? If not what are the expected outcomes?

What factors or drivers do you think influence the funding of transgenic projects? (Exploring ideas that pose challenges to gain continual funding)

- What sort of results is required to get continual funding?
- Is economic output of research development an important aspect?
- Is there a preference to allocate grants to non-transgenic projects?

Intellectual property rights

What are your opinions on the ownership of publicly developed GM crops? (Exploring ideas behind ownership and liability for public developments)

- How should the responsibility be shared between different partners in the project?
- How should the ownership be distributed?
- Do you think a risk-averse attitude in public organisations (in terms of liabilities) prevents public commercialisation?

What intellectual property difficulties have you encountered? (Challenges with securing licences or minimising the need for licences)

- Do you think public developers understand the importance of IP and whether strategies have been put in place to minimise the need to licence?
- What are the challenges to securing intellectual property rights for research and development? commercialisation?
Commercialisation pathway for GM crops

What do you think are the difficulties in commercialising a publicly developed crop? 
(Commercial understanding and market assessments)

- Are the challenges mainly based on the lack of expertise and understanding of the markets?
- Do you think public developers understand how the commercial market functions?

Complying with GM regulatory requirements

What comments can you provide about the current GM regulatory system? 
(Exploring the current regulatory challenges faced by the public sector)

- What is your opinion of the efficiency of the current regulatory system?
- How should the regulatory body address GM crops that come from neighbouring countries that have not yet been approved in your country?
- Are there challenges with advanced scientific techniques and perspective from the regulators?

What do you see as the main problems for public researchers in complying with GM regulations?

- Is it the regulatory costs? Or is it the understanding of the regulatory system?
- What improvements to the regulatory system would you like to see and why?

Public acceptance of GM crops

What are your opinions on improving the public’s attitude towards adopting GM crops? 
(Understanding the influence of consumer’s acceptance on public GM crop developments)

- What are the major concerns of farmers/consumers?
- What value or benefits do the farmers/consumers want to see?
- What methods would you suggest to improve public acceptance?
Public-Private Partnership

What value do you see in forming public-private partnerships?

(Difficulties in forming public-private partnerships for commercialising public GM crops)

- What do you think are the essential criteria in forming a public-private partnership?

- Have there been any successful/unsuccessful public-private partnerships that you have encountered?

- Why do you think they have succeeded/failed?
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<th>Description</th>
<th>Principal Investigator</th>
<th>Number of years</th>
<th>Indian Rupees</th>
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<td>2009</td>
<td>Development of efficient regeneration and genetic transformation systems of mungbean [BT/PR10869/AGR/02/613/2008]</td>
<td>Dr Raman Saini, Kurukshetra University</td>
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<td>Ribozyme mediated antiviral activity directed to Mung Bean Yellow Mosaic Virus [BT/PR10660/AGR/02/658/2008]</td>
<td>Dr J K Deb, Indian Institute of Technology, Kharagpur</td>
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<td>Development of salinity stress resistance in rice varieties</td>
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<td>Transgenic approaches to improve sesame (Sesamum indicum Linn) oil quality with omega3 fatty acid</td>
<td>Dr Selvi Subramanian, PSG College of Technology Coimbatore, Tamil Nadu-641004</td>
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<td>Genetic enhancement of indigenous aromatic rice of Assam (Joha Rice) using genomic approach with particular reference to Aroma</td>
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<td>Molecular cloning and characterization of salinity and/or drought stress-induced helicase from rice and its functional validation</td>
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<td>Genetic modification of starch biosynthetic pathway in indica rice cultivar in favor of resistant starch production [BT/PR12533/AGR/02/05/2009]</td>
<td>Dr A Basu, Indian Institute of Technology, Kharagpur</td>
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<td>Abiotic stress tolerance transgenic plant production in cotton by over expression of SINAC transcription factor gene from foxtail millet (Setaria italica L.) through Agrobacterium tumefaciens mediated transformation [BT/PR15256/AGR/02/791/2011]</td>
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<td>Development of yellow mosaic virus resistance in black gram (Vigna mungo L. Hepper) and cowpea (Vigna unguiculata L. Walp): Transformation of black gram and cowpea with MYMV-Vig. genes [BT/PR3342/AGR/02/820/2011]</td>
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<td>Engineering Broad Spectrum Resistance against Gemini viruses [BT/PR14812/AGR/02/760/2010]</td>
<td>Dr Supriya Chakraborty, Jawaharlal Nehru University</td>
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<td>Evaluation of transgenic banana for resistance to Banana bunchy top virus [BT/PR14745/AGR/02/756/2010]</td>
<td>Dr R Selvarajan, National Research Centre For Banana</td>
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<td>Molecular and physiological Characterization of annexin transgenics of Green Gram (Vigna radiata L.) For oxidation stress Tolerance [BT/PR14568/AGR/02/746/2010]</td>
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<td>Generation of Virus-resistant rice for India: Diversifying transgenic resistance to popular varieties – Phase - II [BT/PR15033/AGR/02/773/2011]</td>
<td>Prof. Indranil Das Gupta, Delhi University, South Campus</td>
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<td>Metabolic engineering of oil biosynthetic pathway in safflower [Carthamus tinctorius] for fortification with Omega 3 fatty acid [BT/PR4077/AGR/2/832/2011]</td>
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<td>Biotechnological Approaches for Improving Agricultural Productivity of Coastal Region. Component 1: Development of rice cultivars for climate change using genes identified and characterized from mangrove plants and their associates for salinity and submergence tolerance. Component 2 : Assessment of halophytes as a source of new crops for saline affected lands [BT/PR4999/AGR/2/246/2012]</td>
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<td>Development of low sinapine mustard (Brassica juncea) lines through antisense and RNAi technology</td>
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<tr>
<td>BT/PR6363/AGII/106/874/2012</td>
<td>Metabolic engineering of phytic acid pathway for improving iron bioavailability in wheat</td>
<td>Dr Ajay Kumar Pandey, National Agri - Food Biotechnology Institute Mohali, Punjab-160071</td>
<td>4</td>
<td>4,465,200</td>
<td>82,067</td>
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<td>BT/PR6027/AGII/106/859/2012</td>
<td>Introduction of very-long-chain polyunsaturated fatty acids biosynthesis pathway in Indian mustard (Brassica juncea)</td>
<td>Dr Girish Mishra, University of Delhi, North Campus Delhi, Delhi-110007</td>
<td>3</td>
<td>8,842,949</td>
<td>162,527</td>
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<tr>
<td>[BT/PR5746/AGII/106/861/2012]</td>
<td>Metabolic engineering for production of terpenoids in tobacco plants</td>
<td>Dr V Siva Reddy, International Centre for Genetic Engineering &amp; Biotechnology New Delhi, Delhi-110067</td>
<td>3</td>
<td>9,246,429</td>
<td>157,996</td>
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<td>[BT/PR4534/AGR/2/843/2012]</td>
<td>Development of haploid-inducer lines of Brassica juncea through genetic engineering of centromere histone protein</td>
<td>Dr Shripad R Bhat, National Research Centre On Plant Biotechnology New Delhi, Delhi-110012</td>
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<td>6,413,053</td>
<td>109,581</td>
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<td>[BT/PR6377/AGII/106/882/2012]</td>
<td>Genetic engineering of sugarcane for water deficit stress tolerance</td>
<td>Dr Appunu Chinnaswamy, Sugarcane Breeding Institute Coimbatore, Tamilnadu-641007</td>
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<td>8,021,972</td>
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<td>[BT/PR7202/AGII/106/904/2012]</td>
<td>Enrichment of Vitamin E in sesamum oil by transgenic approach</td>
<td>Dr A Ganapathi Bharathidasan, University Tiruchirappalli, Tamilnadu-620024</td>
<td>3</td>
<td>3,664,600</td>
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<td>[BT/PR8217/AGIII/103/875/2013]</td>
<td>Engineering rice for resistance to major lepidopteran pests using a novel synthetic cry2AX1 gene</td>
<td>Dr D Sudhakar, Tamil Nadu Agricultural University Coimbatore, Tamilnadu-641003</td>
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<td>3,860,200</td>
<td>63,240</td>
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</table>

| Total | Average | 196,706,863 | 3,913,653 |
## Appendix 3. Public-private partnership projects funded under India’s SBIRI scheme

<table>
<thead>
<tr>
<th></th>
<th>Partner Company</th>
<th>Collaboration with</th>
<th>Project Description</th>
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<tbody>
<tr>
<td>1</td>
<td>Bejo Sheetal Seeds Pvt. Ltd., Jalna</td>
<td>Indian Agricultural Research Institute, New Delhi</td>
<td>Development of dual resistance in tomato against virus infection &amp; insect damage (Phase I)</td>
</tr>
<tr>
<td>2</td>
<td>Devleela Biotechs, Raipur</td>
<td>Indian Agricultural Research Institute, New Delhi</td>
<td>Production of virus free garlic through tissue culture (Phase I)</td>
</tr>
<tr>
<td>3</td>
<td>Krishidhan Research Foundation Pvt. Ltd., Jalna</td>
<td>Jawaharlal Nehru University, New Delhi</td>
<td>Development of transgenic okra resistant to yellow vein mosaic virus (Phase I)</td>
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<tr>
<td>4</td>
<td>Maharashtra Hybrid Seeds Company Limited, Jalna</td>
<td>Indian Institute of Science, Bangalore</td>
<td>Evaluation of transgenic cotton containing antisense AV2 gene for resistance to cotton leaf curl disease (Phase I)</td>
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<tr>
<td>5</td>
<td>Nuziveedu Seeds Limited, Hyderabad</td>
<td>International Centre for Genetic Engineering and Biotechnology (ICGEB), New Delhi</td>
<td>Stacking of Candidate genes (validated in planta) addressing different moisture stress resistance strategies in maize (<em>Zea mays</em>) (Phase I &amp; II)</td>
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<tr>
<td>6</td>
<td>Oriental Aquamarine Biotech India Private Limited, Coimbatore</td>
<td>Cochin University of Science and Technology (CUSAT), Kochi</td>
<td>Design modification and commercialization of nitrifying bioreactor technology for the establishment of organic recirculation prawn seed production system (Phase II)</td>
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<tr>
<td>7</td>
<td>Ocimum Biosolutions Ltd., Hyderabad</td>
<td>International Centre for Genetic Engineering and Biotechnology, New Delhi</td>
<td>Development and validation of miRNA expression platform for plants, modelled in rice (Phase I)</td>
</tr>
<tr>
<td>8</td>
<td>Rasi Seeds Private Limited, Attur, Tamil Nadu</td>
<td>Tamil Nadu Agricultural University (TNAU), Coimbatore.</td>
<td>Transgenic Cassava production with genes conferring resistance to Indian cassava mosaic virus disease (Phase I)</td>
</tr>
<tr>
<td>9</td>
<td>Sri Biotech Laboratories India Private Limited, Hyderabad</td>
<td>University of Hyderabad, Hyderabad.</td>
<td>Production, formulation and commercialization of microbial agents for weed management in rice (<em>Oryza sativa L</em>) (Phase I)</td>
</tr>
</tbody>
</table>

Source: *SBIRI database*
Appendix 4. Funding criteria and models of SBIRI and BIPP

The Small Business Innovation Research Initiative (SBIRI)

SBIRI targets early stage development and commercialisation, accelerating biotechnology through small and medium enterprises (SME). It provides start-up fund for discovery and product development phases. The SBIRI funding structure consists of two stages;

Phase one- Establishment of pre-proof of concept

- 80% of the project cost will be covered by a government grant if the total project cost is less than Rs 2.5 million (approximately $41,000USD)
- 50% of the project cost will be covered by a government grant if the total project cost is between Rs 2.5 million and Rs 10million (approximately $164,000). A maximum of Rs 5 million ($82,000).
- If the project cost excess Rs 10million, in addition to the Rs 5 million grant, applicants may apply for an interest-free loan up to 50% of the total cost.

Phase two- Product and process development

- A loan with 1% simple interest if the total project cost is less than Rs 10 million ($164,000)
- A loan with 2% simple interest if the total project cost is less than Rs 100 million ($1,640,000)

Source: SBIRI 2015. Using the average exchange rate in 2014 where 1 USD equates to 60.88 rupee
### The Biotechnology Industry Partnership Program (BIPP)

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>I</td>
<td>Areas with major social relevance but uncertain market driven demand</td>
</tr>
<tr>
<td>II</td>
<td>High risk, discovery innovation research with relevance for making India globally competitive.</td>
</tr>
<tr>
<td>III A</td>
<td>Evaluation &amp; validation of already existing products of high national importance promoting local innovation (Clinical trials)</td>
</tr>
<tr>
<td>III B</td>
<td>Evaluation &amp; validation of already existing products of high national importance promoting local innovation (Agriculture field trials)</td>
</tr>
<tr>
<td>IV</td>
<td>Shared cost major facilities, critical for enabling innovation.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Model</th>
<th>Investment, cost-sharing and sharing of benefits</th>
</tr>
</thead>
</table>
| The government supported- privately managed facility will be located in a National Laboratory and managed by consortia of industries or a single industry which has no conflict of interest. | 1. 100% grant in aid  
2. User charges basis  
3. Co-ownership with government  
4. Differential fee for public and private user |
| Public institution in partnership with a private investor who has no conflict of interest. | 1. Cost sharing with the industry  
2. Up to 50% grant  
3. Shared profits  
4. Ownership will depend on contribution  
5. Differential fee for public and private user |
| Specialised facility for discovery and innovation to be established, operated and managed by a single private industry. | 1. A loan as per SBIRI norms  
2. User charges basis  
3. Differential fee for public and private user  
4. Should devote time for education and training of DBT-identified trainees for capacity building. |

Source: BIRAC 2014.
## Appendix 5. CIMBAA’s timeline and funding arrangement

<table>
<thead>
<tr>
<th>Block</th>
<th>Activity</th>
<th>Partners</th>
<th>Phase I</th>
<th>II</th>
<th>III</th>
<th>IV</th>
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<td></td>
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<td>2002</td>
<td>2003</td>
<td>2004</td>
<td>2005</td>
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<td>Co-ordination of public</td>
<td>Project initiation</td>
<td>All Partners</td>
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<td>activities and technical</td>
<td>Project co-ordinating committee</td>
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<td>meetings</td>
<td>Confidential, Consortium and Research Agreement</td>
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<td>Co-ordination of public sector technical meetings</td>
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<td>Legal/IR</td>
<td>NRI, Nunhems</td>
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<td></td>
<td>Ownership of regulatory package</td>
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<td>Ownership of registered material (licensing function)</td>
<td>AVRDC</td>
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<td>Communication</td>
<td>Development of communication strategy</td>
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<td>Nunhems, Cornell UCD, UoM</td>
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<td>Seed production</td>
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<td>Provision of seed to breeders</td>
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<td>Assessment of Sustainable</td>
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<td>Studies</td>
<td>Protein production and ELISA development</td>
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</table>
CIMBAA’s initial timeline with activities actually funded by the various organisations; **Brown**= Programme for Biosafety System, **Green**= Department for International Development, **Red**= Eislen foundation, **Purple**= Indo-Dutch tailor made biotech programme, **Blue**= Australia/India Strategic Research Fund, **Orange**= Taiwanese government grant and **Pink**= Nunhems. Some proposed activities were never funded/undertaken. CIMBAA was closed in May, 2010.
Author/s:
Chiu, Jing-wen

Title:
Obstacles to successful commercialisation of public investments in the development of GM crops

Date:
2017

Persistent Link:
http://hdl.handle.net/11343/190638

File Description:
Obstacles to successful commercialisation of public investments in the development of GM crops

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