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Enhancing Agricultural Growth: Biotechnology and Nanotechnology

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सत्यमेव जयते

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MINISTER OF STATE FOR AGRICULTURE
GOVERNMENT OF INDIA
KRISHI BHAWAN, NEW DELHI 110001

August 27, 2015

Message

It is a great privilege and honor for me to inaugurate ASSOCHAM's 4th Bio Nano Agri Summit: Technologies to Transfer Agriculture in India". I appreciate ASSOCHAM's for taking this initiative to boost the growth of agricultural sector in India.

The Indian Bio-Nano technology sector is one of the fastest growing knowledge based sectors in India and is expected to play a key role in shaping India's rapidly developing economy. With numerous comparative advantages in terms of Research and Development (R&D) facilities, knowledge, skills and cost effectiveness, the bio-Nano technology industry in India has immense potential to emerge as a global key player.

The Bio-Nano technology is proving its worth as a technology that can contribute to sustainable agriculture development. Genetically modified crops have proved their effectiveness and efficiency in increasing crop yield, reducing post-harvest losses and making crops more tolerant to stress and also helps in improving nutritional value of foods. Whereas Nanotechnology also plays an important role in agriculture by providing new tools for improving the crop production efficiency, processing of food and food safety efficiency. Apart from this, nanotechnology is also helpful in determining and improving environmental consequences on production of food as well as storage and distribution.

I appreciate the efforts undertaken by ASSOCHAM for pushing the frontiers of collaboration, with private sector and other stakeholders and organizing regular interaction like with the industry and other partners. I also congratulate ASSOCHAM and Sathguru Management Consultants for bringing out this study which presents the overall picture of the Agricultural Bio-Nano technology sector in India, comprising it to the global production and best practices. I am sure that this Summit will fulfil its objective of brainstorming and devising methods for taking agricultural sector to new heights.

I wish the Summit a great success.

(Mohanbhai Kundariya)

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FOREWORD

The 4th Bio-Nano Agri Summit 2015 on "Technologies to Transform Agriculture in India" is significant and important not only for farmers but also for the stakeholders in agriculture and its allied sectors. Bio-Nano technology in agriculture holds immense potential as it can facilitate increased production thereby contributing towards agricultural growth and national food security.

I am hopeful that the deliberations in this summit would focus on mechanisms to promote and establish knowledge-based and technology-driven agriculture, by harnessing the collaborative synergies of all the stakeholders.

I extend my heartfelt thanks to Sathguru Management Consultants Pvt Ltd for bringing out this informative study. This extensively researched publication will highlight various issues in the application of Bio - Nano technology to meet the current challenges in agriculture and a way forward in its implementation.

I would also like to acknowledge the hard work put in by my colleagues Dr Om S Tyagi, Sr Director and his team members Mr Vipul B. Ganjingwar, Mr Amit Bunger and Mr Nitesh Sinha for organizing this summit.

I not only wish the Summit a great success and also assure all stakeholders that ASSOCHAM shall continue to organize such programs for greater degree of excellence.

Best Wishes.

D.S. Rawat
Secretary General

Knowledge Partner

ACKNOWLEDGEMENT

This Knowledge Report on **"Enhancing Agricultural Productivity: Biotechnology and Nanotechnology"** has been prepared by Sathguru Management Consultants as a part of the ASSOCHAM 4th Bio-Nano Agri Summit 2015 on "Technologies to Transform Agriculture in India".

The research has been conducted by studying various reports, recent publications and substantiated with the sectorial know-how of our technical team in order to understand the current trends, future focus areas, regulatory aspects and market scenario across both the technology domains.

I would like to acknowledge the contribution of Mr. Venu Gopal Chintada, Mr. Akshat Medakker, Dr. K. V. Satyanarayana, Ms. Rituparna Majumder and Mr. Sumit Darphale towards development of this knowledge report.

Yours' sincerely

K Vijayaraghavan

Chairman and Director
Sathguru Management Consultants

TABLE OF CONTENTS

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EXECUTIVE SUMMARY

According to Food and Agriculture Organization (FAO), the global population is expected to reach 9 billion by 2050 and to meet this demand of growing population, global agricultural production should be 60% higher in year 2050 than it was in the years 2005/2007. The alarming concerns of rising population and food security instigates the need to address productivity concerns through sustainable technological interventions. Biotechnology and nanotechnology are enabling technologies that are highly interdisciplinary and are transformative in nature with an ability to create new opportunities for addressing issues related to availability of high quality seeds, effective nutrients, pesticides and herbicides, combating the complexities of climatic changes due to unreliable rainfall, prolonged dry spells and extremes of temperature, shortage of water, labor and other energy sources.

Agricultural biotechnology has been effectively employed over decades to augment food production and boost productivity through crop protection, nutrition, quality augmentation and addressing abiotic stresses, reduce growing concerns related to agricultural land reduction and preserve the natural resources by minimizing the use of agrochemicals that pose hazard to the environment. Likewise, nanotechnology applications in agriculture span a wide array of inputs and services ranging from crop nutrients, plant protection products, natural resource management, and nanosensors for detection, identity preservation and utilization of agricultural waste.

The biotech industry is driven by multitude of support programs and initiatives promoted by Government of India through substantial financial and infrastructure support. Public private consortiums, availability of skilled technical resource, accessibility of promising technologies worldwide, agro-chemical industry diversification, favorable policy impetus and environmental concerns are other factors that have driven the research by the industry. On the other hand, in addition to public funding, the nanotech industry is driven by the enhanced properties exhibited by nano sized particles and materials, their widespread potential applications and novel performance.

Assessment of "State of Current" research in biotech by public and private sector in India indicates the industry is driven by immense encouragement from the government, through its multi partner international projects and proactive initiatives taken by the private sector seed companies, both multinational as well as home grown Indian companies with well-established research capacity. In recent times, the industry has witnessed the growth of various Genetically Modified (GM) and Non GM technologies being used for crop improvement. Moving over from crop protection traits the industry is gradually shifting towards investing in development of traits addressing abiotic stresses, yield enhancement and nutritional quality improvement as well as input use efficiency like Nitrogen and water use efficiency. Today, innovative improvements and refinements of existing breeding methods are being deployed to develop advanced products with enhanced efficiency and specificity of breeding, better understanding of final product by using molecular tools that could address the public concerns related to the GM crops especially those curtailing the use of transgenes. "State of Art" technologies being deployed globally in terms of new techniques and applications include Genomic selection, Gene Silencing through RNAi and new plant breeding techniques (NPBT). Technological advancements of biological products include products with new and multiple strains, broad spectrum, stacked products, novel formulations aimed towards improving product efficiency, shelf life and effectiveness.

Research in nanotechnology in agriculture is largely driven by public institutes with limited research by Indian private players. The Indian Council of Agricultural Research has constituted a dedicated nanotechnology platform to foster the use of nanotechnology in agriculture. Few nano-products in the agricultural sector have been put on the market by smaller companies, including India; but the market adoption of these products is limited. In a recent trend observed, technologies developed by Indian public institutes have been transferred to industry. Assessment of "State of Art" technologies for Nanotechnology in agriculture indicate emerging trend for insecticide-related research as the possibility of using alternative insecticide active ingredient that are less harmful to non-target organisms and may potentially reduce the development of resistances. Recent trend of green nanotechnology is closely interconnected with the principles of green chemistry e.g, manufacturing nanomaterials from less toxic chemicals, using less energy and use of sustainable raw materials and green manufacturing.

Globally, commercialization of biotech crops has witnessed varied level of acceptance in different markets and are at different stages of commercialization and market adoption. In India, only Bt Cotton has been commercialized, while other transgenic crop seeds are yet to be approved. Bio pesticides represent only 4.2% (USD 159.6 million) of the overall pesticide market in India and is expected to exhibit an impressive annual growth rate of about 10% in the coming years. However, despite the potential advantages, nanotechnology applications in the agricultural sector have not yet made it to the market to any large extent in comparison with other industrial sectors. No new nano-based products for the agricultural sector have been launched by the large agro-chemical companies, though the patent applications from large players are continuously growing. Although no significant data is available on economic impact of these product, the emergence of nanotech applications in consumer products has raised a number of ethical and societal concerns like effects on human, animal health and environment; consumer perception and intellectual property issues. Though nanopesticides and nanofertilizers have the potential to reduce environmental contamination through the reduction in pesticide application rates and reduced losses; nano-materials may also create new kinds of contamination of soils and waterways due to enhanced transport, longer persistence and higher toxicity of active ingredients.

The biotech regulatory system is challenged with absence of a proper and structured guidance from the regulatory authorities as well as limited knowledge among the industry stakeholders about the accurate regulatory requirements. GM crops has been in the news for all the wrong reasons with controversies and growing opposition to GM seeds. In India, this has been exacerbated by the lack of dissemination of science-based information to all stakeholders to enable them to engage in an objective and transparent debate. There is limited capacity among the stakeholders to generate appropriate regulatory safety data during the biotech product development process. The biologicals sector is paralyzed due to lack of awareness about biological products and their benefits among end users and availability of spurious products in the markets. Additionally, government policies related to promotion and marketing of biological products without ensuring quality and performance check have increased the number of poor quality products in the market which have rippled the faith of the famers and extension workers.

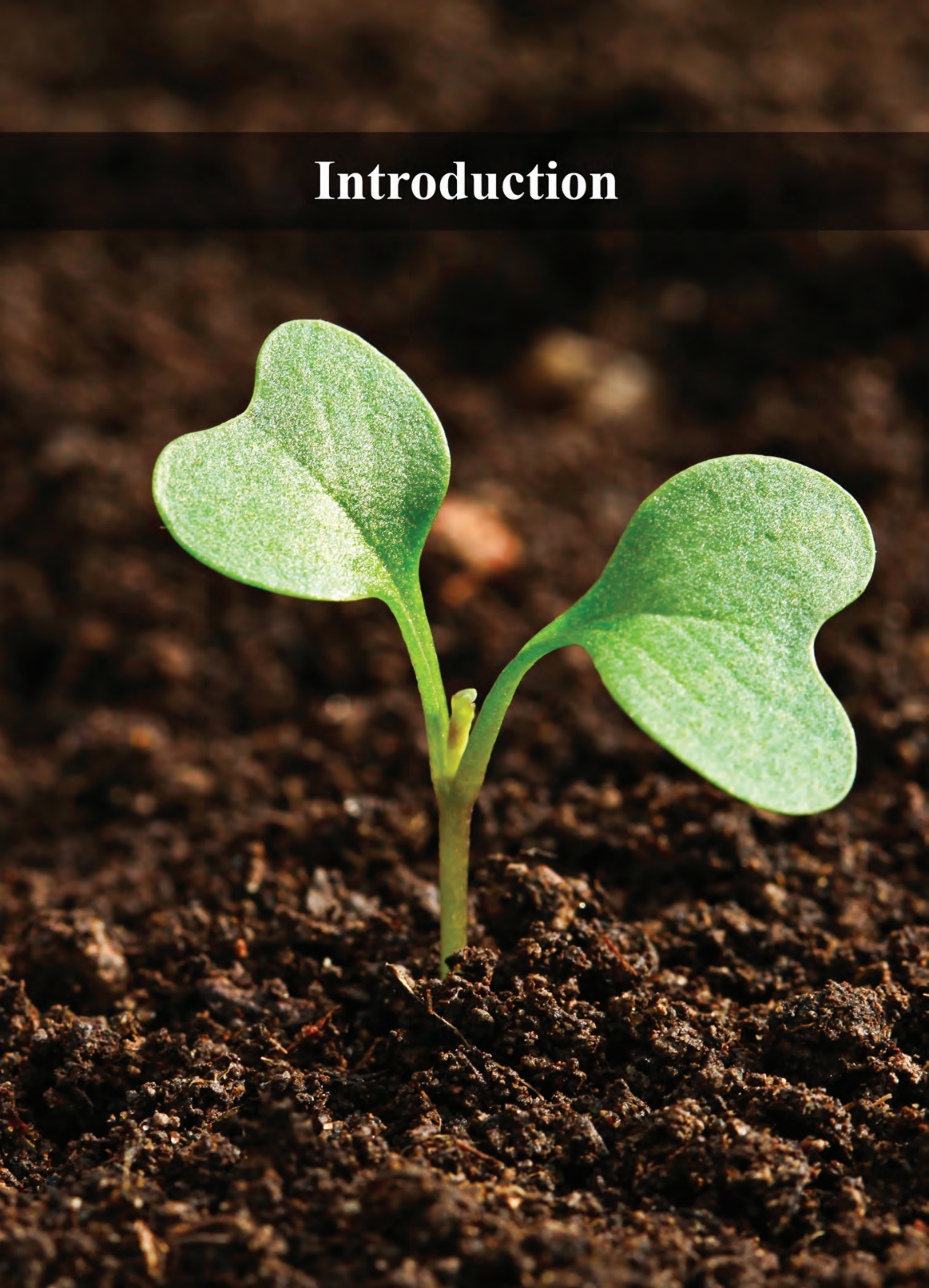
The biotech crops have the potential to expand manifold and in order to realize this market opportunity, the industry needs to overcome policy and regulatory challenges by large and undertake some targeted initiatives. Despite existing challenges in the system the changing regulatory environment with recent approvals for field trials is a light of hope for the industry.

On the other hand, evolving regulatory guidelines, lack of standard definition of nanomaterials, long gestation periods, cost of equipment, and uncertainty of results are some of the challenges in commercialization of nano-enabled products. Challenges in transfer of technology relate to inadequate infrastructure for piloting and characterization of nanomaterials; scalability and cost effectiveness of the process/technology. VC funding and corporate investments in nanotechnology are still far from their level of investment in other industries. Absence of standardized measurement techniques and instruments for nanomaterials and internationally agreed protocols for toxicity testing of nanomaterials pose challenges for nanotechnology regulatory framework and guidelines. However, with increasing R&D in the area of nanotechnology for agricultural applications and with standards and regulations in place in due course of time, it is expected that products/ technologies with well characterized and size determined nanoparticles would be made available in the market.

Though the genetic modification of crops looks promising, acceptance of the technology for food crops by the regulatory authority still remains a farfetched goal. Successful innovation needs the right policies, infrastructure and market structure. Additionally, promoting cross-fertilization of knowledge and capabilities can drive new, innovative business models and attract investment. The future thrust areas would include promoting pooling of resources for result oriented research through effective public private partnership, capacity building on various aspects of biotech crop development and deregulation, infrastructure improvement and quality compliance as well as wide scale communication across all stakeholders. The Indian government needs to streamline the regulatory system through steps such as promoting relevant technologies and traits for self-sufficiency in food production, and forming a single regulatory authority to govern all bio agriculture domains.

Furthermore, nanotechnology should not be considered as panacea for all ills in agriculture and it should be used judiciously to address the emerging needs. Some of the future strategies would include promoting development of adequate regulations and standards for nanotechnology and its applications, capacity building in terms of through interdisciplinary research units for basic and applied research, promotion of public private partnership, infrastructure, facilitating technology transfer and financial support from public agencies for development as well as characterization of nanomaterials. Applications with clear benefits and acceptable/low risks should be introduced first into the market, driving the acceptance of other applications to be introduced later on.

Introduction

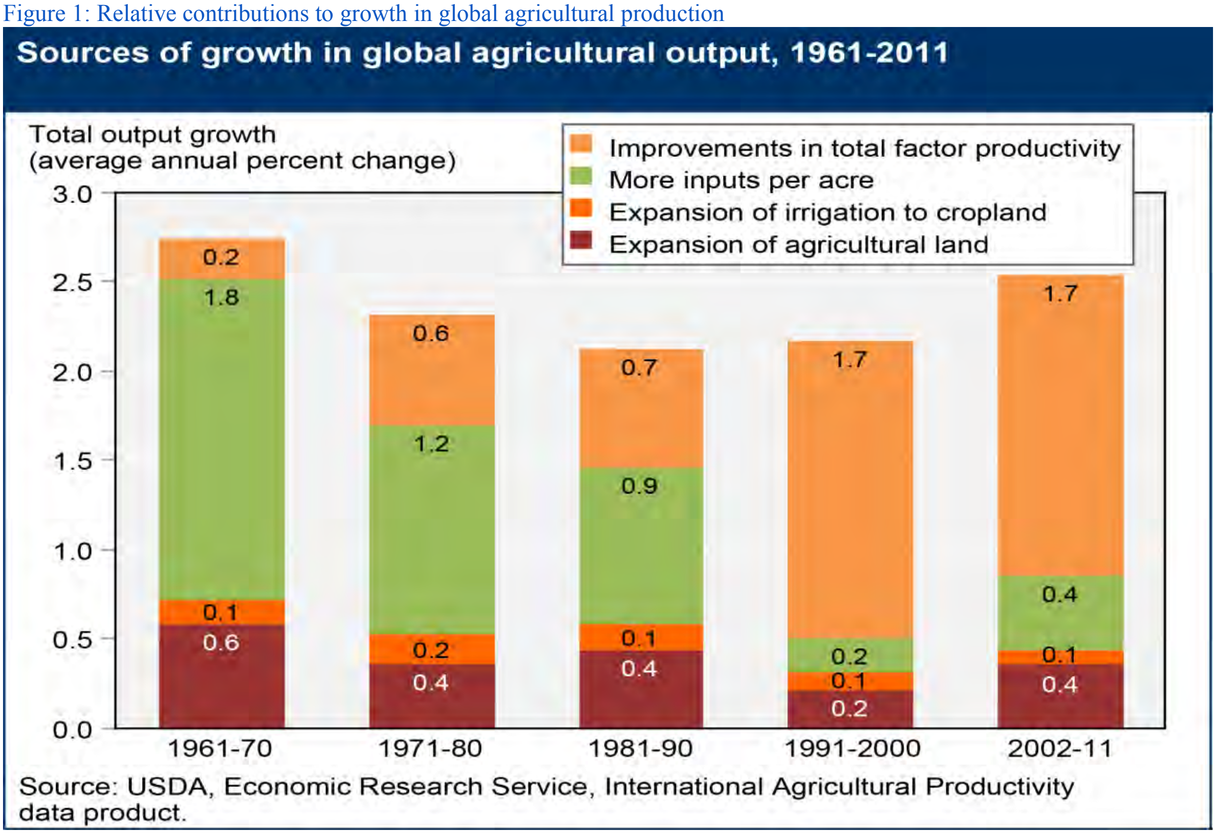


INTRODUCTION

In an endeavor to achieve global food security, the global agricultural production in the year 2050 should be 60% higher than it was in the years 2005/2007; which equates to 24% and 77% increase in developed and developing countries respectively[1]. In order to bridge this gap through increased agricultural production, total crop production between the years 2006 to 2050 should be much higher than it was during the same number of years from 1962 to 2006.

Global gains in agricultural productivity from the 1960s to 1980s was driven by input intensification and crop-area expansion, but the productivity gains achieved during the 1990s and 2000s were driven largely by innovations (total factor productivity) in the seed sector and nominally by input intensification or new land being brought into cultivation. During the decade of 2002-2011, improvements in total factor productivity accounted for about two-thirds of the total growth in agricultural output worldwide (Fig. 1). This clearly highlights a shift from heavy investments on increased fertilizer and pesticide inputs to investments in technology driven improvements (including genetic modification) that increased yields with fewer units of input. Despite these efforts, there is lot to be done and achieved in order to meet the growing demand for food to feed the burgeoning population.

Figure 1: Relative contributions to growth in global agricultural production



In India the area under agricultural cultivation has largely remained constant since the 1980s and the average farm size has also decreased. Per capita availability of land has fallen from 0.91 hectare in 1951 to about 0.32 hectare in 2001 and is likely to decline further to 0.09 hectare by 2050[2]. This decline is

[1] Alexandratos and Bruinsma, 2012. ESA Working paper No. 12-03. Rome, FAO
[2] Indian Biotech Agriculture Industry: Vision 2025, 2013, Accenture - CII Report

due to rapid urbanization, the rise of industrial belts, soil erosion, and climate change. Furthermore, food grain production has also failed to keep pace with the population growth in the country with per capita food output declining since 1995 going significantly below that of the other major global grain producing regions. This gap is attributed to dearth of technologically improved and high quality seeds, effective nutrients, pesticides and herbicides, complexities of climatic changes causing unreliable rainfall, prolonged dry spells and extremes of temperature, shortage of water, labor and other energy sources. The alarming concerns of rising population, shrinking agricultural land and water bodies, declining productivity and growing environmental and agricultural problems instigates the need to adopt sustainable technological interventions in the sector.

Biotechnology and nanotechnology are enabling technologies that are interdisciplinary and transformative in nature with an ability to create new opportunities for addressing existing problems and global issues. These technologies have the potential to disrupt or create entire industries. In the next two decades, bio- and nano- technologies, converging with information technology will have a significant impact on society, industry and the consumers globally.

OBJECTIVE OF THE REPORT

The report studies the trends and potentials of essential technological intervention through biotechnology and nanotechnology to transform agriculture in India. The objectives of the report relate to -

- Understanding the "State of the Current" research trends for both the technology domains in terms of novel techniques and their applications in Indian agriculture.
- Studying the "State of the Art" technology trends in terms of novel techniques and their applications in Indian agriculture for both the domains.
- Analyzing trends and challenges in commercialization and market adoption.
- Regulatory framework, scenario and challenges for both the domains

SCOPE OF THE REPORT

- The agricultural biotechnology section includes information on biotech crops and biological inputs like Biofertilizers and Biopesticides.
- The nanotechnology section covers potential applications of this technology in crop nutrition, crop protection, biosensors, waste utilization etc. This report covers only on-farm operations and does not include food processing industry.

A. Agricultural Biotechnology

INSIGHT SUMMARY

For about 10,000 years, farmers have been improving wild plants and animals through the selection and breeding of desirable characteristics. In the twentieth century, with technological advancement crop breeding has witnessed a paradigm shift with breeders using biotechnology for introgressing traits for increased yield, disease and pest resistance, drought resistance and enhanced flavor using specific gene sequences known to enhance or introduce new characteristics into the crops. This report is our small endeavor to highlight the progress of agricultural biotechnology in India in terms of new technologies, tools and traits being deployed by the public and private sector research organizations. Biotechnological applications in agriculture are targeted towards increasing productivity through crop protection, nutrition, quality augmentation and addressing abiotic stresses. Assessment of "State of Current" research by public and private sector in India indicates that biotechnology research in agriculture is being driven by immense encouragement from the government and proactive initiatives taken by the private sector seed companies - multinational as well as home grown Indian companies with well-established research capacity. The report studies in detail the "State of Art" technologies being deployed globally in terms of new techniques and applications with successful examples which can be the next generation drivers for further technological advancement in the sector. Technologies like Genomic selection, Gene Silencing through RNAi, and new plant breeding techniques have been discussed in the report. The potential of modern product formulations for improving product efficiency, shelf life and effectiveness for biological products have also been discussed.

The report further discusses the trends and challenges in commercialization, market adoption of biotech seeds and other biological inputs. Potential market growth levers in terms of innovation, market stakeholders and awareness building have been discussed. Furthermore, regulatory framework and national policies have also been referred. Despite existing challenges in the system, changing regulatory environment with recent approvals for field trials is a silver lining for the industry. Socio-Economic and environmental impact of biotechnology in agriculture have also been looked into.

Strategic way forward and recommendations to address collaborative effort, capacity building, strengthen regulatory assessments, infrastructure and communication advocacy are provided in the report.

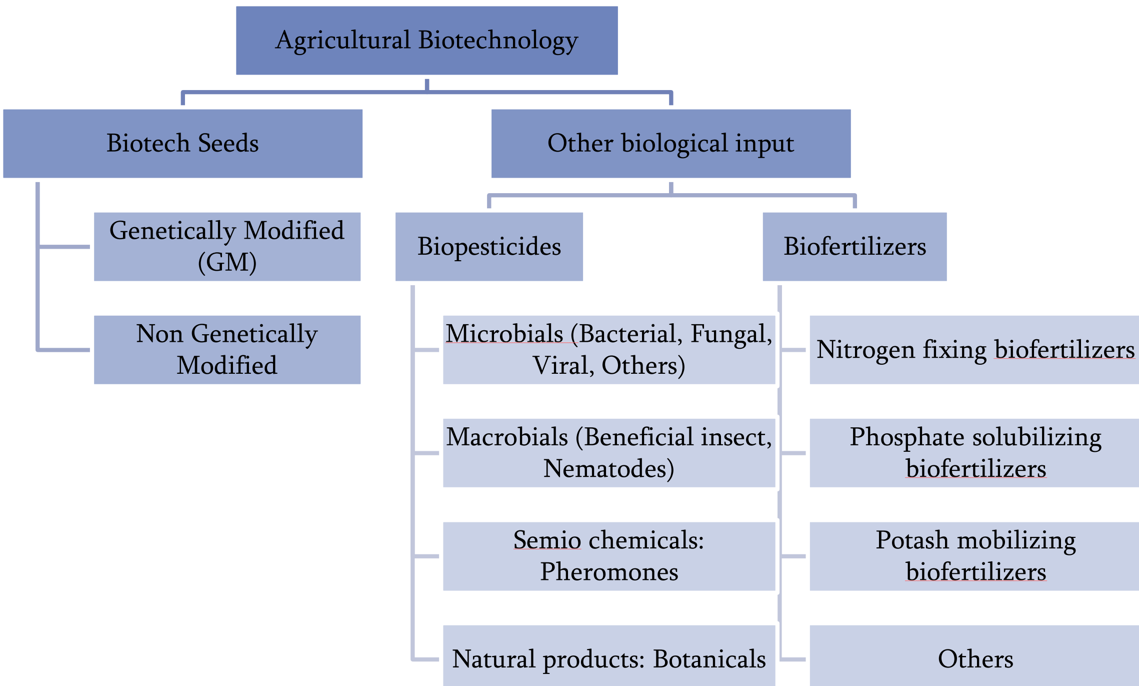
INTRODUCTION TO BIOTECHNOLOGY

Agricultural biotechnology, is an area of agricultural science which involves the use of scientific tools and techniques, including genetic engineering, molecular markers, molecular diagnostics, and tissue culture, to improve living organisms: plants, animals, and microorganisms. Over decades biotech crops and other biological inputs have been developed through use of modern biotechnology. The report broadly covers the contribution of biotechnology in development of genetically modified as well as non-genetically modified seeds and other agri-inputs.

NEED FOR AND ROLE OF BIOTECHNOLOGY IN AGRICULTURE

Agricultural biotechnology can be effectively employed to augment food production, boost productivity, reduce growing concerns related to agricultural land reduction and preserve the natural resources by minimizing the use of agrochemicals that pose hazard to the environment through a multitude of sustainable biotechnological intervention. Biotechnological techniques and tools have been used to address pressing agricultural issues as highlighted above through development of technologically improved biotech crops and biological inputs. For the first 17 years since the of commercialization of biotech crops from 1996 to 2012, economic benefits of US$47.7 billion for herbicide tolerant crops and US$68.9 billion for insect resistant crops have been realized worldwide[3].

Figure 2: Different Segments of Agricultural Biotechnology



The Table 1 below illustrates the target area, anticipated effects and potential solutions in agriculture which biotechnological interventions can address and facilitate movement towards achieving food security.

[3] ISAAA, 2014, Biotech Traits, Annual Updates

Table 1: Target areas in agriculture can be addressed through biotechnological intervention[4]

Target Areas	Effect	Potential solutions
Crop Protection	Reducing the use of inorganic materials and chemicals in agriculture and increasing productivity	• Development of insect, disease resistant and herbicide tolerant varieties, eco-friendly biological products replacing inorganic fertilizers
Crop Nutrition	Enhanced Nutrition and yield improvement, address food security	• Modern traits like: Nitrogen Use Efficiency, phosphorus uptake
Address abiotic stress	Adapting to adverse local agro-climatic conditions and minimizing climate change impact on productivity	• Considering the local environmental concerns various abiotic traits like drought tolerance, salinity tolerance, submergence tolerance and heat/cold tolerance are under development in India. • Multi-stacking genes to develop bio-engineered rice with enhanced drought and multiple disease and pest resistance.
Quality/Nutrition Enhancement	Quality augmentation to improve standards of produce	• Development of Innate™ potato with improved qualities • Long life banana that ripens faster on the tree to hasten harvest period • Development of bio-fortified rice (golden rice) with higher levels of iron and b-carotene (an important micronutrient which is converted to vitamin A in the body) is close to commercialization in India.

DRIVERS FOR GROWTH OF AGRICULTURAL BIOTECHNOLOGY IN INDIA

The increasing repertoire of modern techniques and tools of biotechnology available today provide plenty of opportunities for the agricultural industry involved in providing solutions through technological and genetic improvement to deploy them and develop crops with new traits and other improved inputs. The major drivers of the industry includes:

1. **Government Support and Initiatives:** Department of Biotechnology (DBT), Ministry of Science and Technology (MoST), Government of India (GOI) have been carrying out multi-faceted efforts for promotion of R&D in agricultural biotechnology. Agricultural universities are receiving substantial financial and infrastructure support from respective state governments. Government policy initiatives to develop infrastructural facilities like biotech parks, favorable intellectual property rights (IPRs) regime and encourage patent culture are attracting investments from public as well as private sector. Below are the few government initiatives driving the research of the agri biotech industry:
   a. Establishment of Biotechnology Industry Research and Development Assistance Council (BIRAC)
   b. Ongoing schemes like Biotechnology Industry Partnership Program (BIPP) and expanding Small Business Innovative Research Industry (SIBRI)
   c. Government Initiatives like promotion of Integrated Plant Nutrient Management (IPNM) have boosted the agro-chemical industry to also invest in R&D of biological products.

[4] Sathguru compilation, various sources

2. **Skilled human resource pool:** With about 40,000 biotechnology students passing out every year in India, there is no dearth of skilled human resources to undertake research activities in the country.
3. **Public Private Partnership:** Formation of public private partnerships (PPP) or consortiums for trait development/ event access have proved to be successful models in India by facilitating technology access for even small players and significantly reducing the cost of product development and deregulation for individual players.
4. **Industry Diversification**: Dearth of new chemical molecules for crop protection, negligible approvals and phasing out chemical compounds/formulations has triggered the chemical input companies towards diversification of research for development of biological products.
5. **Policy Momentum:** The seed companies with R&D centers recognized by the Department of Scientific and Industrial Research, Ministry of Science and Technology enjoys a weighted reduction of 200% of the expenditure made on R&D as per section 35 of IT Act. There is an exemption for seed companies from payment of income tax (as it falls under agricultural income, but not exempt on income from trading/investing activities), excise duty and VAT. For certain cases, the Government allows FDI up to 100% under the automatic route in the development and production of seeds and planting material.
6. **Labor shortage:** Over the last couple of years, the problems of farm labor shortage, high wages are directing farmers to adopt new technologies which could reduce the inter-cultivation practices like weeding, spraying etc. Pest and disease resistant crops such as Bt cotton reduced the number of sprays significantly and thereby addressed the problem of labor shortage. Herbicide tolerant crops could have a huge potential in the future.
7. **Farm productivity:** The increase in agricultural input costs is affecting the overall revenue from farm produce. Farmers are looking for innovative methods/ technologies to either reduce the cost or improve the crop productivity. Crops and other inputs derived from agricultural biotechnology have the potential to meet this twin requirement.
8. **Premium price:** Protection offered by IP laws is helping private industry to generate significant revenue by creating a market domination and offering products at premium price. Even farmers are ready to invest in order to avoid future losses due to pest attack or unfavorable weather conditions. More and more companies are investing in biotech R&D with the hope to leverage it in the future.
9. **Environment friendly crop production:** Ever increasing consumer base for chemical free and organic products is pushing FMCG sector to procure environment friendly produce. Increasing awareness of environmental concerns amongst farmer fraternity is boosting the demand for bio-products which have low environmental impact.

APPLICATIONS OF AGRICULTURAL BIOTECHNOLOGY IN SEEDS

RESEARCH IN INDIA (STATE OF THE CURRENT)

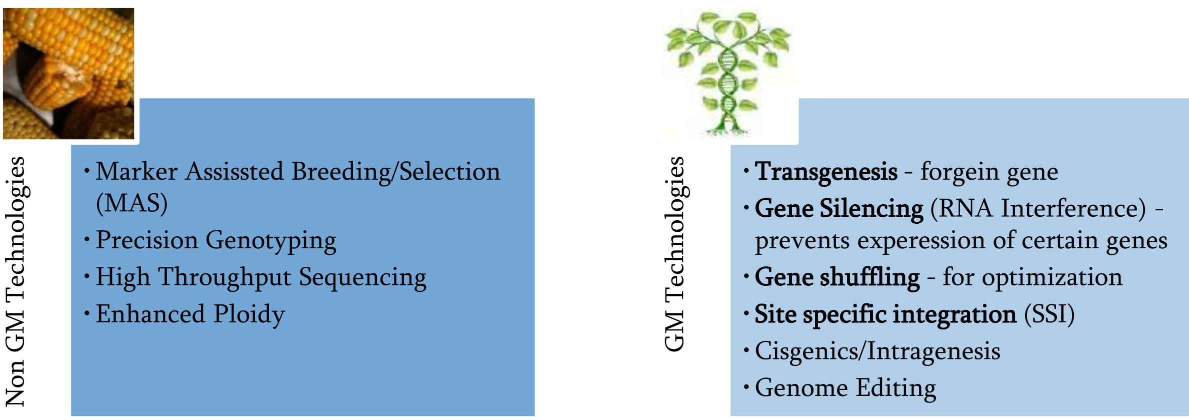
Research in biotech seeds has been the fastest growing technology in India in the recent past to increase the crop productivity levels of the country and meet the growing food demand of population. The Indian seed industry has gradually witnessed a paradigm shift in research techniques progressing from conventional plant breeding to molecular breeding and genetic engineering. The industry has been extensively using various technology platforms for development of more than 200 biotech crops in order to address issues related to crop protection, nutrition, yield enhancement and tolerance to biotic and abiotic stresses across 36 crops.

The last two decades have witnessed an advancement of R&D in biotech seeds by the public and private sectors, triggered by several initiatives from DBT. The growth of R&D in biotech seeds has been facilitated by the use of diverse technologies and tools by the sector. The public sector biotech crop research work is primarily conducted at central government-funded public sector research institutes, universities and research centers through various in-house research programs, as well as multi-partner international collaborative projects. Private sector companies, primarily MNC's are investing in the modern platforms for development of biotech crops. The Indian companies are also catching up slowly.

NOVEL TECHNIQUES

In recent times, the industry has witnessed the growth of various Genetically Modified (GM) and Non GM technologies used for development of biotech crops (Figure 2). However, Next Generation Sequencing (NGS) technologies and technologies like Cisgenics, Genome Editing which are extremely promising but are not being used extensively by the Indian industry.

Figure 3: GM and non GM technologies used by Indian Biotech Crop Industry



With time, the Indian industry has also decoded to progress with various Non GM technologies to reduce time to market of products and also avoid the high costs associated with conducting regulatory studies of biotechnology derived crops.

- Advancements in molecular breeding has been made through the introduction of molecular markers associated with the trait of interest (short sequence of nucleic acid which makes up a segment of DNA) to identify specific genes thereby increasing the selection efficiency. Modern tools like Single Nucleotide Polymorphism marker (SNP) are being deployed by researchers to improve the effectiveness of MAS.
- MAS have helped to develop disease resistant varieties of wheat and hybrids in rice and other crops.

Companies like Mahyco, Bioseed, Rasi and Metahelix have significantly advanced their position in crop genetic improvement by developing capacities for genetic transformation and trait development independently. Indian MNCs like Advanta have made significant contribution to the R&D sector by developing molecular marker technology and other biotech methods to enhance seed traits for several agricultural crops.

Nitrogen Use Efficiency (NUE): Produces plants with yields that are equivalent to conventional varieties requiring significantly less nitrogen fertilizer because they use it more efficiently. **Arcadia** has successfully introduced NUE technology into crops like Rice and Canola.

Public and private research organizations including MNC's and progressive Indian seed companies are investing in GM technologies like gene silencing through RNA Interference. While some of the Indian companies with well-established R&D have adopted new technologies, few small companies entered into collaborative research agreements with public institutes tapping public funding for development of biotech crops.

NOVEL APPLICATIONS

The biotech seed industry in India began with the introduction of single gene product. In order to enhance the durability of the technology and discourage the development of resistance by target pests, the concept of stacking has come into deployment within the industry by the development of second and third generation products with stacked genes. This concept evolved with pyramiding the genes for multiple traits in a single crop.

The Indian biotech seed industry over the last few years have been investing heavily on development of traits addressing abiotic stresses as well as nutritional quality improvement and yield enhancement. Many Indian companies are putting in serious efforts for development of crops with improved input use efficiency.

Figure 4: Trait Generation Growth

First Generation Traits	Second Generation Traits
Insect /Pest Resistance	Yield Enhancement
Herbicide Tolerance	Nutritional quality enhancement
Virus Resistance	Nitrogen Use Efficiency (NUE)
Insect Resistance +Herbicide tolerance	Water Use Efficiency (WUE),
Disease Tolerance/Resistance	Climate resilient genotypes
Cytoplasmic Male Sterility	Drought and Salinity tolerance,
	Heat and Cold tolerance

Figure 4 illustrates the first generation traits under development by public and private sector scientists. Most of the traits are addressing crop protection concerns e.g.: insect pest resistance and disease resistance while few are targeted to improve product quality e.g.: increasing Lycopene content in tomato, improving chip color in potatoes etc. and also enhancing yield. The stacked traits provided integrated solution of insecticide resistance and herbicide tolerance. The next generations traits like Tomato with improve quality parameters and shelf life, Rice with Water Use Efficiency (WUE) and NUE are in progress by the private industry and public institutes of the country.

A latest technology with multiple traits under development is "**Triple-stack**" in rice: includes nitrogen use efficiency (NUE), water use efficiency (WUE) and salt tolerance (ST).

Table 2: Highlights of traits under development by Public and Private Biotech seed sector[5]

Traits	Private	Public
Herbicide tolerance (HT)	RRF Cotton, Corn; Glytol Cotton; Rice, Mustard	Cotton, Corn, Rice, Cabbage, Cauliflower
Insecticide Resistance (IR)	Corn; Cotton; Rice, Brinjal, Chick Pea, Okra, Pigeon Pea	Cotton, Corn, Brinjal (Fruit and short borer), Rice, Sorghum, Potato (late blight), Chick Pea (Pod Borers), Castor, Cabbage, Okra, Cauliflower, Tomato, Mustard (Aphid Resistance)
IR + HT	Corn, Rice, Cotton	Syngenta (stacked events), Bayer, Pioneer, Advanta, Bioseed
Disease Tolerance/Resistance	Mustard, Rice, Vegetables, Bajra, Maize, Wheat, Pearl millet, Bittergourd	Rice (Gall midge, BLB), Sorghum (Shoot fly), Tomato (Peanut bud necrosis), Wheat (Leaf and stripe rust, Karnal bunt, Powdery mildew)
Virus Resistance	Tomato, Okra, Cotton, Chilli, Brinjal, Sunflower,	Groundnut (Tobacco steak virus), Soybean (Yellow mosaic virus), Papaya (PRSV), Watermelon (WRNV), Rice (Tungro)
CMS	Cotton, Rice	Mustard, Rice
Yield enhancement	Rice, Corn, Mustard, Pearl Millet, Tomato, Brinjal, Bittergourd, Cauliflower	Mustard (Seed yield and oil content), Cotton (Fibre strength, Oil content), Tomato (Delayed Ripening), Potato (Delayed sweetening)
Drought tolerance	Maize	Rice
Salinity tolerance	Rice	Rice
Nitrogen Use Efficiency	Rice	
Water Use Efficiency	Tomato	
Submergence tolerance	Rice	Rice
Heat/Cold tolerance; Temperature insensitivity	Vegetables: Cauliflower, tomato, okra	Wheat
Abiotic Stress		Mustard, Chick Pea, Rubber
Nutritional qualities	Mustard, Pepper, Wheat, Brinjal, Tomato, Maize	Mustard (Low glucosinolate), Maize (Quality protein, Biofortification), Wheat (Biofortification), Rice (Biofortification)

However, the transition from Green Revolution to Gene Revolution through R&D in biotech seed research in India has experienced a slow progress. This is mainly because GM crops have often been misquoted to be against nature and biodiversity concerns have been raised time and again.

GLOBAL TECHNOLOGY TRENDS AND INNOVATIONS (STATE OF THE ART)

In the last two decades, globally GM crops have focused on crop production traits e.g.: insect resistance and herbicide tolerance. Lately, technologies are targeted to address issues like food quality enhancement, yield enhancement and environmental benefits. Efforts have also been put into developing biotech traits in non-food crops. The industry is gradually moving towards deployment of new and improved techniques as well as advanced tools to develop biotech seeds.

NEW TECHNIQUES

5 Sathguru compilation, various sources

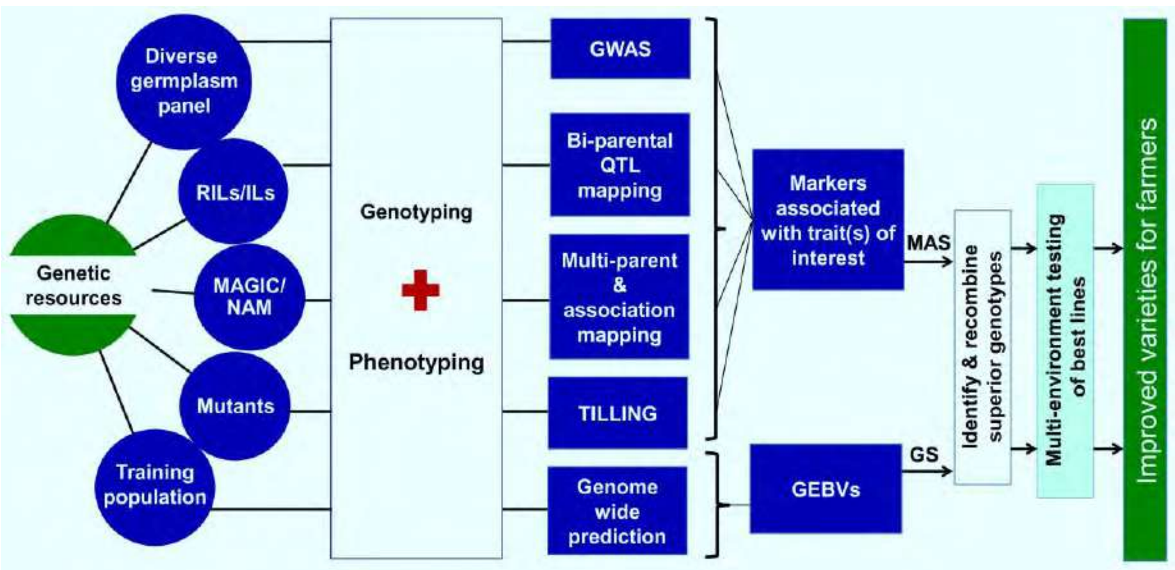
Lately, the industry is focusing on deploying new breeding techniques using molecular tools that could address the public concerns related to the GM crops especially those curtailing the use of transgenes. Companies worldwide have gradually started investing in enabling platform technologies that would help develop crops using non GM techniques.

APPLICATIONS OF GENOME SEQUENCING TECHNOLOGIES TO CROP BREEDING

Rapid developments in Next Generation Sequencing (NGS) technologies in the past decade have opened up many new opportunities to explore the relationship between genotype and phenotype with greater resolution. As the cost of sequencing has decreased, breeders have begun to utilize NGS with increasing regularity to sequence large populations of plants, increasing the resolution of gene and Quantitative Trait Locus (QTL) discovery and providing the basis for modeling complex genotype-phenotype relationships at the whole-genome level.

Knowledge about the identity and map location of agriculturally important genes and QTLs provides the basis for parental selection and Marker-Assisted Selection (MAS) in plant breeding. In genomic selection (GS), genotypic and phenotypic datasets on training populations (TP) are used to develop models to predict the genomic estimated breeding values (GEBVs) of lines. The GEBVs serves as a predictor as to how well a plant will perform as a parent for crossing and generation advance in a breeding pipeline (Varshney et al., 2014). The use of genomics assisted breeding, in both MAS and GS, allows for more selection cycles and greater genetic gain per unit of time. NGS technologies have augmented the speed, throughput, and cost effectiveness of genome-wide genotyping. Despite the potential, very few Indian companies have invested in breeding programs based on genotyping.

Figure 5: Role of NGS in genomics-assisted breeding[6]



NGS occupies a critical position in a genomics-assisted breeding pipeline; it helps improve the speed and precision of trait mapping to identify genes and QTLs that are the targets of MAS, and it underlies the ability to calculate GEBVs based on genome-wide prediction that predict the breeding value of individuals in a breeding population using GS.

[6] Varshney et al., 2014. PLoS Biol 12(6): e1001883.

RNA INTERFERENCE BASED GENE SILENCING TECHNOLOGIES

RNAi is an important technology used for development of biotech crops through gene silencing. Recently numerous GM products are under development for building resistance in the crop against nematodes, insects, fungi, virus, parasitic weeds etc. RNAi based GM plants are also developed in order to manipulate metabolism for improving various industrial traits as well as nutritional value Table 3 below illustrates few examples of RNAi based biotech crops under development.

Table 3: Example of RNAi based technologies for biotech crop

Target	Examples
Nematodes	**Transgenic soybean**[7] developed by targeting essential nematode genes
Insects	**Tobacco engineered to have RNAi activity**[8] targeting the cytochrome p450 monoxygenase gene (CYPAE14) of the cotton bollworm
Fungi	**Transgenic potato plants**[9] targeted against plasma membrane-localized SYNTAXIN-RELATED 1 (StSYR1) grew normally and showed increased resistance to *Phytophthora infestans.*
Viruses	Potato Virus Y (PVY)-resistant potato
Parasitic Weed	A parasitic weed- striga resistant variety of maize[10]
Metabolism manipulation	Industrial: Phytochrome RNAi enhances major fibre quality and agronomic traits of the cotton[11] Nutritional: suppression of an endogenous photomorphogenesis regulatory gene, DET1, using fruit specific promoters significantly increased carotenoid and flavonoid in the fruit [12]

NEW PLANT BREEDING TECHNIQUES (NPBT)

Today, innovative improvements and refinements of existing breeding methods are being practiced by plant breeders and scientists to develop advanced products with enhanced efficiency and specificity of breeding and better understanding of final products.

Table 4: Overview of biotechnology driven 'New Plant Breeding Techniques' (NPBTs)[13]

New Plant Breeding Technique	Description of technique	Considerations for regulation
A. Site specific mutagenesis		
Oligonucleotide-Directed Mutagenesis (ODM)	A mismatch pairing is created by oligonucleotide of 20 - 100 nucleotides	Induced site-specific mutations via the natural DNA repair mechanisms
Meganuclease (MN)	A single protein chain that cleave DNA in a site-specific way	

[7] Klink et al., 2011. Planta, 230:53-71
[8] Mao et al., 2011. Transgenic Res. 20, 665–673.
[9] Eschen-Lippold et al., 2012, activation of defense against *Phytopthora infestans* in potato
[10] De Framond et al., 2007, Integrating new technologies for Striga control, World Scientific Publishing Co. pp 185–196
[11] Ibrokhim et al., 2013 Nature Communications | 5:3062
[12] Davuluri, et al., 2005. Nature Biotechnology, 23, 890–895.
[13] Lusser and Davies, 2013, Comparative regulatory approaches for groups of new plant breeding techniques.

Zinc Finger Nuclease (ZFN)	Two proteins artificially connected by peptide linker, cleave DNA in a site-specific way	Nuclease genes delivered into the cell are integrated into the plant as a transgene or transiently expressed in the cells. Targeted specific mutation in the genome.
Transcription Activator-Like Effector Nuclease (TALEN)	Two proteins artificially connected by peptide linker	
CRISPR-Cas-Nucleases	Guide RNAs direct the Cas9 nuclease activity to target sequences in the genome	
B. Deploying genes from cross-compatible species		
Cisgenesis	Transfer of an intact gene between closely related species, transferred gene is unchanged i.e. with native regulatory elements	Deploy gene transfer technologies like transgenesis. Specific vectors have been constructed for cisgenic/ intragenic approaches, which use DNA sequences originating from the same species or related species to insert the target genes (P-DNA), instead of bacterial DNA
Intragenesis	Regulatory elements of a gene may be changed	
C. Breeding with transgenic inducer line		
RNA-dependent DNA methylation (RdDM)	Gene expression modified by promoter methylation without changing the genomic sequence	Does not lead to changes in the genome. Transgenesis is used during the breeding process and is not present in the final product. The epigenetic changes may be inherited and stable for few generations
Reverse breeding	Relies on suppression of meiotic recombination during propagation of an elite hybrid plant; haploid chromosomal set are then converted to double haploids	Does not lead to changes in the genome. Involves an intermediate step where foreign genetic material is present to suppress meiosis. No foreign genetic material is present in the end product.
D. Agro-infiltration techniques	Plant tissue is infiltrated with Agrobacterium suspension	Desired genes are expressed locally and only transiently in the plant
E. Grafting techniques	Grafting on GM rootstock	Introduces transgenes only in the Rootstock, the scion grafted on the rootstock remains free of transgenic DNA.

NOVEL APPLICATIONS

The latest biotech crops commercialized include Innate™ potato and Enlist™ Duo in USA, Maize (Insecticide and herbicide resistance) in Vietnam, Fruit and Shoot Borer resistance Brinjal in Bangladesh, Drought tolerant Sugarcane in Indonesia.

INNATE™ POTATO	Developed by Simplot - A food staple with lower levels of acrylamide, a potential carcinogen, and less wastage due to bruising; and reduced lignin alfalfa with event kk179. New technology was developed by transferring genes from one potato variety to another and would help to produce potatoes with higher digestibility, 50 to 75% lower levels of acrylamide and higher yield.
ENLIST™ DUO	A second generation of herbicide tolerance product. Featuring dual-action/weed management systems for dealing with herbicide resistant weeds of soybean and maize contains pyramided genes to confer tolerance to herbicide glyphosate and 2, 4-d choline.

Among other technologies in pipeline Simplot has already requested approval for an enhanced Innate™ potato with late-blight resistance and lowered reducing sugars and fortified bananas in US and pest resistant Cow Pea in Africa. Additionally, Golden Rice is progressing with field testing and late-blight resistant potatoes are being field tested in Bangladesh, Indonesia, and India.

Today, biotech crops are developed for stress protection, seed treatment, water optimization in order to target specific sites of pest occurrence, enhance tolerance to environmental variations, increase persistence and being cost effective.

TRAIT UP™: SEED TREATMENT

A non-transgenic platform to express or silence genes in seeds and plants, and acquired traits are expressed within days post treatment of seeds (vector DNA is applied as seed treatment); Morflora, Israel

India has the potential to become a major producer of transgenic rice and several GM vegetables. In future, R&D research in India would focus on intensification of genomics research for development of next generation traits like abiotic stress tolerance, increasing yield, stability, nutritional enhancement.

MARKETS FOR BIOTECH SEEDS

The last couple of years has seen increased attention towards and use of biotech seeds in agriculture in India as well as on global level. This can be attributed to recent socio-economic-technological and climatic changes occurring across the agricultural value chain. However the problem of crop loss due to pest attack requires an alternative solution which is addressed by pest/disease resistant biotech crops.

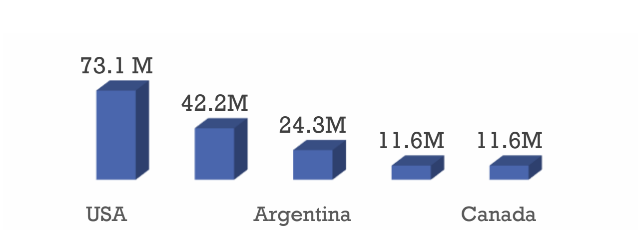
COMMERCIALIZATION AND MARKET ADOPTION

The commercialization of biotech crops has witnessed varied level of acceptance in different markets and are at different stages of commercialization and market adoption globally. In the case of Indian market, only Bt Cotton has been commercialized, while other transgenic crop seeds are awaiting approval.

Globally, the principal biotechnology crops available today are Soybean (50%), Corn (31%), Cotton (14%) and Canola (5%)14. As of today, the two biotechnology traits widely available in the market pertain to herbicide tolerance and various insect resistance capabilities. However there is gradual shift to other non –biotic stress traits such as drought, salinity tolerance and nutritional improvement.

The Indian Biotech-seed industry is dominated by a single GM crop i.e. Bt cotton. Despite the fact that other hybrid crop seeds of improved varieties are sold in the market, more than 90 percent of the revenue comes from this segment. Though this transgenic crop has made huge progress (220 fold increase) in last decade, it has recorded declining growth rate (4-5 %) over last couple of years.

Figure 6: Top 5 countries growing biotech crops by hectare



Over the years the number of agri-biotech firms performing R&D in the area of GM crops have increased to 64 (IGMORIS), including nearly 45 seed companies selling Bt cotton hybrids. While majority of the sublicensing firms upgraded their scientific knowledge and infrastructure to the levels required for technology absorption (by backcrossing and testing) and meeting the regulatory requirements of the country, some of the companies selling Bt cotton hybrids stagnated and could not expand their research capacities beyond the levels required for testing and release of GM event

[14] James, C. 2014, Global status of commercialized biotech crops; ISAAA brief No. 49

introduced hybrids[15]. The GM seed segment witnessed shuffling in terms of division of revenue among the companies. The companies which used to dominate Bt cotton market no longer hold supremacy as they faced strong competition on account of pricing and quality.

In the near future Asia will have the first GM rice varieties in market and this will help the region to be the point of emergence of technology providers as the key source of GM events. The rice events for insect resistant varieties and biofortified rice (Golden Rice) are close to commercialization.

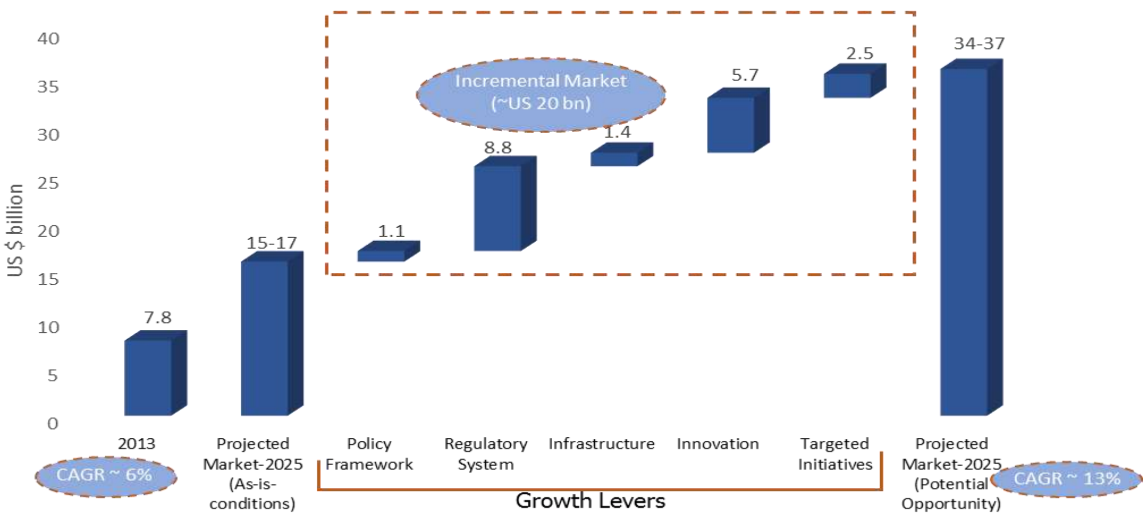
MARKET CHALLENGES CUM GROWTH LEVERS

The biotech crops have the potential to expand manifold, from current US $7.8 billion to US $ 34–37 billion by 2025. However, to realize this market opportunity, the industry needs to overcome policy and regulatory challenges and undertake some targeted initiatives.

Successful innovation needs the right policies, infrastructure and market structure. Additionally, promoting cross-fertilization of knowledge and capabilities can drive new, innovative business models and attract investment. The challenges are enormous, but the opportunity the sector presents is both substantial and achievable. There is need to establish a framework to take to market successful research projects developed at public institutes as well as sharing the licensing/trait fee in a transparent manner.

Of late, GM crops has been in the news for all the wrong reasons with controversies and growing opposition to GM seeds. In India, this has been exacerbated by the lack of dissemination of science-based information to all stakeholders to enable them to engage in an objective and transparent debate.

Figure 7: Growth Levers for incremental biotech seed market[16]



IF CULTIVATION OF BIOTECH CROPS APPROVED IN INDIA – COMMERCIAL PERSPECTIVE

Indian seed industry has witnessed how the Bt Cotton technology has changed the way cotton cultivation was done in India a decade before. With the same aspiration, private as well as public

[15] Vijayaraghavan & Satyanarayana, 2015, Business of Agriculture, July – August, Pg 32 - 36
[16] CII – Accenture, Indian Biotech Agriculture Industry: Vision 2025, 2013, Pg: 14

institutes are investing in research to develop critical traits in other crops. Prospective impact of some of the traits of major crops which are in advanced stage of research and are close to commercialization have been analyzed and presented in table 5 below. Considering the current level of seed replacement rate and adoption level of improved seed in each crop, the overall market is estimated to grow by 12%, 18% and 29% by the end of year 1st, 3rd and 5th respectively. This growth would be in addition to current seed industry growth rate of 10-15%. In addition, if we consider the incremental price fetched by these innovative biotech seeds, the market would show multifold growth in value terms above estimated growth rate.

Table 5: Estimated market potential for few identified biotech crops (USD Million)[17]

Crops	Focus Trait/s	Stage of development/commercialization (as on 2013)	Current Market Size	1 YR (30% growth) E	3 YR (50% growth) E	5 YR (80% growth) E
Brinjal	Insect resistant	Ready to Launch	11.96	14.48	16.16	18.67
Mustard	Herbicide tolerant	BRL-II completed	66.00	75.70	82.17	91.87
Golden Rice	Nutritional improvement	Ready to Launch	0.00	8.80	9.24	9.70
Corn	Insect and herbicide resistant	BRL -1 (2nd year)	198.00	233.98	257.96	293.94
Rice	Abiotic stress tolerance	BRL-II	462.00	487.41	504.35	529.76
Okra	Insect resistance	BRL-II	58.00	72.02	81.31	95.25
Total Market Size			795.96	892.39	941.95	1029.50
% increase				**12%**	**18%**	**29%**

NATIONAL POLICIES AND REGULATORY FRAMEWORK

Indian government has been promoting agri- biotech industry through a robust regulatory framework and policies after the approval for commercial release of Bt cotton in India in 2002. The Indian Regulatory Framework is stands with the support of Central Government through Department of Biotechnology (DBT), Ministry of Science and Technology (MoST) and Ministry of Environment and Forests (MoEF). The state governments are also supporting through State biotechnology Coordination Committee (SBCC).

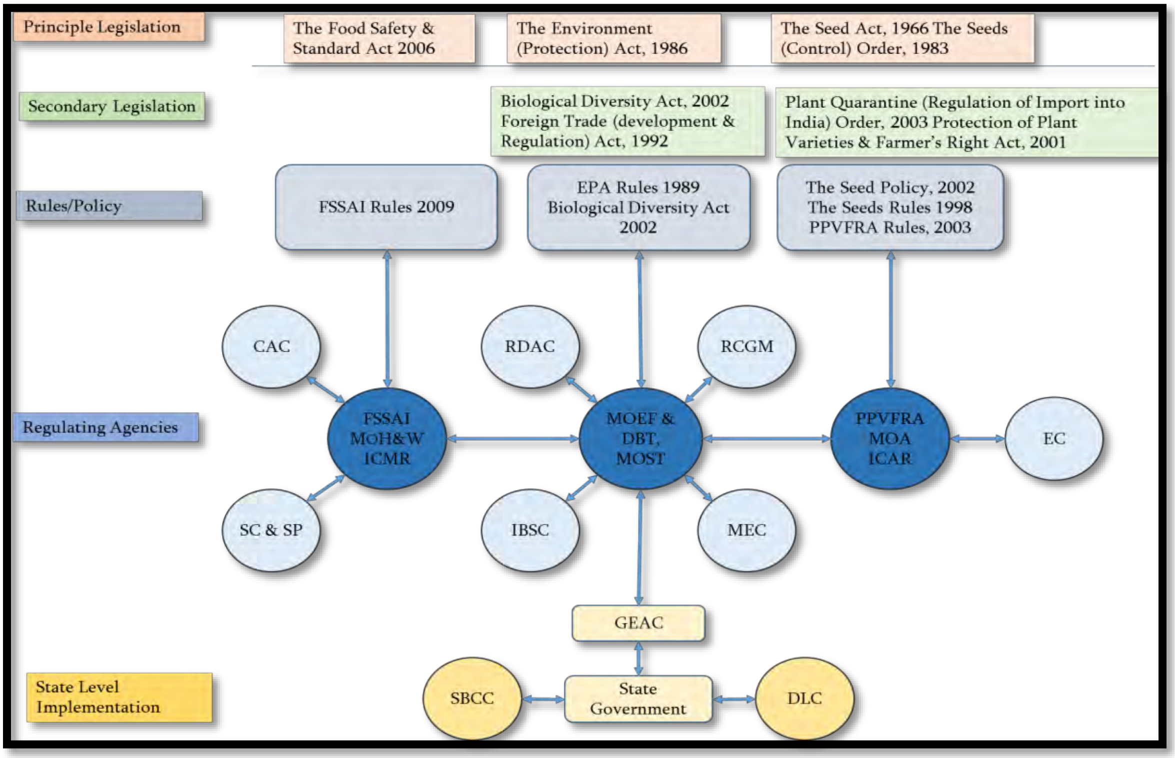
The regulation of GM crops from development, environmental release to commercial approval has been covered by three legislative Acts enacted by the Parliament of India and administered by different ministries. These include the

A. Environment Protection Act (EPA) 1986 implemented by MOEF - "Rules for the Manufacture, Use, Import-Export and Storage of Hazardous Microorganisms/ Genetically Engineered Organisms or Cells, 1989 (Rules, 1989)" notified under the Environment (Protection) Act, 1986.
B. DBT has published a series of guidance documents in 1990, 1998, 1999 and 2008.
C. The Seed Act 1966 & the Seeds (Control) Order by Ministry of Agriculture (MOA) and
D. The Food Safety and Standard Act 2006 (subsumed the Prevention of Food Adulteration Act 1954) by the Ministry of Health and Family Welfare (MOH&FW).

[17] Sathguru Analysis based on various sources

The other policies that have been instrumental in creating a robust framework includes the Protection of Plant Varieties and Farmers' Rights Act, 2001, National Seeds Policy, 2002, Biological Diversity Act, 2002, National Seed Plan, 2005, OECD scheme, 2008.

Figure 8: Indian Regulatory and Policy Framework for agricultural Biotechnology[18]



There are six competent authorities that function into a three-tier system; the first tier includes the 'Policy Advisory Committee' such as the Recombinant DNA Advisory Committee (RDAC); the second tier consists of 'Regulating and Approval Committees' such as the Institutional Biosafety Committee (IBSC) at the institutional level, the Review Committee on Genetic Manipulation (RCGM) and the Genetic Engineering Approval Committee (GEAC) at the national level, and finally, the third tier includes the 'Post Monitoring Committee' comprising of the State Biotechnology Coordination Committee (SBCC) and the District Level Committee (DLC).

Protection of Plant Varieties and Farmers' Rights Authority (PPVFRA) is instrumental in governing the import of transgenic planting material. The Food and Safety Standards Authorities of India (FSSAI) governs import of GM products with the help of Central Advisory Committee (CAC) and Scientific Committee (SC) and Scientific Panel (SP) on genetically modified organisms and foods.

NEW POLICIES: BIOTECHNOLOGY REGULATORY AUTHORITY OF INDIA (BRAI)

DBT is also working towards seeking approval for Biotechnology Regulatory Authority of India (BRAI) Bill, which is currently under discussion in the Lok Sabha. The Bill aims to provide a single window platform for risk assessment of biotech crops across all sectors of biotechnology. The authority

[18] Choudhary et al., 2014, Plant Biotechnol. J. doi: 10.1111/pbi.12155

will be an independent, autonomous, statutory agency to regulate research, transport, import, manufacture and use of organisms and products of modern biotechnology.

CHANGING REGULATORY ENVIRONMENT

Though the genetic modification of crops looks promising, acceptance of the technology for food crops by the regulatory authority still remains a farfetched goal. A transparent and predictable regulatory approval system would further provide a gear to the research work in the sector.

However, recently, the regulatory environment for GM crops have seen a silver lining since 2014 when the Government cleared the way for regulatory field trials which had been put on hold since late 2012 , after a supreme court-appointed expert panel recommended suspension for 10 years until regulatory and monitoring systems could be strengthened. This approval came four years after the government barred the commercial planting of a transgenic brinjal after protests from anti-GM activists and it was made mandatory to secure No Objection Certificate (NoC) from the state governments to conduct field trials for GM crops.

GEAC meetings resumed and in March 2014, GEAC approved field trials for 11 crops. By July 2014 GEAC granted permission to 80 field-trial applications. Eight Indian states largely aligned with the existing government and approved field trials of GM crops, allowing tests for GM mustard (Delhi University), Bt chickpea (Sungrow Seeds), Nitrogen Use Efficiency (NUE) rice (Mahyco) and Bt brinjal (Bejo Sheetal). There are as many as 20 GM crops already undergoing trails across the country at various stages.

However, due to state-government blocks many of the approved trials never begun. These local bottlenecks have hurt biotech industry in India's universities and public-sector institutions and have turned the country into a hostile place for GM crop research. However, India's government seems to be trending more cautiously on commercial cultivation of transgenic crops than on field trials.

GEAC's approval of field trials of Bt brinjal event opens up an opportunity for the Government to revisit the moratorium on Bt brinjal event EE-1[19]. With resumption of GEAC meetings and recent field trials approvals, companies are expected to further gear up their research and commercialization efforts in GM crops. Companies are also awaiting the approval of the country's first stacked trait - the insect resistant and herbicide tolerant cotton, Bollgard II Roundup Ready cotton (BG-II RRF™) being developed by Mahyco and sourced from Monsanto.

Nevertheless, DBT future plans includes strengthening the regulatory system of the country, encouraging stakeholders and refining or upgrading *in-country* quality standards of the system.

DBT FUTURE FOCUS

1. Promotion of regulatory science research units,
2. Establish central agency for regulatory testing and certification laboratories
3. Create a center for biotechnology communication
4. Funding for Regulatory Science
5. Establish a non-statutory unit to assist RCGM/GEAC
6. Creation and updation of existing regulatory testing facilities in public sector
7. Devise accreditation and notification systems for the laboratories engaged in Biotech Research and notification of field trial sites

[19] Choudhary and Gaur, 2015. Biotech Cotton in India, 2002 to 2014. ISAAA Series of Biotech Crop Profiles. ISAAA

CHALLENGES

However, the regulatory uncertainties in the country have impeded the growth of Indian agriculture. Currently the system is challenged with absence of a proper and structured guidance from the regulatory authorities as well as limited knowledge among the industry stakeholders about the accurate regulatory requirements. There is limited capacity among the stakeholders to generate appropriate regulatory safety data during the biotech product development process. The system has had difficulties earlier with new organisms/crops, new traits or new intended uses. The indefinite delays in the approval process further demotivates the scientists.

Additionally, the state level bodies have not been taking an active role in acknowledging and popularizing the technology benefits to the desired beneficiaries across various corners of the state. As with Bt cotton there have been cases where the suppliers have been pushing substandard hybrid varieties to the farming communities. In such cases the policy makers at the state level need to ensure that the seeds do meet the quality standards as has been specified under the Seed Act.

APPLICATIONS OF AGRICULTURAL BIOTECHNOLOGY IN OTHER AGRI INPUTS

Biological products like biopesticides and biofertilizers have gradually replaced the highly toxic pesticides in the market with its gradual progress in research and application. In the last decade, the industry has grown quite steadily in the country with excellent application prospects and extensive social and economic benefits coupled with encouragement by the government as a part of its various Integrated Pest Management (IPM) programs. Adoption of biotechnology to reduce the consumption of pesticides and fertilizers has been effective in minimizing the harmful effects of agro-chemicals on the environment through the development of biological inputs.

RESEARCH IN INDIA (STATE OF THE CURRENT)

Biological product types have evolved gradually from its inception phase to growth phase in India. The Ministry of Agriculture (MoA) and DBT are largely responsible for supporting the production and application of biopesticides. Private sector players are gradually moving towards development of improved formulations with better shelf life and increased efficiency. The Biological industry players are investing in development of production infrastructure with modernization and process automation.

NOVEL TECHNIQUES

The modern products are better formulated for improved shelf life with higher rates of efficacy, minimum residue levels, and easier application methods as compared to those products of its earlier generation and are available at a much economical cost. Most of the technologies used in producing biological inputs are standardized by Domestic Research Institutes and State Agricultural Universities.

However, the effective growth of the biologicals industry is curtailed due to concerns of product quality, inefficient production technologies and lack of awareness of microbial biopesticide products amongst farmers, despite active promotion.

NOVEL APPLICATIONS

The major strains used for development of various biological products are Trichoderma, Beaveria, Verticillium, Paecilomyces, Metarrhizium, Bacillus thuringiensis, Neem, Pongamia (Karanj) extract, Bacillus subtilis, Trichogramma, Chrysopa, Nuclear Polyhedrosis virus, Granular Polyhedrosis Virus. As of early 2013, there were approximately 15 types of primary Biopesticides registered, 400 registered active ingredients and over 1250 actively registered biopesticide products in India. Rhizobium, Azotobacter, Azospirillum are the biofertilizers included under Fertilizer Control Order.

GLOBAL TECHNOLOGY TRENDS AND INNOVATIONS (STATE OF THE ART)

NOVEL TECHNIQUES

Globally, the industry has developed a better understanding of the biology of the microorganisms with US and Europe advancing towards the next generation of biologicals products. Technological advancements of biological products include products with new and multiple strains, broad spectrum, stacked products, novel formulations.

Industry players are using signal molecules to activate the defense mechanism in plants against certain attack of insects and pests. **Harpin protein signals** derived from plant pathogen, *Erwinia amylovora*

is one such technology which turn on the plant's natural defense systems (SAR) (Eg: N-Hibit™, Plant Health Care). Other innovations include development of product formulations with new or multiple mode of action. **Induced Gene Expression Triggers Technology (iGET)** facilitates microbial association with the plant to induce gene expression and changes in plant physiology to enhance multiple biochemical pathways (***Trichoderma***: Excalibre).

Combinational or bio stacked product formulations have also been effective in mitigating the effect of various insect and pests on plants through combinational strains, bioactive compounds (combination of known and novel lipopeptides) and combination of biological and chemical products (Poncho®/VOTiVO®, Bayer Crop Science). Products with improved shelf life through Encapsulation Technologies, storage stable formulations have also been developed by various industry players.

NOVEL APPLICATIONS

Today, application based biological products are directed towards development of products for seed treatment (**Catalytic Seed treatment** through Rhizobia, advanced bacteria protector, modified starch and natural plant extracts), seed coating (**Chitosan based seed coating: Yield Enhancing Agent**) as well as for varied application technologies. Modern application technologies include slow release of granules, foliar spray technology, and novel delivery mechanism.

MARKETS FOR BIOLOGICALS

Over the years, Indian farmers have been adding chemical fertilizers to soil without balancing it with the use of organic matter that has led to nutrition depletion affecting soil health and crop productivity. The ever increasing demand for chemical free and eco-friendly crops is the key driver for producers to shift to production systems with low/no use of agro-chemicals. Although Indian chemical fertilizer consumption is far less than the developed countries, increasing per acre fertilizer consumption will not add much to productivity unless it is balanced by organic matter. In such a scenario, only biological fertilizers help to improve the organic matter of soil without compromising on the productivity.

Also, stringent regulations, long development processes and high cost of chemical active ingredient development vis-à-vis low regulations in biologicals lures players to invest in bio-products. In addition, developed markets such as Europe are emphasizing on adopting sustainable production practices forcing agri-input players to involve bio-products including seeds in their portfolio to complement existing chemical business.

COMMERCIALIZATION AND MARKET ADOPTION

The biologicals – Bio-pesticides and Bio-fertilizers, have received good response and is gradually picking up the market share replacing chemical pesticides and fertilizers. Most of the agro-chemical firms have diversified into biologicals either by developing their own products or through the acquisition of companies with a biological product portfolio.

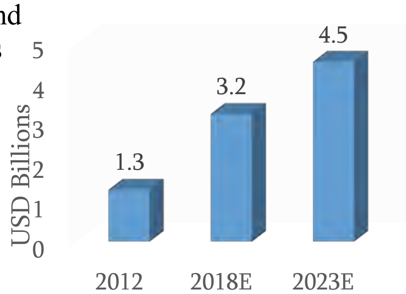
Bio-pesticides are used globally for controlling insect pests and diseases. Bio-insecticides, bio-fungicides and bio-nematicides are rapidly growing market segments and are expected to boost the demand for bio-pesticides in future. Globally, there are more than 430 registered bio-pesticide active-ingredients and 1320 active product registration[20]. The global market for bio-pesticides was valued at USD 1.3 B in FY12, and it is expected to reach USD 3.2 billion by FY18 and USD 4.5 billion by 2023[21].

Figure 9: Global Bio-pesticide Market

[20] US-Environmental Protection Agency (EPA), 2014

[21] FICCI – Tata Strategic management Group, 2013, Indian Agrochemicals Industry; Imperatives of Growth, Pg: 26

Bio-pesticides are used globally for controlling insect pests and diseases. Bio-insecticides, bio-fungicides and bio-nematicides are rapidly growing market segments and are expected to boost the demand for bio-pesticides in future. Globally, there are more than 430 registered bio-pesticide active-ingredients and 1320 active product registration[22]. The global market for bio-pesticides was valued at USD 1.3 B in FY12, and it is expected to reach USD 3.2 billion by FY18 and USD 4.5 billion by 2023[23].



North America dominates the global bio pesticide market and accounts for about 40% of the global bio pesticide demand. The US bio pesticide market was valued at around USD 205 million in FY12 and is expected to grow to ~USD 300 million by FY20. European market is estimated at ~USD 200 million, and is expected to be the fastest growing market due to the stringent pesticide regulations and increasing demand from organic producers. Asian markets also present a good growth opportunity for bio pesticides as China and India adopt more of them.

Currently, bio pesticides represent only 4.2% (USD 159.6 million) of the overall pesticide market in India and is expected to exhibit an impressive annual growth rate of about 10% in the coming years. The bio-pesticides segment has registered growth at a remarkable CAGR of 36.6% in terms of consumption from FY07 - FY12[24]. The bio-pesticides market has been significantly projected to grow in the next five years, reaching revenue worth INR USD 338 million by FY18. This growth performance has been primarily anticipated on account of growing health consciousness in consumers and environmental concerns among the Indian farmer fraternity. The bio-pesticides market in India is concentrated among few players operating in the space. In the entire market, about nine major companies accounted for more than 90% of the entire bio-pesticides market in the country during FY13.

THE MAIN FOCUS OF MULTINATIONAL CROP PROTECTION FIRMS– MICROBIAL BIO PRODUCTS[25]

Among the three categories of bio-pesticides (microbial, biochemical and macro-organisms), microbial market segment has witnessed strong interest from MNC crop protection firms. It can be easily understood by looking at the recent acquisitions by the large multinational plant protection companies (Table 6).

Table 6: Recent acquisition in biological segment

Acquiring Company	Company Acquired
Bayer Crop Science	AgraQuest & Prophyta
BASF	Becker Underwood
Syngenta	Pasteuria & DevGen
Monsanto	Rosetta Gren & Alnylam Pharma
Novozymes	Natural Industries & T J Technologies

Microbial products are normally produced either through solid fermentation or liquid fermentation which allows large volume production at single site. Moreover, most bacterial based products can be formulated to have a standard shelf-life of 2 years, with no need for refrigeration in the logistic system.

[22] US-Environmental Protection Agency (EPA), 2014
[23] FICCI – Tata Strategic management Group, 2013, Indian Agrochemicals Industry; Imperatives of Growth, Pg: 26
[24] Ken research, India Pesticides Industry Analysis to 2018 - Advent of Technologically Advanced Bio-pesticides
[25] Microbial Pesticide: a key role in the multinational portfolio by Bill Dunham

All these characteristics drives the natural interest of MNCs in microbial products, rather than biochemical or macro-organisms.

MARKET CHALLENGES

Since biological products generally with live organism(s), utmost care is needed, at all the steps, beginning from the production till the end use to maintain the microbial load and vigor. As discussed again and again, biologicals though offer a great promise are still not able to perform up to the mark. Major constraints associated with biologicals development and growth are:

1. **Lack of Awareness:** Agriculture market is witnessing an increase in demand for environment friendly, chemical residue- free organic products. However the lack of awareness, knowledge, and confidence in farmers is one of the chief reasons for the lagging of these eco-friendly pest control alternatives. The results of bio-products are sometimes not homogenous or consistent, and hence the users find themselves confused about adoption of these greener technologies.
2. **Lack of Faith and Inconsistent Field Performance:** A key factor involved in the lack of success has been the rapid decline in the size of populations of active cells, to levels ineffective to achieve the objective, following introduction into soil. Also the markets are flooded with the spurious biological products adding to the woes of genuine biological manufacturing players
3. **Competition with chemical pesticides and fertilizer:** Practically, Biologicals are neither as effective as chemical inputs nor do they produce quicker results. Also in case of chemical pesticides, lesser quantity is sufficient enough to kill a vast quantity of pests which is the main reason why farmers choose chemical inputs over biologicals.

NATIONAL POLICIES AND REGULATORY FRAMEWORK

The manufacture, sale, import, export and use of biopesticides is regulated by the MoA under the Insecticide Act (1968). Central Insecticides Board (CIB) advises Central and State Governments on technical matters whereas the Registration Committee (RC) approves the use of biopesticides and new formulations to tackle the pest problem in various crops.

There are no separate regulatory frameworks for biologicals in India and they come under the purview of Insecticide Board of India. The regulations under which the manufacturing and sale of biofertilizers are covered are The Essential Commodities Act, 1955, Fertilizer (Control) Order (FCO) 1985 framed under Commodities Act and Fertilizer (Control) Amendment Order, 2006 and 2009. Directorate of Plant Protection, Quarantine & Storage (Directorate of PPQS) is the concerned authority involved in the regulatory process of biofertilizers. The promotion of biofertilizers in India is mainly carried out by the National Biofertiliser Development Centre. Import of biofertilizers is regulated by 'Plant Quarantine (Regulation of Import into India) Order, 2003 issued under the Destructive Insects & Pests Act, 1914'.

CHALLENGES

Registration of biological inputs apart from being time consuming, are more expensive than the cost of production. Availability of spurious products in the market is a serious issue since this creates a negative impact on farmer confidence and the reliability of biological products.

The central and state government should play more active role in motoring of the quality the products that are moving into the market. Though a system of referral laboratories accredited by the DBT for quality testing has been established, enforcement of standards remains an issue.

The existing policy of providing grants and low interest loans to biofertilizer producers have led to the production of poor quality biofertilizers as these producers are setting up large number of inefficient production plants. Additionally, government policies related to promotion and marketing of biofertilizers without ensuring quality and performance check have increased the number of poor quality products in the market which have rippled the faith of the famers and extension workers on biofertilizers.

SOCIO ECONOMIC IMPACT OF AGRICULTURAL BIOTECHNOLOGY

In 2014, 7.7 million small holder cotton farmers having an average land holding of less than 1.5 hectares benefited from planting Bt cotton over 11.6 million hectares equivalent to 95% of the 12.25 million cotton area. Provisional estimates by Brookes and Barfoot (2015) indicate that India enhanced farm income from Bt cotton by US$16.7 billion in the twelve year period 2002 to 2013 and US$2.1 billion in 2013 alone, similar to 2012.

Several peer-reviewed research studies have been conducted over the years to estimate the socioeconomic impact of Bt cotton. Out of them, three studies were carried out prior and eleven post the commercialization of Bt cotton in India. The results of these studies on Bt cotton were consistent with the study undertaken by Gandhi and Namboodiri in 2006 showing yield gains of approximately 31%, a significant 39% reduction in the number of insecticide sprays, leading to an 88% increase in profitability, equivalent to a substantial increase of approximately US$250 per hectare.

These studies as referenced chronologically in the Table 7 below confirms the socioeconomic benefits of Bt cotton in India for the years 1998-2013.

Table 7: Various studies done to assess socio-economic impact of Agricultural Biotechnology[26]

Publication	Period studied	Yield increase	Reduction in no. of spray	Increased profit	Average increase in profit/hectare
ICAR FD trials 2002	2001	60-90%	5-6 to 1 (70%)	68%	$96 to $210/ hectare
IIMA 2006	2004	31%	39%	88%	$250/ hectare
Sadashivappa & Qaim 2009	2006-07	43%	21%	70%	$148 /hectare or more
Qaim et al. 2009	1998-06	37%	41%	89%	$131/ hectare or more
Subramanian & Qaim 2010	2006-07	43%	21%	134%	$161/hectare or more
Kathage & Qaim 2012	2002-08	24%	–	50%	$107-213/ acre
Mayee & Choudhary	2012	98%	82.80%	–	$453/ hectare

[26] Choudhary and Gaur 2015. Biotech Cotton in India, 2002 to 2014. ISAAA Series of Biotech Crop Profiles. ISAAA

ENVIRONMENTAL IMPACT OF AGRICULTURE BIOTECHNOLOGY

Benefits

- Significantly reduced the release of greenhouse gas emissions from agricultural practices. In 2007, this was equivalent to removing 14.2 billion kg of carbon dioxide or equal to removing nearly 6.3 million cars from the road for one year
- A reduction of 359 million kg in pesticide spraying (1996-2007)
- Conservation of soil and moisture by optimizing the practice of no till
- Higher productivity per unit, thereby avoiding forest clearance for agriculture purposes

Potential Threats

- Herbicide-resistant crops possibly becoming weeds in Following Years
- Potential gene escape and development of Super-weeds
- Detrimental impact on Non-target organisms
- Development of higher degree of pest resistance

STRATEGIC WAY FORWARD FOR AGRICULTURAL BIOTECHNOLOGY

I. PUBLIC PRIVATE PARTNERSHIP: The current R&D investments and funding's are fragmented across various organizations and projects. Pooling of resources in a planned manner will facilitate result oriented research. This can be achieved through meaningful public private partnerships (PPP) at the conceptualization stage of research work. The government needs to encourage the views of private sector leaders during such decision making and conceptualization phase. However, such models can only be successful when there is a clearly identified path to the market. The industry should promote more of PPP for facilitating better product development processes. All such PPP models will need to ensure proper product stewardship at all levels of the value chain:

   a. Processes for maintaining product quality, integrity and resolving product complaints;
   b. Scientifically valid efficacy tests supporting claims and promotions;
   c. Commercially acceptable product efficacy levels

II. CAPACITY BUILDING: One of the major challenges that can be addressed through such PPP models is capacity building in terms of handling of biotech crops in laboratories. National level labs needs a special training with respect to maintaining GLP and other testing standards. Young scientists need to train in biosafety data generation/ data analysis/dossier preparation. The regulatory agencies need to develop a specific guideline required for handing GM crops and products and encourage setting up CROs in the area of toxicology.

III. INFRASTRUCTURE IMPROVEMENT AND QUALITY COMPLIANCE: There should be more testing laboratories with adequate infrastructure and manpower to check the quality of biological products at various stages of production, marketing, procurement and application. For bio efficacy testing, Indian Council of Agricultural Research (ICAR) institutes, State Agricultural Universities (SAUs) and some traditional universities having good infrastructural facilities may be notified by Central Insecticides Board (CIB). There should be a strict and transparent monitoring of production units to ensure quality product. The existing production units should be subjected to accreditation. Testing laboratories need to be developed or upgraded as per GLP standards and accreditation secured for efficacy assessment of transgenic crops.

IV. COMMUNICATION ADVOCACY: A specific plan with specific objectives for public communication needs to be devised which will help to communicate the decision makers that modern biotechnology can be an effective tool for increasing agricultural productivity, and thereby economic growth, without imposing unacceptable risk to the environment or human and animal health. It will also enable members of the public to make informed decisions about appropriate uses of biotechnology by providing accurate information about benefits, risks and impacts. The farming community has limited awareness about the benefits of biological products and its intended use. Hence an extensive training of extension workers and communication programme need to be implemented. The Central and State governments can organize the training programmes which are strictly in conformity with the uses approved by the regulatory authorities. Consumer awareness on various factors of biologicals including product quality, use, active ingredients, etc. needs to be created by the government, non-government and private agencies.

BALANCED APPROACHES FOR ADOPTION OF BIOTECHNOLOGY

Although the Government promotes agricultural biotechnology through various funding and new projects and enthusiastic scientists actively carrying out multitude of agri biotech research, however, the real essence of these activities can only be realized with s a clear, identified path to market through a promising regulatory environment. The industry would be directing their work towards on plant-microbe and virus interactions and emphasize approaches for gene silencing and recombination with a special reference to containing crop viral diseases. The Indian government needs to streamline the regulatory system through steps such as promoting relevant technologies and traits for self-sufficiency, and forming a single regulatory authority to govern all bio agriculture domains.

B. NANOTECHNOLOGY IN AGRICULTURE

INSIGHT SUMMARY

Nanotechnology makes use of size and structure dependent novel properties of materials at nanometer scale. This report outlines the drivers for application of nanotechnology in agriculture and examines the current state of the research in various areas fo application. Nanotechnology applications in agriculture span a wide array of inputs and services ranging from crop nutrients, plant protection products, natural resource management, and nanosensors for detection, identity preservation and utilization of agricultural waste. Review of nanotechnology development pathway and R&D support by various public agencies in India indicate the importance being given to this emerging technology. The Indian Council of Agricultural Research has constituted a dedicated nanotechnology platform to foster the use of nanotechnology in agriculture. Assessment of research by public and private sectors in India indicate that nanotechnology research in agriculture is largely driven by public institutes with limited research by Indian private players. Despite the potential advantages, nanotechnology applications in the agricultural sector have not yet made it to the market to a large extent in comparison with other industrial sectors. Few nano-products in the agricultural sector have been released in the market by smaller companies, including India; but the market adoption of these products is limited. In a recent trend observed, technologies developed by Indian public institutes have been transferred to industry. Evolving regulatory guidelines, lack of standard definition of nanomaterials and long gestation periods are some of the challenges in commercialization of nano-enabled products. Challenges in transfer of technology relate to inadequate infrastructure for piloting and characterization of nanomaterials; scalability and cost effectiveness of the process/technology. VC funding and corporate investments in nanotechnology are still far from their level of investment in other industries. Nanotechnology in agriculture is still in its early phase of development and no significant data is available on economic impact of these products. But the emergence of nanotech applications in consumer products has raised a number of ethical and societal concerns like effects on human, animal health and environment; consumer perception and intellectual property issues. Though nanopesticides and nanofertilizers have the potential to reduce environmental contamination through the reduction in pesticide application rates and reduced losses; nano-materials may also create new kinds of contamination of soils and waterways due to enhanced transport, longer persistence and higher toxicity of active ingredients. Research into safety assessment is needed to evaluate the impact of these new technologies on the environment, ecological systems and human health. Absence of standardized measurement techniques and instruments for nanomaterials and internationally agreed protocols for toxicity testing of nanomaterials pose challenges for nanotechnology regulatory framework and guidelines.

Way forward and recommendations to address challenges related to regulations, infrastructure, investments, and technology transfer are provided in the report.

INTRODUCTION TO NANOTECHNOLOGY

Nanotechnology is the application of scientific knowledge to manipulate and control matter at dimensions between approximately 1 and 100 nanometers (nm) to make use of size and structure dependent properties and phenomena distinct from those associated with individual atoms or molecules or with bulk materials. At this scale, the physical, chemical, electrical, biological and optical properties of a material start differing in a unique and peculiar way. This uniqueness and peculiarity has opened up new opportunities for applications in different industrial sectors.

The application of nanotechnology and engineered nanomaterials to agricultural inputs is one of the means being suggested for boosting agricultural crop production. Nanotechnology applications in agriculture are not confined to the farm production level, but can extend across the agricultural value chain. Most of the nanotechnology based innovations, like smart delivery systems, pathogen detection, identity preservation and tracking, are extensions of applications from other sectors.

NEED FOR AND ROLE OF NANOTECHNOLOGY IN AGRICULTURE

The application of nanomaterials in agriculture aims to reduce applications of plant protection products, deliver active ingredients to specific sites, minimize nutrient losses in fertilization, and increase yields through optimized nutrient management. Nanotechnology derived devices are also explored in the field of plant breeding and genetic transformation. Nanomaterials and nanostructures with unique chemical, physical, and mechanical properties have been recently applied for developing nanosensors for soil analysis, easy bio-chemical sensing and control, water management and pesticide and nutrient delivery. In recent years, agricultural waste products have attracted attention as a raw material for production of nanomaterials like nanocomposites.

If Indian agriculture is to attain its national goal of sustainable agriculture growth of over 4%, it is important that the nanotechnology research is extended across the entire agricultural value chain. This would require focusing on technologies that increase agricultural productivities, product quality and resource-use efficiencies that reduce on-farm costs, increase farm income; and conserve and enhance the quality of the natural resource base.

Table 8: Potential applications of nanotechnology in agriculture

Target Areas	Potential Applications
Agricultural input efficiency	• Nanofertilizers for slow release and efficient use of fertilizers by crops • Nanopesticides - pesticides encapsulated in nanoparticles for controlled release, nano-emulsions for greater efficacy
Efficient utilization of natural resources	• Nanoparticles for soil and water conservation • Nanosensors for soil quality and plant health monitoring • Nanosensors for precision agriculture • Nanomaterials for removal of soil contaminants
Improve quality of agriculture produce	• Nanosensors for pathogen and contaminant detection • Nano-barcodes for identity preservation and tracking
Agricultural productivity enhancement	• Nanotechnology presents new plant gene delivery systems to improve crop resistance against plant diseases and increase food security • High throughput DNA sequencing and nanofabricated gel-free systems • Nanoarrays and expression profiling
Agricultural waste management	• Production of nano cellulose and nanocomposites from agri waste

DRIVERS FOR NANOTECHNOLOGY IN AGRICULTURE

Technological interventions in agriculture are of vital importance particularly to address global challenges such as population growth, climate change and the limited availability of important plant nutrients such as phosphorus and potassium. Nanotechnology in agriculture could play a fundamental role for this purpose and research on agricultural applications is going on for nearly a decade now.

Drivers for research:

- The key driver of research into nanotechnology is the enhanced properties exhibited by nano sized particles and materials that enable widespread potential applications
- Public funding has encouraged research in nanotechnology for agriculture

Drivers for Industry:

- Increased/ novel performance of nanomaterials for replacement of traditional materials
- Increased focus on agricultural input use efficiency
- Focus on reducing impact on the environment and human health
- Improvements in manufacturing processes - avoiding volatile organic solvents

NANOTECHNOLOGY RESEARCH IN AGRICULTURE - STATE OF THE CURRENT

NANOTECHNOLOGY IN CROP PROTECTION

An estimated 2.5 million tons of pesticides are used on crops each year[27]. It is estimated that more than 60-70% of the applied pesticides are lost to the air during the application stage itself and also as run-off, affecting both the environment and application costs to the farmers. Therefore, safe and efficient pesticide applications methods are essential for preventing the adverse effects of pesticides and nanotechnology can be used as an innovative tool for delivering agrochemicals safely. The aims of nanopesticide formulations are: (a) to increase the apparent solubility of poorly soluble active ingredient (a.i.) or (b) to release the a.i. in a slow/targeted manner or (c) protect the a.i. against premature degradation and/or (d) decrease the toxicity due to elimination of organic solvents.

Table 9: Potential Applications of Nanotechnology in the Pesticides: State of the current

Function	Process/technology	Examples & References
Enhanced solubility of a. i.	Nano- and micro-emulsions	Primo Maxx, Banner MAXX (Syngenta)
Faster decomposition in soil and/or plant	Nanocatalyst-conjugated a.i.	Dimethomorph[28]
Controlled release	Nanocapsules, nanocomposites Polymer based	Bifenthrin[29] Thiram[30]
Protection against premature degradation	Nanocapsules with catalyst a.i. conjugate Polymer based Nanogel	Emamectin[31] Pheromones[32]

[27] Fenner et al., 2013. Science. 341:752-758
[28] Jianhui et al., 2005. Chin. Sci. Bull. 50:108-112.
[29] Liu et al., 2008. Pest Manage. Sci. 64: 808-812
[30] Kaushik et al., 2013. J Environ Sci Health B. 48: 677-685
[31] Qing et al., 2013. Polym Adv Technol 24:137-143
[32] Bhagat et al., 2013. Sci Rep 2013. 3:1294

Function	Process/technology	Examples & References
Enhanced uptake/efficacy	Nano & micro emulsions	Permethrin[33]
Enhanced toxicity to target organism (lower dose)	Nanoemulsion	Permethrin[34]
Nanoparticle as a.i.	Nanometals	Silver: EPA approved Nano-Ag biocide; Nano-Si[35]
Degradation of pesticide	Biopolymer stabilized nanoparticles	FeS for degradation of Lindane[36]

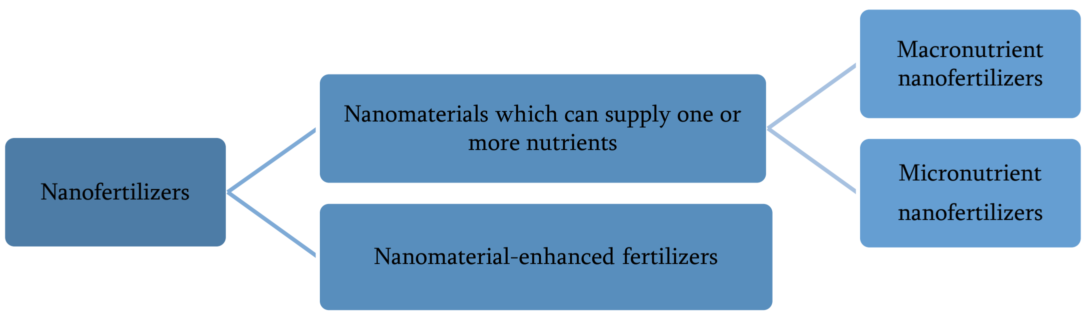
a.i. - active ingredient

Nano-pesticides will reduce the rate of application because the quantity of product actually being effective is at least 10-15 times smaller than that applied with classical formulations. Nanotechnology could also result in improvements in the efficacy of herbicides and nanomaterials as adjuvants for herbicides are already available in market. Nanoparticles can be used for the bioremediation of resistant or slowly degradable pesticides by photocatalytic degradation. Application of photocatalytic degradation has also gained popularity in the area of remediation of contaminated water.

NANOTECHNOLOGY IN CROP NUTRITION - FERTILIZER FORMULATIONS

Due to low fertilizer efficiencies of N, P and K fertilizers (30-35%, 18-20% and 35-40%, respectively) and heavy application of fertilizers, significant amounts of these nutrients are transported into surface and groundwater bodies, disrupting aquatic ecosystems and threatening health of human and aquatic life. Therefore, there is an urgent need to develop highly efficient and environmentally-friendly fertilizers to replace the conventional fertilizers. Compared with the conventional ones, nanofertilizers are expected to significantly improve crops' growth and yields; enhance the efficiency of fertilizer use; reduce nutrient losses; and/or minimize the adverse environmental impacts[37].

Figure 10: Classification of Nano-Fertilizers[34]



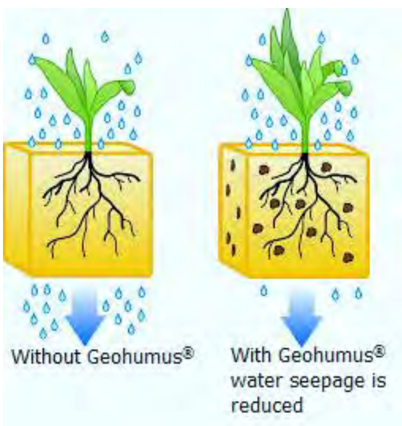
[33] Anjali et al., 2010 Ecotoxicol Environ Saf. 73:1932-1936
[34] Kumar et al. 2013. Environ Sci Pollut Res 20: 2593-2602
[35] Debnath et al., Powder Technol 2012. 221:252-256
[36] Paknikar et al., 2005. Sci Tech Adv Mat. 6:370-374
[37] Liu and Lal, 2015. Sci Total Environ. 514:131-139

Table 10: Comparison of nanotechnology-based formulations with conventional fertilizers applications[38]

Properties	Conventional technology	Nano enabled fertilizer technologies
Solubility and dispersion of micronutrients	Less bioavailability to plants due to large particle size and less solubility	Nano-sized formulation of mineral micronutrients may improve solubility and dispersion of insoluble nutrients in soil, reduce soil absorption and fixation, and increase the bioavailability
Nutrient uptake efficiency	Bulk composite is not available for roots and decrease efficiency	Nanostructured formulation might increase fertilizer efficiency and uptake ratio of the soil nutrients in crop production and save fertilizer resource
Controlled release modes	Excess release of fertilizers may produce toxicity and destroy ecological balance of soil	Both release rate and release pattern of nutrients for water-soluble fertilizers might be precisely controlled through encapsulation in envelope forms of semi-permeable membranes coated by resin-polymer, waxes, and sulfur
Effective duration of nutrient release	Used by the plants at the time of delivery, the rest is converted into insoluble salts in the soil	Nanostructured formulation can extend effective duration of nutrient supply of fertilizers into soil
Loss rate of fertilizer nutrients	High loss rate by leaching, rain off, and drift	Nanostructured formulation can reduce loss rate of fertilizer nutrients into soil by leaching and/or leaking

Nanotechnology may set the stage for a shift away from the current practice of using bulk generic fertilizers to targeted fertilizers i.e. 'large volume-low value, to low volume - high value' products. Indian researchers observed significant increase in yields with foliar application of nanofertilizers; 640 mg ha^{-1} foliar application (40 ppm concentration) of nano phosphorus gave 80 kg ha^{-1} P equivalent yield under arid environment[39]. Currently, research is underway to develop nano-composites to supply all the required essential nutrients in suitable proportion through smart delivery system.

NANOTECHNOLOGY FOR SOIL IMPROVEMEMNT/ MOISTURE RETENTION



Nanomaterials are being increasingly developed for increasing soil and water management. Geohumus®, a product of Geohumus International is a soil enhancer with water storage capacity based on nanotechnology. It can store large amounts of rain water at the root and make it available to the plants over a prolonged period without evaporating or seeping away. Only 100g of Geohumus® is necessary for a surface of 1m². Sequoia Pacific Research of Utah (USA), developed a nanotech based soil binder called SoilSet, a quick setting mulch which relies on chemical reactions on the nanoscale to bind the soil together. DesertControl Inc. has developed NanoClay, made up of flakes that are 0.7-1.5 nm thick, that works as a binder and retains moisture in the sand. It can be used to reclaim arid and hyper-arid deserts and to prevent desertification and the advancement of sand dunes. Geoflow in San Francisco integrated PolyOne's Nanoblend Concentrates into emitters of its irrigation system. The addition of Nanoblend to the emitters helps to ensure the consistent release of herbicide, which prevents Geoflow's irrigation systems from becoming clogged by roots. Indian researchers from CAZRI,

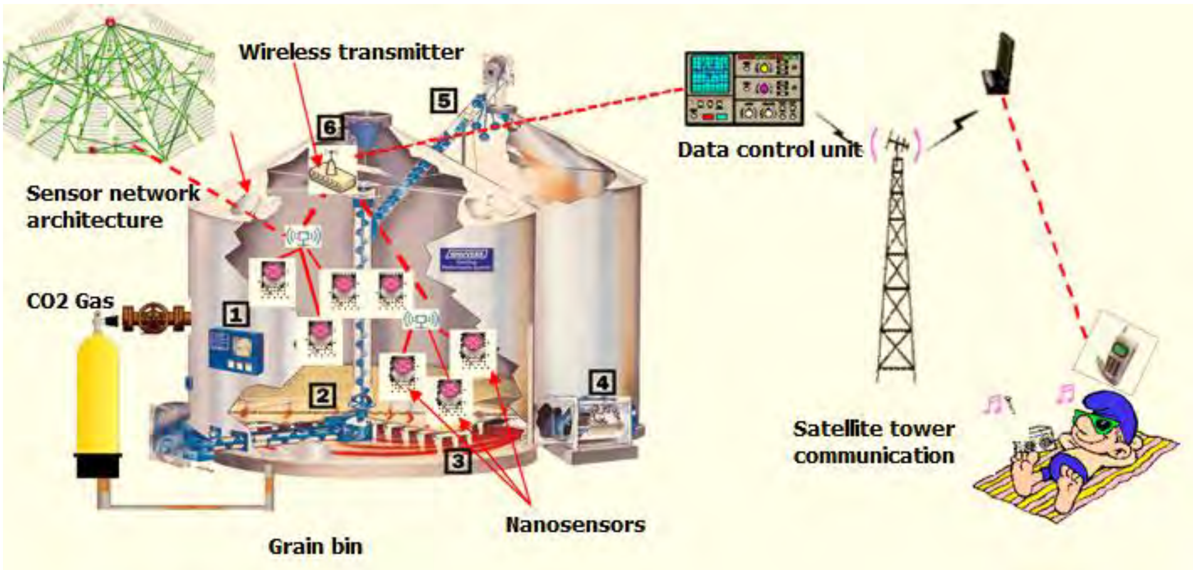
[38] Cui et al., 2010. In: International conference on Nanoagri, Sao Pedro, Brazil, pp 28-33
[39] Tarafdar et al., 2012. J. Bionanosci. 6:84-89

Jodhpur have observed that nanoparticle induced polysaccharide produced by microbes improved soil aggregation, carbon build-up and moisture retention under arid environment[40].

NANOTECHNOLOGY IN BIOSENSORS

The advantages that nanotechnology brings to biosensors systems are: greater sensitivity/specificity, faster detection rates, novel detection methodologies, further miniaturization allowing more variables to be measured, durability and longevity through advances not just in sensor technologies, but in energy supply and durability of materials. Nanosensors can provide quality assurance by detecting microbes, toxins, and contaminants throughout the food value chain. Grain quality monitoring nanosensors are being developed using conducting polymer nanoparticles, which respond to analytes and volatiles in food storage environment and thereby detect the source and the type of spoilage (Fig. 11). The development and use of such nanosensors is highly relevant for India in monitoring buffer stocks and food grains stored at various warehouses and godowns of public distribution system.

Figure 11: Example of a futuristic wireless nanosensor network for grain quality monitoring[41].



Most of the nanosensor systems for agricultural production are still largely at research level and demonstration of ability to operate in the field, and scale-up to manufacturing levels will determine the progress towards application status.

NANOTECHNOLOGY IN SUPPLY CHAIN TRACKING/IDENTITY PRESERVATION

One of the major constraints in developing countries including India is the quality maintenance of agricultural produce. Nanotechnology can enhance agricultural supply chain management by improving supply chain visibility, food authenticity, tracking and traceability and ultimately food security through features that assist avoid counterfeiting, product adulteration and diversion.

[40] ICAR 2014. Final Report: NAIP Component-4. ICAR, India
[41] Neethirajan and Jayas 2011. Food Bioprocess Technol. 4: 39-47

The identity preservation system can be used to distinguish organic versus conventional agricultural products. Enhancements/ refinements of the RFID tags with nanotechnologies and development of nanobarcodes will provide the industry greater supply chain and product traceability. Nanotechnology in tracking and tracing within agricultural supply chains is still at research stage.

NANOTECHNOLOGY IN AGRICULTURAL ENGINEEERING & PRECISION FARMING

Nanotechnology has many applications in machine structure and agricultural tools to increase their resistance against wear, corrosion and ultraviolet rays; producing strong mechanical components with use of nano-coatings and use of bio-sensors in smart machines for mechanical-chemical weed control; production of nano-cover for bearings to reduce friction.

Crop growth and field conditions can be monitored through advancements in nanotechnology. Real-time monitoring can be done by employing networks of wireless nano-sensors across the cultivated fields, providing essential data for agronomic processes like optimal time of planting, fertilizer application and precise delivery of water for the crops. John Deere is using nanotechnology to meet the needs for remote sensing and increased measurement points for higher-resolution yield maps in industrial agriculture, and to enhance the range of parametric data that is captured by current sensing platforms.

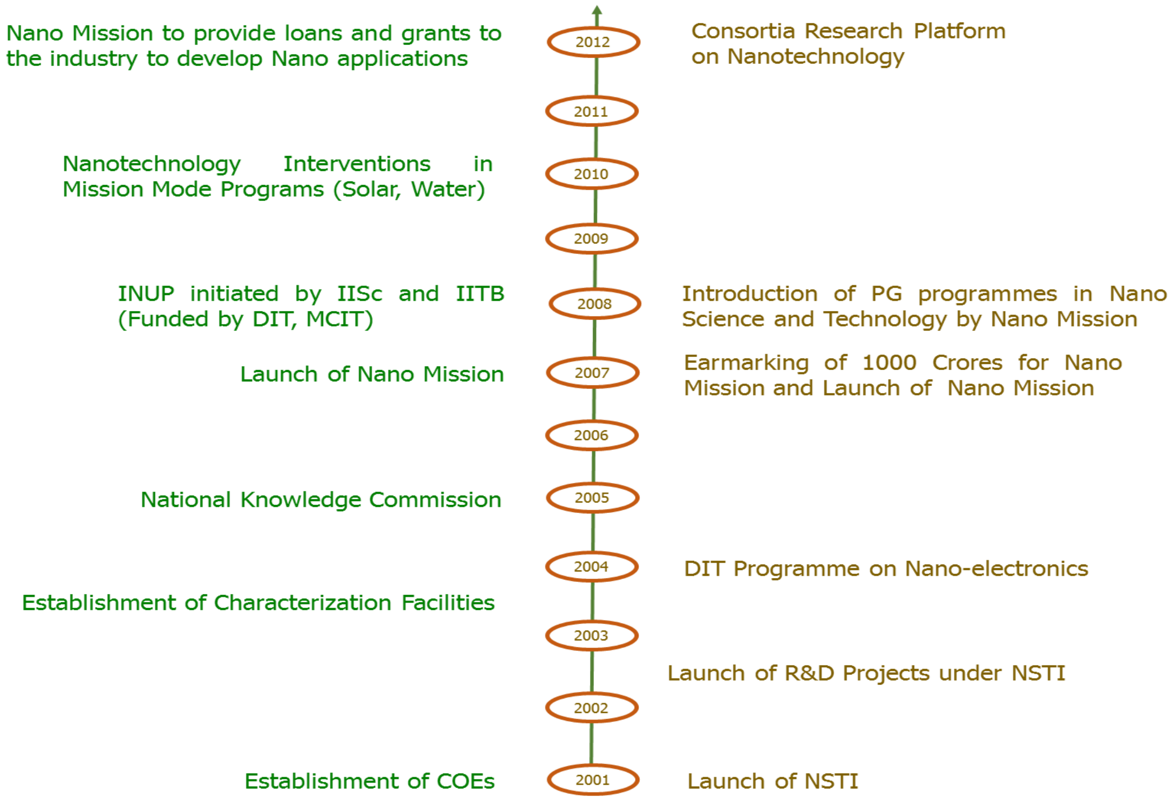
NANOMATERIALS FROM AGRICULTURAL WASTE/BIOMASS/BYPRODUCTS

In recent years, agricultural waste products have attracted attention as source of renewable raw materials for nanomaterial production. Rice husk, by product of rice milling, is used for high-quality nanosilica production which can be further utilized in making other materials such as glass and concrete. Production of nano lignocellulosic materials could be one of the best way for management of lingo-cellulosic agricultural waste. These can be applied in food packaging, as lightweight reinforcement in polymeric matrix, construction and transportation vehicle body structures. Cellulosic nanowhisker production technology from wheat straw has been developed by Michigan Biotechnology Incorporate (MBI), and is expected to make biocomposites that could substitute fiber glass and plastics in many applications. Embrapa, Brzail has produced nanocellulose from coconut fibre under its programme "Nanotechnology Applied to Agribusiness". Agriculture has tremendous potential to produce nanomaterials from waste products. However, issues of scale-up and manufacturing still need to be resolved before nanomaterials from agricultural waste can reach the market.

REVIEW OF NANOTECHNOLOGY RESEARCH IN AGRICULTURE IN INDIA

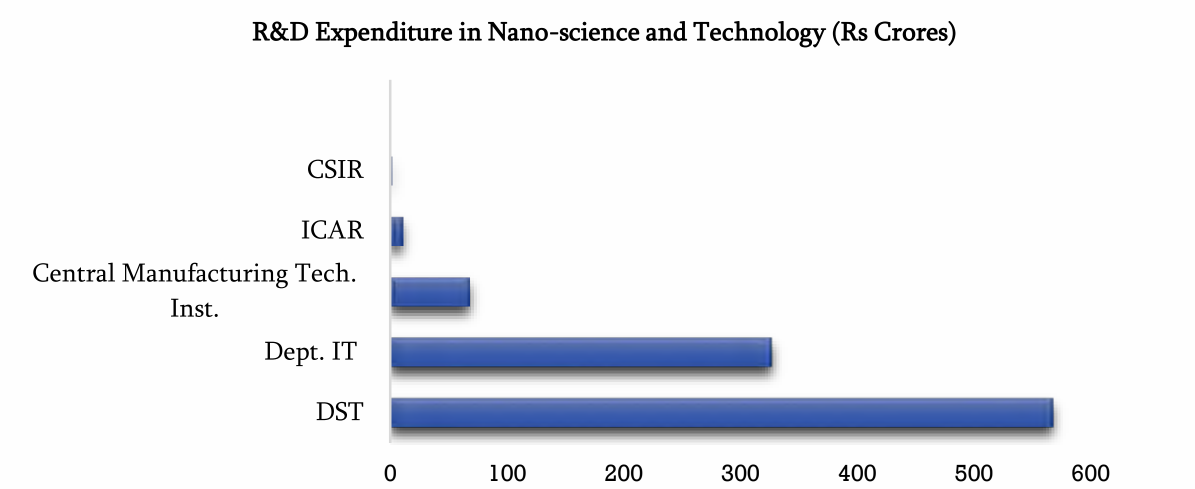
Nanotechnology as a distinct area of research started with Nano Science and Technology Initiative (NSTI) in the Xth plan period (2002-2007) with an allocation of INR 60 crores. In 2007, this programme was further strengthened with another major initiative known as 'Nano Mission' with a budgetary allocation of 1000 crore for five years. This funding has been utilized to sponsor 90 research projects and create 19 Centers of Excellence (CoE). The CoE consist of eleven "Unit of Nanoscience (UN) that pursue the basics research in several broad areas of Nano science and Technology whereas seven "Centres of Nanotechnology" mainly focused on R & D in niche areas or in specific dimensions such as water remediation and purification.

Figure 12: Nanotechnology Development Pathway in India



The R&D expenditures in the field of nanoscience and technology by various agencies from 2001-12 are indicated in Fig. 13.

Figure 13: Expenditure on Nanotechnology R&D by various stakeholders (2001-2012)[42]



[42] Bhattacharya et al., 2012. CSIR- NISTADS Strategy Paper on Nanotechnology Number I. NISTADS, India

The Indian Council of Agricultural Research has constituted a nanotechnology platform to spur the use of nanotechnology in agriculture. The Consortia Research Platform on Nanotechnology, with a total cost of 200.00 crores for the project from 2012 - 2017 has several themes for research focus involving various institutes (Table 11).

Table 11: Theme wise research focus and leading institutes under the Consortia Research Platform on Nanotechnology[43]

Theme	Leading Institute
Synthesis and Characterization of Nano-materials	TNAU, Coimbatore; ISI, Kolkata; NDRI, Karnal
Quick diagnostic kits	GBPUAT, Pantnagar; NRC for Banana, Trichy; CPCRI, Kasargod; IVRI, Izatnagar; IISS, Bhopal; DMR, New Delhi; IIHR, Bangalore
Nano based strategies for pest management	NBAII, Bangalore, NBAIM, Mau
Enhanced agri-input use efficiency	TNAU, Coimbatore; NIANP, Bangalore; NDRI, Karnal; CIAE, Bhopal
Nano-food systems and packaging material	NDRI, Karnal; CIFE, Mumbai
Biosafety analysis and policy framework	NDRI, Karnal; NAARM, Hyderabad

ASSESSMENT RESEARCH BY INDIAN PUBLIC AND PRIVATE SECTOR IN AGRICULTURE

In India, the nanotechnology research in agriculture is largely driven by public institutes. The public research within ICAR network is mainly concentrated on nano particle synthesis, release of nutrients from nano-fertilizers, slow and steady release of pesticides, release of active ingredients from nano-encapsulated herbicides etc. Most of the Indian scientists have been adopting microbial process over physical and chemicals processes for nanomaterials production. Biologically produced nanomaterials may be important for the agricultural uses as they are naturally encapsulated and hence stable and safer to biological systems. However, challenges related to large scale synthesis of nanomaterials persist which is a prerequisite for applications in the field of agriculture.

Research groups at IARI (New Delhi) and ISI (Kolkata) have developed nano-forms of elemental sulfur, acephate and hexaconazole. CAZRI (Jodhpur), TNAU (Coimbatore), PAU (Ludhiana) and other institutes are researching on various nano fertilizers. Some of these technologies like biosynthesized nano-nutrients have been licensed to industry which is testing them (Table 13).

Council for Scientific and Industrial Research (CSIR) has initiated a major project “Nano-SHE” in 12th Five Year plan to evaluate and create a database on various toxicological aspects of nanostructured materials. The project addresses issues reacted to the synthesis of nanomaterials; development and validation of methods to assess toxicity/safety and risk of engineered nano materials; nanodevices/sensors for diagnostics; bench marking new nano-products; guidelines for safe handling of nanomaterials; and dissemination of outcomes to civil society.

The research by Indian private players is limited and details are also not publicly available. However, few players have tapped public funding from BIRAC (DBT) to de-risk their research. Saveer Biotech along with Indian Statistical Institute, Kolkata is working on commercial scale production of nanopesticides and nanofungicides. Tata Chemicals Limited, Pune is researching on inorganic and polymer nano-composites for micronutrient & pesticide delivery for boosting crop health and yield.

[43] ICAR, 2012. Project Document/EFC Memo for the XII Five Year Plan (2012-2017)

GLOBAL TECHNOLOGY TRENDS AND INNOVATIONS

An inventory of current and potential future applications of nanotechnology in the agri/feed/food sector was recently developed[44]. A comparison between current and future applications indicates a trend from inorganic materials like silver towards organic nanomaterials like nano-encapsulates and nano-composites.

Another clearly emerging trend for insecticide-related research is the possibility of using alternative insecticide active ingredient (a. i.) that are less harmful to non-target organisms and may potentially reduce the development of resistances. Many of these alternative a.i. are unstable and require protection against premature degradation, which can be achieved by nano-formulations.

The incorporation of molecular recognition agents, such as aptamers into crop rhizospheres, which may help in efficiently delivering specific fertilizer nutrients needed by crops, could be transformative in this regard. Researchers at Agriculture and Agri-Food Canada (AARC) and Carleton University are developing an Intelligent Nano Fertilizer platform to synchronize the release of nutrient according to crop demand. This fertilizer is made of nano-sized nitrogen molecules coated in a polymer coating that contains nano-sized biosensors (aptamers) that allow the fertilizer to be released into the soil when the plant needs it. These biosensors detect chemical signals being transmitted from the roots of the plant to the soil and release nitrogen. The research team is collaborating with fertilizer company Agrium and nanotechnology firm NanoGrande. This intelligent nanofertilizer technology platform can be extended for efficient delivery of all the nutrients including micronutrients.

The potential of nanotechnology in agriculture is large, but a few issues are still to be addressed, such as increasing the scale of production process and lowering costs, as well as risk assessment issues. In this respect, particularly attractive are nanoparticles derived from biopolymers such as proteins and carbohydrates with low impact on human health and the environment. Similarly, the potential of starch-based nanoparticles as nontoxic and sustainable delivery systems for agrochemicals and biostimulants is being extensively investigated.

Recently, there is a trend of green nanotechnology that is closely interconnected with the principles of green chemistry and green manufacturing. Green chemistry principles are, for example, used to manufacture nanomaterials from less toxic chemicals, using less energy and use of sustainable raw materials.

MARKET POTENTIAL FOR NANOTECHNOLOGY IN AGRICULTURE

COMMERCIALIZATION AND MARKET ADOPTION

Despite the potential advantages, nanotechnology applications in the agricultural sector have not yet made it to the market to any large extent in comparison with other industrial sectors. Few nano-products in the agricultural sector have been put on the market by smaller companies but the market adoption of these products is so far limited. In many of the products, the identity, size and the role of potential nanoparticle is often not declared in the products. No new nano-based products for the agricultural sector have been launched by the large agro-chemical companies, though the patent applications from large players are continuously growing. This indicates that large players are actively patenting and keeping broad patent claims in order to ensure future freedom to operate and to guarantee future exploitation in case of promising commercial developments.

[44] RIKILT and JRC, 2014. EFSA supporting publication: EN-621, 125 pp

Table 12: Crop Protection and Nutrition Products with Nano-materials in the Global Market[45]

Product	Manufacturer	Potential nanoparticle	Reported particle size (nm)	Application
Allosperse® delivery system	Vive Crop Protection	Encapsulation with polymer (azoxystrobin-based fungicide, VCP-01, Bifenthrin 10 DF insecticide, Herbicides)	polymer particles <10 nm	Crop protection
Nano Revolution 2.0	Max Systems LLC	Unspecified	n/a	Adjuvant for herbicides
Biozar Nano-Fertilizer	Fanavar Nano-Pazhoohesh Markazi Co, Iran	Iron, zinc and manganese nanoparticles	n/a	Biological fertilizer
Nano -5	Uno Fortune Inc, Taiwan	G-protein	n/a	Plant growth regulator
Nano Gro	Agro Nanotechnology Corporation	Unspecified	Minerals in nanomol (10^{-9}) concentration	Plant growth regulator
Primo Maxx	Syngenta	Registered as Micro-Emulsion	100 nm	Plant growth regulator
Banner Maxx	Syngenta	Registered as Micro-Emulsion	n/a	Fungicide
PrimeraOnePro piconazole	PrimeraTurf	Registered as Micro-Emulsion	100 nm	Fungicide
Aerosil 200 Hydrophilic Fumed Silica	Evonik	SiO2	12 nm	Various purposes
Geohumus	Geohumus International	Biocompatible high performance polymer	clay part is at nanoscale	Soil Wetting Agent
Irrigation emitter/ plastic pipe	Geoflow	Nanoclay platelets (PolyOne's Nanoblend MB)	n/a	Ensure slow release of herbicide

COMMERCIALIZATION IN INDIA

There have been some claims of commercialization of nanotechnology based products by some small players in India. Though products are available in the market with prefix "nano", the identity and the role of potential nanoparticle is often not declared in these products. Some of the products are labelled as "nano" for containing lesser amounts of the active ingredient/ nutrients than the conventional products or for association with novelty or enhanced activity.

However, with increasing R&D in the area of nanotechnology for agricultural applications and with standards and regulations in place in due course of time, it is expected that products/ technologies with well characterized and size determined nanoparticles would be made available in the market.

Table 13 illustrates the recent technologies developed by the ICAR network that have been transferred to industry. No reports are available to indicate if these products have been commercialized and made available in the market by the licensees.

[45] Sathguru Analysis, Various sources

Table 13: Technologies developed by ICAR and transferred to industry in India

Product/ technology	Developer	Licensed to	Potential nanoparticle	Application
Nano-induced biological phosphorous fertilizer (NB-PHOS) using *Aspergillus flavus* CZR-2	CAZRI, Jodhpur	Prathista Industries Ltd	Nano particles as trigger for efficient nutrient mobilization	Crop nutrition
Nano-formulation of Bioactive Molecules – • **Imidacloprid and PEG based surfactants** • **Carbofuran & Azadirachtin A** • **Nano Sulphur** • **Nanohexaconazole**	IARI, Delhi	Insecticides India Limited, Delhi. M/s Aegis Agro Chemicals, Hyderabad Coromandel International, Hyd	Surface modified sulphur NPs (20-100 nm)	Crop Protection Crop Protection Crop Protection
Nano-cellulose	CIRCOT	i. Thapar Centre for R & D, Haryana ii. Kanakadhara Agricultural Innovations, Bengaluru (iii) Clean Cotton Impex, Tirupur (iv) Godavari Biorefineries, Mumbai (v) Madhya Pradesh Association of Cotton Processors and Traders	Length and thickness of nanocellulose are less than 500 and 50 nm, respectively	Various industrial applications

CHALLENGES IN COMMERCIALIZATION AND MARKET ADOPTION

Nanotechnology regulatory guidelines are still evolving and this poses challenges for the industry to commercialize their products and gain consumer acceptance. There are no internationally agreed terminology/definitions for nanomaterials or nano-enabled products. There are no standardized measurement techniques for nanomaterials, no standardized protocols for toxicity testing and evaluating environmental impact of nanomaterials.

The long gestation periods, the cost of equipment, and the uncertainty of results poses challenge for sustained funding for nanotechnology research and commercialization efforts. Few large agrochemical companies that entered into research and development have withdrawn or scaled down their investments in nanotechnology due to regulatory uncertainty and public acceptance risks.

The scale of operations in agriculture pose a different set of challenges when compared to nanotechnology applications in other industries. Considering the current small scale of production facilities, generation of such large volume becomes major constraint in commercialization of agriculture nanotech products.

The innovation in this sector is driven by manufacturers and producers because of the beneficial new properties of nanomaterials but the market demand for these nano based replacement or new products is very low. Awareness about the benefits and increase in demand of the nano-products will take time and companies need to make sustained efforts towards this.

CHALLENGES IN TECHNOLOGY TRANSFER TO INDUSTRY

The transfer of the technologies developed at the public funded institutes to the industry is challenging and depends upon their scalability for large scale production and cost effectiveness. Most of the technologies developed by public research institutions are at laboratory or bench scale and commercializing such bench scale technologies is risky for private enterprises. Some of the challenges in transfer of technology are:

- Lack of adequate infrastructure capabilities for prototyping, scale up, characterization of nanomaterials, toxicity and safety assessment
- Lack of adequate funds for the characterization of nanomaterials, toxicity and safety assessment is a major impediment to commercialization of nanotechnology enabled products
- The diversity and complex multidisciplinary nature of nanotechnologies pose a challenge for technology transfer and intellectual property protection. Patent offices have limited skills in assessing nanotechnology patent applications leading to delays.

CHALLENGES FOR INVESTMENTS IN NANOTECHNOLOGY

For companies and SMEs, investment in nanotechnology is costly and risky considering the uncertainty of bringing a new product to the market when no similar technologies have previously been commercialized, or when the demand for the technology/application is not yet clear. Corporate investments in nanotechnology in agriculture is still very nascent. Venture capitalists find the time lag of three to eight years, between research completion and commercialization of a nanotechnology, to be a major detriment. Venture capital accounts for less than 5% of nanotechnology funding and there are very few dedicated nanotechnology venture capital funds like NanoStart and NanoDimension.

POTENTIAL IMPACT OF NANOTECHNOLOGY IN AGRICULTURE

POTENTIAL BUSINESS IMPACT

Lux Research (2008) had forecasted a US$ 3.1 trillion market for nanotechnology-related industry by 2015 which created excitement for the industry around nanotechnology. According to this report, Nano enabled products (finished goods incorporating nanotechnology) will account for $2.7 trillion, followed by nano intermediates (intermediate products with nanoscale features) with $432 billion, while nanomaterials will account for a comparatively small $3.0 billion in sales. This excitement around nanotechnology extended to agriculture sector too and agrochemical companies started exploring the possibilities offered by nanotechnology among other innovative technologies. For instance, Vive Crop Protection is working with six global crop protection companies on products with US$ 8 billion total addressable market. It is primarily focusing on reformulation of existing pesticides or replacing organic solvents with biodegradable or bio-inert polymers. It is estimated that increased efficacy of nanotechnology based active ingredients and/or controlled release can benefit the farmers by reducing the amount of pesticides applied up to 50%, save labor costs due to reduced number of sprays and increase the crop yields by 15-20%.

Nano-enabled fertilizers could improve crop yields by 15-20% and reduce the consumption of chemical fertilizers by 50-80 percent as per the application rates of some of the nano formulations available in market. This reduction in consumption will significantly benefit the fertilizer industry by reducing the logistics cost when compared to conventional fertilizers.

The global precision farming market size, as per Markets and Markets, is expected to grow at a CAGR of 12.2% from 2014 to 2020 and reach $4.55 billion by 2020. Though precision farming is still in its infancy in India, nanotechnology is expected to play a significant role in the advancement of new tools for guiding farmers about the right time to plant and harvest, the amount of fertilizers and pesticides needed for better yield production. Losses due to food spoilage and rejection of exports due to pesticide residues are a major concern for India. Food safety in India can be significantly improved by use of nanosensors to monitor food quality or to detect pathogens, chemicals or contaminants in food.

SOCIO ECONOMIC IMPACT

The emergence of nanotechnology applications in consumer products has raised a number of ethical and societal concerns like effects on environment, human and animal health; consumer perception and intellectual property issues. Some studies on consumer preferences demonstrate that overall public opinion is not negative towards nanotechnology and that it is particularly influenced by perceived benefits and usefulness of the technology. These studies suggest that nanotech products with clear benefits and acceptable/low risks for the consumers, like medical and environmental applications, if introduced first into the market could drive the acceptance of other applications introduced later on, e.g. pesticides solutions, where societal concerns already exist.

Regulations, especially on labelling, can have adverse effect on public opinion and create negative connotations around the new technology. There is an industry concern that labelling of nano-products might have retroactive effect on products already present in the market that contain nano-sized materials like clay, silica and that might fall under the nano-definition.

Patenting on nanotechnology is being extensively done with applications in different fields which could lock-up huge areas of technology. The nano based inventions could infringe existing granted patents with the consequent risk of a decreased freedom to operate for R&D and applications in the field of agriculture.

ENVIRONMENTAL IMPACT

Nano-pesticides and nanofertilizers have the potential to reduce environmental pollution through the reduction in application rates & reduced losses of agrochemicals and also reduced emission of nitrous oxides from the smart fertilizers. It is estimated that increased efficacy of nano active ingredients and controlled release by nanoencapsulation can reduce the amount of pesticides applied up to 50%.

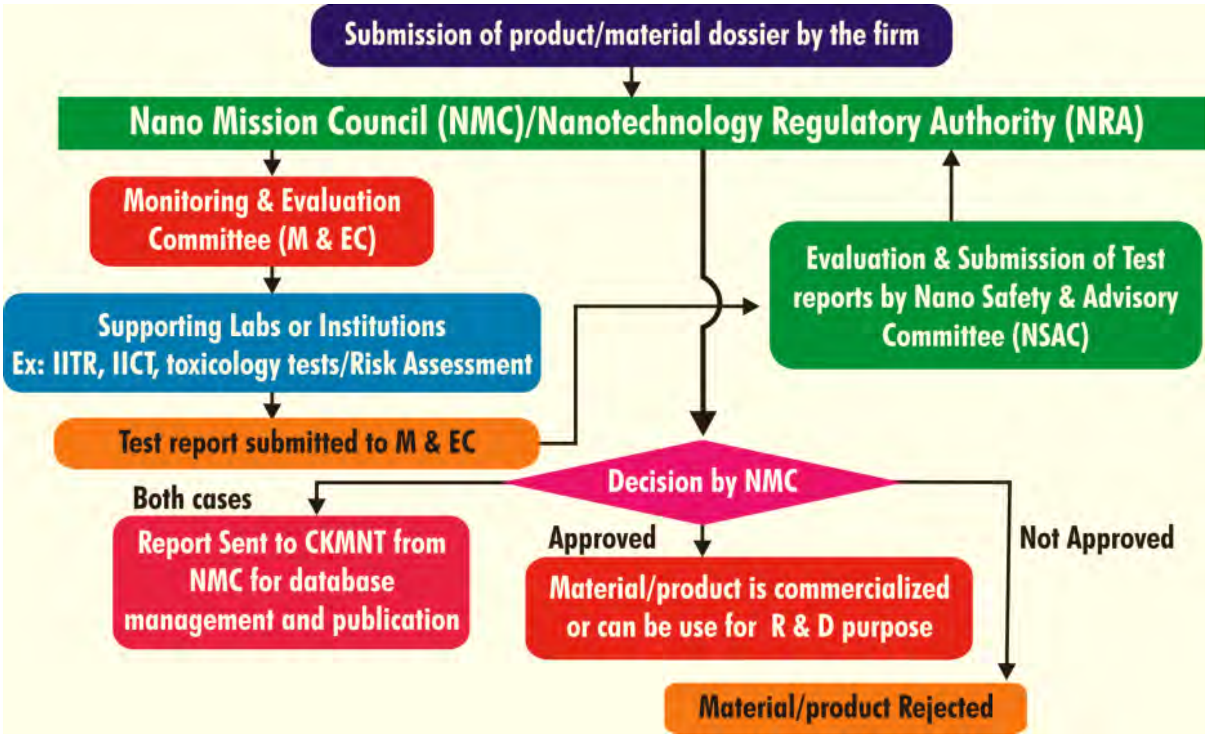
However, nano-materials may also create new kinds of contamination of soils and water bodies due to enhanced transport, longer persistence and higher toxicity of the nano based active ingredients.

Despite the potential uses of nanotechnology, the issues of safety of its application to humans, environments and ecosystem need to be addressed. Indeed, there are many potential points of human exposure to nanomaterials along the agri-food chain (from farmers to consumers), and the threat of possibility of nanoparticles reaching non targeted sites can pose health and environmental problems. Accordingly, any large-scale adoption of nanotechnology for agricultural purposes must be preceded by thorough research with in-vivo soil-plant systems to provide a better understanding of its agro-ecological ramifications, the mechanisms of reaction and fate of nanoparticles and nanomaterials being used. Risk management strategies should be put in place in parallel to the technological developments.

NATIONAL REGULATORY FRAMEWORK

In India, several initiatives have been taken towards regulations for nanotechnology. DST has constituted a working group of Nano mission for the regulation of nanotechnology. Centre for Knowledge Management of Nanoscience & Technology (CKMNT) has prepared a report on "Regulatory Framework for Nanotechnology - A Global Perspective" for the working group on nanotechnology regulation. CKMNT has also prepared "Guidelines and best practices for safe handling of nanomaterials".

Figure 14: Proposed Regulatory Framework in India[46]



In India, development of safety standard for nanotechnology & nanomaterials is in early stage. Bureau of Indian Standards (BIS) has responsibility for standards of nanotechnology including safety standards. In general, BIS follows all the recommendations set by the International Organization of Standards (ISO). BIS has set up a working group including professionals from industry, academia, and the government sector. There are four other organizations involved with developing health and environmental regulations for nanotechnology in India: the Ministry of Environment and Forests (MoEF), the Ministry of Chemical and Fertilizers (MoCF), the Ministry of Health and Family Welfare (MoHFW), and the Ministry of Labor and Employment.

WAY FORWARD AND RECOMMENDATIONS

1. **Regulations:** Development of Indian regulations for nanotechnology and its applications; standards for nanomaterials or nano-enabled products; and internationally agreed terminology/definitions for nanomaterials will help a long way in shaping the nanotechnology industry in India and attracting investments into this industry. Development and promotion of regulations that will stimulate private sector research in fields of common interests, both to the public and to the industry, should be fostered.
2. **Building scientific capabilities:** Nanotechnology requires a high degree of multidisciplinary and cross-sectoral collaboration within and between academic researchers and industry. Scientific capabilities should be built through creation of interdisciplinary research units for basic and applied research in agriculture and investments in human resource development. International collaborations by way of MoUs with global nanotechnology research institutes focusing on agriculture should be promoted for skills up gradation and knowledge sharing.

[46] CKMNT, 2013. Report on Regulatory Framework for Nanotechnology: A global perspective

3. **Investments:** To accelerate research in nanotechnology in agriculture, an increase in investment is needed. Government funding agencies, agriculture and allied industries, venture capitals, and other financial institutes should consider investing in R&D. Funding should not be restricted to development of applications based on nanomaterials but also extend to characterization of nanomaterials, toxicity assessment, and studies on environmental fate and behavior. Dedicated funding mechanisms for nano manufacturing should be created.
4. **Public - private partnerships** are crucial for fostering the transition of nanotechnology from research to commercialization. For companies and SMEs, investment in nanotechnology is costly and risky. Government can mitigate these risks by initiating schemes for public private partnerships having consortia of companies and public laboratories and institutions. These will give an opportunity for pooling knowledge and resources from corporates, SMEs and public institutions. Few such consortia are already in place like Genesis (France), InnoCNT (Germany) and NanoNextNL (the Netherlands). Collaboration between industry and academia can shift investments from fundamental R&D to more applied research and commercialization.
5. **Infrastructure:** Top priority should be given for the development of infrastructure for piloting/scale up and nano manufacturing. Industry cluster models/ nanotech parks with facilities for characterization of nanomaterials, toxicity testing, scale up and manufacturing should be developed.
6. **Facilitating Technology Transfer:** Strengthening the technology transfer framework for nano - enabled products/ technologies and enhancing the IP protection will attract both industry and investors.
   a. The nanotechnology regulations and standards developed should ensure adequate safety, health and environment for the society.
   b. Scientific communication and dissemination of information to all the stakeholders should be focused to address the concerns of society on the use of nanotechnology and nano-products.

BALANCED APPROACHES FOR ADOPTION OF NANOTECHNOLOGY

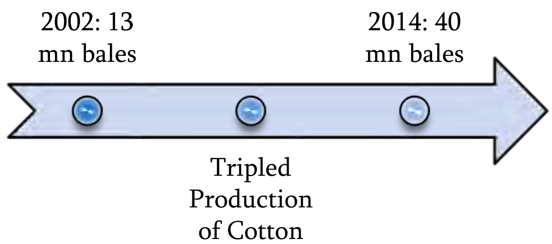
Nanotechnology should not be considered as panacea for all ills in agriculture and it should be used judiciously to address the emerging needs. There is a need to evaluate the extent to which nanotechnology options are able to contribute to the goals of agriculture development and applied only in the areas where it offers significant advantages at nominal cost so that all sections of the society get benefited. Applications with clear benefits and acceptable/low risks should be introduced first into the market, driving the acceptance of other applications to be introduced later on.

APPENDIX

THE BT COTTON DEVELOPMENT SUCCESS

According to International Service for the Acquisition of Agri-Biotech Applications (ISAAA), India has the fourth largest area of 11.6 mn Ha under biotech crops globally which has been cultivated by 7.7 mn farmers of the country thereby ensured a 95% adoption rate among the farmers. India boarded the league of biotech crop growing countries with the commercial approval for Bt cotton cultivation in 2002. Nearly 96% of the country's cotton area is now covered by Bt hybrids.

Figure 15: Bt cotton production



The first transgenic event commercialized in India was a single protein event MON531 with the cry1Ac as insect resistant cotton hybrids in 2002. As over the years the hybrids developed a resistance to pink bollworm, the developers introduced second-generation cotton seed that contains two different Bt proteins cry1Ac and cry2Ab2 and joined the global network of biotech countries cultivating stacked traits. Globally 13 countries plant biotech crops with two or more traits in 2014 occupying about 28% of the area under biotech crops. The sacked trait product Bollgard II with Roundup Ready Flex Cotton provides growers a combination of both traits packaged into the cotton seed. This trait provides proven broad-spectrum weed control that targets grass and broadleaf weeds to reduce pressure on yield, while offering the highest level of protection from worm damage relative to any other worm control options. Currently, the Bt cotton event developers are putting in their efforts for development of a three-protein Bt cotton technology.

Figure 16: GEAC's approval for commercial release of different Bt cotton events in India, 2002 to 2012

2002	2006	2008	2009
• **MoN - 531** (cry1Ac: Mahyco/Monsanto) - Commercialized	• **MON-15985** (cry1Ac and cry2Ab2: Mahyco/Monsanto) - Commercialized • **Event 1** (Cry1Ac: J K Agrigenetics) - Commercialized • **GFM Event** (cry1Ab and cry1Ac: Nath Seeds) - Commercialized	• **BNLA - 601** (cry1Ac: UAS, Dharwad & CICR (ICAR), Discountinued since 2010	• **MLS - 9124** (synthetic cry1C: Metahelix Life Sciences) - Approved, Not placed in the market yet

The Genetic Engineering Appraisal Committee (GEAC, which was then called as Genetic Engineering Approval Committee and subsequently renamed) - the apex regulatory body related to GMOs under the Ministry of Environment, Forests & Climate Change (MoEF&CC) in the Government of India have given approval to six events (one of 6 has been discontinued) of Bt cotton in India from 2002 to 2012.

The Growth of the Indian Biotech industry can be summarized into three broad phases which initiated with collaboration between Mahyco and Monsanto for the Bt cotton technology as has been summarized below:

Table 14: The Growth of Indian Biotech Crop Industry[47]

The Growth of Indian Biotech Crop Industry	
Phase I	• Mahyco and Monsanto, took the initiative of introducing the Bt cotton technology into India in 1995. • Post receipt of the Bt cotton seeds with event MON531 (Bollgard ITM) containing the gene cry1Ac in 1996 Mahyco introduced the gene into its parental lines and developed Bt cotton hybrids. • Mahyco also sourced the second event MON15985 (Bollgard IITM) with two genes cry1Ac and cry2Ab from Monsanto.
Phase II	• The initial success of Mahyco' s Bt hybrids encouraged several firms (having well established plant breeding division) to enhance their competitiveness by quickly accessing to sublicense these events from Mahyco - Monsanto joint venture company and introgress it into their best-performing hybrids adoptable to various agri-climatic regions. • Few firms adopted a different technology access option by collaborating with other organizations (JK seeds with IIT, Kharagpur for Event-1 featuring cry1Ac; and Nath seeds with a Chinese firm for GFM event featuring fused genes cry1Ab and cry1Ac). • Majority of the Bt cotton sublicensing firms upgraded their scientific knowledge and infrastructure to the levels required for technology absorption (by backcrossing and testing) and meeting the regulatory requirements of the country. • Metahelix was the only Indian firm that developed its GM event MLS-9124 with synthetic cry1C gene via in-house R&D. • Single gene hybrids were phased out and replaced with dual gene Bollgard-II cotton hybrids introduced in 2006.
Phase III	• The next phase began with sublicensing of the GFM event and MON 15985 for its hybrids launched later. • Many of the private sector companies followed the Merger and Acquisition route to consolidate market share in cotton seed market; for instance acquisition of Prabhat Agri Biotech, Pravardhan Seeds and Yaaganti Seeds by Nuziveedu Seeds

CASE STUDY: IMPACT OF THE AVAILABILITY OF REFERENCE TOMATO GENOME ON TOMATO BREEDING

The Tomato Genome Sequencing Project was a landmark in the history of sequencing projects where both Sanger's and next-generation sequencing (NGS) technologies were employed, and a highly accurate and well assembled plant genomes along with a draft of the wild relative, *Solanum pimpinellifolium*, were released in 2012. The utility of this genome has already been demonstrated by a relatively large number of studies (Table 16) predominantly in screening and identifying candidate genes related to fruit development and ripening processes, databases and bioinformatics studies based on the tomato sequence, and serving as a reference genome for other Solanaceae species.

Table 15: Research areas enabled by the tomato reference genome and the primary outcomes[48]

Research areas	Outcomes	Specific examples
Assembly guidance and as benchmarks for other genomes	Genome and transcriptome assembly Gene prediction	Tomato 150 genomes Project, SOL-100 project
Gene annotation	Gene location, structure, and function RNaseq annotation	*sulfite reductase* (*SiR*) gene; location of alcohol dehydrogenase involved in fruit ripening

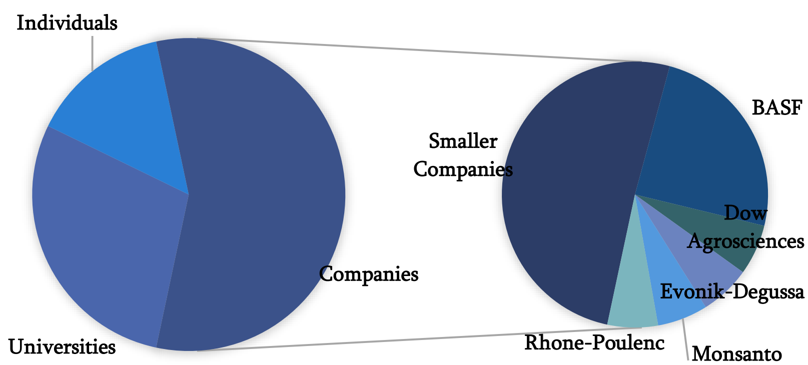
[47] Compiled from Vijayaraghavan & Satyanarayana, 2015; Business of Agriculture, July – August, Pg 32 - 36
[48] Menda et al. 2013

Epigenetics and expression	Genomic methylation miRNA and transcript identification, Tissue specific expression, Gene and networks prediction, Protein expression	*SUN*, *OFP*, *GABBY* transcription factor expression analysis; prediction of regulatory elements for genes involved in tocopherol synthesis.
Phenotype to genotype	Trait-specific marker development Gene mapping and expression QTL analysis SNP location, linking with gene function	Markers for Terminating Flower (TMF), a gene involved in flowering, Physical locations of SNPs on the SolCAP tomato array
Gene families	Gene family prediction Genome distribution Phylogenetic analysis Database framework	Identification of Receptor-like Kinases (RLKs); Phylogenies for Ethylene Response Factor (ERF) and ERECTA genes, involved in plant architecture
Comparative genomics	Genome polymorphism Candidate gene prediction Resequencing Gene and sequence conservation Comparative mapping Orthologs mapping	Mapping *S. pimpinellifolium* reads to 'Heinz 1706' to calculate SNPs

Within short span, the publication of the genome has made a tremendous impact on tomato research. Additional data is being generated on expression, metabolomics, and epigenetics, all of which interplay to result in phenotype. It is critical to develop methods that link these various data types so that a greater understanding of tomato and how it may be improved can be gained; especially in terms of flavor, disease resistance, and adaptations to climate change.

Scientific publications and patents on nanomaterials (NMs) used in plant protection products have exponentially increased since the millennium and an analysis focusing mainly on inorganic nanopesticides and fertilizers was carried out by Gogos et al., 2012. The study revealed that 56% of patents were held by companies that are mainly represented by smaller enterprises (Fig. 17); Universities (29%) and individuals (15%) share the remainder. However, BASF was holding 27% of all company patents.

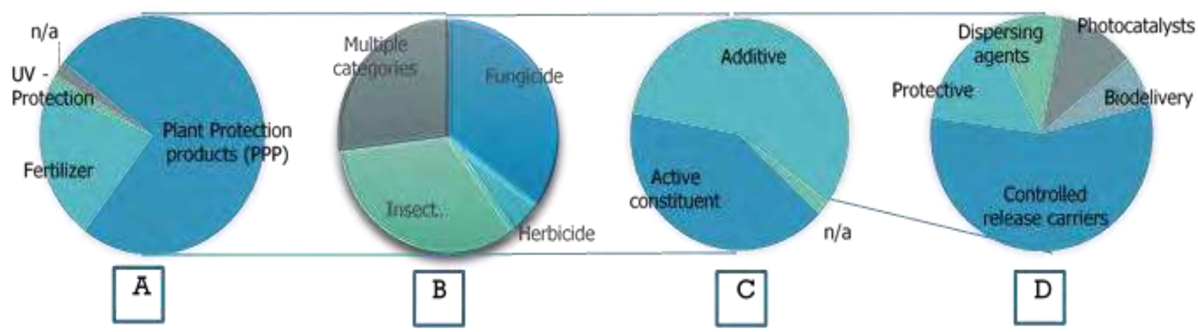
Figure 17: Nanotech patents distribution



Patents on nanomaterial based plant protection products and fertilizer applications as visualized between companies, academia and individuals.

Plant protection products (PPP) featured in 74% of the patents & publications (Fig. 18A). Overall, 35% of the PPP were as fungicides, 33% as insecticides and 27% were considered for multiple categories (Fig. 18B). In 41% of the PPP, nanomaterials (NMs) were the active constituent (Fig. 18C). However, in 57% of the PPP, NMs were additives (Fig. 18C) that acted as controlled release carriers (Fig. 18D, 56%), protective (15%) or dispersing agents (11%) and photocatalysts (11%).

Figure 18: Agriculture nanomaterial application



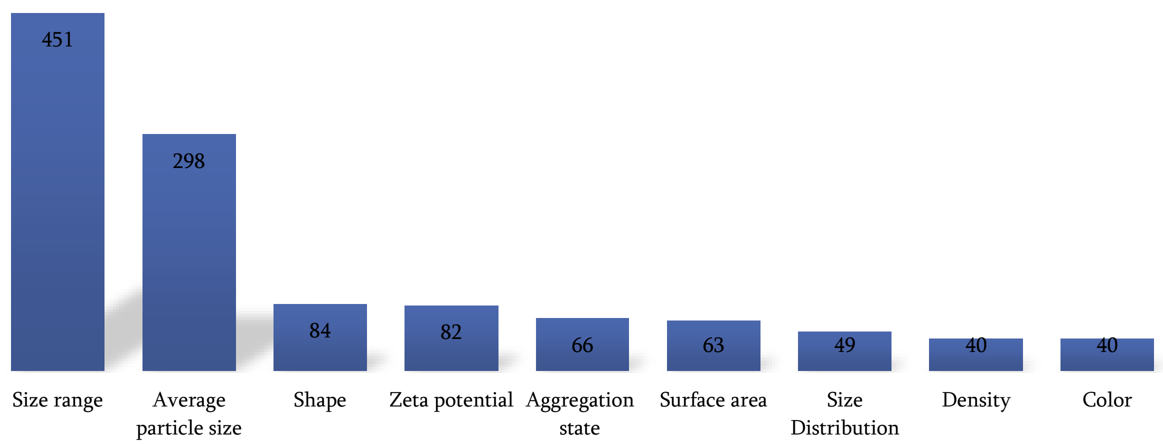
Purposes of Agricultural NM Applications (A), Types of PPP containing NM (B), General functions of NM in PPP (C) Role of NM additives in PPP (D)[49]

[49] Gogos et al., 2012. J Agric Food Chem 60: 9781-9792

The current level of knowledge does not allow a fair assessment of the advantages and disadvantages that will result from the use of various nanopesticides. Investigations into the environmental fate of nanopesticides remain scarce and a great deal of research will therefore be required over the coming years for (i) the development of experimental protocols to generate reliable fate properties, (ii) investigations into the bioavailability and durability of nanopesticides, and (iii) evaluation of current environmental risk assessment approaches, and their refinement where appropriate.

The increasing use of nanomaterials has generated a greater need for environmental and toxicological monitoring, risk assessment and the need for development of innovative detection methods for nanomaterials. An important element of any nanomaterial toxicity screening is a detailed and comprehensive physicochemical characterization of the test material being studied. This is a critical factor for correlating the nanoparticle surface characteristics with any measured biological/toxicological responses, as well as to provide an adequate reference point for comparing toxicity results with the hazard-based findings of other investigators. Fig. 19 gives an overview of a number of the most important physicochemical characteristics reported in the 633 records in the Nano Inventory[50]. Only in a limited number of papers these sizes are measured, more often the size of the nanomaterials as stated by the supplier is given.

Figure 19: Overview of the physiochemical characteristics reported in the Nano Inventory



Research efforts exploring the potential benefits of nanotechnologies, nanomaterials and nanoparticles as sources of nutrients and crop protection ingredients for crop production need to be strengthened. However, much needs to be learnt about the potential use of nano-encapsulated nutrients and nanomaterials on the metabolism and growth of crops and plant rhizosphere soil microorganisms. Efforts need to be made to understand the mechanisms of reaction and fate of nanoparticles and nanomaterials with in-vivo soil-plant systems. New technologies and products based on nanomaterials need to be developed and tested under controlled conditions in greenhouses and in the field before they can be commercialized widely.

[50] RIKILT and JRC, 2014. EFSA supporting publication: EN-621, 125 pp

Knowledge Partner

CENTRAL INSTITUTE OF HORTICULTURE MEDZIPHEMA, NAGALAND

Recognizing the huge potential for development in the North-Eastern region and to provide institutional support to tap this potential, Government of India has set up the "Central Institute of Horticulture" at Medziphema, Nagaland in the year 2005-06 under the Central Sector Scheme. The institute is spread over 43.5 ha area at Medziphema, Nagaland. This institute is set up for holistic development of horticulture in NE Region of India.

Vision

To emerge as the pioneering, innovative, farmer focused and self-supporting institute in the country.

Mission

To provide excellent, innovative and relevant training to all the stakeholders so as to empower individuals and enable horticulture industry to bring about socio-economic development and sustainability in North East Region.

Focus Areas

* *Training of State Government Officials and Farmers/ Beneficiaries of North Eastern Region. (More than 2000 nos. of Trainers' & 15000 nos. of Farmers' trained)*
* *Production and supply of Quality Planting Material. (Scion block developed for 9 fruit crops & more than 150000 root stocks raised & 100000 plants propagated)*
* *Accreditation and certification of horticulture nurseries in NER.*
* *Transfer of technology through method & result demonstration & publication of folders, manuals, leaflets etc.*
* *Promotion of Organic Farming. (established organic model farm)*
* *Certificate course in Modern Nursery Management Practices of Horticulture Crops of three months duration.*
* *Marketing and agri-business promotion through exhibitions, seminars, workshops, exposure trips, buyers & sellers meet.*
* *Coordination with State Horticulture Departments of NER and other National Organizations.*

Quality Planting Material Production

Demonstration of improved technologies

PHM & value addition

Human Resource Development

Sathguru Management Counsultants

About Sathguru

Sathguru Management Consultants (Sathguru) is a multidisciplinary advisory firm providing strategy, innovation and policy advisory to public and private sector entities in life science sector covering a broad spectrum of disciplines such as agriculture, food, animal sciences, human health care and industrial biotechnology. Sathguru provides a one stop solutions to all stakeholders in the life sciences sector ranging from researchers conceptualizing their next big idea to large corporates acquiring cutting edge technologies or finding growth avenues to multinational exploring growth opportunities in developing world to public sector developing policies, creating sector development platforms or creating life science infrastructure.

Since its formation in 1985, Sathguru has strived towards professional excellence and has grown to be the largest Indian strategic and technology management firm and a leader in life science sector.With offices in India (Hyderabad and New Delhi), the United States (Boston) and East Africa (Malawi) and strategic partners across regions including Asia, Latin America, Europe and Israel, Sathguru is well entrenched in the global innovation ecosystem and leverages business opportunities across regions globally. Sathguru engages over 200 highly qualified full time techno-commercial professional with varied background and experience across life sciences including doctorates and business professionals. Sathguru's deep understanding of global market, competition and trends (technology and business) coupled with its network of global partners allowing Sathguru to access modern technologies and develop winning business strategies for its clients.

Services:

- Innovation Advisory
- Corporate Strategy
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- Policy and Regulatory Advisory
- Corporate Finance and Transaction Advisory
- International Development and Project Management

Indicative partners & clients:

North America: Cornell University - University of Florida - RTI International - University of Wisconsin, Madison (USA) - EMPRABA (Brazil) - Tufts University - Pfizer - Merck - Syngenta ConAgra - Ironwood - Evofem - Ezra - Aphios

EU and MENA: University of Sheffield - Fraunhofer - PBL (UK) - Yissum (Israel) - GSK - Novartis - DSM Entrepreneurial ventures – AbBiotics (Spain) - Lipidor (Sweden) - Lipocure (Israel) - JPMed (Israel)

Asia: A*Star network (Singapore) - Myongi University (Korea) - Korea Research Institute of Chemical Technology Transpacific IP - SK Bio (Chinga, Korea) - LG Life sciences (Korea) - Shin Poong Pharma (Korea) - Maruho (Japan)

ASSOCHAM

THE KNOWLEDGE ARCHITECT OF CORPORATE INDIA

EVOLUTION OF VALUE CREATOR

ASSOCHAM initiated its endeavour of value creation for Indian industry in 1920. Having in its fold more than 400 Chambers and Trade Associations, and serving more than 4,50,000 members from all over India. It has witnessed upswings as well as upheavals of Indian Economy, and contributed significantly by playing a catalytic role in shaping up the Trade, Commerce and Industrial environment of the country.

Today, ASSOCHAM has emerged as the fountainhead of Knowledge for Indian industry, which is all set to redefine the dynamics of growth and development in the technology driven cyber age of 'Knowledge Based Economy'.

ASSOCHAM is seen as a forceful, proactive, forward looking institution equipping itself to meet the aspirations of corporate India in the new world of business. ASSOCHAM is working towards creating a conducive environment of India business to compete globally.

ASSOCHAM derives its strength from its Promoter Chambers and other Industry/Regional Chambers/Associations spread all over the country.

VISION

Empower Indian enterprise by inculcating knowledge that will be the catalyst of growth in the barrierless technology driven global market and help them upscale, align and emerge as formidable player in respective business segments.

MISSION

As a representative organ of Corporate India, ASSOCHAM articulates the genuine, legitimate needs and interests of its members. Its mission is to impact the policy and legislative environment so as to foster balanced economic, industrial and social development. We believe education, IT, BT, Health, Corporate Social responsibility and environment to be the critical success factors.

MEMBERS – OUR STRENGTH

ASSOCHAM represents the interests of more than 4,50,000 direct and indirect members across the country. Through its heterogeneous membership, ASSOCHAM combines the entrepreneurial spirit and business acumen of owners with management skills and expertise of professionals to set itself apart as a Chamber with a difference.

Currently, ASSOCHAM has more than 100 National Councils covering the entire gamut of economic activities in India. It has been especially acknowledged as a significant voice of Indian industry in the field of Corporate Social Responsibility, Environment & Safety, HR & Labour Affairs, Corporate Governance, Information Technology, Biotechnology, Telecom, Banking & Finance, Company Law, Corporate Finance, Economic and International Affairs, Mergers & Acquisitions, Tourism, Civil Aviation, Infrastructure, Energy & Power, Education, Legal Reforms, Real Estate and Rural Development, Competency Building & Skill Development to mention a few.

INSIGHT INTO 'NEW BUSINESS MODELS'

ASSOCHAM has been a significant contributory factor in the emergence of new-age Indian Corporates, characterized by a new mindset and global ambition for dominating the international business. The Chamber has addressed itself to the key areas like India as Investment Destination, Achieving International Competitiveness, Promoting International Trade, Corporate Strategies for Enhancing Stakeholders Value, Government Policies in sustaining India's Development, Infrastructure Development for enhancing India's Competitiveness, Building Indian MNCs, Role of Financial Sector the Catalyst for India's Transformation.

ASSOCHAM derives its strengths from the following Promoter Chambers: Bombay Chamber of Commerce & Industry, Mumbai; Cochin Chambers of Commerce & Industry, Cochin: Indian Merchant's Chamber, Mumbai; The Madras Chamber of Commerce and Industry, Chennai; PHD Chamber of Commerce and Industry, New Delhi.

Together, we can make a significant difference to the burden that our nation carries and bring in a bright, new tomorrow for our nation.

ASSOCHAM
INDIA

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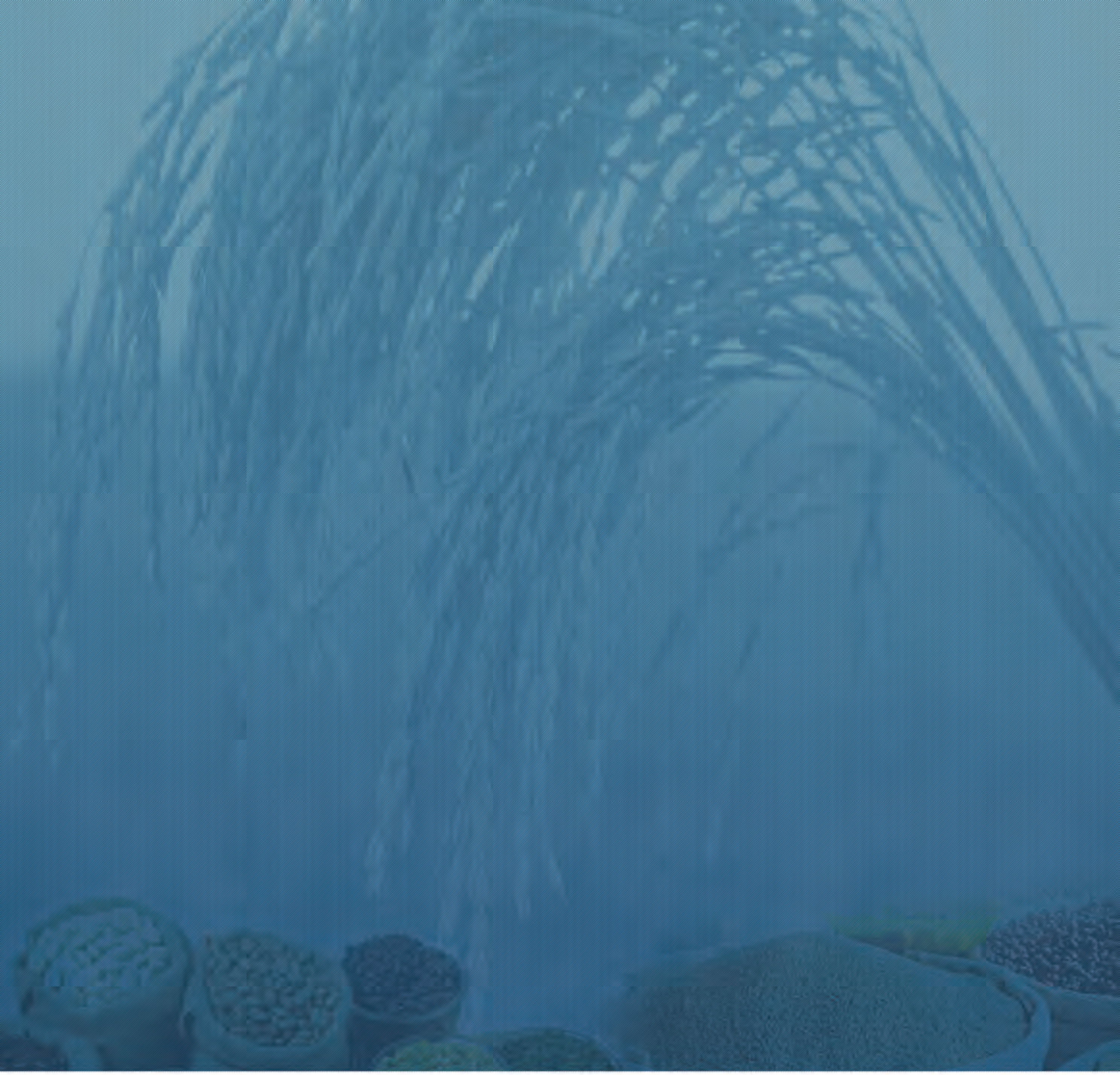
ASSOCHAM OVERSEAS OFFICES



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