Chapter 1
Intellectual Property Rights for Nanotechnology in Agriculture

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Abstract Nanoscience studies biological properties of materials at the nanoscale. Nanotechnology research develops improved materials, devices, systems and therapeutics. Nanomaterials can be protected for their intellectual property rights by innovators. However, due to the interdisciplinary nature of nanotechnology, there is a risk of overlapping patent claims and lack of distinction between nano-based and traditional patents. Scientists also must solve ethical and social issues, from health to environmental risk and consumer perception.

This chapter reviews the status of intellectual property rights protection of nanomaterials. The main points are: concerning patent number, there has been recently a tenfold increase of nanomaterial patents; for instance there has been an increase of granted patents from 386 in 2004 to 1106 in 2014 by the United States Patent and Trademark office. Concerning regulatory and policy bodies, the World Intellectual Property Organization and World Health Organization are working to make a comprehensive intellectual property right regulation for nanotechnology products. The United States is the leader of nanotechnology products development, and has made guidelines to make patent search easier for nano-based product. The European Patent Office has also created a new classification for the nano-based inventions. The chapter also gives emphasis on nanotechnology applications in agriculture, such as nanopesticides and nanobiosensors. Environmental, toxicity and health issues associated with nanotechnology products are mentioned.

Keywords Environmental risk • Intellectual property rights • Nanotechnology • Patents • Regulations • World Intellectual Property Organization (WIPO) • Nanopesticide • Nanosensor

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Abbreviations

BIS	Bureau of Indian Standards
CPCB	Central Pollution Control Board
CSIR	Council of Scientific and Industrial Research
CSTP	Committee of Scientific and Technological Policy
DRDO	Defence Research and Development Organization
DST	Department of Science and Technology
EC	European Commission
ECHA	European Chemical Agency
EFSA	European Food Safety Authority
EPA	Environmental Protection Agency
EPO	European Patent Office
EU	European Union
FAO	Food and Agriculture Organization
FD&C Act	Federal Food Drug and Cosmetic Act
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide and Rodenticide Act
HEAL	Health and Environment Alliance
IISc	Indian Institute of Science
IIT	Indian Institute of Technology
IPR	Intellectual Property Rights
ISO	International Organization of Standardization
JPO	Japan Patent Office
MSDS	Material Safety Data Sheet
NIFA	National Institute of Food and Agriculture
NSTM	Nano Science and Technology Mission
OECD	Organization for Economic Co-operation and Development
PCT	Patent Cooperation Treaty
PPE	Personal Protective Equipment
REACH	Registration, Evaluation, Authorization and restriction of Chemicals
TRIPS	Trade Related aspects of Intellectual Property Rights
TSCA	Toxic Substances Control Act
UNO	United Nations Organisation
USDA	United States Department of Agriculture
USPTO	United States Patent and Trademark Office
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WPN	Working Party on manufactured Nanomaterials
WTO	World Trade Organization

1.1 Introduction

Nanotechnology is an emerging branch which introduced new terrain on scientific development in a significant way. It deals with interdisciplinary subject with understanding and control of matter at dimension of roughly 100 nm and below. At this scale, the physical, chemical and biological properties of materials differ from the properties of individual atoms and molecules or bulk matter, which enable novel applications. Nanotechnology research and development are directed towards understanding and creating improved materials, devices and systems that exploit these properties as these are discovered and characterized (Raliya et al. 2013). These developments and expectations from nano based applications led governments and industries around the world to invest in nanotechnology research and development. The expectations from nanotechnology have risen to enormous heights, with the American government heralding it as the bringer of the 'Next Industrial Revolution' (Selin 2007). Nanotechnology research and products are reaching newer heights which impends its link up with policy regulation. Intellectual property rights is one such important policy, referring to protection and granting of monopoly rights for limited period to designated innovators by law (Sherman and Bently 1999). Intellectual property rights law comprises of patent, copyright, trademark, design rights and trade secrets. Enforcement of these laws on agriculture sector was traditionally limited because most agricultural research and development was conducted by public sector institutions in both developed and developing countries (Fink and Primo Braga 1999). The development and dissemination of the technologies led to the green revolution which did not pose substantial conflicts around intellectual property rights. However, post 1980s era, role of the private sector in agricultural research and development has increased significantly. In developed countries, almost one-half of agricultural research has been funded by the private sector (Helpman 1993). The emergence of research driven interdisciplinary subjects like nanotechnology has led to increase in reliance on intellectual property rights protection. This advancement for translation of basic scientific research into product for commercialization has accelerated a complexity for intellectual property right protection. Moreover, a research activity in this field has to deal with ethical and social issues, starting from health to environmental risk to consumer perception (Sweeney 2006).

Implementation of new technology in agriculture sector is of extreme importance, particularly to deal with population growth, climate change, pest management and limited availability of nutrient. There are many more important factors, with single aim to solve: how to increase crop production? Nanotechnology may play an effective role for this purpose. Already, there are many important developments on this aspect like enhancement of nutrients absorption by plants, protection of plants, nano-formulated food ingredients and water treatment processes. Nanotechnology derived devices are also explored in the field of plant breeding and genetic transformation. The potential of nanotechnology in agriculture is large, but issues such as increasing the scale of production processes and lowering costs, as

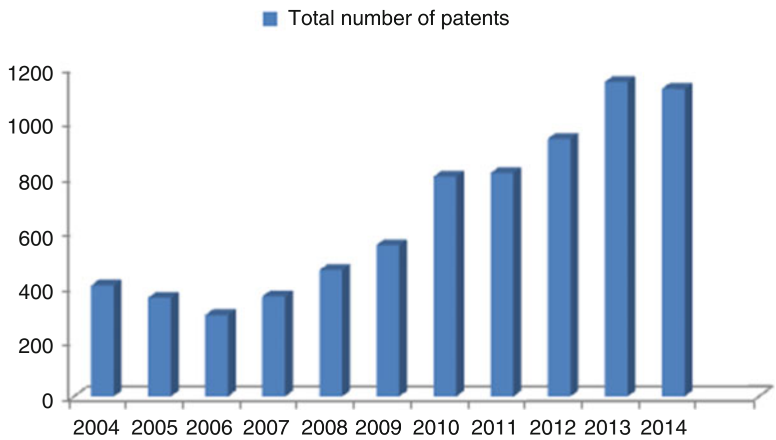

Fig. 1.1 Trend showing increase in the number of nanotechnology patents in the last 10 years as granted by United States Patent and Trademark Office and European Patent Office

well as risk assessment issues are needed to be addressed. This spur in nanotechnology development can be observed by increase in the number of nano related patents (Fig. 1.1) in recent years (Parisi et al. 2014). Patenting on nanotechnology, in general, presents some important concerns as it is an interdisciplinary field with multiple applications and the risk of overlapping patents claim exist. Further, distinction between nano-based patents and traditional patents are not well distinguished. There is a need to understand different regulations and various fields of nanotechnology applications. We have described here some important regulations related to nanotechnology with context to few countries where nanotechnology research is promising. Different application of nanotechnology in agriculture sector is highlighted and risk factor associated with regulatory and environmental risk factor is discussed.

1.2 Intellectual Property Rights Related to Nanotechnology

In the international scenario, nanotechnology inventions are generally protected by patents where other intellectual property rights such as trade secrets might also be applicable (Foster 2007). Some of the international bodies looking into nanotechnology aspects at international forum are discussed here.

1.2.1 United Nations

The United Nations is one of the global governing bodies, and various organizations established under the roof of the United Nations are helping to regulate nanotechnology innovations around the world include:

World Intellectual Property Organization (WIPO): WIPO, established in 1967, is a self-funding agency of the United Nations which acts as a global forum for intellectual property services, policy, information and cooperation. At present, the World Intellectual Property Organization, with headquarters at Geneva, Switzerland, has 188 states as its members. In the milieu of protection of intellectual property rights for new and emerging technologies, the standing committee on the Law of Patents of the World Intellectual Property Organization (SCP 2009) found that the patent system has to constantly conform to the question as to whether a new technological innovation falls within the existing definition of "invention" in the existing patent law. However, it emphasizes the importance of the public welfare perspective. It also states that the regime of intellectual property rights needs to be carefully evaluated to bring an innovation either under laws governing intellectual property rights by creating a new legal mechanism to protect it or alter the existing patent laws to accommodate it. The World Intellectual Property Organization does not grant patents but facilitates international patent protection under the Patent Cooperation Treaty system and complements intellectual property services at the national and/or regional level. An applicant who files a patent application under this treaty can seek protection for an invention in 148 countries throughout the world. The role of the Patent Cooperation Treaty also stretches to help Patent Offices in granting patents and making the wealth of technical information accessible to the public (Havas 2014).

In order to make prior art in various fields accessible, the World Intellectual Property Organization divided the different categories of inventions into different classes. As for nanotechnology, it was tagged as Class B82. This class is further sub divided into (Arnold and Keserü 2013)

1. B82B – Nanostructures formed by manipulation of individual atoms, molecules, or limited collections of atoms or molecules as discrete units; manufacture or treatment thereof.
2. B82Y – Specific uses or applications of nano-structures; measurements or analysis of nano-structures, manufacture or treatment of nano-structures.

Food and Agriculture Organization (FAO): The Food and Agriculture Organization of the United Nations in its expert meeting during 2009 stated that a tiered approach for prioritization of the classes or types of material to be used for an invention in nanotechnology which may help in risk assessment strategies. For this, additional data needed to be generated which would reduce the uncertainties in risk assessment. The need to develop validated testing methods was stressed to address specific data gaps. In 2013, the Food and Agriculture Organization and the World Health Organization published a report, analyzed and summarized the scientific information on nanotechnology and postulated the possible courses of action to be followed by the Food and Agriculture Organization (FAO), the World Health Organization (WHO) and other organizations in this matter (FAO/WHO 2013).

Working Party on manufactured Nanomaterials (WPN): The Organization for Economic Co-operation and Development (OECD) established a working party on manufactured nanotechnology in 2006 under the Committee of Scientific and Technological Policy (CSTP), which works on international co-operation in health-related and environmental safety-related aspects of manufactured nanomaterials (Raimond 2008). According to a Directorate report of the Organization for Economic Co-operation and Development (2007) the three key nanotechnology patent powerhouses were the United States Patent and Trademark Office (USPTO), the European Patent Office (EPO) and the Japan Patent Office (JPO). The report also stated that on the basis of patent applications analyzed between 1978 and 2005, about 33 % of the patent applications were from the United States, followed by Japan and the European Union (EU). The Organization for Economic Co-operation and Development, at present, offers testing guidelines which are globally accepted for hazard recognition and characterization of food chemicals, pesticides, veterinary drugs and other substances to which humans are exposed (FAO 1995).

1.2.2 United States

In the United States nanopesticides are regulated by the Environmental Protection Agency, identifiable in its website since July 2011, which seeks public comment regarding those products regulation and incorporation into their existing Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for registration of new pesticide products (Kah and Hofman 2014).

An expert consultation on agri-nanotechnology under the patronage of the World Health Organization and Food and Agriculture Organization suggested a “tiered approach” to risk assessments concerned with engineered nanotechnology materials. In such a tiered approach, priorities could be set based on scientific literature to the product which has risks to public, worker and/or the environment health. Risk assessments could be performed after obtaining product data, leaving low-risk applications further down the priority list. Under the current regulations, companies have the discretion to determine as to whether a nano-scale product, whose macro form is already considered to be safe by the company, may be regarded to be safe in nano form and whether needs to be reported to the Food and Drug Administration or not. However, due to exponentially larger surface-to-mass ratio of the engineered nanotechnology materials which may have different properties as compared to their macro-versions and the determination of acceptable daily intakes would become impossible if companies do not submit data to the regulators for their independent assessment (Suppan 2011). It is critical that there is neither an official nor an unofficial entry of the nano-materials used in consumer or industrial products or industrial processes. Therefore, it is highly necessary that a registry to be formulated which would be an initial step in establishing eventual nanotechnology regulations.

In 2013, the United States Food and Drug Administration (FDA) released a nanotechnology regulatory science research plan which would regulate nanotechnology innovations in an appropriate and balanced manner and at the same time to ensure transparency and enable responsible development of products with new and beneficial properties. The Food and Drug Administration's regulatory approach would have the following attributes (National Science and Technology Council 2014):

1. FDA shall maintain its product-focused, science-based regulatory policy.
2. FDA's approach would respect variations in legal standards for different product-classes.
3. Where pre-market review authority existed, attention to nanomaterials would be incorporated into standing procedures.
4. Where statutory authority did not provide for premarket review, consultation would be encouraged to reduce the risk of unintended harm to human or animal health.
5. FDA would continue constant post-market monitoring.
6. Industry would remain responsible for ensuring that its products met all applicable legal requirements, including safety standards.
7. FDA would collaborate, as appropriate, with domestic and international counterparts on regulatory policy issues.
8. Both for products that are not subject to premarket review and those that were; FDA would offer technical advice and guidance, as needed, to help industry meet its regulatory and statutory obligations.

Since long, the United States has been the leader of nanotechnology (Smith 2013). However, searching for previous patents related to nanotechnology is a tedious job as it is an interdisciplinary field. An additional difficulty in such searches is that all nanotechnology-related inventions may not necessarily contain the word "nano" in its article. In order to overcome such problems, the United States Patent and Trademark Office in October, 2004 established an index to the United States Patent Classification System for Nanotechnology called "Class 977". This would serve as a cross-reference to help examiners and the public to search prior art including issued United States patents and published patent applications (Paradise 2012). The United States Patent and Trademark Office defined certain guidelines (mentioned below) under which nanotechnology innovations must fall to be considered under Class 977 (Shand and Wetter 2007):

1. They must associate with research and technological innovation in a length scale of 1–100 nm in at least one dimension.
2. They must provide a basic idea of the properties of the materials in the nanoscale to create and use structures, devices, and systems that have size-dependent unique characteristics and functions.

Class 977 includes many subclasses (Bhattacharya et al 2012; Kisluik 2010), under which patents were obtained (Fig. 1.2). Apart from Class 977 other important codes

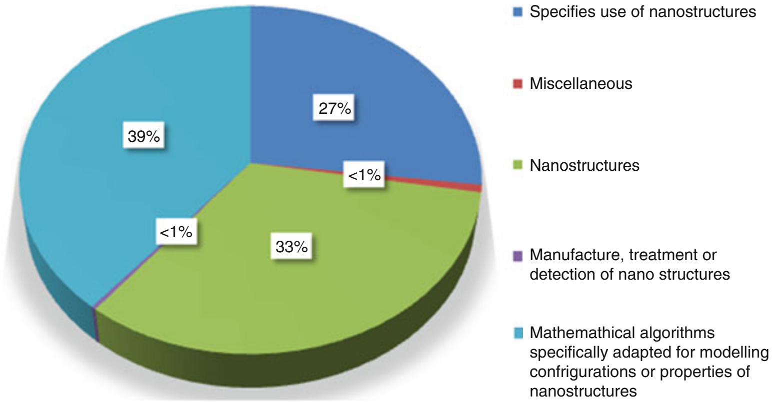

Fig. 1.2 Diagrammatic representation of the percentage of nanotechnology patents obtained by the various sub-classes of Class 977 as of July 2010

are title 35 of the United States Code section 102 which bars the patenting of inventions if those are not novel and can be anticipated by prior art and the title 35 United States Code section 103 which bars patenting obvious inventions (Schauwecker 2011).

1.2.3 European Union

In the European Union nanoparticles are regulated under Registration, Evaluation, Authorization and restriction of Chemicals which in short form is known as REACH. Under REACH, a registrant needs to upgrade his registration for a substance which is already registered in its macro-form but introduced into the market in the nano-form. However, it must fulfilled the following conditions - changes in composition, quantities, uses and safety report to enable appropriate risk management are labeled properly. Evaluation can then be carried out by Member States of REACH and the European Chemicals agency which ask for additional data for the same (European Commission 2011). European Union has also specific regulations dedicated to plant protection products and fertilizers (Bucheli 2014).

The European Commission implemented the communication on the Second Regulatory Review on Nanomaterials in October 2012 (Zornoza 2012) which evaluated the adequacy and execution of European Union legislation for nanomaterials and listed the Commission's proceedings in the field of nanomaterials. Further, the related Staff Working Document (Bergesion and Cole 2015) gave an overview of different nanomaterials in the market and their hazardous properties, along with background information on the definition.

On 13th December 2014, a regulation was applied under the head Article 18 of Regulation (European Union) No. 1169/2011 stating that "All ingredients present in the form of engineered nanomaterials shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word 'nano' in brackets" (Regulation (EU) 1169/2011). According to article 2 (2) (t) Regulation (European Union) 1169/2011 (Meulen et al 2014):

> "Engineered nanomaterial" means any intentionally produced material that has one or more dimensions of the order of 100 nm or less or that is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic of the nanoscale.

The European Commission provides instructions to the European Food Safety Authority (ESPA), the European Union's risk assessment body for food and feed safety, to provide scientific outputs as technical risk assessment guidelines, scientific opinions on specific products and technical and scientific assistance to the European Commission (EFSA Scientific Committee 2009; EFSA Scientific Committee 2011). Till date, the European Food Safety Authority has already published two scientific opinions on potential risk and risk assessment principles for nanotechnology entering the food and feed chain.

The European Food Safety Authority's major conclusions incorporated that significant level of vagueness and uncertainty persists regarding the characteristics of nanomaterials and involved potential risks which arise in difficulties to recommend any specific and suitable risk assessment strategy for the same. According to the food information to consumers, all ingredients present in the form of engineered nanomaterials must be properly labeled. However, unlike biocides, no labeling is required for nanomaterials in pesticides (Rauscher 2014).

In 2011, the European Food Safety Authority stated that the risk of an engineered nanomaterial in the food and feed category will be determined by its chemical composition, physicochemical properties, interactions with tissues and potential exposure levels but there are currently uncertainties related to the identification, characterization and detection of engineered nanomaterial due to lack of suitable and validated test methods.

The European Union, very similar to the United States Patent and Trademark Office, faced the problems of retrieving nanotechnology-related prior art. In order to solve this problem, the European Patent Office created a new classification for the nano-based inventions, called Y01N. This class was further sub-divided into subclasses as Y01N2 (nanobiotechnology or nano-medicine), Y01N4 (nanotechnology for information processing, storage and transmission), Y01N6 (nanotechnology for materials and surface science), Y01N8 (nanotechnology for interacting, sensing and actuating), Y01N10 (nanotechnology for optics) and Y01N12 fornanomagnetics (McLennan and Rimmer 2012). At the European Patent Office, there are no sectional guidelines for granting a patent. However, novelty and inventiveness are some principles upon which patents are being granted (Escoffier 2006).

1.2.4 India

India is among the fastest growing economies in the world but still lagging behind in research on nanotechnology as evident from the number of patents filed. India is fast adapting to the new trend of nanotechnology and started its nano-mission in 2001 with the project Nano-Science and Technology Initiative by the Department of Science and Technology (DST) which was extended till 2006. Under this project, 19 Centres of excellence were established across the country for research, development and applications of nanotechnology which was followed by the Nano-Science and Technology Mission started by the Department of Science Technology in the year 2007 with a budget of Rs 1000 crores. This mission aimed to provide facilities to scientists, institutions and the industry for promoting basic research. It also helped in developing adequate manpower, international collaborations, developing infrastructure and producing useful products. This mission resulted in about 5000 research articles and useful products like pesticide removal technology from drinking water, nano hydrogel based eye drops, water filters for arsenic and fluoride removal and nano silver based anti-microbial textile coating (Jaiswal 2014). The Union Cabinet gave its clearance on 20th Feb 2014 for the continuation of the Nano-Science and Technology Mission to its second phase in the 12th plan period after success in the first phase where India's place improved by one position in the global listing. For this purpose the Government allocated a grant of Rs 650 crores to the Department of Science and Technology (Kumar 2014; Ali and Sinha 2014).

Discussions on nanotechnology regulations concern on intellectual property rights and risk regulation. Analysis of the regime of intellectual property rights revealed that the requirements of Trade-Related Aspects of Intellectual Property rights (TRIPS) agreement is that all member states of the World Trade Organization (WTO) should adopt minimum standards of intellectual property and allow patents in all fields of technology [Article 27 (1) of TRIPS which provides that patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application]. This means that all World Trade Organization members are supposed to provide intellectual property rights in the field of nanotechnology (TERI 2009).

In India, according to Section 2(1)(j) of the Patents (Amendment) Act 2005, an invention is 'a new product or process involving an inventive step and capable of industrial application'. Also, as stated by Section 2 j (a), an 'inventive step' is one which helps to achieve technical advancement and/or having economic importance or both. Additionally, it should also be 'non-obvious' to even a person skilled in the art. However, Section 3(d) adds to the stringency of the patentability of an invention (Chowdhury et al. 2014). According to this section, granting of patents is barred to a derivative form of an already known substance; unless the derivative has exceptionally improved efficacy. It also states that mere discovery of a new property or new use of an already known substance is prohibited. On the other hand, the post-grant opposition clause in Section 25(2) of the Indian patent legislation (2005)

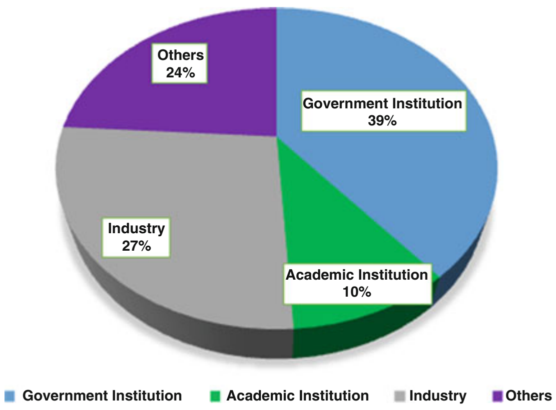

Fig. 1.3 Diagrammatic representation of the percentage of nanotechnology patents attained by various organizations in India till 2007

allows third parties to challenge the validity of a patent after it has been issued. Lack of novelty or non-obviousness, if proven, may lead to amendment or even withdrawal of the patent by the Patent Office. Section 10 of the Patents Act requires detailed information on the invention on the best method of performing the invention known to the applicant to be furnished at the time of application, for claim protection. Insufficient disclosure, if not, can be a valid ground for pre-grant opposition as per Section 25(1)(g) or per Section 25(2)(g) for post-grant opposition (Barpujari 2010).

Regulation is an important part of a technology to be successful but presently there is no strict regulatory framework for nanotechnology in India. It is imperative to devise a regulatory framework which can look into the pros and cons of a particular invention, study public perspective and identify the associated ethical issues. Nanotechnology research community in India is small and limited to a handful of premier institutes (Fig. 1.3) like laboratories of the Council of Scientific and Industrial Research (CSIR), Defense Research and Development Organization (DRDO), Indian Institute of Science (IISc) and Indian Institutes of Technology (IIT). Therefore, it is essential to escalate institutional capacity in order for nanotechnology to blossom in India.

1.3 Nanotechnology Applications

Advances in science and technology can provide potential solution for improvement in the current production system by increasing the resource efficiently (Ditta 2012). This is where various nanotechnology applications (Table 1.1) can play a myriad of roles for improving agricultural output. The nanotechnology application in agricultural sector offers advantage as compared to conventional practices (Aouada and de Moura 2015). Some of the applications of nanotechnology in the agriculture sector have been discussed below.

1.3.1 Nanopesticide and Nanofertilizer

The most common application of nanoscience in agriculture is the application of fertilizers and pesticides to crops using nanodevices (Perez-de-Luque and Hermosín 2013). The use of nanoparticles as carriers of fertilizers and pesticides in agriculture increase the effectiveness of the active materials and reduce their volatilization. It also decrease the contamination of underground water resources (Aouada and de Moura 2015; Perez-de-Luque and Hermosín 2013). One of the major advantages of nanoparticles is the gradual and controlled release of agrochemicals. The controlled release systems allow controlled delivery of active ingredients for a desired period in the vicinity of the roots or the vegetative parts (Aouada and de Moura 2015). Nanotechnology products like nanocapsules, nanoemulsions play an important role in plant protection by acting as smart delivery system of the active ingredients for the control of disease and pest in plants e.g- Neem oil emulsion as larvicidal agent (Parisi et al. 2015).

1.3.2 Soil Improvement

A major application of nanotechnology that co-ordinates with agriculture is the improvement of soil characteristics. The physical and chemical nature of soil largely impacts the efficient growth of the plants. The soil characteristics can be improved by enhancing the water infiltration, aeration, availability of nutrients specially the liquid agrochemical and reducing the shear strength (Bandyopadhyay et al. 2009). Nanotechnology sector has contributed towards the soil improvement by way of producing nanomaterial products like zeolites and nano-clays which help in retention of liquid agrochemicals or water in the soil and allow slow release to the plants (Parisi et al. 2015).

1.3.3 Water Resource Management

Providing access to clean potable water is one of the major global challenges particularly in the developing countries. Water crisis, even in the developed countries, has a tremendous impact not only on health but also on agriculture, manufacture and power industries (OECD 2011). Some of the major water pollutants include microbes, heavy metals, organic chemicals, etc. Moreover, indiscriminate uses of agrochemicals continuously pollute the ground water and shallow water systems (Bhattacharya et al. 2013). The conventional methods of water purification systems are inadequate for the efficient treatment of waste water (Bhati et al. 2015).

Table 1.1 Various nanotechnological application in agricultural sector

Field of application	Products description	References
Nanopesticide and Nanofertilizer	1. Neem oil (Azadirachta indica) nanoemulsion as Larvicidal agent	Anjali et al. (2012), Milani et al. (2012), and Sastry et al. (2009)
	2. Macronutrient Fertilizers Coated with Zinc Oxide	
	3. Pesticides encapsulated in nanoparticles for controlled release	
	4. Ammonia from Buckyballs used as fertilizer	
Soil improvement	Soil-enhancer product, based on a nano clay component, for water retention and release	http://www.geohumas.com/us/products.html
Water resource management	1. Filters coated with TiO2 nanoparticles for the photocatalytic degradation of agrochemicals in contaminated waters	Mc Murray et al. (2006) and Bhati et al. 2015
	2. Carbon nanotube filters for toxin removal	
	3. Gold nanoparticles for pathogen detection	
	4. Nanoparticle for toxic metal detection and removal	
Crop improvement	1. Mesoporus silica nanoparticles transporting DNA to transform plant cells	Torney et al. (2007) and Shrivastava and Dash (2009)
	2. Development of a purple coloured rice variety 'Khao Kam' through the drilling of a nano sized hole in the cell wall and membrane of rice cell to insert a nitrogen atom	
	3. Transfection reagents	
	4. DNA loaded supported gold nanoparticles, process for the preparation and use thereof	
Food industry	1. Airtight plastic packaging with silicate nanoparticles	Sastry et al. (2009) and Momin et al. (2013)
	2. Nanoemulsion based ice cream	
	3. Frying oil extender (Oil Fresh) uses nanoproducts to keep frying oil fresh for a longer time	
	4. Polymer composites with nanoclay as improved materials for food packaging	
Nanobiosensor	1. Pesticide detection with a liposome-based nano-biosensor	Vamvakaki and Chaniotakis (2007) and Sastry et al. (2009)
	2. Contamination of packaged food	
	3. Pathogen detection	
	4. Nanosensors linked to a GPS tracking unit for real-time monitoring of soil conditions and crop growth	

Nanoscopic materials such as carbon nanotubes, nanofibres or sponges are used as nanofilters for water purification. For the removal of heavy metals like arsenic, magnetic nanofibres are used for nano-filtration (Bhati et al. 2015; Sekhon 2014).

1.3.4 Crop Improvement

Improvement in the quality of crop plants through conventional breeding approach has been a continuous phenomenon for a long time. The application of genetic engineering to generate transgenic lines is considered to be invaluable in plant genetic research. Nanotechnology also promotes gene transfer by having certain advantages such as small size of nanoparticles, stable integration of gene in the host genome, rapid expression of the transgene, not subjected to microbial attack, easily synthesizable and less toxic. The commonly used nanoparticles as vectors for gene transfer include calcium phosphate, carbon, silica, gold, etc. The nuclear physics laboratory of the Chiang Mai University, Thailand, has developed a new variety of white-grain rice through the application of nanotechnology to modify the traditional purple coloured rice variety (Prassana 2006). Apart from use of nanomaterial as delivery system for genetic modification, the genetically modified plants or microbes can be used for the production of nanomaterials. The agricultural waste products could also be processed to obtain nanomaterials e.g- nanofibres from wheat and soy hulls are used for bio-nanocomposite production (Parisi et al. 2015).

1.3.5 Food Industry

Food industry is a global multi-trillion dollar and multi-technological industry. The application of nanotechnological techniques in the production, processing or packaging of foods are termed as nanofoods (Momin and Joshi 2015). Use of nanoparticles such as micelles, liposomes, nanoemulsions, etc. as well as the development of nanosensors for ensuring food safety has gained tremendous recognition in recent years. The encapsulations of nutraceuticals, flavor enhancers within nanocapsules and nanoparticles that can selectively bind and remove chemicals from food are some of the recently used nanotechnological innovations (Özer et al. 2014). Also fabrication of food grade vitamin E nanoemulsion showed considerable antioxidant and antimicrobial activity (Dasgupta et al. 2015a). Application of nanotechnology has provided great advantages to the food industry and consumers in terms of reduction of preservatives, salts etc. Development of improved tastes and textures through nanoscale processing of foodstuffs and maintaining hygiene during food processing through antibacterial nanocoatings on food preparations are also popular (Özer et al. 2014). Moreover, enzyme assisted synthesis of gold nanoparticles and thermal co-reduction approach for synthesis of silver nanoparticles have been used to bring size variation in nanoparticles (Maddinedi et al. 2015; Dasgupta et al. 2015b). Another major application of nanotechnology is in the food packaging industry where addition of nanoparticles can improve antimicrobial properties etc. Nanoparticles also act as sensors which inform about the quality of the food (Echegoyen 2015; Ranjan et al. 2014; Dasgupta et al. 2015c). Nanobased materials have the ability to considerably enhance the functional properties of packaging materials and improve the shelf life of packaged foods.

1.3.6 Nanobiosensors

A biosensor is a sensing device to screen a particular material by measuring the biological interactions and assessing these interactions into a readable form with the help of electrochemical interpretation. As the name suggests, biosensors are used for detecting a biological specific material such as antibodies, proteins, enzymes, immunological molecules and so on (Malik et al. 2013). Presently, biosensors are applied for the rapid detection of not only body fluids but also food and environmental samples (Thakur et al 2013; Wu et al. 2013). The biosensor technology has shown constant progress in implementing nanotechnology to improve their multidetection capability and sensitivity (Sagadevan and Periasamy 2014). Nanoparticle based biosensors can be easily synthesized without any advanced fabrication processes. Metallic nanoparticles such as gold, silver, platinum, copper etc have been extensively used for their ability to increase an electronic signal. Similarly, magnetic nanoparticles, nanowires, carbon nanomaterials as well as biological nanomaterials have been employed in the synthesis of biosensors (Sagadevan and Periasamy 2014). Environmental monitoring of pollutants present in the atmosphere with help of biosensors is a pre-requisite for the removal of the harmful contaminants from the soil and waste water. Biosensors incorporated with nanomaterials have numerous applications in the real time detection of pesticides, pathogens, toxic materials, odour producing microbes in soil, air, water, etc (Baruah and Dutta 2009). For monitoring plant health and growth condition nano biosensors are being used (Parisi et al. 2015). Nanotechnology has also applications in the dairy industry where it provides thermal insulation and corrosion protection of dairy processing instruments (Baruah and Dutta 2009).

1.4 Agrinanotechnology Regulations in Major Countries

The applications of nanotechnology in the agricultural field are not in the market on a commercial scale as compared to other industrial applications. The inventions of nanotechnology remain confined to academic sector or patent ownership of large companies but fail to capture the market. This is due to the fact that presently huge capital investment is required for nanotechnological inventions which are not cost effective because of regulatory issues and low public acceptance (Parisi et al. 2015). As nanotechnology finds application in various sectors, different regulations are involved in assessing the safety of the nanoproducts. Over the past decade, there has been a rise on the commercialization of nanoscale products. This has led to a change in the regulatory regimes for the efficient application of nanotechnology in agriculture. Adapting to safe manufacturing practices, product testing and assessing potential environmental risks hazard plays a crucial role in enabling the acceptance of nanotechnology in the market (Watson et al. 2011). Different countries impose different regulations on the production and marketing of nano-based products. Here, we have discussed the regulations of few major countries engaged in nanotechnology research.

1.4.1 The United States

US agencies such as the United States Department of Agriculture (USDA), Environment Protection Agency (EPA), Food and Drug Administration, Consumer Product Safety Commission and the cabinet level National Science and Technology Council confers regulations on various aspects of agronanotechnology. The US food and drug administration's nanotechnology task force 33 reported in 2007 that no further legislations are required for the nanomaterials. The Toxic Substances Control Act formed by the California Department of Toxic Substances Control has made it mandatory for the manufacturers to provide information on nanomaterials present in specific chemicals (Watson et al. 2011; Soliman 2012). The National Institute of Food and Agriculture created under the United States Department of Agriculture, manages several nanotechnology grant programs. Environmental Protection Agency under the authority of Fedral Insecticide, Fungicide and Rodenticide Act, registers pesticides and approves nanoscale versions of even conventional substances as newly registered. The Food and Drug Administration under the authorization of the Federal Food, Drug and Cosmetic Act approves food additives, food packaging, processed foods and dietary supplements. Nanoscale materials used as food additives in the processing or packaging of foods require approval from the Food and Drug Administration as safe to be marketed. But items which are "Generally recognized as safe" or are below the threshold of regulation are exempted from the regulatory approval of Food and Drug Administration. On the other hand, certain items such as food products do not have pre-market approval and which impends; Food and Drug Administration and other public to depend on the manufacturers for their safety consent (Watson et al. 2011).

1.4.2 The European Union

European Union regulations on agronanotechnology comprise of several horizontal and vertical legislations. The Food Law Regulation (European Commission) 178/2002 establishes principles and obligations comprising all the stages of food/feed production and distribution. This helps in assessing and managing the risks associated with the use of nanomaterials in food. The Registration, Evaluation, Authorisation and restriction of Chemicals is a horizontal legislation which encompasses both bulk and nanosized materials which needs to be registered at the European Chemical Agency provided they are manufactured or imported in more than one ton per year and are not subjected to other exclusions. Regulation (European Commision) 258/97 is a vertical legislation on the Novel foods and Novel Food ingredients. This regulation makes the pre-market approval of nanoenabled foods mandatory and considers re-evaluation of any nanoscale additives for safety purpose. Directive 91/414/EEC is another vertical legislation regulating the evaluation, marketing and use of pesticides. This legislation is complemented with the Regulation (European Commission) 1107/2009 which follows strict criteria in the approval of substances to be used as pesticides (Watson et al. 2011).

1.4.3 India

The Bureau of Indian Standards lays down the standards for nanotechnology usage with safety standards. The Bureau of Indian Standards follows the guidelines and recommendations of The International Organisation of Standardisation which has developed 42 standards for nanotechnology. The Health and Safety standards mainly deal with the characterization of nanomaterials like gold, silver, zinc oxide, etc. which are used for making water filters in India. The Material Safety Data Sheet for nanomaterials provides information such as physical nature, toxicity, reactivity, health effects, etc. which are considered by The Bureau of Indian Standards for developing Indian standards for nanotechnology in water sector. In the event of an industry which manufactures nanoparticles and discharges its waste into water bodies, the Central Pollution Control Board (an apex body of the Ministry of Environment & Forests) has the authority to inspect the industry, obtain their records and report on the nature of the nanoparticles discharged (Bhati et al. 2015).

1.5 Environmental Implications and Management

Nanotechnology is an evolving technique that has transformed the scenario of global industry but certain risks are associated with the environment and human health. Its regulation and mitigation are also not very clear. The guidelines for the application of nanotechnology are introduced at the regional and national level but there is a need to focus on it at the international platform (Falkner and Jaspers 2012). The main problem for the decision and policy makers is the vagueness associated with the risks of nanotechnology which limits the development of international synchronization.

Nanomaterials can be formed either by natural or synthetic processes. Nanoparticles are said to have many commercial benefits but some are toxic in nature. The physico-chemical nature of nanomaterials can have huge impact on the fate of environment. Insufficient knowledge of nanomaterial toxicity and risks may hinder the pace of industrial application of nano-enabled technologies. Therefore, the potential activities of these materials must be studied comprehensively. In the absence of definitive data, nanomaterial research and regulations could be supported by an efficient characterization of factors leading to toxicity and risks (Linkov et al. 2009a). Studies clustered the nanomaterials into ordered risk categories using Multi-Criteria Decision Analysis by taking into account the variables associated with the toxicity and risk of nanoparticles. However, their research finding does not quantify the environmental risks but attempts were made for recommendations on precise measurements of nanoparticles (Linkov et al. 2009b).

Although nanotechnology offers significant benefits to mankind but have detrimental health effects too. Due to the small size, the nanoparticles can disperse into anatomical barriers to reach the liver, lungs, kidneys, etc. and damage the cells which can cause lesions, granulomas, cancers, Parkinson's disease, Alzheimer's disease, etc. (Chaudhry et al. 2008; Miller and Senjen 2008; Chau et al. 2007; Oberdorster et al. 2005). As a consequence, there is a potential threat to the millions of people working in vast expanses of agricultural lands due to the use of nano fertilizers and pesticides which can enter into the food chain (Rico et al. 2011). Nanomaterials in foods are detrimental for human consumption because these are chemically more reactive and have greater access to our bodies than larger particles which can even compromise with our immune response, impairment of DNA replication and transcription resulting in long term pathological effects (Hoet et al. 2004; Miller and Senjen 2008; Chaudhry et al. 2008; Chaudhry and Castle 2011; Momin et al. 2013).

Detailed understanding of the biological mechanism of nanoparticles is required before application in the field. This will enable the formulation of regulatory rules and help in risk management. Prior to use of products containing nanoparticles in the agricultural sector, a scrupulous analysis is needed for the distribution and amount of particles absorbed by the plants in the food chain. The evolution of a participatory, dynamic and responsive nanotechnology policy is required to develop coordinated risk management strategy in Indian agriculture and food system for the positive economic impacts of this technology to reach the agrarian society (Sastry et al. 2010; Sastry and Rao 2013).

There should be vigorous training of the personals involved in nano agricultural sector. The use of Personal Protective Equipment should be stringent for the workers associated with nanomaterials. Till date, researchers have been trained to cater to the needs of the industry but should be skilled enough to carry out new research experiments, analyse and interpret the results and simultaneously be able to incorporate and implement the theory, tools, and techniques of nanotechnology. There should also be strict rules for the nanotechnology industry to adhere to the engineering controls for effective risk management.

Many countries have recommended various precautionary measures to manage the risk associated with nanoparticles. The Health and Environment Alliance, Belgium recommends a list of measures to manage the risks associated with nanomaterials and stop the commercial sale until appropriate measures are taken. There is a need of a comprehensive policy by uniform international body to alleviate the risk involved with nanotechnology applications.

1.6 Limitation of nanotechnology for Intellectual Property Rights protection

Nanotechnology related inventions are upsurging across all Research & Development and industry sectors. Millions of patents on nanotechnology can be retrieved in the world wide database. For searching prior art on nanotechnology, the patent offices worldwide has classified nanotechnology under the International Patent Classification (WPN 2015). The United States Patent and Trademark Office received around 618330 patent applications in the fiscal year 2014, with a sum total of 24,090 patents related to nanotechnology granted in 2014, which is a growth of more than 12.68 % in the number of nanotechnology patents in comparison to 2013 (USPTO 2014). To grip on the number of patents and scrutinize a nano-invention poses serious concerns among the patent grantees to review that the new patent has additional utility as well as novelty over earlier inventions. Simply submitting a smaller version of a known structure is not patentable. While nanotechnology opens opportunities for new inventions and discoveries, new challenges are confronted at the patent office as the grantees may lack expertise or adequate domain knowledge to assess nanotechnology patent applications leading to disregard the previous inventions (Paradise 2012). The recent increase of patent applications by universities and private sectors are also another potential challenge for IPR protection for rewarding innovations with patent grant (Heller and Eisenberg 1998). The patent owners can exercise their right to exclude others to undergo research work on its invention, which can seriously restrict future research on nano-inventions. Premature disclosure of trade secrets by pressure from the academic circles to publish or report in government funding projects can reduce the ability to secure patents. Shortcuts in drafting a provisional application also increases the possibility of falling short of minimum disclosure requirements causing limitations in scope of claims that can be supported by the final specification (Tullis 2012). The recent euphoria for patenting and the inability of patent offices to handle a large number of patent applications has resulted in the rejection of valid claims (Miller et al. 2004). Commercialization of nanotechnology in the agri-food sector requires a thorough assessment of toxicity and safety concerns before hitting the market (Sastry et al. 2011). A large number of patents have been filed in the area of nano food (eg. nanoemulsions of vitamins, flavours and colorants) and in agricultural system for the delivery of agricultural chemicals and targeted drug delivery (Srinivas et al. 2010; Ehr et al. 2011). Measures should be taken to assess those success patent claims in the field trial before granting patent rights. Regulatory rules to be formulated and thorough investigation is required before these innovations could be transformed into commercialization.

Patent protection is effective only within the issuing country. Thus increased administrative effort is required for securing international patents. Strong patent protection may spur research and invention but also lead to a patent thicket. Though a patent is granted to a nanotechnological invention but becomes invalid due to the operation of a previously granted patent for a similar type of invention leading to expensive litigation. Innovators lacking the resources to litigate patent validity may be forced to license these patents rather than contest them (Barpujari 2010). Delay in commercialization of nanotechnology products will give rise to problems such as unintentional infringement of patents, creating business uncertainty and concerns over patents with some nanotechnology inventions, ending up in courts rather than by the patent office (Clarkson and DeKorte 2006). The nanotechnology IPR landscape is still somewhat chaotic and limitations can be observed when most of the patents do not result in active commercialization.

1.7 Intellectual Property Rights Regulations for Nanoagritechnology

There is no doubt that nanotechnology is the next revolution "in standing" to flourish the agriculture sector. Although patents were granted to nanotechnological applications and processes but more cohesive and clearer policy between different countries is necessary. Nanaotechnology is a multidisciplinary field with application in diverse arena. Therefore, patent granters and examiners need to be trained both in international, national and regional level about its multidimensional aspect. WIPO can play a pivotal role by networking collaboration between different agencies like WHO, World Trade Organization (WTO) where each having distinct, but complementary mandates to work on issues relating to nanotechnology patent issues, public health aspect and trade policy respectively. Most of the developed countries have included the "nanotechnology" term in their existing patent classification system and assigned a separate class. But developing countries like India are yet to assign a separate class and lacking peer policies on nanotechnology. This can be revamped in line of Drug and Cosmetic Amendment Bill 2015, where the word "Drug, Medical technology, Clinical trials" etc. are included and regulations are clearly mentioned.

Another way of promoting nanotechnology research and smoothening patent grants is "stronger public-private partnership". One way to achieve this is cohesive licensing model where incentive to research and development driven companies may be given to promote nanotechnology products. It will help to control price in future which is one of the major hurdle in other fields like drug industry. Continuous discussions are being made in different platforms and policies are being amended but concentrating solely on intellectual property rights will not help for success stories. Different international and national regulatory agencies on social, health and economics should come under same platform to help on policies formulation for promoting innovation on nanotechnology. Countries should increase their gross domestic product investment in nanotechnology research to promote innovation especially in agriculture sector, where nanotechnology holds a potential for "Agriculture Revolution".

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