

REPORT

Safety and Benefits of Nanotechnology

**Agriculture, Water Safety,
Food & Food Safety,
Nutrition, Packaging**



International Life Sciences Institute India

About ILSI India

International Life Sciences Institute India

www.ilsa-india.org

ILSI India is an entity of the International Life Sciences Institute (ILSI), headquartered in Washington DC. ILSI India provides scientific inputs and secretariat assistance to the South Asian Region, which includes Bangladesh, Bhutan, India, Maldives, Nepal, Pakistan and Sri Lanka.

ILSI India activities primarily focus on local and regional issues and involve leading national and international experts in the deliberations. ILSI India is the leader in the region in focusing attention and devoting resources on critical areas is food and water safety, nutrition, risk assessment, harmonization of food regulations, improvement in the health profile of malnourished children and women, and agriculture sustainability including biotechnology and new plant breeding technologies. The overall objective is improving public health. Special attention is given to the food fortification. All activities follow Principles of Scientific Integrity which are part of ILSI Mandatory Policies.

ILSI India carries out its mission through sponsoring workshops, symposia, conferences, seminars, training programs, research projects, and publications.

ILSI India works closely with government, industry, research institutions, academia, and international organizations. ILSI India's Board of Trustees is comprised of individuals from industry, academia, government and research organizations who bring a range of expertise, experience, and perspective to their work defining and achieving ILSI India's goals. These individuals are unpaid volunteers who take their scientific and fiduciary responsibilities to the organization seriously. They serve on ILSI India's Board of Trustees as individuals and do not represent their employers. Country Committees have been established in the South Asian Region for management of country programs.

Founded in 1978, ILSI is a non-profit, worldwide organization whose mission is to provide science that improves human health and well-being and safeguards the environment. ILSI entities design programs to foster multi-sector collaboration conducting, summarizing, and disseminating science related to the world's most pressing health issues. ILSI strategy encourages global action on identifying and then resolving outstanding scientific questions in four thematic areas that capture the core of ILSI's work:

- **Food Safety**
- **Risk Science and Toxicology**
- **Nutrition and Health**
- **Sustainable Agriculture and Nutrition Security**

These focus areas provide structure for responding to and raising awareness of the pressing issues society faces. They also help elucidate new opportunities for driving scientific progress. ***ILSI's work is guided by its Code of Ethics, Scientific Integrity and Organizational Standards of Conduct.***

ILSI accomplishes this work through its worldwide network of ILSI Entities. ILSI's scientific publications are duly recognized all over the world. They include the journal Nutrition Reviews and the book Present Knowledge in Nutrition. Please visit www.ilsa.org for more information on ILSI and its network.

REPORT

Safety and Benefits of Nanotechnology

**Agriculture, Water Safety,
Food & Food Safety,
Nutrition, Packaging**



International Life Sciences Institute India

Introduction

ILSI India organized a symposium on “Safety and Benefits of Nanotechnology” on July 26, 2021, in Virtual mode. The symposium was chaired by Prof. P K Seth, Chairman, ILSI India. The symposium was organized against the fact that nanotechnology has been gaining an increasing degree of interest because of its inherent physicochemical properties. In the agriculture and food industry context, the overuse of agrochemicals and post-harvest losses are two major pressing issues that need immediate interventions due to their immense environmental and economic consequences. Moreover, nanomaterials safety and usability concerns have been affecting public acceptance and thereby global outreach of nanotechnological solutions.

The key objectives of organizing the symposium were to:

- Discuss different nano-based platforms for agrochemical's sustainable and ecologically safe delivery systems
- Examine different nanomaterial solutions for detection of nutritional parameters, diseases, contamination status of water bodies as well as strategies for decontamination of water to ensure a clean water supply.
- Discuss the measurement of nanomaterial toxicity and governing strategies. Also, discuss the need for strict governing principles and long-term exploration of toxicity studies.
- Discuss the need for effective information sharing of nanotechnological advances and solutions for greater public acceptance as well as significance of research in developing governing policies.

The symposium was chaired by Prof. P. K. Seth, Chairman, ILSI India. Around 400 participants registered from India and other Asian Countries representing Government, Research Institutes, Academic Institutions, International Organizations, Regulatory Authorities and Industry. Symposium abstracts, speaker's CV, presentations and recording are available on ILSI India website: www.ils-i-india.org.

Index

• Key Findings.....	4
• Section One- Opening Session.....	5-6
○ Welcome Address.....	5
Ms. Rekha Sinha, Executive Director, ILSI India	
○ Opening Address.....	6
Prof. P.K. Seth, Chairman, ILSI India	
• Section Two- Technical Session.....	7-14
○ 2.1-Nanotechnology Applications in Agriculture and Food Science	
Dr. P Gopinath, Professor, Department of Biosciences and Bioengineering,	
IIT Roorkee.....	7
Dr. H N Mishra, Professor Food Technology, Indian Institute of Technology,	
Kharagpur.....	7
○ 2.2-Nanotechnology for Improving Availability and Quality of Water	
Prof. T Pradeep, Indian Institute of Technology, Madras.....	9
○ 2.3-Risk Governance of Nanomaterials in Food	
Prof. Qasim Chaudhry, University of Chester, UK.....	11
○ 2.4-Safety of Nanomaterials: A Journey from Research to Policy	
Prof. Alok Dhawan, Director, Centre of Bio-Medical Research, Lucknow.....	14
• Section Three- Discussion.....	15
• Section Four- Way forward.....	16
• Acknowledgement.....	IBC

Key Findings

1. Due to its high surface area and enhanced reactivity, nanomaterials can provide several innovative platforms for use in agriculture and food industry.
2. Nanoformulations like nano-pesticides, nano-fertilizers can work as sustainable, efficient, and cost-effective methods with reduced environmental impact. These agrochemicals can be administered as microencapsulated nanospheres, controlled release formulations, or as nanoscale additives/coatings.
3. Post-harvest losses of agricultural produces can also be reduced by developing packaging materials using antimicrobial nanomaterials as coatings.
4. Nutritional quality of food items can be improved and disease detection can be performed rapidly with the help of different nano-sensors. Efficient, point-of-care nano-sensor-based devices are being developed to detect water contaminants (heavy metals, pesticide/fertilizer residues, etc.).
5. Nutritional enrichment and controlled delivery of nutrients by nano-based food items can benefit health and at the same time open up newer avenues for the food industry.
6. Water resources can be decontaminated using different nanomaterials like biopolymer-based filtration systems and novel nanoparticles. Several such water filtration and monitoring units can be globally monitored, and large data can be gathered for efficient forecasting and management.
7. With the increasing applicability of nanotechnology in the agriculture and food processing industry, risk assessment and governing principles need to be carefully evolved keeping in view clear, broad principles.
8. Nanotoxicological studies need to be conducted for the determination of the safety and bio-security of nanomaterials. Cytotoxicity and genotoxicity of the nanomaterials using several tools like Flow cytometer, TEM need to be performed. More long-term studies on the effect of nanomaterials on the environment should be undertaken. Molecular simulations and similar in-silico methods are providing predictive models and algorithms for toxicity determination of the nanomaterials.
9. Public outreach and information dissemination also need to be carried out at large scale for a greater public acceptance. Organizing more public outreach programs like seminars and workshops can help ameliorate the knowledge gap, thereby increasing the general acceptance of nanotechnology in agriculture and food.

Section One

Opening Session

Welcome Address

Ms. Rekha Sinha, Executive Director, ILSI India

ILSI India, an entity of the International Life Sciences Institute (ILSI) with headquarters in Washington DC., provides scientific and financial assistance to the South Asian region. It works on the most pressing health issues in the region, with headquarters in New Delhi. Four thematic areas are mainly addressed by ILSI India: Food Safety, Risk Science and Toxicology, Nutrition, Health and Wellness, Sustainable Agriculture, and Nutrition Security. ILSI India works on a tripartite basis, i.e., with scientists from Government, Academia and Industry. It functions by sponsoring scientific meetings (workshops, conferences, and webinars), sponsoring research, bringing out publications (scientific journals, stand-alone monographs), and organizing training programs. ILSI India has performed exceptional work in the region, including on Food Fortification, Vitamin-D, Nutrient Risk Assessment, and New Plant Breeding Technologies. Recently, a center of excellence in the new scientific area of the Gut microbiome has been set up by ILSI India, called Knowledge Center on Functional Foods, Immunity, and Gut Health (K-FFIG).

Numerous studies have shown that nutrition plays a pivotal role in cognition, IQ, and brain health.

With increased longevity, there is an increased incidence of Alzheimers, Dementia and Parkinsons. To address these as also brain development and cognitive issues, ILSI India has established a New Task Force on Nutrition and Brain Health (NABHI). NABHI is investigating the role of nutrition, physical activity, lifestyle, and gut microbiome in promoting brain health from pediatrics to geriatric. Over the years, ILSI India has sponsored studies/research and training programs on nutrition and food safety, which have led to stakeholders' capacity building and triggered action in improving the population's nutrition status and helped modernize the food control system in the South Asian region. It has also sponsored several activities related to new food technologies. Nanotechnology was first discussed at the 2007 ILSI India Conference on Food Technologies. ILSI Global also had co-sponsored the major program on Nanotechnology in January 2021 called FOODTOX.

At its core, scientific integrity has been an integral part of all ILSI India activities. The 8 Principles of Scientific Integrity has been followed for all the activities, including research and publications.

Opening Address

Prof. P. K. Seth, Chairman, ILSI India

Nanotechnology has been providing innovative and sustainable solutions while addressing critical challenges in almost all fields of study, including agriculture, healthcare, automobile, etc. Overuse of pesticides and fertilizers has resulted in reduced productivity and decline in nutritional values. In such a scenario, nanotechnology provides platforms where minimal fertilizers or pesticides can be applied in the crop production system, thereby decreasing overuse-related toxicity and post-harvest quality management. Moreover, food preservation and packaging materials can also use nanotechnology interventions to enhance the product's shelf life. Several nano-based sensors have also been developed to monitor and manage food production and its nutritional properties.

Furthermore, leaching of fertilizers and pesticide residues have resulted in a drastic reduction in clean drinkable surface and groundwater. Notably, in a developing nation like India, where water supply with the help of pipelines is

challenging, the contamination of groundwater has been a cause of major health-related problems. Further, levels of nanotechnology-based sustainable and novel solutions have provided efficient platforms for reducing the toxic pesticide/fertilizer contaminated groundwater by using efficient nano-based pesticide or fertilizer delivery systems or improved water purification systems. Nanotechnology can be used as flavour enhancer without altering the usual flavor of the product. On the other hand, as the applications are increasing, toxicity parameters of such nano-platforms are also being investigated thoroughly. Guidelines are being laid down and regulatory reforms are also taking place to enhance the safety of nano-based products. Therefore, there is a greater need for discussion on the benefits and safety of nanotechnology addressing the food-related challenges. The topics to be discussed in the symposium would therefore provide critical insights on such issues.

Section Two

Technical Session

Chair: Prof. P K Seth, Chairman, ILSI India

2.1-Nanotechnology Applications in Agriculture and Food Science

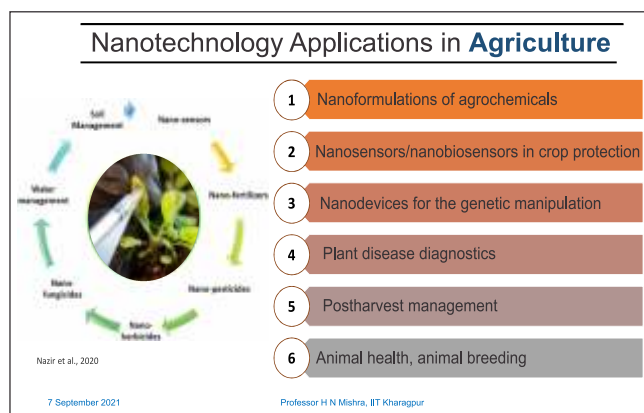
Dr. P Gopinath, Professor, Department of Biosciences and Bioengineering, IIT Roorkee

Dr. H N Mishra, Professor, Food Technology, IIT Kharagpur

With several advantages like high surface area, enhanced reactivity, nanomaterials have provided numerous exciting platforms for several fields of study, including environment, agriculture, energy, biomedical, and food (safety and biosecurity). Different kinds of nanomaterials have been investigated for their application in the context of agriculture and food sciences, including nanotubes, nanoemulsions, biopolymeric nanoparticles, nanocomposites, and

nanofibers. Nanomaterials can be used in agriculture and food production in several different ways.

Nanotechnology deals with the class of materials having at least one of the dimensions in the range of 1-100nm. Nanomaterials possess a higher surface-to-volume ratio as compared to their bulk counterpart. Along with enhanced physio-chemical properties, nanomaterials are more energy-efficient, cheaper, and have easily tunable characteristics. It can be produced using either top-down or bottom-up approaches.



Source: Presentation on "Nanotechnology Applications in Agriculture and Food Science"

Nano-Agrochemicals

Nano-pesticides: Pesticides in the form of nanoformulations can be administered in the following manner-

1. Microencapsulated Nanospheres: Providing advantages like enhanced penetrations and improving efficiency of the pesticide and reducing the dosage and enabling encapsulating in the nanospheres of polymers like PCL (polycaprolactone), PLA (poly(lactic) acid), etc.

2. Controlled Release Formulations: Controlled release of the pesticides, reducing application dosage, and improved efficiency. Absence of residues at the time of harvesting by using biodegradable polymers.

3. Nanoparticles: Smaller nanoparticles and nanoemulsions make them more potent, achieving more significant effects at lower chemical doses.

Nano-Fertilizers

These are fertilizers made of nanoparticle formulations of nanotechnology to improve nutrient efficiency. While conventional fertilizers have less bioavailability and

reduce the soil microbiome, nano-fertilizers improve the bioavailability of the fertilizers with the controlled release of nutrients. They also enhance the crop yield

and enrich the soil microbiome. Therefore, nano-fertilizer provides a better and sustainable alternative with fewer environmental impacts. There are three classes of nano-fertilizers:

1. **Nanoscale Fertilizers:** Nanoparticles that contain nutrients.
2. **Nanoscale additives:** Traditional fertilizers with nanoscale additives.

3. **Nanoscale coatings:** Traditional fertilizers loaded or coated with nanoparticles.

These nano-fertilizers can either be polymeric core-shell nanoformulations or nanofibers containing fertilizer/microbial spore/nutrients.

Nano-sensors in Agriculture

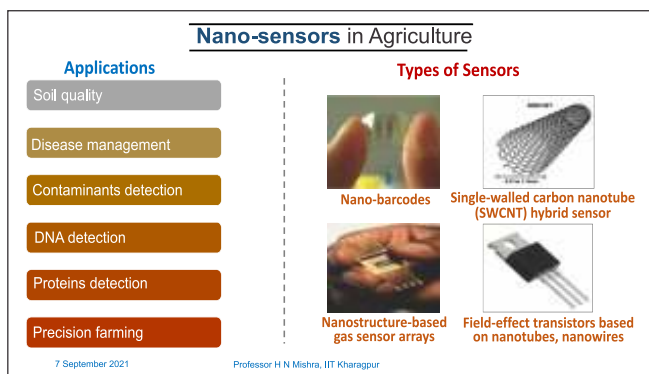
Nano-sensors can be used for the detection of diseases and monitoring nutritional qualities rapidly and easily. As a point of care device, the easily operable nano-

sensors can be used for the detection of different microorganisms, which can cause food spoilage

Nanotechnology in Food Science

Four major target areas are expected to be significantly enhanced by nanotechnology:

1. **Materials with novel functionality**
2. **Micro and nanoscale processing**
3. **Product development**
4. **Methods and instrumentation for food safety and biosecurity**



Source: Presentation on "Nanotechnology Applications in Agriculture and Food Science"

Nanotechnology Applications- Food Processing

Using nano-encapsulation techniques, improvements in the flavor release and retention for optimum delivery and better culinary balance can be achieved. For example, SiO₂ nanomaterials are used as carriers of fragrances or flavors in food products. Nanotechnology can also enhance the nutritional value of the food items in the form of edible coatings, hydrogels, polymeric micelle, etc., for enhancing the shelf-life and reducing respiratory degradation of the food item. Microbial

contamination can also be reduced using functional nano-formulations containing antimicrobial agents. For example, 'self-cleaning' nanocoating with antimicrobial compounds can be used as packaging material to reduce microbial contamination. Moreover, efficient and highly sensitive nano-sensors like immune-sensors, e-nose, or e-tongue can be extremely helpful for examining the quality of food items rapidly.

Nanotechnology- Challenges and Risks

Several challenges which require immediate attention are cost-effectiveness in the near future, significant changes in current food regulations and

legislation, long-term health risks like oxidative damage, carcinogenicity and potential environmental impacts.

2.2 -Nanotechnology for Improving Availability and Quality of Water

Prof. T Pradeep, Indian Institute of Technology, Madras

Access to clean, usable water has been getting increasingly scarce, more so since the industrial and green revolution. The problems of heavy metal toxicity and pesticide and fertilizer residues in water bodies are crucial issues that need tremendous attention to improve the quality of life. Therefore, water has turned out to be the simplest and simultaneously the most complex problem of humanity. To address such issues and provide affordable clean water, nanotechnology has been

providing numerous sustainable and novel solutions, which can be grouped together in a field of study, namely 'Aqua nanotechnology.' The development of several advanced materials related to that domain has resulted in new adsorbents, new sensors, novel catalysts, and novel phenomena. Therefore, it is possible to have clean water by developing sustainable materials affordably or affordable materials sustainably.

Possibility of Nanomaterial Fabrication with Atomic Precision

Significant technological progress has been achieved in Aqua nanotechnology with the engineering advancements in nanomaterials fabrication with atomic precision. Moreover, the capability of characterization of such materials also plays a vital role in developing the field. For example, advanced mass spectrometric determination of ligand attachment with atomic precision has led researchers to understand chemistry at

the nanoscale. There have been numerous other methods also to understand science at the nanoscale. Nano-sensors with atomic sensitivity have also helped tremendously in a similar manner. Therefore, it is now possible to fabricate novel materials which can have industrial applicability to sustainably scale up the application and the fabrication of the materials, with detailed understanding of their science.

Arsenic Removal from Water: Research to Technology

Arsenic (As) affected groundwater areas suffer tremendously to get clean water. Long-term exposure to this heavy metal has been reported to cause cancer and skin ailments. In several regions of India, groundwater contains a much higher content of As from its permissible limit of 10ppb, for example, 60 ppb As content in Nadia district of West Bengal has been found. Several areas of Punjab have been found with increasing levels of arsenic. A novel material has been developed to remove As from the water sources that can remove As in a very short contact time. The novel material, a biopolymer-reinforced synthetic granular nanocomposite, can be loaded in a tube-like filtration device that can remove the As from the water source, reducing the As concentration to ~2 ppb. These nanocomposites are a class of metastable materials, which can remove both As^{3+} and As^{5+} as a result of their surface chemistry, at high adsorption capacities.

Moreover, these materials are also proven to be having very little environmental nanotoxicity.



Source: Presentation on "Nanotechnology for Improving Availability and Quality of Water"

There are several other models for such filters. These solutions are now available at 10 L per day to 1 ML per day. They provide water at a cost of 2.1 paise per litre. Geo-tagging of such treatment plants and real-time monitoring of the water purifiers with the help of efficient sensors can provide big data, which can be

beneficial in solving several other problems related to groundwater management. Such monitoring systems have already been implemented in several regions of Punjab, which are currently providing priceless data related to groundwater quality.

Atmospheric Water Harvesting

Not only in the water treatment industry, nanotechnology has provided several critical technologies for atmospheric water harvesting also. Using an electrospray needle, microscale droplets (300-400nm) can be prepared. These microdroplets can create nanostructures that can collect water from humid air when the temperature goes below the dew point. Using this, VayuJAL Technologies are

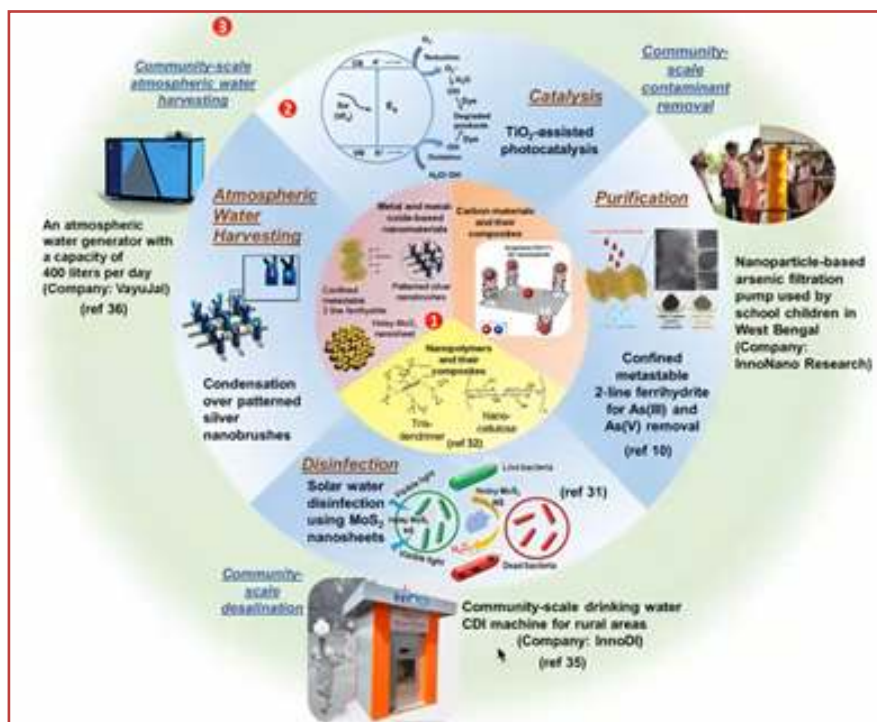
harvesting thousands of liters of atmospheric moisture to provide clean water. It is also possible to create advanced materials like Zr-based metal-organic frameworks, which can absorb humidity in the night time and release humidity at day using sunlight. Another technology called hydrate-based desalination (HyDesal) is known where clean water as well as energy are produced simultaneously.

Antimicrobial Nanomaterials

Another class of advanced materials like MoS₂ sheets with Mo-rich holes can produce hydrogen peroxide upon irradiation of sunlight. The hydrogen peroxide generated can effectively inactivate the microbes without any specific microbe selectivity. Therefore,

broad-spectrum antimicrobial materials can also be prepared using nanotechnology. Using this technology, a column device containing holey MoS₂ can be fabricated to remove water contaminants.

Future Perspective: From Hydroinformatics to Digital Twin of Water Resources



Source: Presentation on “Nanotechnology for Improving Availability and Quality of Water”

Several other exciting technologies can be developed using such advanced nanomaterials.

New sensors are also coming up, which can drastically reduce the cost of measurements and can be used to create numerous point-of-use devices. Information from different sectors, including the water purification industry, computer simulations and VR/AR, can be strategically amalgamated to prepare an extensive

Hydro-informatics system. A Digital Twin of water resources can be designed by using data from all the sources. This digital twin can provide real-time modelling of ground and surface water bodies, water supply networks, and management of several essential data. Thus, it might be concluded that several recent advancements on the technological and industrial fronts have made it possible to achieve an increased supply of clean water to households.

2.3-Risk Governance of Nanomaterials in Food

Prof. Qasim Chaudhry, University of Chester, UK

Like any new technology, risk governance for nanotechnology is comprised of five key factors:

1. Public Perception
2. Regulation
3. Risk Assessment
4. Risk Management
5. Risk Communication

Currently, over 1300 nano-based consumer products are already available in the global market. Among which, the majority belong to cosmetics and personal care products (~60%). However, food and nutritional supplements based on nanotechnological interventions are comparatively nascent, holding ~10% of the consumer products. There are several advantages of using nanotechnology in the agriculture and food industry, such as:

- **Nutrients and functional foods** improved uptake and bioavailability
- **New tastes and flavors** less salt, fat, sugar, etc.

- **Fresh, 'Natural,' wholesome foods** fewer colors, flavors, preservatives.
- **'Smart' and 'Intelligent' packaging** food safety, authenticity, and traceability
- **Hygienic food processing and packaging** less foodborne diseases
- **Lightweight, robust and functional packaging:** less cost of transportation, the safety of foods in the supply chain
- **Extended shelf life of food products:** Less food wastage
- **Efficient food production:** using fewer agrochemicals

Because of these properties, nanotechnological interventions in the agriculture and food industry are expected to rise in the future, thereby increasing the need for more stringent regulatory and risk management systems.

Regulation of Nanomaterial Risks

The EU Regulation of Nanomaterials in Food/Feed

In the EU, the risk of nanomaterials in food/feed and related applications is covered explicitly or implicitly under different regulatory frameworks, for example:

- **Food Additives [Regulation 1333/2008]** requires a risk assessment for new and already authorized additives when there is a "significant change in the production methods or in the starting materials used, or if there is a change in particle size, for

example through nanotechnology". Risk assessment is also required where flavorings and enzymes are obtained from new production processes giving rise to significant changes in the production process.

- **Food Packaging [Regulation (EU) N°10/2011]** on measures for plastic materials and articles: from May 1 2011, lays down that nanomaterials can only be used if listed in its Annex I and explicitly

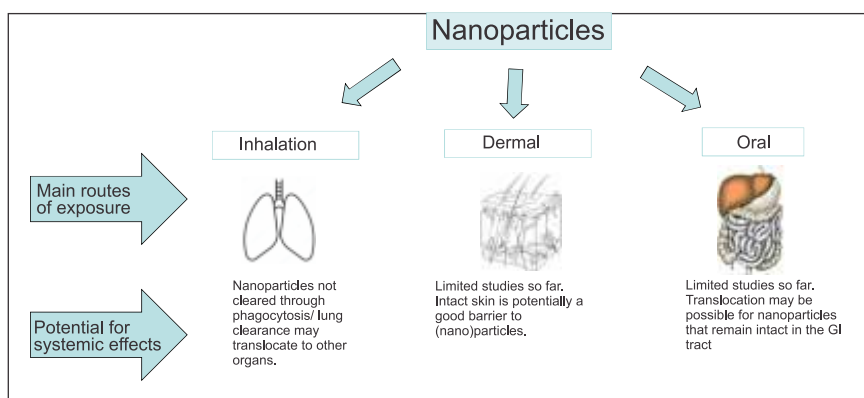
authorized and mentioned in the specifications in Annex I. Also, [Regulation (EC) N°450/2009 for active and intelligent materials and articles]: “substances deliberately engineered to a particle size which exhibits functional physical and chemical properties that significantly differ from those at a larger scale.”

- **Food Information Regulation [(EU) No 1169/2011]** requires labelling for any nanomaterial used in food products.
- **Novel Foods [Regulation (EU) 2015/2283]** requires safety assessment and authorization for any nanomaterial before being used in foodstuffs. The European Food Safety Authority (EFSA) carries out safety assessments of novel foods. The use of nanomaterials in food/feed products is specifically regulated under the **EU Novel Food Regulation (EU) 2015/2283**, which provides a

regulatory definition (provisional – pending alignment with the EU Recommendation 2011); requires risk assessment and novel food authorization for any use of nanomaterials in food/feed products; designates EFSA to evaluate risk assessment dossiers and verify that appropriate and up-to-date methods have been used to assess safety.

Risk Assessment

The use of nanomaterials in food/feed applications has also raised concerns over the safety of the consumer. For example, the fate of insoluble/poorly-soluble nanoparticles in the body, the uptake and bioavailability of nanoparticles compared to conventional forms, interaction of nanoparticles with different organ systems in the body, potential effects upon long-term exposure, etc.



Source: Presentation on “ Risk Governance of Nanomaterials in Food”

Risk Assessment of Nanomaterials in EU

Food contact materials

- Positive EFSA opinions where lack of migration of nano-additives to food/simulants is demonstrated (silicon dioxide; carbon black; titanium nitride)
- **Food additives:** First examples are currently undergoing risk assessment by EFSA.
- **Pesticides, fertilizers:** No regulatory risk assessment in the EU yet

Cosmetic ingredients (SCCS Opinions) e.g. TiO₂, ZnO, SiO₂, Carbon black, etc.

- Positive opinions, where lack of dermal penetration is demonstrated – indicating absence of systemic availability
- Negative opinions, where indications of adverse effects after inhalation exposure

Public Perception of Nano Foods

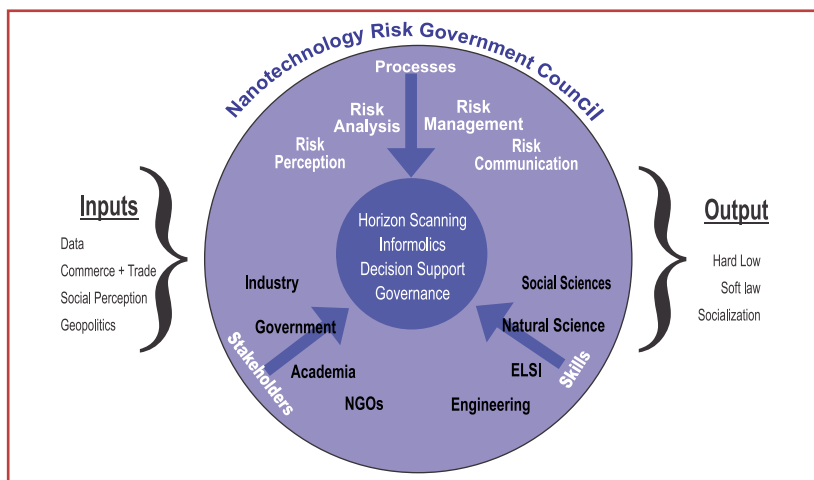
Public perception of novel foods is generally inconsistent. Whilst people are willing to eat unhealthy traditional food items (high fat, high sugar), they are generally reluctant to accept novel food items. This is also evident towards nano-food, and is a manifestation of primarily a lack of public awareness and clear communication. Similar behavior toward GM foods

raised concerns over real and perceived risks. Nano-foods have also raised a similar debate. Several surveys have reported that while consumers are conducive toward other nanotechnology applications (e.g. paints, textiles), they are not entirely supportive of use of nanotechnologies in food.

Risk Communication and Risk Governance

Careful assessment and communication of different parameters that significantly affect the safety of the nano-based food items need to be performed. For this, stringent and thorough governing principles need to be established and strictly followed and enhance public outreach enhanced. Three European projects,

NANORIGO, RISKGONE, and Gov4Nano, are currently working together to develop a framework for risk governance and a Risk Governance Council is being set up with supporting infrastructure for data, tools and instruments.



Source: Presentation on “Risk Governance of Nanomaterials in Food”

2.4-Safety of Nanomaterials: A Journey from Research to Policy

Prof. Alok Dhawan, Director, Centre of Bio-Medical Research, Lucknow, India

Nanotoxicology is a study of the toxicity of nanomaterials. Nanomaterials, even when made of inert elements, at times become highly active at the nanometer dimension due to their altered physical and chemical properties. The toxicology studies are intended to determine whether and to what extent these properties may pose a threat to the environment and to human beings. The same novel properties making nanoparticles attractive could make them potentially toxic too. Exposure to nanomaterials can be due to contact via skin, inhalation and oral ingestion. However, it could also happen indirectly through the environment or food chain. The former can be controlled and mitigated, while assessment of the latter is very difficult both to ascertain as well as to mitigate.

While assessing the toxicity of engineered nanomaterials (ENMs), several things need to be accounted for, such as, size, shape, surface area, coatings, stability, dispersion, uptake and excretion of ENMs. Depending on the materials and its intended use, the appropriate model needs to be identified to assess the toxicity of the ENMs. Initial toxicity of ENMs is done *in vitro* and subsequently *in vivo* using various animal and alternate animal models. This allows for hazard identification as well as an

appropriate risk assessment.

Hazard identification of ENMs can be done *in vitro* and *in vivo*, using various models by assessing cytotoxicity, genotoxicity, immunotoxicity, neurotoxicity, hepatic toxicity, renal toxicity, cardiotoxicity etc. For assessing the environmental impact of ENMs, several models at different trophic levels have been used such as *E. coli*, *Drosophila*, Zebrafish, *Daphnia*, and plants. Globally, an effort is being made to develop ENMs through “safe by design approach” and employ the precautionary principal for their usage.

In India, guidelines have now been published both for the safety assessment of nanopharmaceuticals¹ as well as for the nano-based agri-input and food products².

1. https://dbtindia.gov.in/sites/default/files/uploadfiles/Guidelines_For_Evaluation_of_Nanopharmaceuticals_in_India_24.10.19.pdf
 2. <https://dbtindia.gov.in/sites/default/files/Guidelines%20Document.pdf>
- Nanomaterials can be tailored for site-specific delivery of cargo (for example, drug delivery) to specific tissue or organ systems

Section Three

Discussion

- Nanomaterials can be tailored for site-specific delivery of cargo (for example, drug delivery) to specific tissue or organ systems
- Bacteriocin, a strain-specific antimicrobial agent, can be used as bio-polymer conjugate for efficient and targeted antimicrobial activity.

Carboxymethyl cellulose can be used as a functional edible coating.

- Exosomes are part of the cellular system; therefore, they do not come under same regulatory guidelines as other nanomaterials. On the other hand, if liposome systems are being used, they come under the regulatory guidelines.
- Novel nanomaterials need to be followed with the regulatory framework and clinical trials for therapeutic applications.
- Biodegradable materials are being used for targeted drug delivery so that the degraded product can be excreted through the excretory system.
- Nanotechnological research is strictly integrated with the regulatory guidelines before it can be allowed for commercialization. Several testing and certifications need to be done too.
- Micro- and Nano plastics are increasingly creating pressing issues in the environment. These Nanoplastics are hard to detect and manage. Careful research and caution need to be performed.
- Nanotechnology, being a two-edged sword, needs to be carefully monitored and researched upon. Not all nanoparticles are of concern, but careful considerations have to be taken for those nanomaterials that can sustain in the environment for a longer period of time.

Section Four

Way Forward

Knowledge Dissemination and Skill Building

- Dissemination of knowledge regarding the suitability and safety of nanomaterials is a key to achieve better public outreach. Seminars and workshops should be organized regularly for information sharing and increasing interest among students and people. Regular training programs on different nanomaterial characterization aspects can also be held to build a qualified workforce. Webinars and e-courses need to be conducted by various universities and industry on nano-based products and their applications for better information sharing and building public awareness.

Center of Excellence on Nanomaterial Toxicology

- More Centres of Excellence in Nanomaterial toxicology need to be established to streamline different regulatory tests and approval acquisition, as per the Government guidelines.

Analytical Laboratories for Nano Toxicology

- More analytical Laboratories need to be set up in collaboration with universities and companies to generate quality data regarding nanotoxicology. Nanotechnology being a developing field of science, needs more characterization data and broad application range before it can be considered suitable for commercial applications.

Safety Parameters

- Pre-market testing of products produced using nanotechnology have to be conducted to ensure consumer safety. Toxicological tests have to be conducted as is the case in many developed nations. Specific standards and quality parameters need to be assessed and established for the nanomaterials before being considered suitable for consumers. Science based regulations and testing guidelines regarding nanotoxicology are required. For this purpose, establishing more collaborative ventures among Indian and foreign institutes may help tremendously in capacity building.
- Industries need to tightly follow the regulatory guidelines before bringing nanomaterial-based products to the market.
- The Safety-by-design model of material development can be implemented, where the design of the materials needs to be done considering the safety of the material primarily.

Research on Nanomaterial and Human Health

- The dynamic behavior of nanomaterials in the human body in general and gut microbiome in particular needs to be appropriately analysed. This could be an important field of research in immediate future.

Studies on Environmental Impact

- Studies on environmental effects on the whole picture, journey from nanomaterial synthesis to the market shelf, need to be undertaken (for example, microplastics to nanoplastics).

ILSI India

- ILSI India should organize more Activities on Nanotechnology, especially regarding nanomaterial safety and regulatory guidelines related to nanomaterials development.

Acknowledgement

ILSI India thanks **Prof. P. K. Seth**, Chairman, ILSI India and the speakers : **Prof. H. N. Mishra**, *Professor of Food Technology, IIT Kharagpur*, **Prof. T. Pradeep**, *Chair Professor and Professor of Chemistry, IIT-Madras*, **Prof. Qasim Chaudhry**, *University of Chester, United Kingdom* and **Prof. Alok Dhawan**, *Director, Center of Bio-Medical Research, Lucknow* for their contributions and **Dr. P. Gopinath**, Head, Centre of Nanotechnology, Department of Biosciences and Bioengineering, Indian Institute of Technology Roorkee for making a presentation and also preparing the first draft of the Report.



Rekha Sinha
Executive Director
ILSI India





International Life Sciences Institute India

Phone: (91-11) 29843478, 29848752, 29843477, 41654760
Email: info@ilsi-india.org Website: info@ilsi-india.org