NANOTECHNOLOGY RESEARCH: CHALLENGES TO LAW, ENVIRONMENT AND HEALTH

—*Vani Kesari A.*[*]

Abstract—Nanotechnology and its research are knowingly or unknowingly making a very significant impact on our day to day lives. In general terms, nanotechnology may be understood as a field of research and innovation wherein materials, devices are built up on the scale of atoms and molecules. It involves an interdisciplinary field of research wherein it encompasses the understanding of the fundamental physics, chemistry, biology and technology of nano metre-scale objects. While among the scientific community the development and the research of nanotechnology for industrial, consumer, medical, environmental uses etc are highlighted yet there are certain apprehensions being raised which is posing a challenge to regulators. Undoubtedly, the benefits of nanotechnology much depends on the fact as to the possibility to tailor the structures of materials at extremely small scales to achieve specific properties, thereby enormously extending the material science toolkit. Yet the benefits of development of this field of scientific research cannot be overlooked.

Eric Drexler, the scientist who coined the term nano-technology in his seminal work "Engines of Creation ", has warned of developing "extremely powerful, extremely dangerous technologies" as that of nano-technology.[1] *The possible impact surrounds on human*

[*] Associate Professor & Former Director, School of Legal Studies, Cochin University of Science & Technology & Director, Prof. N.R. Madhava Menon Interdisciplinary Centre for Research Ethics & Protocols (An Inter University Centre of Excellence) CUSAT. <vanikesaria@cusat.ac.in>.

[1] Eric Drexler, Engines of Creation-The Coming Era of Nanotechnology <https://www.nanowerk.com/nanotechnology/reports/reportpdf/report47.pdf> (accessed on 15 April 2022).

health, product safety, environment, occupational safety of workman in the industries etc. The International regulatory framework in this regard is silent. Even more, most of the legal systems do not have any policy framework On the other hand, nation states are making significant investment for research and development of nano products while the laws are silent on the product safety and other related health and environmental concerns. Since freedom of scientific inquiry is an essential basic right, the question of regulating research needs to be undertaken carefully. There is lack of proper studies to evaluate the potential risks and associated preventive steps to be undertaken Hence often the risk benefit analysis becomes a difficult task and consequently laying down of regulatory standards by the policy makers seems to be very slow. The paper focusses on the aspect of giant strides made by this technology and focusses primarily on the health and environmental concerns. It high lightens the regulatory concerns in this field and advocates sustainable innovations for the benefit of the future of mankind.

Keywords: Nanotechnology, Nanoproducts, Research, Environment, Health.

Freedom of Scientific inquiry is an innate aspect of human dignity since it leads to human progress. A combined reading of Article 27 of the Universal Declaration of Human Rights.1948 and Article 15 of the International Covenant on Economic, Social and Cultural Rights,1966 gives an understanding that right to Science is a basic human right. It casts responsibility on the state to respect and protect this right i.e., not to interfere with the exercise of the right, to protect the exercise of the right from interference of private players and create conditions under which the right can be realized and that diffusion of it to leads to scientific progress. Of late however, the content , nature and scope of this right has been subjected to greater scrutiny with the onslaught of technological revolution.[2]

Nanotechnology and its research advances is considered as the second great technological revolution that began 200 years before.[3] There is an multidisciplinary convergence in the case of application of nanotechnology such as chemistry, physics, biology, material sciences, engineering and so forth. It is said to

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[2] <https://unesdoc.unesco.org/ark:/48223/pf0000185558> (accessed on 15 October 2021)..

[3] Charles Tahan, "The Nanotechnology R(evolution)" <https://arxiv.org/ftp/physics/papers/0612/0612229.pdf> (accessed on 15 October 2021).

be improving revolutionizing different sectors such as technology and industry sectors, information technology, homeland security, medicine, transportation, energy, food safety, and environmental science etc However of late, certain concerns have been raised about its intrusion on environment, health etc.

The balance between freedom of scientific inquiry and other facets like clean environment and right to health needs to be evaluated in this direction.

I. NANOTECHNOLOGY AND ITS RESEARCH: BASIC UNDERSTANDINGS

Nanotechnology is generally understood as research coupled with technology development at the atomic, molecular or macromolecular levels in the range of approximately 1-100 nanometers to provide fundamental understanding of phenomena and materials at the nanoscale. On the other hand, nanoscale can be understood as about a billionth of a meter.[4] The reason behind the advances in the nano research is that it is possible to tailor the structures of materials at extremely small scales to achieve specific properties, whereby it is found that it is greatly extending the material science tool kit. Moreover it has often been stressed that using nanotechnology, materials can be effectively made stronger ,lighter, more durable, more reactive, more sieve-like, or better electrical conductors, among many other traits.[5] Generally, nanotechnology involves manipulating matter at the atomic and molecular level so as to exploit the unique capabilities and properties of structures fabricated at the atomic and molecular scale.[6] There has been no consensus as to giving a single definition to the term nano technology. However, the Organisation For Economic Co-operation and Development currently defines it as a set of technologies which enables the manipulation, study or exploitation of very small (typically less than 100 nanometers) systems and structures.[7]

Nano' is a prefix used to describe the 'one billionth', or 10^{-9}, of a thing .[8] The concept of nanotechnology was introduced into the scientific world by the physics Nobel laureate Richard P Feynman in his acclaimed lecture titled *'There's plenty of room at the bottom'* in the 1959 meeting of the American

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4 Shree Kanta Subede, "An Introduction to Nanotechnology and its Implications", 4 (4) Himalayan Physics, 78-81 (2013).

5 <https://www.nano.gov/you/nanotechnology-benefits> (accessed on 20 October 2021).

6 Ahmed S. Khan, *Nanotechnology: Ethical and Social Implications*, 4 (CRC Press New York, 2012).

7 <https://www.etui.org/sites/default/files/Nano-working-paper.pdf> (accessed on 29 December 2021).

8 <https://iopscience.iop.org/book/978-1-6270-5469-0/chapter/bk978-1-6270-5469-0ch1> (accessed on 20 November 2021).

Physical Society.[9] Since then, there has been endless research developments which brought forth new and revolutionary changes in chemistry, physics , biology and engineering etc Thus it has multidisciplinary character. Norio Taniguchi, a Professor at Tokyo University of Science in 1974, coined the term '*nanotechnology*' to high lighten the extra-high precision and ultra-fine dimensions in this field of science. It needs to be remembered that the production of nano particles (NPs), both in nature and by humans, dates from the pre-Christian era. For example, it was the Romans who introduced metals with nano metric dimensions in glass making. Thereafter there was rampant use.

Research advances in this field is expected to provide with materials and products with dramatic new properties relevant to virtually every sector of the economy, such as medicine, telecommunications, and computers, and to areas of national security interest.[10] Thus, it has enormous economic impact. Of late, nanoscale iron oxide powder is being used as a base material for rouge and lipstick. Other than this, paints with reflective properties are also being manufactured using nano scale titanium dioxide particles. Nano structured wear-resistant coatings for cutting tools and wear-resistant components have been in use since long time. Similarly in some naval ships the nano structured cemented carbide coatings are used for increased durability. It is used as catalysts and in lubricants, sports products, textiles, medical & health care products, food & nutritional products, food packaging and agrochemicals, veterinary sciences, consumer electronics, construction materials, bio medical research etc Nano engineered materials have witnessed extensive application in pollution control, purification and desalination of water and in effective waste management of hazardous by-products.[11]

Nature has been using nano materials found in both biological systems and man made structures for millions of years.[12] Thus nanomaterials can be organic, inorganic or organo metallic materials that may present chemical, physical and /or electrical properties that change as a function of the size and shape of the material.[13] In fact, nanomaterials are freely available in our nature and the neuroscientists are in fact examining the properties as well as potential uses of these natural nanostructures in an area of research which is called bio mimicry.[14] Minerals like clay which are nanostructured, mica, natural colloids such as milk, blood, fog (aerosole type), gelatin (gel type) etc. Similarly

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9 <https://web.pa.msu.edu/people/yang/RFeynman_plentySpace.pdf> (accessed on 10 November 2021).

10 Small Wonders, *Endless Frontiers- A Review of the National Nanotechnology Initiative*, (October 11, 2021, 10.04 am) <https://www.nap.edu/read/10395/chapter/3#5>.

11 B.S. Murty et al., *Textbook of Nanoscience and Nanotechnology*, 214 (Universities Press (India) Private Limited, 2013)

12 As Edelstein (eds.), Nanomaterials: Synthesis, Properties and Applications, 3 (Taylor & Francis, 1996).

13 <https://science.sciencemag.org/content/363m> (accessed on 21 October 2021).

14 <https://www.nnci.net/nature-helps-nanotechnology> (accessed on 21 October 2021).

mineralized natural materials like shells, corals and bones, skin, claws & beaks of birds or animals, paper, cotton, insect wings, opals ,spider silk ,lotus leaf gecko feet etc have nano materials.[15]

Apart from this there are engineered nanomaterials (ENM's) such as carbon nanotubes, quantum dots, nano titanium dioxide, and nano silver. They are chemical substances or materials that are engineered with particle sizes between 1 to 100 nanometers in at least one dimension. Engineered nanomaterials as known to all, derive many functional advantages from their unique physical and chemical properties.[16] The novel properties in this type of engineered nanomaterials have led to the investment as well as research interests in industrial, commercial, and medical fields. ENMs are used in diverse areas such as biology, medicine, pharmacology, biomedical imaging, drug delivery, bio-molecular sensing, tissue engineering, data storage, photocatalytic pigments, cosmetics, food, etc.[17] Nevertheless, the use of ENMs and their eventual release into the environment also evoke concerns related with some undesirable effects that have been observed for ENMs once they enter the air, soil, or water.[18] Apart from this there are ultrafine nanomaterials or incidental nano materials(INP) which are produced unintentionally generally as a side which generally occur in a product development or during a manufacturing process. Welding is one of the processes that generate high levels of INPs that are known to contain mostly iron (Fe) and manganese (Mn) oxides, among many other metals.[19] These particles no doubt cause health implications for welders due to the toxicity of Mn even at low levels of exposure. Similar activities include smelting, surface treatments etc. such incidental nanoparticles. Thus it can be asserted that in any industrial process that involves combustion or generation of metal fumes likely produce INPs.

II. RESEARCH FRONTIERS IN NANOTECHNOLOGY AND CHALLENGES

No doubt the development of nanotechnology research had contributed immensely to economic and social development. It needs to be stressed that

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[15] <https://nanoyou.eu/attachments/188_Module-1-chapter-2-proofread.pdf>. (accessed on 21 October 2021).

[16] <https://www.turi.org/Our_Work/Toxic_Chemicals/Chemical_Information/Engineered_Nanomaterials> (accessed on 21 October 2021).

[17] Athanasios Valavanidis et al, "Engineered Nanomaterials for Pharmaceutical and Biomedical Products- New Trends, Benefits and Opportunities", Pharmaceutical Processing, <https://www.openaccessjournals.com/articles> (accessed on 12 December 2021).

[18] Erick N. Bandela et al., "Engineered Nanomaterials (ENM's) and their Role at the Nexus of Food, Energy and Water", 2(1) Material Sciences for Energy Technologies, 29, 30-40 (2019).

[19] Natalia I Gonzalez et al., "Size, Composition, Morphology and Health Implications of Airborne Incidental Metal Containing Nanoparticles", J. Occup. Environ. Hyg <https://www.tandfonline.com/doi/full/10.1080/15459624.2018.1559925?scroll=top&needAccess=true>. (accessed on 16 January 2022).

the effect of nanotechnology on the environment can be two dimensional in the sense their potential for nano technological innovations to help in improving nature needs to be clearly distinguished from the conceivably novel kind of pollution that nano innovative materials may cause whenever discharged into the environment. No doubt the use of nanomaterials enhances efficiencies of monitoring devices, remediation of environmental pollution, and renewable energy production yet its negative effects at times over weighs the positive effects. There are three scenarios in which usually emission takes place such as emission during the production of raw materials, secondly emission during use of or thirdly at the stage of disposal The real threat to environment is the volume and heterogeneity of engineered nanomaterials (ENMs) released into the environment during manufacture, use, transport, and disposal have been increasing steadily increasing at the same time. Therefore, an evaluation of the potential impact of the ENM's is important to bring in regulatory frameworks which propagates responsible research as conceived under the International Human Rights legal paradigm. Studies suggest that ENMs could interact with organisms in the nature as well as in environmental complex matrices.[20] Natural organic matter (NOM), such as the humic substances found in water, sediment, and soil, is one of the substances capable of interacting with ENP. It needs to be considered that the ENM's are essential for the industrial economy[21] but the concern lies in the fact that there has been considerable interest in the research and development of ENM's whose properties differ in fundamental and valuable ways whose hazards are unpredictable and not foreseeable. The nanoparticles can enter the environment and its emissions can be observed during three important circumstances such as release of nano emissions during the production of raw material and nano enabled products, release during its use and also disposal of nano products.[22] The naturally occurring nanomaterials found in nature is said to be not affecting the environment. However, this is not the case of incidental or manufactured nanomaterials. Research studies observe that these ENM's enterthrough various routes into the air, water, and soil. Physicochemical and biological transformations make these nano materials highly reactive and toxic to environmental and biological systems.[23] This has led to new phenomenon called as *"nanopollution*". It is stated that Manufactured Nano Particles (MNP) or nanowaste are causing disturbance to the ecosystem as there is studies report that MPNs are passing through the food chain from smaller to larger organisms found in nature which can

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[20] Renato Grillo et al , *Environmental Impact of Nanotechnology: Analyzing the Present for Building the Future* https://www.frontiersin.org/articles/10.3389/fenvs.2018.00034/full(Accessed on 12 January 2022).

[21] Vinita Viswa Karma, "Impact of Engineered Nanomaterials for Environmental Industries"*, Handbook of Nanomaterials for Industrial Applications – Micro and Nano Technologies,* Elsevier, 952-958 (2018).

[22] Mirco Bundschuh, *Nanoparticles in the environment: Where do we come from and where do we go to"*, <https://doi.org/10.1186/s12302-018-0132-6>. (Accessed on 14 January 2022).

[23] Prasanth Kumar et al., "Nanomaterials and the Environment", Jnl. Nano Mat., 2014, available at <https://www.hindawi.com/journals/jnm/2014/528606/?utm_source=google&utm_medium=cpc&utm_campaign=HDW_MRKT_GBL_SU>. (Accessed on 18 January 2022).

ultimately have a grave impact on the functional ecosystem.[24] Dissemination of toxic or persistent nano substances causes environmental harm. There is a high energy demand for synthesizing nano particles which is an additional burden on the environment.[25] It has been reported that the behaviour of nanoparticles in the environment is expected to depend not only on the physical and chemical character of the nanomaterial, but also and perhaps predominantly on the characteristics of the receiving environment as well, reveals scientists.[26] On entry into an environment usually it is stressed that the nanoparticles may either remain intact or may dissolve or undergo speciation. . Speciation is nothing but association with other ionic or molecular dissolved chemical substances.[27] It may also undergo chemical or biological transformation whose impact may be hazardous to health and environment. Studies reveal that the exposure of NP's affect the physiological and biochemical levels in plants due to abiotic and oxidative stresses caused by NP's and this can ultimately affect the food supply integrity. The reason for this is plants are essential components of the functioning of the ecosystem and they play a decisive role in our food chain.[28] The pollution caused by ENM's are said to be invisible and is said to have adverse impact on marine and aquatic organisms as well.[29] The intentional release of ENM's in water and soil especially in remediation techniques apart from the incidental release of them in the environment is another growing source of concern.[30]

It has also been reported that ENM's have detrimental effects on health. It has been observed that the fundamental reasons behind the argument that it affects health is that these nanomaterials being considered as chemicals when used, can have the reaction with our body and moreover the introduction of the nanomaterials into the daily life results in the possibility that human can contact those materials, in an aggressive manner which might have deliteroius effect on health. It needs to be understood primarily that nanomaterials have

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[24] Eman M. Osman, "Environmental and Health Safety Considerations of Nanotechnology: Nano Safety". BJSTR, (2019) <https://biomedres.us/fulltexts/BJSTR.MS.ID.003346.php>. (Accessed on 18 January 2022).

[25] B. Zhang, "Environmental Impacts of Nanotechnology and its Products" <https://faculty.atu.edu/cgreco/aseemw_2011/>. (Accessed on 18 January 2022).

[26] <https://ec.europa.eu/health/scientific_committees/opinions_layman/nanomaterial>. (Accessed on 18 January 2022).

[27] <https://ec.europa.eu/health/scientific_committees/opinions_layman/nanomate>. (Accessed on 18 January 2022).

[28] S. Asli et al., "Colloidal Suspension of Clay or Titanium Dioxide Nanoparticles can Inhibit Plant Growth and Transpiration via Physical Effect on Root Water Transport" 32 (5) Plant, Cell, Environment, 32 (5) 577, 577-584 (2009).

[29] Jayant Kumar Biswas, "Nanopollution in the Aquatic Environment and Ecotoxicity: No Nano Issue", 5 Curr. Pollution. Rep. 4-7 (2019).

[30] Dana Kuhnel, *Environmental Impacts of Engineered Nanomaterials-Imbalances in the Safety Assessment of Selected Nanomaterials*, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6120010>. (Accessed on 18 January 2022).

extremely small size, smaller than the physiological barrier in our body,[31] hence, the nanomaterials can easily enter into our body and generate further reaction.

The major portal through which ENM's enter into our human body are skin, gastrointestinal tract, lung, nasal cavity, and eyes. The most common route is however through inhalation which is of grave concern as the workplaces and transit areas wherein a lot of workmen are involved are exposed to the air borne particles. This affects the lungs and air pathways. Chronic obstructive pulmonary diseases are some of the common reported diseases. Other organs of the body such as the brain, the liver, the spleen etc may also be affected when the NM's move from the lungs to other parts of the body. Inhalation of nanoparticles may cross the mucous membrane inside the nose and then reach the brain through the olfactory nerve.[32] The cardiovascular impact and associated health risks have been brought to light by the Scientific Committee on Emerging & Newly Identified Health Risks (SCENIHR) of the European Union in its preliminary report in 2007. It is also pointed out that the general public may face health risks by the use of consumer products made of nanomaterials such as cosmetics, sunscreens, clothing or cling wrap, or through ingestion of products that contain nano-ingredients, for instance foods, beverages, nutritional supplements or lipstick etc As the industry expands occupational hazards due to exposure to NM;s at the manufacturing, packing, transporting etc is bound to rise which might have health repercussions on workers. Intentional use of nanomaterials in the case of agriculture, medicine, military, remediation etc may also affect the health of the public.[33]

On the contrary, it has been reported that the use of nano materials in health care has brought about revolutionary changes especially in health care such as radio imaging, diagnosis of disease , drug delivery, treatment of cancer , gene therapies and also as a to aid in visual imaging etc.[34] Apart from the use of nanotechnology in diagnostics, it is also being used in therapies that involve the genetic manipulations in individuals as well as the molecular pathways . . The use of this type of technology is undertaken so as to tailor treatments based on the genetic make-up of individual patients. Use of nanobots for targeting cancer cells are already being reported.[35] The toxicological impact of the use of nano technology has been a matter of great concern

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[31] Beuy Joob et al., "Nanotechnology for Health: A New Useful Technology in Medicine", 10(5) Med. J. D. Y. Patil 401-405 (2017).

[32] <https://ec.europa.eu/health/scientific_committees/>. (Accessed on 12 April 2022).

[33] <https://www.env-health.org/IMG/pdf>. (accessed on 12 April 2022).

[34] Unmesh Ray, "The Health Impact of Nanotechnology", <https://www.azonano.com/article.aspx?ArticleID=5113>. (Accessed on 12 April 2022).

[35] <https://www.medicalnewstoday.com/articles/244972#Nanobots-and-Nanostars>. (Accessed on 12 April 2022).

III. THE REGULATORY VACUUM: A GLOBAL CONCERN?

Undoubtedly, the countries are in a race to become global leaders in terms of research in nano science and its market. The reason being that this being that to the winner of this race will go vast fortunes such as accelerated rate of economic development, commercial profits and will be the future destination of intellectual capital.[36] The policy debate on regulating nano research can be traced back to 2003 wherein the then US President George W Bush adopted its first policy of long-term funding for nano research and development. Today, the world is caught between nano race and there is a mad rush for patents in this area of research.

As per the statistics, in 2019, 40% of the research publications were on findings in the area of nanoscience in which China was leading, followed by the United States, India and Iran.[37] However, it is interesting to note that most of these legal systems do not have separate legislation or policy on the use of nanomaterials in research nor use of end products of nanotechnology. At the International level also, there is no regulatory instrument dealing with it. World leaders in Nanotechnology research like China do not have any statute dealing with the use of nanomaterials or the research on the basis of it.

Certain other jurisdictions treat nanomaterials as any other material and treat it as chemicals. Hence the regulations dealing with such chemicals are being applied. For instance, United States had adopted a market centric approach. Based on its previous experience of debates surrounding biotechnology, the US takes the position that no single legislation is needed but regulations on new technologies shall be on the model of Coordinated Framework for Regulation of Biotechnology of 1986. The Environment Protection Agency (EPA) can impose certain restrictions to the use of any chemicals if found to be risky and hazardous. The Toxic Substances Control Act ,1976 provides the necessary regulatory measures which EPA can take in case of any chemicals including nanomaterials. Under Section 4of the Act, the EPA has got the necessary power to regulate any chemical if it is found that the chemical imposes an unreasonable risk or is affecting both health of the individuals and environment alike. The raging debate as far as the application of the Act to nanotechnology and its products is that whether a nanotechnology version of an existing chemical product is a "new" substance which requires a Pre-Manufacture Notice (PMN) to be submitted to EPA for the product to be

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[36] Darry S.L. Jarvis & Noah Richmond, "Regulation and Governance of Nanotechnology in China : Regulatory Challenges and Effectiveness", 2(3) EJLT, (2011) <http://www.darryljarvis.com/uploads/2/2/6/9/22690064/nanotechnology_jarvis__richmond.pdf>. (Accessed on 12 April 2022).

[37] <https://statnano.com/news/67470/2019%E2%80%99s-20-Leading-Countries-in-Nanotechnology-Publica>. (Accessed on 12 April 2022).

marketed?[38] The procedure contemplated under the TSCA is that EPA has 90 days to request more information or impose restrictions on the new substance. Environmentalists argue that the nanotechnology version of an existing chemical might have the same chemical structure but different physical and chemical properties and hence needs regulation. This has been opposed by commercial research and market forces. Another obstacle with regard to effective regulation is that TSCA exempts substances from PMN requirements which are produced in low volume or have less environmental risk and exposure. This may be suitable for a traditional chemical substance, but the question is can it be extended to nano products?

The Food and Drugs Administration (FDA) also investigates safety issues surrounding its use in medicine and personal consumer products. FDA contains six semi-autonomous regulatory centers which regulate different product categories. However, it needs to be stressed that FDA does not regulate a technology or use of it in research. Currently it adopts a product-by-product approach which is problematic as far as nano products are concerned. Eachcentre and each regulated product category have its own statutory as well as regulatory standards. Since nanotechnology is expected to result in a range of different product categories to be regulated by FDA which may range from drugs to cosmetics FDA applies different regulatory standards to nano products which had resulted in inconsistent protection standards. The National Institute of Occupational Safety and Health (NIOSH) is also an agency engaged in making recommendations on potential toxicity of nanomaterials on workers involved in manufacture and handling of nanomaterials. NIOSH is investigating on it and making recommendations to ensure safety of workers it needs to be understood that it is a toothless tiger as it lacks rule making power. The Consumer Product Safety Commission (CPSC) is yet another independent government agency created through the Consumer Product Safety Act of 1972 which functions to protect the public from unreasonable risks of injury or death associated with the use of various types of consumer products under the agency's jurisdiction including nano products. Usually, product risk assessments are not made until after the product is available for public use. Hence special type of risk assessment may be needed for nano products.[39] The Food and Drug Administration (FDA)gives guidance to the food as well as drug industry on different products having nano materials especially on drugs and food items.[40] However, critics point out the fact as to the unsuitability of existing regulations to newly emerging nano medicines as they might pose novel risks wherein traditional safety requirements may not be appropriate.

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[38] Gary E. Merchant et al., "Nanotechnology Regulation: The United States Approach" (2008). <https://www.researchgate.net/publication/228126936_Nanotechnology_Regulation_The_United_States_Approach>. (Accessed on 12 April 2022).

[39] *CPSC Nanomaterial Statement*. <https://www.cpsc.gov/s3fs-public/CPSCNanostatement.pdf?9SxJOywA>. (Accessed on 12 February 2022).

[40] Jordan Paradise, Regulating nanomaterials at the Food and Drug Administration, 21 AMA J. Ethics, 347-355(2019) <https://journalofethics.ama-assn.org>. (Accessed on 2 February 2022).

Various studies have been undertaken by the National Nanotechnology Initiative (NNI) as to the social and ethical concerns raised by the research in nanotechnology. An inter-governmental coordinating committee known as Nanoscale Science, Engineering and Technology (NSET) as a subcommittee of Nano Science and Technology Council (NSTC) are looking into the social and ethical concerns. However, the main challenge is that the nano regulation is in the hands of different agencies such as EPA, FDA, NIOSH etc who apply different definitions to nanotechnology. The statutes put an undue burden on the regulatory agencies that there is an unreasonable risk posed by the nano product. Moreover, the regulatory regime in the US is caught between its market-oriented approach and its commitment for securing the health and safety of its people. The most challenging dimension is that these agencies are not equipped enough to look into the emerging new nano products and their regulations.

When one traces the approach of the US congress in relation to Nano research it can be found that all the legislative steps taken by the Congress was for promoting the research until and unless the potential risk is outwardly proved by the regulatory agencies. The National Science Foundation Authorization Act, 2002 suggested an appropriation of $301 million dollars of the National Science Budget for the research in nanoscience and engineering. Similarly, through the Bob Stump National Defence Authorization Act ,2003 the Congress established the Defence Nanotechnology Research and Development Program. The legislative trend earlier to these legislations, such as the Agriculture Risk Protection Act,2000, Consolidated Appropriation Act 2001 also promoted nano research. 21st Century Nanotechnology Research and Development Act ,2003 can be considered as one of the greatest moves by the US Congress in giving shape to its interest in the field of Nanotechnology research and development. It gave the US President the power to implement the National Nanotechnology program. It aims at ensuring the United States the global leader in the development and application of nanotechnology. The characteristic feature of the Act is that it facilitates research grants to individual investigators and interdisciplinary teams of investigators, establish nano research centers, accelerate the application of nanotechnology in the private sector including startups thereby advancing US productivity and industrial competitiveness in the field.[41] Similarly, under the Consolidated and Further Continuing Appropriations Act of 2015 Title VII, Revitalize American Manufacturing and Innovation Act of 2014, US Congress established the Network for Manufacturing Innovation Program advocates centres for Manufacturing innovation which primarily aims at advancing manufacturing technologies including nanotechnology. Hence it can be inferred that all the legislative efforts are moving towards promoting research and development and not at-risk assessment and consequent regulations based on the same.

[41] <https://www.congress.gov/bill/108th-congress/senate-bill/189>. (Accessed on 12 February 2022).

The European Union (EU) on the other hand has adopted a precautionary approach.[42] EU had introduced regulations of certain types of nanomaterials without even a comprehensive and conclusive scientific data concerning their potential risks. Nano sciences has found its place in most of the strategic documents of the EU for the past 20 years. Since 2008, discussions and studies on regulating nanotechnologies have been under deliberation. Presently, the regulations regarding the application of nanomaterials are Registration, Evaluation and Authorization of Chemicals or REACH 2006[43] as well as Classification, Labelling and Packaging or CLP,2008.[44] There are also sectoral based regulations. The classification of waste as nonhazardous and hazardous is being dealt with under CLP 2008. The system for classifying wastes as hazardous or not is not based on the specific properties of nanomaterials. It is also possible that in the absence of available nano-specific data, they will be most likely be categorized based on its bulk form or even left unclassified due to the non-availability of the nano-specific information.[45] Waste Framework Directive of 2008 only lays down a general framework on waste disposal. It does not give a definition to a waste containing nanomaterials and therefore there are is specifically designed process to measure the possible risks associated with nanomaterials in wastes present in the directive.[46] The regulations concerning nano products such as cosmetic products, biocides, transmission of information to consumers about food and food additives etc.[47] are silent on waste generated on its production. However, the Community Code Relating to Medicinal Products for Human Use, 2001[48] contains procedures for the legal means of authorization of medicinal products for which a register of nanomaterials needs to be maintained,which will facilitate supervision of entities introducing nanomaterials to the market and transparency of data to the buyers can thereby be ensured.

It is laudable that the European Union Green Paper (EU Green Paper, 2011) initiated a public debate wherein important issues to be considered for future research in EU countries and innovation funding programs was taken up.[49] The positive aspect of this document is that it gives more importance to the relevance of an empowering approach towards nanoresearch rather than a risk-driven approach in research on nanoresearch which is quite often taken as it noted that the researchers are unaware of the potential effects of ENM's on environment and health. Moreover, the mechanisms for risk assessment of this

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42 <https://repository.law.umich.edu/cgi/viewcontent.cgi?article=1080&context=mjeal>. (Accessed on 12 February 2022).

43 EC No. 1907/2006.

44 EC No. 1272/2008.

45 <https://ec.europa.eu/environment/chemicals/nanotech/pdf/review_legislation.pdf>. (Accessed on 2 March 2022).

46 Directive 2008/98/EC.

47 <https://sciendo.com/pdf/10.1515/emj-2016-0005>. (Accessed on 11 March 2022).

48 Directive 2001/83/EC.

49 Nanosafety in Europe 2015-2025: *Towards Safe and Sustainable Nanomaterials and Nanotechnology Innovations* <https://www.nanowerk.com/nanotechnology/reports/reportpdf/report159.pdf>. (Accessed on 13 March 2022).

research are found to be very weak. Only independent organizations exist in this regard. An illustration of it is the International Risk Governance Council (IRGC) which is an independent organization based in Switzerland which is engaged in developing the concept and practice of risk governance. But the question is this sufficient?

IV. RESPONSE OF INDIA'S REGULATORY FRAMEWORK

The research in nanotechnology has been in India since a decade. Under the Indian Constitution, one can decipher both right to environment[50] and right to health[51] as a fundamental right[52] but at the same time the development of scientific inquiry[53] is also a Constitutional obligation. Investments in the field of nano research can be traced back to 2001with the Department of Science and Technology (DST) launching the Nano Science and Technology Initiative and then the Nano Mission. Though the public funded research and development in the domain of nanotechnology has been almost a decade old, the regulatory and the legal framework pertaining to nanotechnology is still dormant. This regulatory vacuum had created unethical research practices and consequently innovations with grave threat to environment and health are on the rise in India. The Nano Science and Technology Initiative of 2001 was primarily related to boosting research and development, infrastructure and manpower relating to this arena. The Nano Mission2007 another flagship initiative of the Indian government proposed, a monetary allocation of around 1000 crore rupees for research and product development with specific emphasis of the need for industry participation through the Public Private Partnership model. The regulatory framework on risk assessment and consequent regulations is yet to be evolved in India. The absence of specific law dealing with nano research not only creates an impact on health and environment but having accepted privatization and consequent commercialization if left unattended, the lives of the people in fact might be in peril. In the year 2021, the Nano Mission of Govt. of India constituted a Nano regulatory Task Force brought out a comprehensive document on Guidelines and Best Practices for Safe Handling of Nanomaterials in Research Laboratories and Industries. The guidelines provide the best practices and safety practices while handling nanomaterials in research labs and industries. Research in nanotechnology is undertaken by both public and private research labs. The assessment of risks by virtue of handling, storage, use and waste disposal by virtue of research is hardly undertaken. Hence the guideline mandates identification of hazards as a very basic requirement. The guideline specifies that a proper regulatory framework needs to come in place until then only the guideline needs to be followed. The guideline

[50] *Charan Lal Sahu* v. *Union of India*, (1990) 1 SCC 613 : AIR 1990 SC 1480.
[51] *Paschim Banga Khet Mazdoor Samity* v. *State of W.B.*, (1996) 4 SCC 37.
[52] India Const Art. 21.
[53] India Const Art. 51-A(*h*).

is silent on the supervision and monitoring in the research labs on the use , storage, handling and disposal of ENM's . There is no legal liability either for the research laboratory, researcher or the investigator in this regard. The Council for Scientific and Industrial Research (CSIR) in its guidelines in the year 2019 on "*Ethics in Research and in Governanc*e"[54] speaks about safe laboratory practices and appointment of safety officers as well as Ethics officer to monitor safe laboratory practices. However,it can be observed that most of the Universities or research centers engaged in nano research have such officers. Moreover, in nano research this obligation needs to be made mandatory. Undoubtedly, the public and private institutions as well as industries have the duty to adopt preventive and protective measures proportionate to the risk intensity and consequently the state need to adopt regulatory steps to monitor and enforce regulations. Certain scholars feel that precautionary principle as recognized by the Rio Declaration on Environment and Development1992 can be applied in this context as well. The opponents of the application of precautionary principle state that they being ambiguous and the hazardous nature of ENM's being unknown or unable to be determined it is of no use to apply this principle.[55] Moreover it is stated the principle is incapable of addressing the pollution already created by nano products already in the commercial shelves.[56] However, given the situation of scarcity of research on risk assessment, it can be inferred that the application of precautionary principle is advisable in this area as there needs to be a balance of freedom of scientific research and positive aspects of application of this technology vis a vis its health and environmental impacts.

V. TOWARDS ENSURING NANOSAFETY AND SUSTAINABLE INNOVATION

Research in nanoscience has led to the birth of several subfields of nano sciences which includes new forms of construction materials, optoelectronics and printed electronics, novel surfaces and packaging etc. However, the detrimental effects of nano materials cannot be underestimated. Steps need to be taken to identify the hazards and assess the risks, decide on precautions to be undertaken, initiate steps to prevent or adequately control exposure Monitoring of the exposure is also inevitable. Appropriate health surveillance needs to be carried out where th specific nano materials are associated to produce risk and adverse health impact. Institutions undertaking research need to prepare plans

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[54] <https://www.csio.res.in/CommonNew.php?ds=293&page=1>. (Accessed on 28 August 2022).

[55] Science for Environment Policy The Precautionary Principle: Decision-making Under Uncertainty, <https://ec.europa.eu/environment/integration/research/newsalert/pdf/precautionary_principle_decision>. (Accessed on 15 March 2022).

[56] Andre Luiz Aguar, "Nanotechnology and Environmental Law: The Principle of Precaution and Prevention", 3(1) JNMR <https://medcraveonline.com/JNMR/nanotechnology-and-environmental-law-the-principle-of-precaution-and-prevention.html>. (Accessed on 15 March 2022).

and procedures to deal with situations wherein accidents, incidents and emergencies etc occur. In industries where nano products are manufactured or nano materials are used the employees are to be properly informed and supervised.[57] However given its detrimental impact on health and environment impact assessments, licensing and potentially polluting activities review deems essential. One of the significant challenges for nano regulators is that public are generally supportive nanotechnology research but feel that the area is unregulated. Undoubtedly this may in future lead to an uncertainty where consumers will not be willing to purchase nano products, thus result in stalling nano research.[58]

The model regulatory framework with regard to nanoresearch in India needs to include within its fold appointment of Safety officers to monitor the handling, storage , use and disposal of nanomaterials, incorporate absolute liability for the labs where the nanoresearch is undertaken with regard to meeting safety concerns, risk assessment before research proposal is accepted, fixing the liability in terms of the investigator/researcher and the research institution etc Health surveillance regarding exposure for both the workers engaged in manufacture of nano products as well as those engaged in research needs to be stressed in the draft law. Ethical principles should be spelt out in the law and the appointment of ethics officer as suggested in the CSIR regulations 2019 needs to be incorporated as binding requirement under the law. Thus,a cogent regulatory framework in this regard seems inevitable.

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[57] <https://www.safenano.org/media/64896/Working%20Saf >. (Accessed on 15 March 2022).

[58] Elizabeth A. Corley, "Public Challenges of Nanotechnology Regulations", 50(3) *Jurimetrics*, 371-381 (2012).