Figure1. Anti-cancer nanoscale medication targeting cancer cells without damaging the surrounding body healthy tissue [16]

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Executive Summary

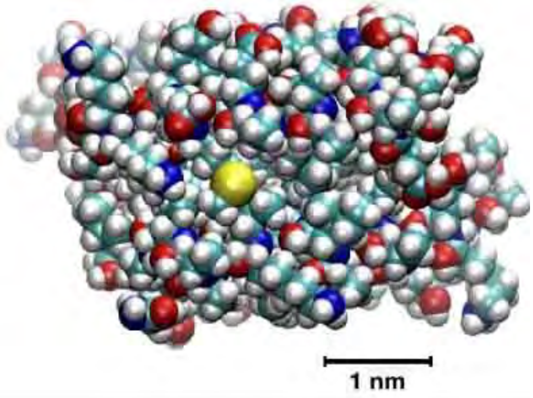

Figure 2. An engineered nanoscale object [24]

The primary purpose of this report is to discuss whether the manipulation of chemical properties at the nanoscale level presents new or exaggerated toxicity, as well as its benefits, potential for harm and risk control frameworks. An example of an engineered nanoscale object is depicted above in Figure 2.

A review of 40 articles based on nanotechnology and associated literature was conducted with the aim of identifying patterns, processes, best practices, risk assessments and frameworks best suited to nanotechnology.

Moreover, risk assessments and management controls frameworks for nanoscale products were researched and are briefly discussed within the report with additional information contained in the attached Annexes.

The report also addresses and recommends quantitative risk measurements to be taken in the absence of qualitative control mechanisms (control banding) and concludes with six recommendations for consideration by Australian manufacturers and regulators.

BACKGROUND

Not since the Iron Age has a tool such as nanotechnology made a huge impact on the lives of mankind. A bold and perhaps mischievous statement to make by someone with scanty knowledge of nanotechnology as it leaves the author open to potential criticism by academics and historians alike. However, comfort may be drawn from the scientific community and manufacturers who favour the introduction of new technologies, though the public at large remains skeptical.

New technology that benefits mankind should not be feared nor seen as some modern wizardry of manufactured material at the nanoscale level. We should embrace it for as long as the benefits derived from such technology outweigh the risks of any of emerging nanoscale products and services.

In 1959, Nobel prize winning physicist, Richard Feynman was giving a talk where he suggested that in the future a gargantuan amount of data could be stored with tremendous density. The title of his talk was “There is plenty of room at the bottom”. Although Richard Feynman did not specifically mention the word nanotechnology to his audience, he did raise the initial concept and idea of tiny machines being created at the atomic level.

The prize for coining the word nanotechnology belongs to Professor Norio Taniguchi of Tokyo Science University in 1974. Finally in 1986, engineer K. Eric Drexler wrote a book titled Engines of creation: The coming era of Nanotechnology. Thus nanotechnology became known and was finally adopted by the scientific community to identify particles at the nanoscale. [24]

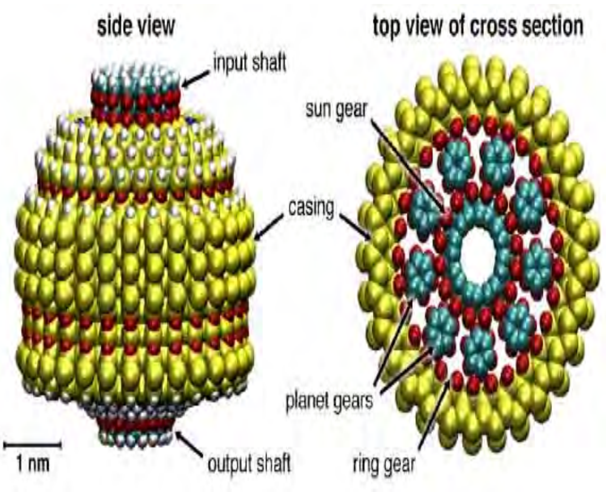

Figure 3. A molecular planetary gear [24]

The concept of nanotechnology is complex and presents new challenges for the scientific community and academics alike, whilst the general public lacks the understanding due to the absence of information. An example of the complexity surrounding a nanoscale object is demonstrated in Figure 3.

Nanotechnology conjures up ideas of tiny machines working intelligently performing a manual task. However, according to the Office of Nanotechnology (AON), the definition of nanotechnology is "the collective term for a range of technologies, techniques and.processes that involve the manipulation of matter at the nanoscale—the size range from approximately 1 nanometre (nm = one millionth of a millimetre) to 100 nm". [21] An example of a manufactured nanoparticle is shown in Figure 4 below.

PURPOSE

The primary purpose of this report is to discuss whether the manipulation of chemical properties at the nanoscale presents new or exaggerated toxicity, as well as its benefits, potential for harm and risk control frameworks. It is not within the scope of this report to discuss all hazards associated with nanotechnology.

Figure 4. Manufactured nanoparticles [2]

TOXICOLOGY AND NANOTECHNOLOGY

"The use of nanoscale materials in consumer products such as sunscreens is not new, and has been used for many years. Consumers using sunscreen that contain micronized Titanium Dioxide and Zinc Oxide have yet to report toxicities or adverse effects from these products." [40]. Despite stringent safety precautions taken by manufacturers of nanoscale consumer products, statements such as the above in the absence of any scientific measurements should be taken with caution.

The British nanotechnology community developed the British Standards Institute (BSI) guidelines for the safe handling and disposal of manufactured nanomaterials. During their research they found that a "lack of current knowledge about the toxicity of nanomaterials and the concern that current safety data sheets do not adequately reflect the hazardous nature of nanomaterials." [13]

Information therefore, regarding toxicity of nanoparticles is not sufficient to make informed decisions on the best methods of conducting health risk assessments and it is only now that data is beginning to emerge. The scientific community faces many challenges regarding toxicology of nanoparticles and at this stage there is insufficient data to conduct quantitative and qualitative risk assessments, and to characterise and explore their interaction with biological structures.

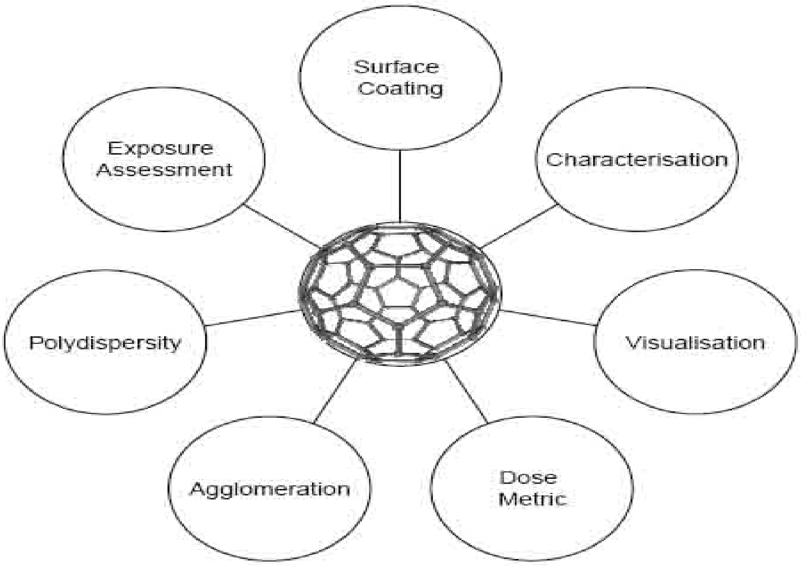

Figure 5. Challenges in nanomaterials toxicology

Figure 5 above demonstrates those challenges faced by the scientific community and manufacturers in designing studies involving toxicological assessment of nanomaterials. The challenges are in part due to the yet not-fully understood chemical, physical and biological profiles of nanoparticles, and the complexity of man-made materials arising from manipulating matter at the nanoscale level.

Saber, Hussain, et al are of the belief "that size does matter and could induce toxicity and in maintaining particle characterisation….. and although smaller sized nanomaterials are generally associated with toxicity, they recommend that most industrially prepared nanoparticles are investigated to obtain accurate toxicity knowledge." [34]

The European Health & Consumer Protection Directorate-General provided an opinion on the appropriateness of existing methodologies to assess the potential risks associated with engineered and other products of nanotechnologies to the European Commission. In their report they advised that the "relationship between the specific exposure to nanoparticles and health effects is poorly understood in contrast with the many epidemiological studies on larger particles of interest." [29]

The report further advised that "consideration of dose response relationships in the toxicology of nanoparticles poses a significant problem. In general in toxicology the paradigm exists that health effects are correlated to the mass of the agent to which the individual is exposed, resulting in an accumulated mass as internal or organ dose/exposure." [29] For example, although there are concerns about the blood - brain barrier being breached evidence is limited.

At the nanoscale level, the interactions with biological systems are causing some concern within the scientific community involved in finding a solution to nanoparticles and associated risks to human health. This concern is also supported by Vyvyan Howard, a pathologist at the University of Ulster, founder of the Journal of Nanotoxicology, who is of the belief that scientists and regulators should proceed with caution especially in light of new developments of DNA and nanotechnology breakthroughs. [22]

On the other side of the Atlantic, Jim Thomson from the Canadian based technology watchdog Group believes that "manufacturers of nanotechnology will face significantly greater hurdles of risk management if it *(nanoparticles)* proves to cross natural humanoid biological barriers". [22]

KNOWLEDGE GAPS

The United States, Japan, Canada, Germany and the United Kingdom, long time leaders of nanotechnology are now being hotly pursued by other countries around the globe eager to obtain the enormous benefits of this new technology. Russia for example recently stated that they aim to be leaders in this new field; Indonesia has pledged many millions of dollars; and Germany is spending enormous amount of funds, closely followed by France, India and China. Despite the enthusiasm displayed by these countries it is acknowledged with scientific circles that a knowledge gap exits regarding nanotechnology.

Dupont and Environmental Defence in their 2007 report found that there was a lack of knowledge when it came to understanding the chemical properties and their influence on nanomaterials in the environment. [8] Moreover, Ostrowski, Martin et al find that there is "a need for a standard systematic approach to assessing the toxicology of nanomaterials in light of the numerous products being brought on the market." [20]

Professor Brian Priestly, Head, Australian Centre for Human Health Risk Assessment (ACHHRA) in Australia recommends that a "precautionary approach be taken in workplaces handling engineered nanomaterials by using protocols based on **A**s **L**ow **A**s **R**easonably **P**racticable (**ALARP**) principle". [1] These views of uncertainty regarding the nanotechnology manipulation are shared by many in the scientific community.

Figure 6 Products with embedded nanoscale materials [28]

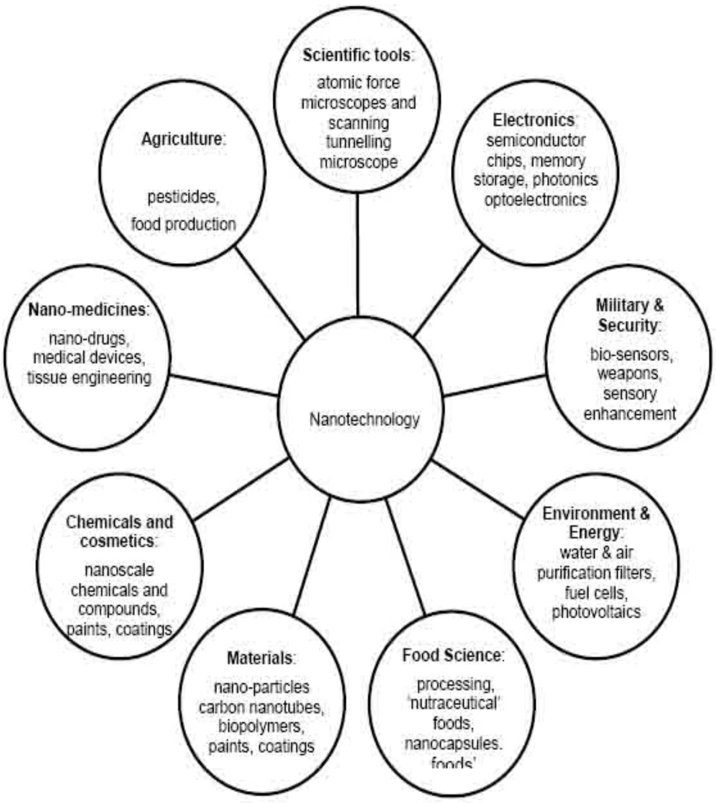

Figure 7 Nanomaterials and their impact on society

The photo in Figure 6 and diagram in Figure 7 to the left illustrate the range of nanoscale products and services arising from nanomaterials currently in use today.

Research indicated that although many professionals in the fields of chemistry, engineering, physics, had a broad understanding of nanotechnology, very few understood the risks involved.

Epidemiologist, toxicologists and Health professionals appear to have a greater understanding of the potential health risks but have yet to reach a consensus on what tools and methodologies are required to address them. Whether this is a result of the lack of collaboration or merely poor risk communication strategies remains to be seen.

To address this knowledge gap; education, training, funds and resources is needed to meet the future with confidence.

HEALTH RISKS

Nanomaterials form part of the environment and are found in natural events such as fires, volcanic eruptions but also from manmade materials such as vehicle exhausts, metal smelting and welding, which is a concern if the particles are less than 10 nm and that they reach the lungs. The main concern is that once nanoparticles enter the body they may have the ability to be distributed to organs including the nervous system. [9]

A recent news article reported that scientists had used nanoparticles in medical applications and found that they indirectly damaged DNA inside cells by transmitting signals through a protective barrier of human tissue. The article went on to say that the new findings, reported in the British Journal Nature Nanotechnology (BJNN), could also point to new ways in which nanotherapies might zero in on disease-causing tumours.

The researchers said that using nanoparticles could even shed light on how poorly understood pathogens penetrate into human organs. In laboratory experiments, scientists led by Charles Case of Southmead Hospital in Bristol, Britain, grew a multi-layer barrier of human cells to mimic specialised protective tissues found in the body. [23] Arthur Coppotelli, the senior technical manager for STOK Skin Care advised that environment skin hazards are not visible to the naked eye, and when working with nanomaterials it was not obvious when the skin's natural barriers had been compromised. [10]

RISK COMMUNICATION

The scientific community was recently given a wakeup call when manufacturers in Germany were forced to withdraw their product '*Nano Magic*', from the market barely three days after being advertised. Although the cleaning product did not contain any nanoparticles, it was reported that 80 of their customers became ill.

Admittedly, public perception of nanotechnology is not at a level that is keeping pace with the enormous changes occurring on a daily basis, but this should not be used as an excuse for failing to provide appropriate solutions and guidelines to manufacturers. Responsible regulators must therefore provide a balanced report of these technologies and ensure that the appropriate risk communication strategies (transparency, honesty, strengths and weaknesses) to avoid a poor public response as in the case of genetically modified foods.

STRENGTHS AND WEAKNESSES

Poor risk communication strategies and lack of knowledge are two matters that are quite evident throughout the literature; BSI, Dupont/Environmental Defence and the UK based International Risk Governance Council, (IRGC) are the exceptions.

Positive action has been taken by the Australian Government to setup an independent agency responsible for the coordination and collaboration of nanotechnology within Australia. Combined with other scientific fields and emerging technologies, nanotechnology will be able to provide services, food, energy, products, transport, and devices on a scale yet to be imagined. Suffice to say, nanotechnology is here to stay.

DISCUSSION

Since the new millennium, vast arrays of new nanoscale products have appeared on the scene, none of which have shown to cause any adverse or ill effects. If mankind is to take advantage of the new and promising technology, a system must be put in place to instill confidence in manufacturers, regulators and the scientific community, in confidently addressing any risks to human health and the environment.

Presently, quantitative risk assessment and management controls for known hazards allow for a comparison to be made between an actual workplace exposure and a health based occupational exposure limit. However, there is no evidence of any data being collated or measurements being taken for future epidemiological studies.

“Quantitative risk assessment allows for a comparison between actual workplace exposure and a health risk-based occupational exposure limit.” [3] This paradigm of risk assessment may require to be reevaluated under the circumstances surrounding nanotechnology. Khara, Greieger et al believe that as the scientific community is in the early stages of understanding nanomaterials that quantitative risk assessments may produce premature results” [31]

“Qualitative risk assessment can be based on comparisons between engineered nanoscale particles and incidental nanoparticles or to larger respirable particles, or fibers of similar chemical composition.” [4]. If this approach is taken, it will mean bypassing any quantitative risk assessments and the lack of any historical data for future retrospective analysis.

Control banding is a form of qualitative risk assessment and was first inferred to by BSI and does not involve quantitative measurements. It was developed in Britain to be used by small to medium sized enterprises, (SME). Furthermore, John J. Whale of Monash University, Melbourne proposes a similar approach to traditional hazard controls and supports control banding as an alternative to current risk assessment methodologies. Moreover he infers that current hazard groupings of chemical, biological, radiation, physical, and manual handling, should be restructured in line with control banding. [5]

A combination of BSI control banding, the Dupont and Environmental Defence model and the IRGC Risk Governance framework for the health risk assessment of nanoscale products should be considered as an alternative for current methodologies. Moreover, it is not possible to conduct health risk assessment studies as very few organisations have the expertise to undertake health risk assessments of nanotech products and services. See Annex A for more control banding information.

CONCLUSION

Australia is lagging behind other developing countries in identifying suitable health risk assessment controls of potential or perceived hazardous nanotech products and services. Regulators have been slow in adapting to the fast growing technologies and it would appear that manufacturers have been given a free rein to produce materials containing nanotechnology. If responsible safeguards are not implemented, to identify potential *nanotech sicknesses,* future generations may be facing a '*potential explosion of nanoscale illnesses'* simply because we failed to act. *We must not forget the lessons from asbestos.*

RECOMMENDATIONS

The knowledge gaps, lack of HRA methodologies and the uncertainties surrounding nanotechnology is courting disaster for the future. The following suggestions have been recommended as a means of addressing the above concerns, develop a nanotechnology industry and instil confidence in the public arena.

a. Implement control banding for Nanotechnology Risk Assessments, (NRA);

b. Consider quantitative HRA in the absence of qualitative HRA.

c. Implement nanotechnology training & education

d. Implement a national risk communication strategy;

e. Distribute safety guidelines to industry, & communities; and

f. Develop an infrastructure to support industry, institutions & employers.

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ANNEXES:

A. Health Risk Assessment Concepts

B. Domestic and International Nanotechnology Perspectives

C. Hazardous Materials - Screening and PPE

ACRONYMS

ACHHRA	Australian Centre for Human Health Risk Assessment
ALARP	As Low As Reasonably Practicable
BJNN	British Journal Nature Nanotechnology
BSI	British Standards Institute
HRA	Health Risk Assessment
HSE	Health Safety and Environmental
IRGC	International Risk Governance Council
nm	One millionth of a millimetre
NNSTF	National Nanotechnology Strategy Task Force
NRA	Nanotech Risk Assessment
PPE	Personal Protective Equipment
SME	Small to Medium size Enterprises

HEALTH RISK ASSESSMENT CONCEPTS

The pace of nanotechnology has outstripped the regulators and the manufacturers' ability to undertake health risk assessments. Manufactures and/or engineers involved with the creation and manufacture of nanotechnology products became self regulators using standard government regulated hazard guidelines. It is of relevance to note that, DuPont and Environmental Defence in North America are the only organisations to document Risk Management controls procedures for Nanotechnology. [8] The following categories are potential HRA processes for hazardous materials arising from nanotech products.

Regulators must be cognizant that the longer it takes to find a solution the longer people are exposed to unknown hazardous materials. There are no guarantees that over the next ten to twenty years exposure to nanoparticles will not begin to emerge as physical, psychosocial or mental illnesses. The author's research indicates that regulators should take the long view approach and combine the BSI, (control banding), IRGC (conceptual framework) and Dupont/Environmental (risk management framework) approach to meet with Australian conditions and standards.

BSI - Control Banding. The proposed risk control banding protocol uses known controls, made up of multiple layers. It is comprised of hazard controls such as elimination, substitution, known hazard controls, specific hazard group control solutions matrix and Australian standards. The "Control Band system has four bands of hazard controls such as:

- Low hazard level with low level controls,
- Moderate hazard level with the use of selected primary controls,
- High hazard level and multiple primary and secondary controls, and
- Unacceptable hazard level and/or no controls". [11]

IRGC - Conceptual Framework. With the growing interest and development of nanotechnology and its applications within society, Kshitij Aditeya Singh of the UK based International Risk Governance Council, proposes that a conceptual framework for nanotechnology be considered in view of the "present regulatory scenario, international situation and the science-policy interface. The framework has been developed taking into account the four generations of nanotechnology products and their potential character and also integrates risk-benefit." [26]

DOMESTIC AND INTERNATIONAL NANOTECHNOLOGY PERSPECTIVES

Overseas, countries, whether they are located in Europe, Asia, the Americas, Africa or the Indian sub continent have different strategies and approaches on how to deal with nanotechnology products and services. The reactions of scientists and academia are mixed on the best approach to the assessment and risk management of nanotechnology. A brief outline of Western countries nanotechnology risk management perspective is shown below:

Australia. The National Nanotechnology Strategy Task Force (NNSTF) in their report to the Australian Government, Minister for Tourism and Resources in 2007 advised, that "Nanotechnology also raises health, environmental, social and ethical issues." [21] This was a clear message to government that they as public guardian had failed to keep pace with the fast and energetic manufactures of nanotechnology. As a result of these findings the NNSTF made three important key recommendations regarding the health, safety and environmental (HSE) of nanotechnology. The three recommendations involved the:

- Creation of Heath, Safety and environmental Forum,
- Implementation of a regulatory framework, and
- The availability of funds for research. [25]

Victorian OH&S Regulations 2007. The Victorian Occupational Health and Safety, (OH&S) Regulations 2007 state that the employer must ensure that the risk of a task affecting an employee is eliminated so far as is reasonably practicable.

- Where it cannot be eliminated, an employer must reduce that risk so far as is reasonably practicable by substituting the way the task was to be performed with a process that presents a lower level of risk; or
- using engineering controls; or
- isolating the plant from people. [37]

Local Government Regulations. There does not appear to be a specific policy for nanotechnologies at this stage amongst local government and it may be because hazard is covered under the Victorian OHS Regulations 2007. However in view of the fast emerging nanomaterial appearing for human consumption, local government will require to review their policies and procedures. A lack of technical expertise is however a limiting features of government at this level.

Drexler. Drexler, considered to be the father of nanotechnology believes that designing machines on a nano scale and organized on the factory model requires attention to system-level concerns such as material flow, parts handling, power supply, waste heat management and so forth. [24]

Dr. Zhaoxiang Deng. According to Dr. Zhaoxiang Deng of Deng Research Group, building functional DNA nanodevices in the laboratory is in its infancy and a "a lot of fundamental work still has to be carried out before we will see any interesting real-world applications." He says that to use future DNA nanomachines, or even nanorobots, in a complex setup will require highly sophisticated forms of control mechanisms that integrate and synchronize vastly disparate elements and functions. [30]

Ashley Blom. Ashley Blom, an orthopaedic surgeon and professor at the University of Bristol believes that nanotechnology has the potential deliver novel therapies across human barriers without having to cross them. However he did go on to say that nanotechnology has the capacity to be both a risk and an opportunity. [22]

Author's point of view. It is of relevance to note that smoking and asbestos were not associated with morbidity until scientists had strong evidence that illnesses were associated with years of exposure to smoking and asbestos. It was unfortunate that many manufacturers were in denial long after an association had been made and still refused to compensate the victims.

Can society afford to wait for future maladies to emerge and will regulators as guardians of public health take proactive action to ensure the safety of its public or will they favour nanotechnology for the material benefits that it promises to bring.

The author proposes that in the absence of any measured dose-response data for engineered or manufactured nanomaterials, qualitative risk assessment and control approaches be introduced.

HAZARDOUS MATERIALS - SCREENING & PPE

BSI in their report on nanomaterials recommended that all nanomaterials are considered potentially hazardous unless sufficient information to the contrary is obtained." [13] The guide categorized "hazardous material as:

1. OH&S publications that listed substances assigned to workplace exposure limits;
2. What may be identified as a carcinogen or mutagen in a safety data sheet;
3. Identification of very toxic, toxic, harmful, sensitizing, corrosive or irritant; and
4. Cause of occupational asthma." [13]

A review of the data compiled and in line with current industry practices, three areas engineering and administrative controls for perceived hazardous nanomaterials have been identified:

- Manufacturing nanomaterials
- Handling nanomaterial
- Nanomaterial equipment maintenance & cleaning

Professor Priestly head of ACHHRA appears to support a proactive screening approach to control mechanisms and is of the opinion that "in the case of nanotechnologies, we have the unique opportunity to be proactive and incorporate toxicity screening into the development of engineered nanomaterials before their application and release, as such information is very useful in reengineering nanomaterials to reduce the potential risk associated with their use: [1]

There are no universally accepted guidelines on personal protective equipment when working with nanomaterials. This may require a review of current personal; protective equipment and upgraded to higher levels of protection according to the nanoparticles of interest. Finally, during the research, one article indicated that nanoparticles had been identified as having the ability to penetrate the epidermis and enter the bloodstream. [9]