

## Ethics and Regulation in Bionanotechnology: A Step Further in Ethical Rules and its Applications

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**Article History:** | Received: 10.07.2023 | Accepted: 12.08.2023 | Published: 19.08.2023 |

**Abstract:** Nanobiotechnology can be defined as the interconnection between technology and nanoscale. Many questions have been raised on ethical and regulatory issues. This has to do with the safety of humans and the environment. In nano biotechnology their a lot of risks and benefits in nanobiology. The EU Commission intends to place nanobiotechnology in the structure. The development of bionanotechnology is fast-growing including the ethical issue. This write-up shows the importance of ethical issues in bionanotechnology, these ethical issues cut across all other fields in biotechnology. In nanotechnology, there is a lot of implication that affects society and human. There is a difference in great impact but many needs to know more about nanotechnology. Some researchers are researching ethical and societal problems.

**Keywords:** Ethics, Nanoethics, Nano2life, Nanobiotechnology.

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### 1. INTRODUCTION

Nanobiotechnology is a fast-developing research field, it resembles stem cell research which employs the use of nanoparticles in different fields of science, agriculture, and the environment to solve a particular problem. Nanotechnology deals with the science of nanoparticles which are manipulated and altered at a length of 1 to 100 nanometers. (NNIN 2012). They work based on atomic or molecules level and become subject to forces like quantum mechanics, they are needed on larger scales. Like gold when natural it is inert but in nanoscales, it becomes very active. Technologies have risks but nanotechnology has social and ethical issues, the major one is a high level of uncertainty surrounding the technology. The Royal Commission on environmental pollution (RCEP) stated that it is difficult to know how safe and dangerous nanomaterials are not learning their take and toxicology. (RCEP 2008). Some industries have uncertainties or faults which are seen in the official reports (SCENIHR, 2009). The biggest fear in

nanotechnology is the risk to human health. One of the most important benefits derived from nanotechnology is that its particles behave differently from other bulk particles that exist naturally, this can also be the biggest challenge as predicting how the nanoparticles will react in different situations becomes a problem. Mainly nanobiotechnology is used in drug delivery systems, particularly in Vivo (Jordan paradise 2008). Recent use of nanobiotechnology is in bone and tissue repair, in this case, nanoparticles are instead into bones to enhance new bone growth (Paradise Supra). It has been noted that the uses have some potential dangers to the body. The study between the exposure of carbon nanotubes and exposure to Asbestos the similarity proves that they are responsible for serious chances of contracting cancer (Craig Poland 2008). This reaction could have a deadly effect on human health and also on the cooperate liability and nanobiotechnology market development (Kevin Rollins 2009). For example, silver nanoparticles are another risk to human lives, and silver is widely used in medicine because it has antimicrobial

**Citation:** Oghenetjiri Ukochovwera & Eloho Ukochovwera Ologan (2023). Ethics and Regulation in Bionanotechnology: A Step Further in Ethical Rules and its Applications, *SAR J Med Biochem*, 4(3), 22-26.

properties (Brain Wilhelmi 2008), in recent studies, nano silver can intrude with DNA (Yang *et al.*, 2009) there are many risks to humans from nanotechnology like diamonds to nanoparticles (Amanda Schrand 2007) and iron nanoparticles (Abby Benninghoff 2009) cosmetics and food are important areas in nanotechnology.

Nanobiotechnology stands as the fastest expanding range of people's desires. A lot of European gathering in recent years has emphasized the different aspect of methods of biochemical and biomolecular stages for a better knowledge to use botanical standard and substance to make brand new appliance at the nanoscale. The wide discipline has great pledges in different aspects of life like medicine; for diagnostic, they intrude of using devices is reduced and stronger sides are aimed during therapies, even in the agricultural and environmental administration. There has been little or no concern on the ethical regulation and social clue in this area (Donald Bruce 2006). A report was made by the ethical, legal social advisory (ELSA) personnel on the nano2life European network of the excellence in nanobiotechnology (Bruce 2006). The nano2life was secured by the European Commission (EC) during the sixth program. Twelve countries came together for the European research body to participate in different disciplinary projects, which are concerned with all life sciences; like the mini-technologies, nanotechnologies, sciences, chemistry and physics. The reason is for the development of analysis and operation for medical diagnosis therapy and also to observe food safety and environmental health

To understand the fuss in Europe on the foods that are artificially altered, nano life was created, it was an elementary part of the work. A board to check ethical, legal, and social problems. Its major job was to educate on research projects, lecture scientists, and bring about a wider view on ethical and social problems (Bruce 2006).

Ethics and regulation possess some challenges in the field despite their relevance to nanobiotechnology due to the use of nanomaterials, there could be a limiting factor. This review brings in the knowledge of ethics and regulation in the application of nanobiotechnology; in this various applications like medicine, environment, and agriculture. The ideas are from the personnel, board members, and scientists. The idea is to bring to the knowledge of analysts and industrial companies to be aware of ethical and social issues and most likely questions that may come up in the future of nanobiotechnology, not much work has been put into it yet Nanobiotechnology is at its beginning of finding and inspection; some of the application of nano biotechnologies is at a beginning stage and too inadequate to have standard yet. An invitation was sent out to both natural and social researchers including the ethicist. There is no form of

affirmation in some western areas for a scientist. Some of the areas of science have not been successful with the initial plans. The general public has no interest in any underrated opinion. For now, there is minute knowledge (Renn,2004). It is wrong to see that technology is ethically inactive. A true technology shows the significance of society, showing that it has a crucial part of society. Society will always accept a fresh technology idea as long as it affects their life positively and meets up to the demand of the society. (Bruce2002).

## 2. Western Accesses to Ethics in Nanobiotechnology

Challenges are faced in the ethical sector, one of the solutions is to adjust to proper ethical structure, knowing the beneficial effect of the research (Micheal 2004). The first step to the ethical procedure is to consider the safety of the public and not choke the work. In any country that is unwilling to follow the regulatory structure, the structure will come from the western bodies. The question arises from the EU, whether its exclusive laws will be made with nanotechnology or try to bring in new instructions around the same previous regulation. In the year 2008 reports were submitted on nanomaterials (European commission, regulatory aspect of nanomaterials 2008). The previous ethical regulation could stand with the present issue in nanotechnology but the recent paperwork will be changed when the need arises. The three (3) supposed areas of the ethical structure are:

1. The rules that govern the chemicals
2. Employee safety
3. Brand safety

The EU's strategy for the chemicals is called the registration, evaluation, authorization, and restriction (REACH), It is like a backbone of the EU's strategy (REACH 2006). Under this policy foreign buyers and producers are met to follow procedures and ensure the safety of human health and their environment. The job of the REACH was based on a standard 'no report no sales' (REACH 2006). This helps foreign buyers and producers to enroll their goods based on what is produced and imported, there was a particular amount of chemical they were required to deliver but if it's more than it will be reported, more information could be needed by the European chemical agency of a kind of substance. there is an easy balance between nanomaterials and other materials. Nanomaterials can't be used alone (ICMN 2004). To avoid the registration of the REACH so industries use a very low quantity of nanomaterials. Without taking into consideration REACH; it neglects that nanotechnology is very toxic and it's dangerous to even when in low quantity. Chemicals used to be arranged based on how dangerous they were by harmful substances directives (council directive 1967) but it no longer exists. It is a big challenge when a substance is not on the list of harmful materials, the distributors start to arrange the dangerous materials themselves (Health safety

executive 2004). Due to the characteristics of nanomaterials, it is not easy to estimate how harmful they can be over time or what their reactions are in a different environment or temperature. The supplier's major target is to bring a profitable device and this brought about the harmful classification of substances. The ability to know the danger of using nanotechnology was difficult. The REACH policy does not provide testing materials and the harmfulness of nanomaterials (SCENIHR 2007).

### 3. The Rules in Nanobiotechnology

The common aspect of nanobiotechnology is the medical section but there are no direct regulation regulations. The equipment used in nanobiotechnology has to be introduced to the board of the EU (directive1990). The area that can be demanding is the drug delivery system, this system is graded base on its functions. It is hard to know the group nanobiotechnology best fit because they are arranged based on different groups, it will also demand evaluation checks which will likely lead to inadequate testing being carried out (Giorgia2006). The directives are underdeveloped for nanotechnology even when they are rightly grouped. The analysis carried out is planned for more materials and not nanotechnology.

Nanobiotechnology has an area that is been monitored due to its constant with the skin. It is called the cosmetic law (Regulation on cosmetics 2009), there is little or no knowledge about the effects so it is a major concern for human well-being. The rule of domestic law was all cosmetic items must not be harmful to the body under all conditions (SCNCP 2007). All associations communicated about cosmetic items and defense taken for nanobiotechnology (Article of regulation). Before a cosmetic item containing nanoparticles is been sold out, it must be reported to the cosmetic association six months before being sold out to humans (Article regulation). The decision was helpful because the issues arising were addressed at the beginning for the well-being of the people, and the cosmetic law association could communicate with a scientific commission for consumer safety at all times for more information (Article regulation). Another idea carried out by the cosmetic law association was labeling, and identifying all materials, contents, and nanomaterials in the cosmetic products, with this the consumers are aware of the nanotechnology and make a decision about the risk of the social and ethical problems involved. Another nanobiotechnology ethical issue is the nano foods. There are no definite rules that guide nano food, the nano foods still answer to the EU regulatory association for foods. In general, all foods are under the law and regulation of which is the European food safety authority, which talks about the safety of food. Some nanofood is under the REACH but not all. (Naomi 2009). In nanofood law, all factors are put into consideration the societal, cultural, commercial, and environmental, all undertaken in the harmful

assessment procedure (article 16). This assessment procedure is the body or the individual with the last word. This body or individual is the food safety authority and it answers to the European parliament. The cross-examination of the food is not only directed toward human health but also at religion and traditional obligations. Marie lee, Says the European council should label the food content like the cosmetic law but the council refused the idea. Labeling should be allowed in nanofood, it gives the society a choice, and labeling of this food is of great importance (Maria Lee, 2010).

### 4. Ethics in Nanobiotechnology- Raise

The European commission research created a group called the nanobiotechnology raise for a program in science and society.

The major purpose of these commissions is for;

1. As nano biotechnology seeks to be more developed societal and ethical issues are very needed.
2. Using the deliberation from European genetically modified food to address quickly and answer for the society, media, and government matters. This nano biotechnology -raise will be beneficial to the nanobiotechnologies, the project will bring all nano biotechnologies united with the plan of aiding the previous to aid the future and also helping the scientist to comprehend and recognize the anxiety of the society.

There are some of the other major aims.

1. This is to bring all major relevant in the section of nanobiotechnology; the ethicist, European union, Nano2life, and the rest.
2. Bring the foresight, and early assessment of the scientific improvement, which might be a concern later for the general public and government.
3. To define ethical problems, and social anxiety, as matters, arise, public address, and answer the upcoming question.
4. Apply all lectures gotten from the European general modified meeting to the nanobiotechnology project.
5. Assimilate the endorsement of the European commission's conversation (European strategy for nanotechnology2004). Using the result from the forum, society deliberation checks the general opinion on various issues (Malsch *et al.*, 2004).
6. Taking of important plan in the European commission's plan for nanobiotechnology (European Nanomedicine technology platform 2006).

#### 4.1 THE CURRICULUM

These activities will help this objective by following these plans.

## The Trained Group

The group is to bring together different trained hands from all the relevant areas like the scientific researchers, industry all in nanobiotechnology also personnel who specializes in ethics, social science, and media. The other purpose of this trained group is to bring to the awareness both present and forthcoming challenges, research on other ideas, corrective insight, and societal contexts. In the meeting, there will be a scientific physician with their research for ethical and social implications and will inform what is needed and not needed in science.

## Workshops

Two workshops will be held and major bodies will be the nanobiotechnology scientific and commercial field, it will be led by the ethicist and public communication skills. Their job is to bring to knowledge the societal and ethical challenges that might arise and answer their question. At the end of this conclusion, a report will be issued. This report will be used for lectures in Nanobiotechnologist courses, which will be generally used by scientists, companies, and industries.

## 5. Nanoethics

Nanotechnology offers a broad perspective because it's cut across other technologies each of which may have different characteristics and applications (Schummer 2004). There is a sharp division of opinions regarding Nanotechnology, some people see it as a great potential while others express fears. Nanotech supporters believe it has the potential to transform lives while others believe that nanobiotechnology can bring about self-replicating "Nanobots" that could escape from the laboratory and reduce all life on earth. (Florczyk and Saha 2017).

Most ethical issues on bionanotechnology arise from areas such as environment and safety, equity, government, industries, university, and property ownership.

### 5.1 Ethics in Some of the Major Fields

#### Health and Safety Issues-

Bionanotechnology possesses negative effects on humans because of the use of Nanomaterials and its related devices. (Robert *et al.*, 2002). Small nanoparticles may enter the body and cause nanotoxicology. Bionanotechnology on the application of implant chips to cure diseases and immunization can make a human behave strangely. Safety in handling nanoparticles is not fully gasped. Use of implanting Nano-devices in humans ie implanting of chips or their artificial devices

Humans might miss the toxicity possessed by nanoparticles if the test subject are rats

## Medical Ethics-

Revealing medical information (DNA chips) to insurance companies. Particles that can't be seen or controlled that enter the body can cause harm to the body. nanomedicine could manipulate the human body rather than heal it it may cause transhumanism - changing human nature itself. It may cause privacy violations or misuse of personal information.

## Environmental-

"Grey Goo" at the Grosset level is the fear that a nanoscientist can create self-replicating nanorobots that can replicate themselves and convert everything in the world into copies of itself, thereby wiping the entire biosphere. The release of nanoparticles can harm the environment.

## Societal

Military and terrorist uses may be used to create destructive weapon and constructive ones. Studying the effect it might have on society, new technologies like nanotechnology can create a product that can affect the economy or issues for selfish reasons. It has the potential to change small industries to be a more flexible ones or in the production of bio weapons

### 5.2 Ethical Issues in Nanobiotechnology

The concept of Nanobiotechnology is the application of nanoparticles (Nanotechnology) to the life sciences and may also include the application of biotechnology to nanotechnology (Jeffery *et al.*, 2002).

#### Reason for Ethics in Nanobiotechnology

1. To anticipate problems such as preventable harm, conflicts on justice and fairness, and also issues concerning respect for persons that may likely arise from nano initiative (Weil 2001)
2. To know the ethical issues and to take responsibility at every level of decision-making in both policy and technical people (Mnyusiwalla *et al.*, 2003). Over the past 5 years, nanotechnology has caught a lot of ethical concerns in both environmental and health risks. The potential risk posed by bio nanotechnology uses the use of nanoparticles in its privacy and control threats brought up by the use of nanodevices for the possibilities to treat human diseases, diagnosis, etc. Other ethical issues are issues of equity and global justice, respect for patients, and property rights.

## 6. CONCLUSIONS

Discussing the ethics and regulation is needed to further tackle the problems associated with it and for further development of bio nanotechnology. The guidelines are needed to control the use of the technology, thus not be used for harmful purposes. However, researchers need to produce further research



proposals on the ethical issues and have the public involved in the discussion of the nanotechnological impact on society.

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