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A Literature Survey on Biosafety and Bioethics: Necessary Regulations in Bioinformatics

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Abstract —In recent years, lot of research work at bioinformatics like genome sequence analysis, protein and proteome informatics, gene prediction, informatics of disease diagnosis and drug design are developed. Computer Scientists are involved in developing algorithms, tools, and software to store and analysis genome data. The success of the Human Genome Project, where the entire genome of human beings have been decoded, gave rise to attempts to harness computers to manipulate and process all the data that suddenly have become available. Today, bioinformatics is used in large number of fields such as microbial genome applications, biotechnology, waste cleanup, Gene Therapy etc. Under these circumstances due to growing concerns arising from Genetically ModifiedOrganisms throughout the world (FAO) / (UNEP) has built up an informal working group on bioethics and biosafety. In 1991, this group preferred the "voluntary code of conduct for the release of organisms into the environment "such operative biosafety guidelines and bioethics regulations are incorporated in this book.We discuss two main branches: Biosafety and Bioethics that based on human health. The emergence of bioethics and biosafety clearly illustrates the development of bioinformatics under some polity and legal instructions.

Keywords —Biosafety, Bioethics, Genetically Modified Organisms, Bioinformatics.

I. INTRODUCTION

Bioinformatics forms a key component in the biotechnology and pharmaceutical sector [1]. Onother side, Bioinformatics has some disadvantages such as loss of privacy. Medical and genetic information is more likely to be stored and shared. Reproductive cloning could create result in eugenic practices. Therapeutic cloning is also regarded as unethical by some groups, primarily religious organizations. Transformations of wild species; exposure of wild species to genetically modified crops or domestic livestock could cause "super species" to evolve with resistance to pesticides, herbicides, or fungicides. Loss of biodiversity; development of genetically modified crops or domestic livestock could reduce genetic variety among both domesticated and wild species.Although bioinformatics will generate many new and valuable chemicals, some chemicals with unknown or damaging environmental impacts are likely to be developed. Therefore, disadvantages of bioinformatics include ethical, moral issues surrounding safety, and the effect this has on society [2].

For a long time, biosafety principles were generally applied in microbiological and biomedical research laboratories with consideration of occupational health and safety of environment. Biosafety principles were also applied to research involving rDNA techniques, which result in production, handling, storing and transportation of Genetically Modified Organisms (GMOs) [3] also referred to as Living Modified Organisms (LMOs). With this approach in understanding biosafety, different definitions of the term biosafety have emerged.The following definitions can be applied to describe terminology biosafety:

1) *Definition 1:* Application of safety principles to laboratory practices in which potentially hazardous genomic material or organisms are manipulated or handled.
2) *Definition 2:* Approaches in handling the perceived risks of GMOs released into the environment, such as their possible adverse impacts on biodiversity or human health. Approaches may include guidelines or legally binding instruments at the national and international level.

Hence, biosafety practices deals with the application of safety principles in any environment where hazardous genomic material or agents or microorganisms are handled, to minimize the potential harmful effects to human's health and environment.

On the other hand, Ethics provide guidelines that help one decide what is the right thing to do. Bioethics is defined as the ideals, values or standards that related to genomic data [4]. In addition, it is a set of universal norms that are documented through legal or professional codes of practice, religious texts, literature and philosophy [5].Fig.1 describes the model for understanding the roles and relationships among the various participants, including computing professionals, users, and the general ethics. The roles and responsibilities are by no means mutually exclusive. On the contrary, considerable overlap exists among the three. It called the triad model that describe the importance of ethics.

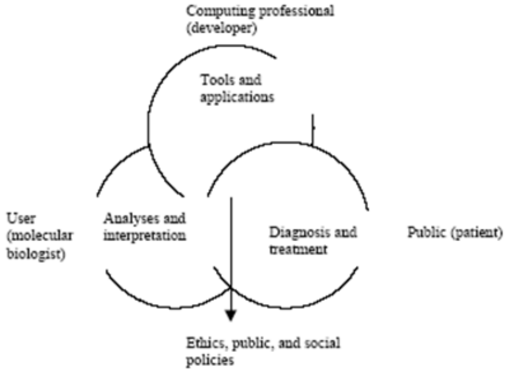

Fig.1: The Triad Model

Development in bioinformatics application has generated a number of human health, environment, economic and social concerns on the safety of the technology. Many of these concerns have legal, policy and ethical aspects to the extent that they are addressed by national and global policies and regulations. In this paper, safety and ethics concerns on application of bioinformatics discussed under the current issues associated with the benefits and risk concerns on bioinformatics: These issues will include

1) *Biosafety of GMOs.*
2) *Biopolicy:* Guiding policy to bioinformatics application and regulation.
3) *Biopolitics:* Politicization of modern bioinformatics issues with the political stream that influence public policy.
4) *Bioethics with respect to bioinformatics:* Refers to principles and practice of applying bioinformatics without doing harm to humans and environment.
5) *Biosecurity:* Protection of high-consequence microbial agents and toxins, or critical relevant information, against theft or diversion by those who intend to pursue intentional misuse.
6) *Bioweapons*:Use of biologic agents or toxins (e.g., pathogenic organisms that affect humans, animals, or plants) as weapons.
7) *Bioterrorism:*Use of biologic agents or toxins (e.g., pathogenic organisms that affect humans, animals, or plants) for terrorist purposes.
8) *Bioeconomy:*Economy depending on bioscience-based technology or bioinformatics-based economic activities.

II. GENERAL CONCERNS OF USING RECOMBINANT DNA TECHNOLOGYDERVIED PRODUCTS

The major concerns of bioinformatics have always focused on application of rDNA technology [6] that may have harmful effects. The general concerns sited in modern time are mainly:

- Development of new weapons for use in biological warfare.
- Development of genetically altered organisms which could harm the environment and human health.
- The technology may contradict nature and therefore may interfere with some people's beliefs and ethical values.
- The commercial value of bioinformatics products has lead to companies patenting genes and organisms. This is a scare to the public and some communities.

It important to know that rDNA technology has created many benefits in medicine, diagnosis and production of therapeutic products. However, bioinformatics under biosafety is essential to promote the usefulness of bioinformatics while taking precaution to avoid the risk associated with it.The use of gene technology has generated a series of beneficial applications and products in agriculture, animal husbandry, medical application, environmental management and industrial production. Parallel to these promises are series of concerns on adverse impacts of bioinformatics.

The likelihood and consequences of gene exchange between GEMs and other organisms needs to be assessed, especially when toxin transgenes are involved. Once released GEMs can be expected to evolve in ways that are beneficial to their own survival. There may be strong selection pressure for modifications that allow escape from debilitating effects imposed by biological or physical containment. Generally, it makes sense to accept the likely persistence of GEMs or their transgenes after release in the environment and minimize the associated risks accordingly[7].

III. CONCERNS ON TRANSGENTIC PLANT OR PLANT BIOINFORMATICS

The advances in plant biotechnology that has generated a lot of concerns are mainly those which involve production of transgenic plants for food through rDNA technology [8]. Other plant bioinformatics applications such as tissue culture have not received a lot of concerns, though they have not been properly accepted in some parts of the world especially in developing countries.Future foods that based on bioinformatics have benefits from more efficient, less costly processing methods, better quality, enhanced freshness and longer shelf lives. However, more practical concerns in the world have been raised on plant bioinformatics [9] because its wide application in major food crops makes it to be seen by many people. We discussed some concerns on transgenic crops as the following:

- Fear of contaminating the human food with genetically modified foods not meant for humans.
- Allergens and toxins in food.

- Unexpected results from transgenic plants, which could harm humans and environment.
- Antibiotic resistance due to use of antibiotic resistance marker genes in marker assisted breeding.
- Gene flow and spread of trait to wild species and threat to biodiversity. More important to contamination of agro-biodiversity in centers of origin.
- Social and economic impact to the society where GM crops can interfere with export trade.
- Production of transgenic crops, which can replace cash crops in developing countries.

Bioengineered plant foods fall under the jurisdiction of three agencies: the U.S. Food and Drug Administration, the U.S. Department of Agriculture and the Environmental Protection Agency. While the FDA determines the safety of genetically modified plants, companies that plant and harvest these crops are asked to voluntarily submit test results -- it is not a requirement. The USDA determines whether the new plant variety will adversely affect the environment or agriculture in general. The EPA regulates pesticides and determines tolerance levels in animals and humans.Discussion within the agricultural realm is necessary to determine what is right and wrong, what moral standard is or should be used, and why it is the proper one to justify singular or collective acts. Ethics in agricultural biotechnology therefore encompass value judgments that cover the production, processing, and distribution of food and agricultural products. The Food and Agriculture Organization of the United Nations asserts that ethical values determine its reason for being these being the values for food, enhanced well-being, human health, natural resources, and nature [10].CAST [11] notes that ultimately the goal of agricultural ethics is to "discover or develop clear, non-contradictory, comprehensive, and universal standards for judging right and wrong actions and policies."

IV. CONCERNS ON MICROBIAL GENOME APPLICATIONS

Applications of bioinformatics in Microbial Genome Applications are used for many areas such as waste cleanup, climate change, and alternative energy [2]. Although this information can potentially and dramatically improve human health, it would raise a number of ethical, legal and social issues (ELSI) such as how this information would be interpreted and used, who would have access to it, and how can society prevent harm from improper use of genetic information. To address these issues, there are four major priorities being addressed by ELSI. The first is the issue of privacy and fairness in the use and interpretation of genetic information. The second priority for ELSI is the clinical integration of new genetic technologies. It has been questioned if health professionals are adequately educated about genetics, genetic technologies and the implications of their use. The issues that surround genetic research are the third priority of ELSI. Such issues include the commercialization of the products from human genetic research. The fourth priority is the education of the general public and health care providers. ELSI funded surveys have revealed that most of the public and health professionals are not knowledgeable about genetics, genetic technologies and the implications of having genetics information [12].

Furthermore, studies of demands life and studies of microbial ecologythat lead to development of novel risk assessment procedures will be facilitated. Microbial Genome Applications can even be applied as measures for traceability the recycling process with less damaging to human [13].

V. DEVELOPMENT OF BIOSAFETY AS A SCIENTIFIC DISCIPLINE

Biosafety has developed as a science of assessment and containment of natural and manmade biological hazards that can drive a system from its health state into a pathological development [14]. The science started as a local matter of safety of laboratory workers, to become a multidisciplinary science with implication at national and global scales. It is now a subject involving a number of international treaties and agreements. The developments in biosafety assessment included principles and guidelines for contained bioinformatics applications for safety of humans and environment.Depending on the level of risks perceived to be associated biological hazards to be handled in the laboratories [15]. Biosafety regulations assign biosafety levels to these laboratories that match the level or scale of risks and containment of the risks. Generally, the risks and containments are categorized into four classes and therefore biosafety levels (BSL) fall into four levels as shownin fig.2.

BSL1: Material not known to consistently cause disease in healthy adults.

BSL2:Associated with human disease. Hazard is from percutaneous injury, ingestion, or mucous membrane exposure.

BSL3: Indigenous or exotic agents with potential for aerosol transmission; disease may have serious or lethal consequences.

*BSL4:*Dangerous/exotic agents which pose a high risk of life threatening disease, aerosol-transmitted lab infections or related agents with unknown risk of transmission.

Fig.2: Biosafety levels (BSL)

In summary, the functions of biosafety regulations are considered to be:

- To protect the environment and human from potential risks of harmful biological agents.
- To ensure perceived risks that are not there does not hinder the product developments and bioinformatics application.
- Help to inform the society of benefits and risks associated with genomic data, and how to manage the risks that may arise.
- Biosafety regulations should not be perceived to be antagonistic to application of bioinformatics but a means to ensure safe application.

Biosafety Risk Assessment (BRA) refers to the practices of determining the risk of biological agents and their genetic materials [8]. The approach of undertaking BRA has to be scientific-based. However, the process of undertaking BRA is influenced by social and political factors. The practice of BRA is also regulated by national and international standards such as those set under Cartagena Protocol on Biosafety (CPB).The main activities undertaken in BRA fall into the following components: Hazard identification, Hazard characterization, Exposure assessment, and Risk characterization.

The category of risks referred to are on:

- Human health
- Environment (focusing on conservation and sustainable use of biological diversity in receiving environment)
- Food and feed quality (nutritional value, toxicity, allergenicity and other impacts)
- Economic and social impacts

Synthetic biology techniques allow genetic constructs to be inserted into or removed from genomes of genetically engineered microorganisms (GEMs). Introduced genes and regulatory sequences could, theoretically, come from any living source or be synthetically produced. Organisms combining novel traits might be more likely to display novel ecological properties. There is a need to ensure that GEMs do not damage the ecosystems to which they are released as in fig.3[16].

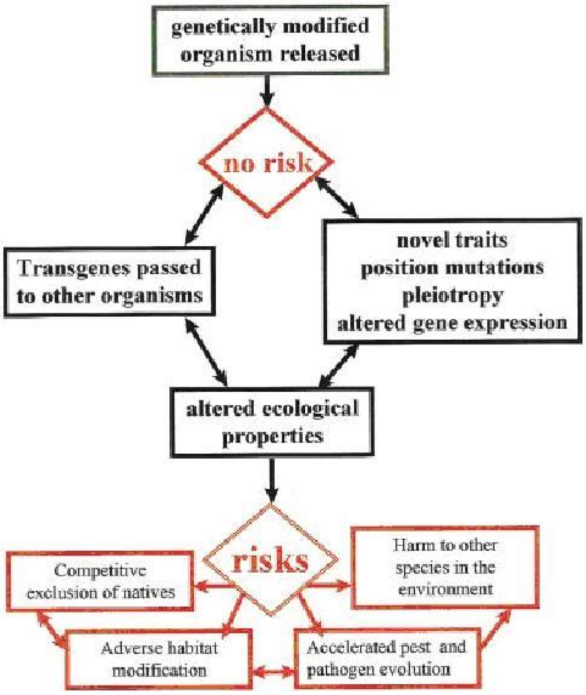

Fig.3. A summary of the relationships between risk and the ecological properties of genetically modified microorganisms.

VI. TOWARD AN ETHICS OF BIOINFORMATICS

If we follow Moor's logic [17], then the ethics of bioinformatics is a part of computer ethics, but as a species of biotechnology it should belong to bioethics instead. Perhaps a way out is to find a way to fuse these two fields of applied ethics together, at least when bioinformatics is concerned.Now the question is: Is the conceptual tool that is usually more or less adequate in dealing with privacy in normal domains of computer ethics actually adequate for bioinformatics?For example, a hacker can certainly break the protective firewall of a bioinformatics server containing a large amount of personal data and genetic codes. The genetic information defines the identity of our bodies and our mental characteristics. Therefore, this makes it much more serious to steal genetic information than to steal credit card numbers.It appears that the emerging ethics of bioinformatics is an amalgam of the two major strands of applied ethics. The disciplines such as applied ethics, bioethics, and computer ethics are not ones whose boundaries are set objectively.

It is true that these fields of inquiry are defined through their subject matter, but as the subject matter itself does change and many subject matters do fuse together, then these fields should also fuse together. Bioethics, as well as computer ethicists, traditionally two separate groups of people, are finding themselves closer to each other than before.

Harmonization of the comprehensive ethical canons needed to address modifications of nature through the design and operation of artifacts and respond to conflicting views of the public good that engineering is committed to serve presents limitations and contradictions. As occurs when engineers develop products in which commercial motivation overshadows social goals. As a consequence, the flourishing of bioinformatics as an offshoot of engineering has outpaced a focus on the ethical issues that confront it [18].The complexity of formulating a bioinformatics ethics arises from the need of bioinformatics to be coherent not only with the ethics of engineering but also with those of biology, medicine, and the physical sciences, the fields with which bioengineering interacts most strongly. Those specialized ethics, which are congruent with general ethics but distinct from it and complementary, must be rooted in the fundamental philosophical issues of each field.The host of specific ethicalissues associated with bioinformatics arises from the need to incorporate the ethical questions of physics, medicine, and biology in addressing the domain, focus, and impact of bioinformatics; its risks and safety factors; the views of nature that govern its activities; and the issues of activism and intellectual responsibility [19].

Domain, focus, and impact questions start with the positioning of the bioinformatics interface: Where should it be placed in the polarity between biological organisms and machines? To what extent should bioinformatics retain the essential characteristics of biological organisms versus those of machines? Also, should there be limits to bioinformatics, the imitation of biology in creating devices? Are there potential dangers as well as benefits, and if so, what should guide the bioengineer? Should the ethical responsibility of bioengineering be exclusively human centric, or should it extend to a broader bio centric domain with responsibility to other advanced life forms?

Relevant to urgent social needs are questions of prevention versus therapy. Historically, many medically oriented bioinformatics activities have focused on therapy and very costly devices. This has improved medical capabilities, but to what extent should escalation of medical costs and principles of social equity make it an ethical imperative for bioinformatics to focus more on prevention? Indeed, what should be the appropriate interface with medicine; what should be the specific role and responsibility of the bioengineer in a clinical environment? The dilemma of the individual versus society affects medicine and bioengineering alike and is at the core of the debate about health care: Should the focus be exclusively on the individual? To what extent should the cost to society also be taken into account?

The issues of medical versus industrial purposes, with their different motivations, also can be a source of contradictions and conflicts for bioengineers: Should they participate in a medical procedure or in the development of an industrial process merely for the technical challenge, without a dear understanding of the ultimate consequences? Should the imperative ethical requirement for bioengineers be to act as independent-minded professionals regardless of the pressure that may be put on them by a hospital, research laboratory, factory, or granting agency?

A closely related issue is the depersonalization of health care brought about by its increasing technology. To what extent should bioengineers focus on the design of the clinical environment in which bioinformatics machines are placed and processes are carried out and endeavor to reduce that depersonalization by taking into account the emotional component of human nature (a component that depends in tum on physiological factors, themselves amenable to medical and bioinformatics research)?What are acceptable risks and appropriate safety factors of bioinformatics designs? Do the efforts expended and the risks generated by a solution produce benefits that justify its development! A correlate ethical issue is the bioengineer's responsibility to follow up on the performance of a design or process, communicate the results whether they are positive or negative, and strongly advocate the adoption of satisfactory, safe, effective designs or processes and the elimination of dangerous and counterproductive ones.

Bioinformatics interventions in natural processes must take into account the many basic and often conflicting values involved in different views of nature. These views range from utilitarian (an emphasis on the way in which humans derive benefits from nature) to the drive to dominate nature for the sake of doing so [20]. Each view involves ethical dilemmas for bioinformatics, starting with the basic issue of whether or to what extent to accept nature as is or to modify it technologically; this can be thought of as an aspect of the conflict between biology (and at times religion) and engineering or medicine.

In terms of activism and intellectual responsibility, to what extent should bioengineers intervene in the philosophical dialogue about the modification of nature, the future' of humans and the human responsibility for other species? Should they participate actively in the political arena by pressing for new visions and their realization rather than seeing their role as a purely technical one? What is the ethical responsibility of bioengineers in predicting the potential modifications of nature that bioinformatics can make possible and to inform society as to how beneficial modifications can be safely accomplished?

Until a comprehensive bioinformatics ethics has been formulated, a provisional set of tenets is needed. Those tenets might include the following:

1) *The harm avoidance tenet*: to minimize the side effects of a design or intervention and devise something that bioengineers would use on themselves if necessary.
2) *The professional tenet:* to act as independent minded professionals regardless of pressure from the environment in which bioengineers operate and intervene in professional and public discussions.
3) The *approval tenet:* not to participate in medical procedures or in the development of industrial or military processes of which bioengineers do not personally approve no matter how technically challenging those procedures or processes are

4) *The conflict of interest tenet:* not to advocate an unsafe, ineffective, or inferior design because one has a vested interest in it.
5) *The risk tenet:* to weigh the risks to human society and the environment of a bioinformatics device or process
6) *The effectiveness tenet:* to make the cost and risk of a design or intervention commensurate with the expected benefits.
7) *The responsibility tenet:* to assume the responsibility to follow up the performance of a design or process and communicate the results whether they are positive or negative.
8) *The finality tenet:* to attempt to expand the capabilities of humans, and, where appropriate, other biological organisms, being mindful of the met-biological nature of bioinformatics as an activity that synthesizes two human drives.Understanding nature and modifying it to preserve and enhance life.

It is unrealistic to believe that bioinformatics ethics will emerge rapidly from all the disparate elements and concerns that will contribute to its formation. A bioinformatics ethics cannot be independent from the fundamental philosophical conceptions and ethics of the society in which bioinformatics is embedded. These issues are shaped and modified by advances in knowledge, social and political events, and the progress of bioinformatics. It is necessary to endeavor to establish some ethical principles that can guide the actions of bioengineers beyond their contingent legal obligations or at least to increase bioengineers' awareness of the ethical dilemmas that may confront them.

Ultimately, all forms of engineering are involved directly or indirectly-in the modification of the biological world. In the future, greater awareness and knowledge of biological processes resulting from advances in bioinformatics will blur some of the boundaries between bioinformatics and other fields of engineering, as in the creation of combinations of machines and genomic organisms. This will add to the complexity of the ethical issues confronting the bioengineer and society.

VII. CONCLUSIONS

Biosafety and bioethics should shape technology, but only with good feedback loops. They are relevant to our life quality. Thinking systematically about bioinformatics, it requires techniques already developed in bioethics, biosafety and related disciplines such as political and social philosophy.Data obtained through bioinformatics techniques are crucial in developing tailor-made drugs that focus on specific individuals and reducing outbreaks of diseases.However, Biosafety and Bioethics play an important role for preserving ofour lives.

Despite of all the hazards associated with releasing novel organisms one must not lose sight of the fact that most GEMs are probably more likely to be beneficial than harmful. Furthermore, taking risks is a part of life we all accept to some extent. When deciding on acceptable levels of risk we should take into account the potential benefits of the GEMs. Finally, biosafety and bioethics principles and practices has to do with the regulation of research and development of genome products based on perceived negative impacts to human health and environment. The impact can be known or suspected risks.

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