Global Bioethics and International Governance of Biotechnology

Minakshi Bhardwaj*

Bioethics

The term "bioethics" is a relatively new term in the field of ethics, when compared to medical ethics and the philosophy of science. The word "bioethics" was coined in 1970 by Potter[1], where he proposed bioethics as a new discipline calling it as "the science of survival," which "would attempt to generate wisdom, the knowledge of how to use knowledge for social good from a realistic knowledge of man's biological nature and of the biological world."[2] A generalized and simple definition was proposed by Macer in 1998, calling bioethics as "love of life" involving analysis of the benefits and risks arising out of the moral choices affecting living organisms for the good of individuals, the environment and society. [3]

Bioethics in the present time has become an integrated discipline involving ethical analysis by looking at various participants who would in the end be affected by a particular decision. "Bioethics" does not denote any particular field of human inquiry but works as an intersection between ethics and life sciences, emerging as a new field in the face of great scientific and technological changes, connecting, medicine, biology and environmental

* Research Associate, ESRC Center for the Economic and Social Aspects of Genomics (CESA Gen), Furness College, Lancaster University, U.K.
Email: m.bhardwaj@lancaster.ac.uk

sciences with social sciences like philosophy, religion, literature, law and public policies. This gives it a very broad meaning. Contemporary bioethics includes both medical and environmental ethics in nature and they need to be considered while making appropriate decisions.

Bioethical Principles

Bioethical principles were derived from ethics principles and extended in interpreting the philosophical thoughts with facts and values of the scientific innovations. The four fundamental principles of bioethics include: (a) *Beneficence,* which is described as practice of good deeds. Beneficence is derived from the Latin 'bene' (well; from bonus meaning good) and 'facere' (to do). Doing good is beneficence. (b) *Non maleficence* which emphasizes obligations not to inflict any harm. In simple terms also it is referred to as do no harm, (c) *Autonomy* is the guiding principle for recognition of human capacity for self-determination and independency in decision-making, (d) *Justice,* the ethical principle of justice which is based on the conception of fair treatment and equity through reasonable resolution of disputes.

Centrism in Bioethics

Centrism in bioethics is based on three different centrice views, biocentric, ecocentric and anthropocentric. They play a fundamental role in the way we analyze the benefits and risks arising out of new technologies. *Biocentric thinking* focuses on each individual organism. It may include the role played by each organism in the ecosystem. It emphasizes the value of each life equally in decision making or the consequences on an organism. *Ecocentric thinking* focuses on the ecosystem as a complete dynamic system and inter-relationships between different entities of the system. Ecocentric thinking does not identify one individual life separately but takes a holistic altruistic approach to the ecosystem, over the impact of one species on the whole system. *Anthropocentric thinking* focuses on human beings and their interaction with nature. It is sometimes criticized by environmentalists and animal rights activists as based on "self-love" approach and does not give equal and due importance to other living beings of the biological system.[4]

Ways to View Bioethics

Bioethics is both a word and a concept. Bioethics as a concept is thousands of years old coming from a long human heritage.[5] There are three different ways to view bioethics and these ways describe the norms of social structures and relationships between people in society and also to their personal lives. *Descriptive Bioethics* is the way people view life, their moral interactions and responsibilities with living organisms in their life. *Prescriptive Bioethics* is to tell others what is ethically good or bad, or what principles are most important in making such decisions. It may also say something or someone has rights, and others have duties to them. *Interactive Bioethics* is discussion and debate between people, groups within society, and communities about descriptive and prescriptive bioethics. It increases communication and dialogue within societies to clarify doubts and tries to develop a universal acceptability of things.[6]

Biotechnology

There are different views on definitions and origins of biotechnology with some people focusing only on some particular aspects like genetic engineering and others taking a holistic view that involves changes in several characters, something that is also used as a base for distinguishing modern biotechnology with old biotechnology. The word "biotechnology" was coined by Karl Ereky, a Hungarian engineer, in 1919 to refer to methods and techniques that permit products to be produced from the raw materials with the aid of living organisms.[7] Since then biotechnology has been defined in a variety of ways. At the international level, a standard definition of biotechnology has been reached in the Convention on Biological Diversity (CBD), which defines biotechnology as "any technological application that uses biological systems, living organisms or derivatives thereof, to make or modify products and processes for specific use". This definition is agreed upon and signed by 168 member nations.[8] This definition was also accepted by FAO and WHO.[9]

There is no doubt that modern biotechnology represents a major breakthrough in scientific research and triumph of human ingenuity. It can be most powerful ally in fighting against disease and disabilities, hunger and

poverty on a global scale. It provides opportunities to cope better with devastation of nature brought about by the earlier industrial revolution and over population what has been described as 'the demographic explosion'. However, the downside of the biotechnology has largely to do with this unprecedented power, its use and its control. The implications and social impact of biotechnology has been compared to those of the splitting of an atom and the technological exploitation of nuclear power. Biotechnology has put enormous power in our hands, and yet the power is essentially ambiguous; it can be used for both good and bad purposes. Also there is a growing concern that this new technology may redefine our relationship to nature by irreversibly and detrimentally changing nature's course. Altering natural evolution through human tampering would cause incalculable risks for human integrity, well being and freedom.[10]

Bioethical principles and biotechnology

The ethical principle of beneficence reflects the goodness of the technology and the way it could be applied to eradicate disease and hunger from the world. In that view, genetic engineering has power to eradicate human suffering, which determines its inherent goodness. Justice also determines that fruits of the technology should be given to those who need it the most, reflecting anthropological concerns that could be overcome using the technology. However, it is still controversial when a holistic view of justice is taken, including biocentric and ecocentric aspects. Often genetic engineering is viewed as a threat, it is based on broader ecocentric views, the risk factors that are involved in using the technology and how those changes have the potential to be transcended to other beings of the system. It applies to the ethical principle of doing no harm to any living being. In the use of genetic engineering, we have to balance human centered values with value of nature.

The principle of autonomy is regarded more in the anthropocentric perspective, as distinguishing the capacity of human beings (agency) from inanimate objects and non-human animals. Human beings regard themselves as the most intelligent species, hence hold the liberty, right and authority to manipulate and use the nature according to their needs. The principle of

autonomy is most controversial in applying biotechnology; and it is sometimes rather applied as principle of respect for autonomy. Proponents of genetic engineering usually try to debate autonomy as an ideal that centers on using human beings' capacity for deliberating about technology and then reflecting on its implications on life.

Components in the ethical debates on biotechnology are shaped by the ways in which we view genetic engineering. Ethical choices are also shaped by individual reflection or a holistic approach. While ethical principles may not change, the values which influence the way people balance these principles are shaped by personal and community choices. Different groups of society emphasize different ethical principles for achieving their goals. For example, in the process of environment conservation different sectors of society are involved. Environmental NGOs oppose the use of genetic engineering, based on more biocentric views, as their only goal is to protect the environment at any cost, which is sometimes also considered radical given the other demands of the society, although it strongly favors the ethical principle of doing no harm. Some governments try to meet the needs of people and conserving the environment by taking a more balanced approach, with the sustainable use of technology without causing undue harm to the environment. It may be socially, environmentally and obviously politically important. We can consider anthropocentric and ecocentric views based on ethical principle of beneficence and justice. The profit-oriented approach of the private sector using the environment for economic gains is based on the ethical principle of autonomy and the ultimate goals of private sector, that is to produce maximum benefit and economic returns for the investment which private sector usually defends it in the name of ultimate social development.

There is no philosophical basis for complete abstinence from biotechnology and bioethical principles only advocate critical analysis of benefits and risks of technologies so that any unintentional harm is terms of morality, theologically, socially and scientifically can be minimized. Bioethical principles help in a justified resolution of ethical dilemmas that arise due to the use of novel technologies and help in balancing different perspectives on rational grounds.

Global Governance of Biotechnology-the Role of UN Agencies

Biotechnology is multi-dimensional so its governance also requires participation from many institutions. At the international level, many United Nation Organisations are involved in establishing regulations and developing strategic frameworks for the future of global approaches in biotechnology. Basically, there are three different areas in which biotechnology applications are used, that include food and agriculture, environmental applications, research in drugs, medicine and health care and general technological developments of science.

Food and Agriculture Oganisation of the United Nations (FAO) is the responsible body for governing the biotechnology applications in food and agriculture all over the world.

Biotechnology in agriculture is one of the other tasks of FAO related to food and agriculture. It is responsible body for providing technical assistance in the global use of different biotechnology applications in food and agriculture, which involves development of agriculture (both plant and animal agriculture), fisheries and forestry as well as food industry. It promotes the use of appropriate biotechnology applications to improve food insecurity through sustainable rural development especially in the developing coutries, which are primary goals of FAO. FAO is also helped by the World Food Programme (WFP) and the World Bank (WB) in carrying out its responsibilities. WFP helps in extending FAO's work at frontline, through food aid in emergency situations. International Fund for Agriculture Development (IFAD) is a funding agency for the projects related to agriculture development in poor parts of the world. It is dedicated to the agriculture development and rural upliftment. Besides IFAD, the World Bank gives financial support to FAO and other research institutes to carry out research in biotechnology and other sciences.

The trade aspects of food and agriculture commodities are under the authority of the World Trade Organisation (WTO). WTO also governs trade of other commodities besides food and agriculture. It is one of the

most critical player in the international trade of GM food, which has been one of the most controversial trade issue at global level.

The medicinal side of biotechnology is under the jurisdiction of the World Health Organization (WHO). One of the six core tasks of the WHO's secretariat is to stimulate the development and testing of new technologies, tools and guidelines for disease control, risk reduction, health care management, and service delivery. It also involves the use of biotechnologies, in medicine and also in looking into the health and safety aspects of food derived from modern biotechnology. Understanding the potential of medical technology and genomics, WHO has established a Human Genetics Program (HGN) that aims to develop genetic approaches to control the most common hereditary diseases and those having a genetic predisposition. There is also a food safety programme within the WHO that is conducting an evidence-based study of the implications of modern food biotechnology on human health and development. United Nations Drug Control Programme is another programme of the United Nations that looks after the medical technology and issues related to unethical production and use of drugs.

FAO and WHO have a joint intergovernmental subsidiary body, Codex Alimentarius Commission (CAC) that was created in 1963 by FAO and WHO to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme. The main purposes of this programme are protecting the health of the consumers and ensuring fair trade practices in the food trade, and promoting coordination of all food standards work undertaken by international governmental and non-governmental organizations.

The environmental aspects of the modern biotechnology are under the jurisdiction of the United Nations Environmental Programme (UNEP). UNEP works to encourage sustainable development through sound environmental practices everywhere. It promotes appropriate technology transfer and its mission is to provide leadership and encourage partnership in caring for the environment by inspiring, informing and enabling nations and peoples to improve their quality of life without compromising that of the

future generations (UNEP). The UNEP secretariat for the Convention of Biological Diversity (CBD) was developed at the 1992 Earth Summit in Rio de Janeiro, where world leaders agreed on a comprehensive strategy for "sustainable development". The convention establishes three main goals: the conservation of biological diversity, sustainable use of its components and the fair and equitable sharing of the benefits from the use of genetic resources.[11] The conference of the parties to the CBD adopted a supplementary agreement to the Convention known as the Cartagena Protocol on Biosafety on 29 January 2000. It seeks to protect biological diversity from the potential risks posed by products of modern biotechnology by establishing various mechanisms like Advanced Informed Agreement (AIA) and establishment in each country of Biosafety Clearing Houses (CBD 2000). The CBD has been internationally accepted and ratified by 186 countries and is legally binding on countries that ratified it. This promotes the safe use and handling of the products derived from modern biotechnology and the trade between the nations.

The United Nations Development Program (UNDP) is the UN's global development network, advocating for change and connecting countries to knowledge, experience and resources to help people build a better life. It involves setting up of information and communications technologies, that have become essential to do research in any field and particularly in biotechnology as the research in biotechnology is developing fast. UNDP helps countries strengthen their capacity to address these challenges at global, national and community levels, seeking out and sharing best practices, providing innovative policy advice and linking partners through pilot projects that help poor people build sustainable livelihoods.

The United Nations Industrial Development Organization (UNIDO) helps "developing countries and countries with economies in transition in their fight against marginalization in today's globalized world. It mobilizes knowledge, skills, information and technology to promote productive employment, a competitive economy and a sound environment."[12] UNIDO was set up in 1966 and became a specialized agency of the United Nations in 1985. As part of the United Nations common system, UNIDO has responsibility for promoting industrialization throughout the developing world,

in cooperation with its 169 Member States. As a technical cooperation agency, UNIDO designs and implements programmes to support the industrial development efforts of its clients. It also offers tailor-made specialized support for programme development. UNIDO is also responsible for the industry related issues of the biotechnology.

In general science and technology education, United Nations Educational, Scientific, and Cultural Organisation (UNESCO) is the responsible body for promoting science and technology collaborations between the countries through education, science, culture and communication. It plays a significant role in the promotion of biotechnology through education worldwide.

Independent international organization also play an important role in the governance of biotechnology by playing a neutral role of information provider and research manager in biotechnology. For example, the International Center for Genetic Engineering and Biotechnology (ICGEB) and Consultative Group on International Agriculture Research (CGIAR) help in carrying out international research, capacity building and policy support. Other UN bodies like United Nations University (UNU) has a think-tank role for coordination and promotion of policy orientation, and it includes consideration of applications of biotechnology.

Biotechnology and Developing Countries

The socio-political ramifications of biotechnologies in developing countries are extremely complex, not only do they differ from country to country but also from sector to sector of a nation's economy. They are also different for the various segments of the society. Generalizations therefore have a scant pertinence. With the world's population expected to exceed 8 billion by 2025, an increasing number of scientists around the world are recognizing that biotechnology, with adequate ethical and safety standards, offers important new tools in boosting food output and feeding the burgeoning population and ensuring adequate health care of the people. [13] Since the majority of the population is concentrated in poor parts of the world, biotechnology undoubtedly would affect most to developing countries both in positive and negative ways.

The prospects of biotechnology for developing countries have been severely debated at international level. Agricultural biotechnology has been projected for increasing productivity and reducing malnutrition through improved varieties that are productive in deteriorated environment and more nutrition delivering. In medicine, there are proposals for vaccines and other diagnostic kits that may be helpful especially for the infectious disease.[14] However, there are other logistical factors involved while practically applying biotechnology that make biotechnology access to poor countries an ethical issue; although it is regarded that biocentric and ecocentric concerns like biosafety issues and precautionary principle may be luxurious reasons for many developing countries to afford. Then there is also an ethical concern for regulatory regimes at international level and the issues for support from international community.

Globally, biotechnology science has been profoundly influenced by two factors, namely, the drastic reduction of public funds for research and the dominant role of the private sector in biotechnology R&D for health care, agrifood and other industrial applications. There is a lack of an enabling environment in most developing countries, which would translate biotechnology R&D or import products and services into community level benefits (BINAS 1997). Developing countries are severely constrained by their lack of technology, resources and expertise, although they have the capability to define how they will adopt biotech and other methods to increase agricultural production, improve health care and increase incomes in their largely rural populations. Their need for technology is evident; however, how to obtain the technology is not so clear, either technology has to be home-grown, imported, or transplanted which needed crossing of many legal frameworks at international level that sometimes become an obstacle for the developmental strategies.

Governance of Biotechnology in Developing Countries

The situation of the governance of biotechnology in the developing countries in general is weak. Many countries in the developing world have considerable potential for biotechnology because of their wealth of biodiversity. However,

the divergent policies toward GM technologies have created a complicated policy choice in the developing countries.[15] Should the governments in the developing world follow the more permissive US approach towards GM technologies, or the more precautionary EU approach? Developing countries officials have come under growing pressure from various donor agencies, international organizations, philanthropic foundations, private business firms, and NGOs to adopt either one set of policies or the other, to fall in line behind Europe or the United States. The separate and distinct interests that some developing countries have in GM technologies risk being obscured in the process.

For example, poor tropical countries face a stronger agriculture production imperative, suggesting that GM crops eventually be of higher value to them, compared with some rich countries. Yet at the same time, these developing countries tend to have weaker scientific, technical and regulatory capacity within their own borders, which could make the safe development and the use of GM crops more difficult to their scientists and farmers. The private industry driven US approach may not be well suited to the developing countries circumstances because of the natural tensions between the commcerical interests and the property rights of the private international firms on one hand and the meager resources and distinct technological needs of farmers in developing countries on the other. Yet the European approach may be equally inappropriate, given that so many farmers and consumers in poor countries are not yet as wealthy and well fed as Europeans. In addition, farmers in most countries face rural environmental protection challenges quite distinct from those caused or faced by agriculture in Europe and other rich countries.[16]

For developing countries five areas of policy have been particularly discussed, which include intellectual property rights, biosafety, food safety and consumer choice, trade and public research investment. Some developing countries, like India, Kenya, Brazil and China have adopted national policies for the GM crops and in some respects these policies are actually more cautious than those adopted in Europe. The degree of the caution is interesting, given the conspicuous unmet food production needs in some of these

countries. The extreme caution is also surprising given the prevalence in some of these countries of precisely the crop-pest and crop-disease problems that GM crops have been designed to address. Governments of the developing countries have to decide whether to be promotional, permissive, precautionary or preventive towards GM crops in above mentioned several distinct policy venues.[17]

Public Opinion of Biotechnology and Governance

Policy-making regarding agricultural biotechnology poses significant cognitive challenges for all concerned. With the development of biotechnology and the opportunity of the technology any citizen paying close attention to these technologies should have similarly complex (evolving) opinions, and since there could be many such citizens, potentially seeing and valuing different things, there can be no simple description of "the public opinion about biotechnology."[18] Nonetheless there is a strong natural desire for simplifying summaries, through opinion polls and surveys among ordinary citizens at least for the short run solutions and determining the public polices, considering the uncertainties in biotechnologies. The uncertainties in biotechnologies have also forced for a public opinion strategy in the governance as it helps the decision making process under uncertainties.

The wealth of the public opinion and surveys provide a rich empirical basis for understanding citizen's attitudes towards biotechnology. It constrains the speculation of those who would speak in the name of public or make sweeping claims about citizen's competence to make public policy choices. Rational factors contributing to social acceptance of biotechnologies include public understanding, social control and social utility. In talking about understanding scientific and technological matters, it is necessary perhaps to distinguish between the factual knowledge and general awareness. Surveys in various countries seem to confirm that there is indeed a difference between the two (Macer 1994). Another rational factor determining social acceptance of biotechnology is the degree to which technology is under society's control. There are several ways for societies to control technology. At the formal level and on day

to day basis, it is exercised by elected officials and the civil service acting on behalf of their fellow citizens. It involves framing a range of legal and institutional mechanisms and at informal level direct participation by people including public consultation panels, parliamentary commissions, citizen's forums and public referendums. The third and probably the most important factor in social acceptance would be the utility of the gene technology.[19] Individuals in society must be able to see concrete benefits for themselves and for those around them. Biotechnology has great potential to offer medical benefits, social and economic that need to clearly balanced with the emotional factors like lack of knowledge; anxiety about risk, safety, irreversibility of damage and misuse of knowledge and crossing natural boundaries.[20]

Conclusions

Biotechnology is a multi-faceted subject involving many parties, linked to each other in both narrow and broad senses. In the governance systems issues need to be separated in order to solve them. However, issues should not be ignored while drafting policies and recommendations. Often national priorities of countries are important, but at the same time there is a need for cooperation and understanding between all the stakeholders to have a balanced ethical approach for the resolution of the ethical issues in effective governance.[21]

Governance system at all levels is built on a foundation of ethical principles. The terminology of ethics may not be that conspicuous in the international and national procedure. However, the principles are inherently applied at all stages of development. Ethical principles need to be applied on a daily basis, starting from individual level to the international governing bodies. The ethics of biotechnology starts from individual organism level and encompasses the whole environment, society and governance systems. In the governance systems, environmental consideration need to be balanced with the need of society while taking a holistic and international approach. Global bioethics is meaningful only when the integrity of society, and environment is kept sustainable for the present as well as the future. Good governance is essential for this.

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Endnotes

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[21] Bhardwaj, *et al.* 2003.