1. Introduction

1.1. 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 (Potter 1970), 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." (Potter 1971). However, in the first issue of *Hastings Center Studies,* Daniel Callahan (Callahan 1971) remarked in his article, "Bioethics as a discipline" that "Bioethics is not yet a full discipline, lacking general acceptance, disciplinary standards, criteria of excellence, and clear pedagogical and evaluative norms." This lack of a clear definition helped bioethics in an unprecedented way by offering opportunities to define itself, in order to move towards defining issues, methodological strategies and procedures for decision making (Jonsen 1998). Since then bioethics in North America has been defined and conceptualized in several ways.

One definition of bioethics could be a discipline looking at the ethical implications of new scientific technologies and value judgments of fundamental human conduct in biology, medicine and environment. 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 (Macer 1998a).

1.1.1 Contemporary bioethics

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. One particular problem is considered from several aspects involving professional and personal morality. At the personal level, it would involve making decisions by a person on what he or she would do in a given circumstance; their choices so as to live their own moral life, and their personal attitude towards things. Recently it is becoming prominent in governance structures involving public attitudes in setting up policies and regulations. At the professional level, philosophers prize elegance of

arguments and care with concepts and logic relationships; while physicians look to empirical grounding for their judgments, clever clinical strategies and good outcomes with their patients (Callahan 1996). Ethicists try to take a more holistic but practical solution trying to balance between risks and benefits.

"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 sciences with social sciences like philosophy, religion, literature, law and public policies. This gives it a very broad meaning. Contemporary bioethics tries to make a linkage between the domain of science with that of ethics and moral values, at the same time evolving methodologies and procedures necessary to tackle new moral problems. It also tries to keep a distinction between the facts of science with moral values taking a more pragmatic approach in the resolving ethical dilemmas.

Contemporary bioethics includes both medical ethics and environmental ethics, as the impacts of novel technologies like biotechnologies are multi-dimensional in nature and they need to be considered while making appropriate decisions. Some believe that bioethics branched out of medical ethics when traditional norms of medical ethics, and medical paternalism in decision-making were not able to resolve the ethical dilemmas and ambiguity of scientific progress and notable events. Some of the technologies used in medicine were also applicable to the environment and natural systems that also led to the inclusion of environmental ethics in bioethics.

1.1.2 Varieties of bioethics

As the field has developed, gradually it has become clear that because of the range of the diversity of the issues, more than one methodology is needed and also no single domain can claim a commanding role in bioethics. At least four general areas of enquiry can be distinguished even though in practice they can overlap and cannot be easily separated. These include

- *Theoretical bioethics* deals with intellectual foundations of the field, it tries to find out the moral roots and ethical warrant that can be found for the moral judgment made in the name of bioethics. Partly it is debated whether its foundations should be

looked for within the practices and the traditions of the life sciences or whether they philosophical and theological starting points.

- *Clinical ethics* includes day to day moral decision making of those caring for patients. It focuses more on individual case rather than a collective decision-making.
- *Regulatory and policies bioethics* aims at providing a legal framework for rules and procedures to be designed to apply to the cases or general practice; it does not focus on individual cases.
- *Cultural bioethics* refers to the effort systematically to relate bioethics to the historical, ideological, cultural and social context in which it is expressed. This is how the trends within bioethics reflect the larger culture of which they are a part (Callahan 1995).

1.1.3 Principles of bioethics

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:

1.1.3.1 *Beneficence* describes practice of good deeds. Beneficence is derived from the Latin 'bene' (well; from bonus meaning good) and 'facere' (to do). Doing good is beneficence. Beneficence is also related to benevolence that emphasizes intentions to do good. It focuses on obligations to prevent any harm (Churchill 1996).

1.1.3.2 *Non maleficence* emphasizes obligations not to inflict any harm. In simple terms also referred to as do no harm. Harm in itself is a vague concept, it is difficult to measure harm and many times it is taken as normative concept. So the prescription to do no harm sometimes has a relatively lower scope in law (Siefert 1996).

1.1.3.3 *Autonomy* is the guiding principle for recognition of human capacity for self-determination and independency in decision-making. The minimum content of principle for respect of autonomy is that persons ought to have independence, free from coercion and other interferences. It is often talked in terms of rights and liberty (Miller 1996).

1.1.3.4 *Justice*, ethical principle of justice is based on the conception of fair treatment and equity through reasonable resolution of disputes. There are different types of justice, for example, libertarian justice, socialist justice, communitarian justice, and feminist justice, and these are based on different virtues (Sterba 1996).

The most well known explanation of the four principle approach is by Beauchamp and Childress (2001) in their text book *Principles of Biomedical Ethics*. Alternatively Macer described these four principles in the language of love as beneficence as loving good, non-maleficence as loving good, autonomy as self-love and justice as love of others (Macer 1998 b).

1.1.4 Theories of ethics

There are several theories of ethics also used in bioethics that are derived from those fundamental principles. Some others avoid principles or even claim we need further principles to resolve moral dilemmas. In fact often the line between the moral theories and philosophical conceptualization of the matter is not distinguishable. Morality, ethics and philosophy are interrelated, and sometimes it is difficult to draw lines between them. The field of ethics, also called moral philosophy, involves systematizing, defending, and recommending concepts of right and wrong behavior. Philosophers today usually divide ethical theories into three general subject areas: metaethics, normative ethics, and applied ethics.

Metaethics investigates where our ethical principles come from, and what they mean. Are they merely social inventions? Do they involve more than expressions of our individual emotions? Metaethical answers to these questions focus on the issues of universal truths, the will of God, the role of reason in ethical judgments, and the meaning of ethical terms themselves.

Normative ethics involves a more practical task, which is to arrive at moral standards that regulate right and wrong conduct. Ideally, these moral questions could be immediately answered by consulting the moral guidelines provided by normative theories. Normative theories include virtue theory based on moral education focusing on developing good habits of our character, deontological theories based on duty and obligation towards others, and teleological or consequentialist theories based on cost and benefit analysis of an action's consequences. Consequential theories include the Utilitarian approach (Mill 1861) and Kantain approach in the resolution of ethical dilemmas.

Finally, *applied ethics* involves examining specific controversial issues, such as abortion, infanticide, animal rights, environmental concerns, homosexuality, capital punishment, or nuclear war. By using the conceptual tools of metaethics and normative ethics, discussions in applied ethics try to resolve these controversial issues. The lines of distinction between metaethics, normative ethics, and applied ethics are often not clear (Fieser 2001).

1.1.5 Centrism in bioethics

Bioethics primarily is based on the similar theories of ethics with more emphasis on the living beings in the natural world. At the present time ethical theories are applied based on the views of direct and indirect implications of an action and its affect on beings that may or may not be directly involved or related with the incident, which can be called as centrism in bioethics. Centrism is based on whose view we emphasize. Commonly three different centric views, biocentric, ecocentric and anthropocentric are used. 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 whole 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 (Macer 1998c).

1.1.6 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 (Macer 1994a). Macer argues 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. Descriptive bioethics is necessary to understand the cultures, ideologies of people; the differences and the commonalities of each society, it is a base of learning process that later lead to framing our own perceptions.

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 be to say something or someone has rights, and others have duties to them. It involves prescribing norms of behavior and set of values that later guide us to make our choices and that we can live with, improving our life and society.

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 (Macer 1998d).

1.1.7 Global ethics

Our Global Neighborhood, the report of the Commission on Global Governance defined "a global civic ethics" as "the foundation for cooperation among different societies and cultures facing common global problems. Such a global ethics comprises a common moral minimum of core values" which include "respect for life, liberty, justice and equity, mutual respect, caring and integrity." (Commission on Global Governance 1995). The World Commission on Culture and Development (1995) identified the same or "common global ethics" as 1) human rights and responsibility, 2) free and fair periodic elections, 3) elements of democracy and civic society such as freedom of speech and information, freedom of association, protection of minority rights, 4) peaceful solution of

conflicts and promise of fair transactions, 5) equality between and within generations. The Institute for Global Ethics proposed "love, truthfulness, fairness, freedom, unity, tolerance, responsibility, and respect for life" as the world ethics (Loges and Kidder 1997). Many committees made similar conceptualizations as to the set of universal ethics desirable to be prevalent in the global village.

The principles of global ethics can include global justice, society before self/ social responsibility, environmental stewardship, interdependence and the responsibility for the whole, reverence for place (Kung 1996). Global ethics is needed not only for the peaceful resolutions of the conflicts but also because there are no human rights without a basic moral consensus. The Declaration on Global Ethics (1993) says, "No new global order without a new global ethics." Global moral foundations based on ethical principles need to be incorporated in the development of societal values with those of universal values.

1.1.8 Agricultural ethics

Agriculture and ethics have been related since the origin of agriculture, as there are many mythological stories found in each culture on the origin of agriculture in many societies. There have been many theories proposed on why human beings started agriculture, and whether it was an invention or a discovery (Fowler and Mooney 1990). Howsoever agriculture was established, since then it has been the main source of human consumption and survival. Since it is directly related to human beings, ethics of agriculture has been closely watched and developed along with agricultural technology. The science of agriculture has been critically analyzed on ethical theories and different set of values have been applied for different aspects of agriculture and its interrelationship with human beings and environment (Thompson 2001).

Agricultural ethics is closely related to environmental ethics. We can regard the ethics of agriculture as old as agriculture itself. In the modern philosophical debates, ethical arguments in agriculture are so far been more taken on an anthropocentric views rather than biocentric and ecocentric views. We can also consider agricultural ethics based more on utilitarian approach whose highest normative principle is that actions are right in proportions as they tend to promote happiness; wrong as they tend to produce the reverse of happiness (Mill 1861), also later described as greatest happiness for maximum people.

Happiness in agriculture can be described as ability to produce food through utilizing nature and its resources.

In global debates, ethical issues in agriculture are oriented towards human needs versus the protection of the environment. If we ignore climatic variation, droughts, storms and earthquakes, nature is intrinsically beneficent and human beings need to be responsible and do justice to nature in the way they utilize nature and its product. The norms for ethics in agriculture are changing as agriculture is turning more to focus on targeted genetic mechanisms of improvement. Molecular engineering of nature has diverted the approach away from ecocentric and biocentric views and global ideals have become more prescriptive in nature. There is a shift towards looking at the intrinsic value of nature from its instrumental value. This can be considered as based on Kantian philosophy based on deontological approach which argues that "act so that you treat humanity, whether in that your own person or in that of another, always as an end and not as means only." Nature should not be used only as means for its great extrinsic value to human beings, but should also rather be utilized and conserved for its own value, sometimes may be just because it exists and since human beings utilize and modify nature for their living, it is their duty to replace and deliver the goods of nature back to nature (Elliot 1995).

1.2 Biotechnology

Biotechnology provides tools both for medical and well as agriculture development. It is a process that integrates life and technology to produce goods that may or may not be beneficial to human kind. 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. In medicine generally a more philosophical perspective to human life is taken while balancing the benefits and risks of technologies. Nevertheless, there is a general acceptance that biotechnology has become desirable and it provides basis for future scientific progress in agriculture as well as medicine. In agriculture, various technologies using cells and DNA are put together under the umbrella of biotechnology, making it as a concept evolving rapidly technologically with which the ethics of biotechnology is simultaneously growing, and becoming multidimensional. In medicine

also similar trends are seen through intensification and depth of the research and its physical and ethical impacts on the lives of patients and relatives, medical laws, and more broadly humanity as a whole.

1.2.1 Definitions of 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 (OECD 1999). Since then biotechnology has been defined in a variety of ways. The Oxford Dictionary (2001 edition) defines biotechnology as "the use of living cells and bacteria in industrial and scientific processes". The World Bank in 1991 defined biotechnology as "any technique that uses living organisms or substances from those organisms to make or modify a product, to improve plants or animals, or to develop microorganisms for specific uses. These techniques include the use of new technologies such as rDNA, cell fusion and other new bioprocesses." (WB 1991). However, with science of biology progressing each day, biotechnology is becoming broader and it can be regarded as a concept that involves many techniques using organisms or parts of organisms in agriculture and medicine for academic and industrial purposes. Biotechnology is also often applied as a term to refer to particular technologies like transgenics, cloning, tissue culturing, genetic engineering, genetic modification and DNA typing; all of them narrowly defining a particular technology used in biotechnology.

Different secretariats for the international governance and the UN bodies have tried to define biotechnology within their mandate; the scope and the purpose for which it needs to be applied. 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 (CBD 2002). This definition was also accepted by FAO and WHO (FAO 2000b) However, defining particular technologies like genetic modification or transgenics, and comparing traditional and modern biotechnology have been more controversial because there have been many other aspects involved besides the technical definition.

Since modern biotechnology involves many novel technologies, there have been many arguments on the definition of modern biotechnology at international level, like in the CBD and Codex Alimentarius Commission. The Cartagena Protocol to the CBD defines modern biotechnology as "the application of nucleic acid techniques, including rDNA and the direct injection of nucleic acid into cells or organelles, or the fusion of cells beyond taxonomic family that overcome natural physiological reproductive or recombination barriers and that are not used in traditional breeding and selection." Modern biotechnology also overlaps but is not limited to genetic engineering, as seen in the definition of CAC 1999 Guidelines for Organic food. "The techniques of genetic engineering/modification include include, but are not limited to: recombinant DNA, cell fusion, micro and macro injection, encapsulation, gene deletion and doubling. Genetically engineered organisms will not include organisms resulting from techniques such as conjugation, transduction and hybridization." However there have been debates on the usage of the terms 'genetic modification' or 'modern biotechnology', for example in the CAC ad hoc Intergovernmental Taskforce On Foods Derived From Biotechnology, there have been critical arguments on replacing the word 'modern biotechnology' with 'Genetically Modified foods and Products derived therefrom' as it may be economically and or politically important for many countries. However, the term 'modern biotechnology' was chosen in order to ensure consistency between CAC texts and the Cartagena Protocol of CBD based on the internationally agreed definition in the Protocol (CAC 2002a). Similar debates have been seen in other international agreements as well.

1.2.2 Modern biotechnology and its implications

Modern biotechnology is regarded to evolve after the discovery of the structure of DNA by Watson and Crick in 1953. The most dramatic implication of modern biotechnology lies in the fact that chemical components of DNA are the same in all organisms and are found in most primitive micro-organisms to the modern human beings and the possibility of re-arranging their order and substituting one gene for the other. On surface level the technology rather seems very simple although it requires rather sophisticated tools and clever methods to manipulate and recombine molecules. "The power of recombinant DNA technology is that it permits researchers specifically to reprogram an organism to produce any desirable or useful biological product." (The International Biology handbook1988).

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. In altering natural evolution through human tampering and would cause incalculable risks for human integrity, well-being and freedom (Becker 1996).

1.2.3 Modern biotechnology and bioethics

As discussed above the implications of modern biotechnology are enormous and thus provide a lot of scope for ethical debate. It is debated that inherently technology itself is neutral and the purpose for which it is applied would determine it as essentially good or bad. The French Philosopher and social critic Jacques Ellul describes technology as an autonomous and uncontrollable force, which pervades social, economic and political life (Ellul 1990). This leads to enslavement to all that the technology demands. If we extend this idea to genetic engineering all life becomes subjected to a form of determinism. On the other side, it is possible to portray technology as a liberator, a product of human choices (Drummand 1997).

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 do no harm, to any living being. Also it focuses on the deontological theory of categorical imperative, which says that we have moral duties to oneself and others, such as developing one's talents and keeping our promises to others. In the use of genetic engineering, we have to balance human centered values with value of nature, in theological terms and also philosophical terms.

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. The minimum content for a principle for respect for autonomy is that persons ought to have independence and be free from coercion. The Kantian version of autonomy is seen in the imperative of treating all beings as rational beings who have their own ends, and therefore it limits the rights and liberty of human beings to interfere in a natural course of events through manipulation using genetic engineering. Proponents of genetic engineering usually try to debate autonomy as an ideal that centres 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. The views are also influenced by the ultimate goals of the individuals or the groups they represent. 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 do 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. Also it supports utilitarian ethics. 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 in terms of morality, theologically, socially and scientifically can be minimised. 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.

1.3. Governance

The concept of governance is not new, it is as old as human civilization. Governance is described in different aspects, based on the institutional framework in which applied, like economics and corporate, environmental, developmental strategies, and ethical perspective. Governance is process of decision-making and the process by which the decisions are implemented. The governance system in general can be described as the framework of social and economic systems, legal and political structures within which humanity organizes itself (UNED 2002). UNDP describes governance as the exercise of political, economic, and administrative authority to manage a nation's affairs (UNDP 1999a). It is the complex mechanisms, processes, relationships, and institutions through which citizens and groups articulate their interests, exercise their rights and obligations and mediate their differences. Governance embraces all methods, good or bad, that societies use to distribute power and manage public resources and problems. Since governance is the process of decision-making and the process by which decisions are implemented, an analysis of the governance focuses on the formal and the informal actors involved in decision-making and implementing the decisions made and the formal and informal structures that have been set in place to arrive at and implement the decisions.

There are three main actors in political governance, government, military and civil society. Civil society is a big term used for many social groups like ordinary people, NGOs, cooperatives, research and financial institutions, political parties etc., or in fact anything that is associated with governance structures (UNESCAP 2002).

Sound governance or good governance is where the public resources and problems are managed efficiently and in response to the critical needs of the society. Good governance systems must be participatory, transparent, accountable, effective and efficient, fair and impartially enforceable and gender balanced (UNDP1999b). It should be responsive to the present and future needs of the society, and should be equitable and inclusive and follows the rule of law. The critical importance of democratic governance in the developing world was highlighted at the Millennium Summit, where the world's leaders resolved to "spare no effort to promote democracy and strengthen the rule of law, as well as respect for all internationally recognized human rights and fundamental freedoms, including the right to development." (UN 2000). Critical evaluation of the governance systems is needed for establishing the rules of law at both national and international level given that the decisions taken at the local level have a foreseeable impact on the global governance structures.

1.3.1 National governance and international governance

The line between national and international governance is thin and basically includes similar norms and actors. The difference lies in the actors involved depending on the level of the government that is under discussion. At national level, there is also a concept of local governance, which involves local governance structures limited to a state or a city or town. They are seen both in the rural as well as urban areas. At the national level, informal decision-making structures such as "kitchen cabinets" or informal advisors may exist, where as in advisors or consultancy is usually formal and is regarded as a legally responsible body. In rural areas some other actors, apart from the usual actors involved, may influence governance, for example influential landlords, farmer associations, religious leaders, locally powerful families. The situation in the urban areas is more complex and there is an overlap between urban governance and national governance. In urban areas, there are some other actors, like NGOs and CSOs, daily wage earners, appointed local decision makers, urban elite, urban poor and urban middle class, national

and local education providers, private sector employees, small scale trade unions, and most importantly sometimes local mafia that may influence the smooth governance systems. At national level, national political parties, research and financial institutions, local governments, judiciary, military, royal families, national and multinational corporations, etc are sometimes influential (UNDP 1999c).

International governance is influenced by national governments, other international agencies, international research institutes, NGO networks, financial institutions and donors, and sometimes even private industry is influential. International governance is influenced politically more than national governance, as international governing bodies face more difficult challenges and pressure in balancing different perspectives of the nations, that may involve economic, social, demographic, geographical aspects. International governance is also difficult since it requires participation from different cultures, and tolerance and understanding of the different perspectives of lives of people in different nations.

1.3.2 Governance and bioethics

The ideals of good governance are based on ethical principles and the way we view ethics. Governance is also related to political philosophy, which has its roots in ethics. One of the ideals of good governance in modern society is participation, not only in the form of gender balance but also participation from all kinds of vulnerable groups in society and it needs to be informed and organized. This means freedom of association and expression on one hand and an organized society on the other hand (UNESCAP 2002a). The ideal of participation is based on the ethical principle of respect for autonomy and recognizes the capacity of the participants that may be influenced in the decision making process. Recognizing the negative right to autonomy imposes on everyone the obligation not to coerce or otherwise interfere in other's actions (Miller 1996a). The ideal of transparency is based on the right to information, which is an extended version of right to education and right to know. It is also related to the utilitarian objective of impartiality that allows impartial consideration and equal consideration to all who could be affected the consequences. In that way transparency aligns with good and mature moral judgment for the choices to be made (Beauchamp and Walters 1994). Responsiveness is another ideal of good governance based on the deontological theories that institutions holding

authority of decision-making should respond to the needs of people within a reasonable timeframe. It is also stems from Kantian theory of duties from rules of the reason, which commands that an act is morally praiseworthy only if neither for self interested reasons nor as the result of a natural disposition, but rather from duty. Equity and inclusiveness of governance is based on the ethical principle of justice that requires all groups particularly the most vulnerable, have opportunities to improve or maintain their well-being (Tillich 1954).

Accountability is the key requirement for good governance. Accountability is necessary for all the social institutions and stakeholders involved in the governance. Who is accountable to whom varies depending on whether the decisions or actions are taken internal or external to an organisation or institution. Accountability cannot be enforced without transparency and the rule of the law. Good governance also means that processes and institutions produce results that meet the needs of the society while making the best use of resources at their disposal. The concept of efficiency in the context of good governance also covers the sustainable use of natural resources and the protection of environment. It is based on Mill's utilitarian philosophy, which claims that the good is characterized by seeking (i.e., attempting to bring about) the greatest amount of happiness for the greatest number of people. Accordingly, in the political realm, the utilitarian will support the establishment of those institutions, procedures and technologies whose purpose is to secure the greatest happiness for the greatest number. In contrast, an ethical deontologist, who claims that the highest good is served by our application of duties (to the right or to others), will acknowledge the justification of those institutions that best serve the employment of duties. Thus in governance the institutions that are not able to deliver the minimum goodness either in terms of fulfilling the duties or providing equitable justice and opportunities need to be reconsidered or changed. Since people are by nature sociable; there being few persons who turn from society to live alone - the question follows as to what kind of life is proper for a person amongst people. The philosophical discourses concerning politics and governance thus develop, broaden and flow from their ethical underpinnings.

Governance and bioethics are also related in the ways we view bioethics. As discussed earlier there are different ways to view bioethics. *Descriptive bioethics* -we can describe the "Bioethic" that people have through surveys, interviews and policy analysis (Macer

1994a). People's views based on anthropocentric, ecocentric and biocentric thinking add to the overall projection and direction of the policies that are established later on. *Prescriptive Bioethics* forms the basis of governance, constitution and laws that governments of the world make for citizens to follow. Also expressed in the form of international guidelines, conventions, treaties and regulations. *Interactive Bioethics* is seen in debates to formulate the policies intended to build a consensus.

1.3.3 Global governance of biotechnology- role of UN agencies

Biotechnology is multidimensional 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 Organisation 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. FAO itself does not do the scientific and technical research, but it a 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 countries, which are primary goals of FAO. It looks into technical, legal, and other normative work related to food and agriculture. FAO is also helped by the World Food Program (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. It provides funding for sustainable agriculture and development of biotechnologies for increasing food production in countries.

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 Organisation (WHO). WHO's objective, as set out in its constitution, is the attainment by all peoples of the highest possible level of health. One of the six core tasks of 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 program within WHO that is conducting an evidence-based study of the implications of modern food biotechnology on human health and development. United Nations Drug Control Program is another program 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 organisations.

The environmental aspects of the modern biotechnology are under the jurisdiction of the United Nations Environmental Program (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 (CBD 1992). 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 communication 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." (UNIDO, 2002). 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. Its core functions include as a global forum, to generate and disseminate knowledge relating to industrial matters and provides a platform for the various actors, and decision makers in the public and private sectors, civil society organizations and the policy- making community in general, and to enhance cooperation, establish dialogue and develop partnerships in order to address the challenges ahead. 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.

All these agencies should work in collaboration with each other on specific issues related to biotechnology that could come under their authority. One of the other responsibilities of the United Nations agencies is to formulate guidelines, regulations, codes of conduct, develop legal procedures and policies for international cooperation in the use of biotechnology for the betterment of the people of the world, which is usually done through negotiations between the member countries. Each agency is responsible for the type of code that needs to be developed in order for governance of biotechnologies in the nations.

Independent international organizations also play an important role 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.

International codes that are useful in governing different aspects of biotechnology are discussed in the following sections of the thesis as relevant.

1.3.4 The European Union

The regulatory procedures for biotechnology in Europe have become very stringent and have been criticized as being greatest barriers to trade. The regulatory procedure of biotechnology in Europe revolves around approaches toward horizontal and sector based legislations. The early regulatory framework for biotechnology was founded on a horizontal approach, which took account of the protection of the both human health and the environment across relevant sectors. Directive 90/220/EEC governed the deliberate release into the environment of genetically modified organisms (GMOs) and placing on the market of products for use as foods, feeds, and seeds as well as pharmaceuticals and directive 90/219/EEC governs work activities involving the contained use of genetically modified micro-organisms (GMMs). Both these are sector-based legislations and introduce provisions to specifically address risk and other issues relevant to the sector in question. The environmental elements still remain linked to the directive 90/220/EEC, which is one point of debate between US and Europe as it mandates a prior, affirmative regulatory approval before a GMO may be released into the environment. A manufacturer or the importer must submit a " notification" or application to the competent authority of the EU Member state where a GMO is marketed for the first time. The notification must provide the general information on the nature of the GMOs, the conditions for their release and an assessment of the possible hazards for human health and the environment. Then the competent authority evaluates within the timeframe of 90 days and, if found safer it could be released into the markets or disapproves it (EU 1990).

In February 2001, the EU adopted major revisions to directive 90/220, designed to improve public confidence in the process by which GMOs are approved. It is named as Directive 2001/18/EC and replaced directive 90/220 in October 2002. The new directive requires mandatory consultation with the public, mandatory labeling and traceability at all stages of the placing on the market, as well as the mandatory monitoring of the long-term effects. This is seen as a barrier to the products from the countries like US that are major exporters of GM food. It is also regarded as a barrier to imports from the other smaller

countries, especially the poor developing countries that may not be able to comply with the standards set by the European Union (EU 2001).

1.3.5 The USA

Pursuant to policies adopted in early 1990s, the United States, in contrast to the EU does not regulate genetically engineered / modified products as such. In contrast to the EC, which uses a process-oriented approach, the responsible federal agencies in the United States prefer a product-oriented approach for the regulation of genetically engineered products. This latter system does not categorize genetically engineered products on the basis of the technique by which they were developed, but solely on the actual product characteristics. Same or similar standards are applied as to non-engineered products under existing regulatory authorities such as Toxic Substances Control Act, the Federal Insecticide, Fungicide, and Rodenticide Act, and the Federal Food, Drug and Cosmetic Act. Because these regulatory programs are administered by different federal agencies, so, too, a variety of agencies are responsible for regulating genetically modified products. So, for example, the U.S. Department of Agriculture (USDA) regulates plant pests, plants and veterinary biologics. The Animal and Plant Health Inspection Service (APHIS) of the US Department of Agriculture (USDA) authorizes experimental field releases by using field test permits. Since 1993, a simplified procedure has been applicable under certain conditions for the approval of releases such as previous field release experience. APHIS regulations under 7CFR Part 340 pertain to the import, interstate movement or release of certain genetically engineered plants. This includes deregulation for commercial release. The Environmental Protection Agency (EPA) controls microbial and plant pesticides, and novel micro-organisms, and transgenic plants that contain pesticidal components, such as genes or gene products that confer resistance against insects. These products are considered pesticides themselves. Regulation of such crops by the EPA is required only when field testing becomes large scale or the determination of a tolerance level or exemption from a tolerance is required. Aspects of plant health and environmental risks of such plants are assessed by the EPA. In addition, the EPA approves changes in the registration for herbicide use on transgenic crops but does not assess aspects of plant health or potential environmental risks of herbicide-tolerant crops.

The Food and Drug Administration (FDA) controls food, feed, food additives, veterinary drugs, human drugs and medical devices. The US Food and Drug

Administration (US FDA) has authority under the Federal Food, Drug and Cosmetic Act to ensure the safety and wholesomeness of most food, except meat and poultry, which are regulated by the USDA, and agents with pesticidal characteristics falling under the jurisdiction of the EPA. Although pre-market approval of a product by the FDA is not formally required, all companies that applied for a new transgenic crop so far completed their consultations with FDA prior to the market introduction of the product. The FDA published in 1992 its statement of policy: foods derived from new plant varieties. The FDA relies on two section of the Act to ensure safety of foods and food ingredients. Whole foods, such as fruits, vegetables and grains are not subject to pre-market approval. The adulteration provisions of section 402(a)(1) place a legal duty on producers to ensure that the foods that they sell to consumers are safe and comply with legal requirements. The FDA has authority to remove a food from the market if it poses a risk to public health. Genetically engineered foods are regulated under this section as well (Maryanski 1997). The food additive provision, section 409, states that substances that are intentionally added to food must be generally recognized as safe (GRAS). Food additives are subject to review and approval by FDA before they are used in food. The FDA does not require labeling of food consisting of or derived from GMOs. Special labeling would be obligatory if the composition of a food developed through genetic engineering differed significantly from its conventional counterpart, for example, if a product contained substances that were not constituents in the human diet before (Rousu and Huffman 2001). The FDA regards the key factors in reviewing safety to be the characteristics of the food and its intended use, rather than the fact that new methods have been used in its production. This is a fundamental difference between the US regulations and those of the European Union, and lies at the root of much of the current controversy regarding GM foods.

Novel food products are not subject to special regulatory approval in the USA if the constituents of the food are the same or substantially similar to substances currently found in other foods (such as proteins, fats, oils and carbohydrates). For example, if a gene from a banana was transferred to a tomato, approval would not ordinarily be required before that food was placed on the market. However, if a sweetening agent that had never been an ingredient of any other food were added to a variety of grapefruit, then the novel food would need regulatory approval. The sweetener would be regarded as a 'food additive' and therefore be subject to other, more stringent, regulations (Madden 2001).

Many GM foods in the USA are not subject to special regulation and they may not be segregated from non-modified foods. For commodity crops (such as soybean and maize) imported into Europe, this can cause problems, since many such foods would have to be labeled under the EU novel foods regulation. For imports into Europe, this problem has been resolved for maize and soybean derived from GM plants by assuming that GM material *will be present*, unless the crop can be traced to a source which has been certified as free from GM material.

The US system is generally regarded as less burdensome for manufacturers than that of the EU, and many more GMOs have been approved. Critics of the U.S. approach say that regulatory efficiency has been achieved at the price of inadequate considerations of the risk, uncertainty and social values (Wirth 2001).

1.3.6 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 (Serageldin and Persley 2000). 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 organisations, 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 commercial 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 equally be 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 (Paalberg 1994).

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 theses 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 (Paalberg 2000).

1.3.7 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 popularity 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 pubic opinion about biotechnology." (Miller and Gregory 1998). 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 policies, 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. Fischhoff categorized five tentative conclusions,

emerging from a review of the studies of public perceptions of biotechnologies, which include that people distinguish among biotechnologies, different people have different views about biotechnology, people have strong opinion about how biotechnologies are managed, people have complex evaluative schemes and respond to evidence (Fischhoff and Fischhoff 2001).

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 b). 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 (Thompson 2001). 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 benefits 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 (Wartburg and Liew 1999).

1.4 Technology and development

Technology has been at the heart of human progress since earliest times. Today technology is talked more about in terms of digital technology, although scientific progress also involves the use of more mechanical technologies. There are different perceptions of technology, some people view technology as a reward of development and

some people consider technology as tool for human development. Technological innovations affect human development in two ways. First it can directly enhance human capabilities, for example, vaccines for infectious diseases, or improved crop varieties to cope with the deteriorating conditions of the environment, or internet access to directly effects by providing knowledge and living standards, people's ability to participate more actively in the social, economic and political life of a community and the world as a whole. Secondly, technological innovation is a means to human development because of its impact on economic growth through productivity gains (UNDP, HDR 2001). Use of technology decreases the costs and increases the income. The cost could be regarded in terms of economics, human labor, efficiency and time consumption. Access to medical technology results in increasing human welfare, through provision of better health care and medical facilities resulting in increase in the human power that can work and contribute in the economic and social growth of the nation. Applying simple technologies, like organic fuel, or wind energy can also help in preventing environmental degradation.

Today's technological advancements are faster and more fundamental, like information technology and breakthroughs in genetics, than in the past. Information and communication technology has connected the world into a network, helping in processing and executing a huge number of instructions in imperceptible time spans. Modern biotechnology, particularly recombinant DNA technology is transforming life sciences. The power of genetics can now be used to engineer the attributes of plants and other organisms, creating the potentials for huge advances, particularly in agriculture and medicine. Genetics is now the basis of life sciences with much research in pharmaceuticals and plant breeding now biotechnology based. Modern biotechnology has also touched other realms of life, since the power of genes is in human hands now, that are termed as Ethical, Legal, Social Implications (ELSI) of biotechnology.

1.4.1 Developing countries vs. developed countries

The world is not balanced in terms of access to technology, although there are many advantages of technologies. The world is divided into developing and developed countries based on the economic patterns, literacy, technological development and also in terms of legal procedures. All these criteria are interlinked and a holistic approach is needed for a total development in the poor parts of the world. Especially there are concerns that

although technology plays and important part in the overall growth and development, limited access of developing countries to the information and communication technology is increasing the gap in other spheres of development. Today only 6.7% of the world population uses the Internet, 3.2% in Latin and Caribbean, 2.3% in East Asia and the Pacific, and only 0.4% in South Asia where as 54.3% in US people use internet. With growth of technology in rich countries, poor countries and poor people will be marginalized, that the existing educational divide will be compounded by a growing digital divide. Watching the staggering growth of new technologies in the developed world, it is easy to forget that more than half the people in Africa have never used a phone.

There are some 145 million children in poor communities worldwide who will never get to go to school and 60% of them are girls. Hundreds and millions of others get only a few years and retain little or nothing. Even many who complete basic education are illiterate. Education and information is needed not only for human capital development through productivity but also for health and nutrition, improved quality of life and reduced poverty resulting in cohesion and equity leading to macro growth and development (World Bank 2000b). Poor countries are also conflict stricken countries where most of the resources are spend in fighting in the wars rather than on development. Also the social structures of most of the developing countries do not provide equal opportunities for all to be able to use their fundamental rights.

Because of the fundamental problems related to development like, poverty, education, overpopulation, lack of technology to access to information, more importantly lack of economic resources and expertise to develop reasonable strategies result in unequal participation at international level. This means that developing countries lose out in international debates for developmental programs and policy developments. It also has a negative effect on the type of international aid that they are able to get access to. Economic compulsions are not able to be tackled because of the huge debt and the lack of markets for their products to get foreign income. In developed countries, such problems do not exist at least on a large scale, however they also face a stiff competitions from other rich countries. Developed countries have to face more of an external international pressure of competition, which is quite different from the poor countries that spend more time and resources in looking for the solutions for fundamental problems within the

countries, followed by the international pressure of growing competition within the world.

1.4.2 Impact of globalization

Globalization is the process of continuing integration of the countries in the world and at the present time strongly underway in all parts of the globe. While the movement of goods, services, ideas, capital and technology across national borders is not a new phenomenon, its process for the past two decades marks a qualitative break. Supported by accelerating pace of technological change, by price and trade liberalization, and by growing importance of supranational rules, globalization has exposed national economies to much more intense competition than ever before. Today globalization involves numerous features that include internationalization of production (agriculture, mechanical, informatics and all others kinds) by changes in the structure of production, expansion of international trade and widening and deepening of international capital flows (Mrak 2000).

Improvements in transportation networks have reduced the costs of transportation and improvements in the information technology has made increasing volume of information available at very cheaper rates. Reduction in the transport and telecommunications costs have raised the intensity of competition and stimulate identification of most economic sites for both manufacturing of the products as well as their marketing. Another aspect of globalization is the expansion of trade of goods and services. Countries win when they gain market access for their exports and technology through international transfers. Also financial flows across national borders have risen far more quickly than trade in the recent years, which is also a distinctive feature of globalization.

Globalization is a controversial issue. Although globalization claims that liberalization of economic polices and technological advancements carry important benefits, on the other hand globalization also demands a drastically changed role of the national governments. It is especially a difficult issue for the governments of the developing countries as competitive environment need clear rules of operation, stable economic environment, unrestricted access to imports, efficient economic and social infrastructure, which is although ambitious but extremely strenuous issue for the poor countries of the world. There are winners and losers of globalization and this applies to both different

countries in the world as well as different groups of populations within the countries. There appears to be growing inequality among the countries resulting from globalization process. Figures show that the gap between per capita income of the richest and poorest countries doubled from a ratio of 30:1 to 60:1 (Lall 1999). The fact of some countries being winners and others being losers in the globalization process indicates that there are significant differences among individual countries in their ability to cope up with globalization. For developing countries, their globalization performance can be measured with the level and the speed of their integration into the global economy. For developing countries economic growth and the quality of the policies seem to be factors of crucial importance (World Bank 1996).

1.4.3 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 and 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 for the people. 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 diseases (Ensor and Witter 2001) 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.

1.5 Scope of this research

As discussed above ethical principles and governance are parallel and at many points interlinked to each other. The overall objective of this research is to analyze the role of ethics in the global governance of biotechnology, focusing primarily on food and agriculture with some highlights on the ethics of medical biotechnology in developing countries. It investigates the roles of various bioethical principles as the basis in the decision making process in the application of biotechnology at national and international level, and how bioethical principles may sometimes be at conflict in addressing the issues of biotechnology. It is also intended to find out how bioethical principles are balanced in legal procedures while balancing interests of all those directly or indirectly involved in the use of biotechnology at global as well as individual country level.

There have been much research done on the frameworks for biosafety, political, trade, economics and public perception of biotechnology, but the role of ethical principles in global governance has not yet been a focus of research. This thesis contains two major case studies related to governance of biotechnology and bioethics. Food and Agriculture Organisation of the United Nations was taken as one global governing body for

biotechnology in food and agriculture and India was taken as an example of developing country seriously involved in applications of biotechnology for its people.

1.6 Thesis hypotheses

Following five hypotheses are considered basic to the present research.

1.6.1 Modern biotechnology has increased the discussion of the ethical issues raised by science in society.

There is a wide literature available on the public perception of biotechnology in rich countries. There have been national and international studies, like Eurobarometer and OECD studies especially carried out for understanding public attitudes in the rich countries of Europe for regulatory frameworks. The inception of *Dolly* led to the beginning of new era of public debate on the biotechnology, when ordinary public led by sociologists and ethicists tried to foresee the implications of genetic engineering on their lives. Before that genetic engineering as such has not been a topic for ordinary people to commonly discuss. Issues of genetically modified food and other organisms have also been taken up in surveys and opinion polls among public to understand the level of awareness and different attitudes. Even for academics conducting opinion studies to understand public opinion and their attitudes towards biotechnology has become fashionable (Macer 1992, 1994b). The private sector also does lot of opinion poll studies to understand the market trends and consumer preferences for their products and the quality demand in the markets.

Biotechnology is a controversial issue, it has been widely discussed by the media, especially the negative aspects. News carrying GM stories have been seen now and then, which also adds to the increased awareness among people on ethics of biotechnology. Even in developing countries in Asia biotechnology has been extensively covered in the media. A number of governments, particularly in rich countries have commissions to examine ethical issues of biotechnology. For instance, New Zealand (Royal Commission on Genetic Modification), Thailand (Asia Pacific IMBN Priority Needs Commission), UK (Agriculture and Environment Biotechnology Commission), USA (National Bioethics Advisory Commission) have been set up by the governments to look into the ethical and other aspects of biotechnology.

Modern biotechnology has increased the discussion of the ethical issues raised by science in society given that besides scientists and policy makers, other groups of society like religious groups and NGOs and academics of other disciplines, like theologians, philosophers, ethicists have shown interests and given another dimension to biotechnology that has added a new division in the literature between those who claim "genethics" that special ethical issues are raised by new genetics, and those who think the ethical issues are the same for the past.

1.6.2. The governance of biotechnology requires multilateral and multi-sectorial cooperation.

Biotechnology is touching many spheres of life. The stakeholders of biotechnology include both ordinary persons to the international governing bodies. Involvement and equal, transparent and timely participation from each sector is necessary for recognizing, collecting and analyzing concerns that each group may have and later on developing balanced but also rational polices at both international and national levels. However, there are some governments and NGOs that want to ignore the ethical concerns not only of their own people but also international pressure for a coherent and unified approach for resolution of the differences in the approaches and priorities of the nations, and make biotechnology concerns and make biotechnology policy to face ethical issues only as national issue, by claiming unique cultural values. For instance, policies of some of the African nations has been criticized worldwide for their non cooperation in resolving hunger and famine within their own countries, and millions of people of their own countries are on the verge of death by not accepting food aid that contains some genetically modified food (BBC). Also some NGOs that have big networks like, RAFI and Greenpeace and Gene Campaign of India have taken very strong radical approach against modern biotechnology.

The central question to governance of biotechnology is if civil society (NGOs, CSOs, academics and also individual representation), governments (local, rural and urban, national and international bodies) and private sector (small and big private sector) that are key players in governing biotechnology can work in isolation and independent of other players, and how their isolation is going to influence the national and international policies.

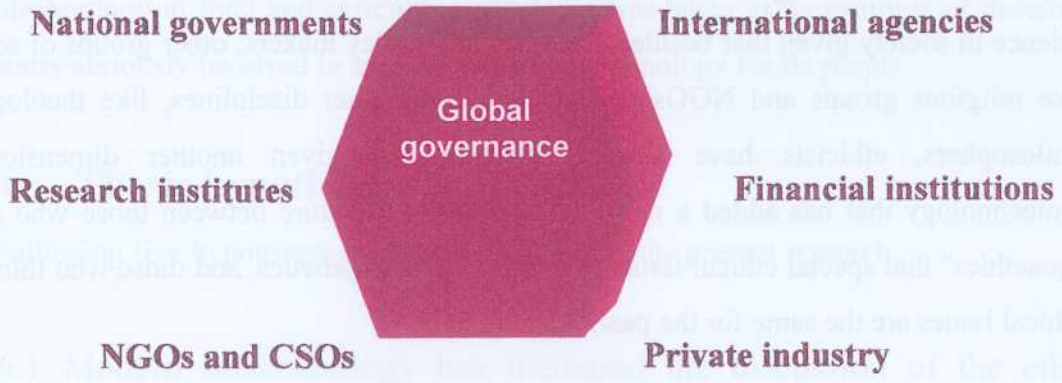

Figure 1: Actors involved in the global governance of biotechnology

1.6.3. Participation from poor countries is also needed in the global governance of biotechnology.

Multisectorial cooperation involves participation from all the parts of the globe. Poor countries also need to be involved in the governance of biotechnology not only because they have natural resources that can be harbored and harvested for the research purposes, but also in ethical terms as modern economic order gives little power to the poor countries. At the international level, least developed countries are in majority at the UN, still in the international negotiations they lose out given that modern governance is becoming politicization of trade and it is affecting participation from the poor countries. Policies and stands of rich countries have dominated in many international agreements and protocols and for poor countries it has been taken as a tradeoff in the name of market access and donor aid for fundamental developmental programs.

For rich countries also, is it possible to disregard the concerns of poor countries in drafting international governance rules when majority of the world is suffering from poverty and the all the other issues that are expanded due to poverty. The international development community used to think - or at least acted as though it thought - that if countries could sustain rapid growth, poverty would take care of itself however, growth does not always translate into poverty reduction. Even today 77% of the nations of the

world are either extremely poor or suffer from overall poverty, although there has been a trend of "pro-poor growth" for several decades now. One of the attributed reasons could be unequal participation from developing countries. Since at international level, biotechnology is projected as pro-poor technology, participation from poor countries become essential and also crudely in the name of having wealth of natural resources, developing countries need to be considered in policy making and governance of biotechnology.

1.6.4. People use ethical principles even when they do not explicitly use the term " ethics".

In daily life human beings are guided by their moral conscience that is developed through experiences, and shaped by culture and socio-economic conditions. Common values, like respect for life and tolerance and patience, care have been taught in every culture of the world, and can be considered universal. In academics, they are considered to be derived from ethical principles. The word ethics may not be especially used to describe the values that people have in general but it is seen in the choices made by people when they provide the reasons for their choice. In this way we can regard ethical principles existing in the human history since the beginning of humanity.

Use of ethical principles and their conceptualization has also been seen in the ancient political theories that were written, debated and documented well. Political theories of Aristotle commonly used ethical terms like happiness (eudaimonia), good (agathos), self-sufficiency (autarkês), justice (dikaiosunê), Rights (exousia). Aristotle did not regarded politics as a separate science from ethics, but as the completion, and almost a verification of it. The state is a development from the family through the village community, an offshoot of the family. A similar attitude was seen when the countries constituted United Nations and drafted Universal Declaration of Human Rights. Therefore it could be regarded that the concepts of ethics are actually not new and it has been developed according to the needs of solving problems at a given time.

1.6.5. The ethical issues raised in the national governance of biotechnology mirror those raised in the international governance.

The central question to the governance at international level is that if we can consider

the UN as a global government, facing the same dilemmas as each nation, even if of larger scale and diversity. The process of governance involves some fundamental rules and principles that are universally applied although at the level of conceptualization and expansion of their values may change or become different. At the national level, various constitutions of nations have been formed based on fundamental ethical principles and human rights that are universally recognized. At international level, we can see consensus for adoption of many regulations is based on balancing the ideals of nations and those ideals are reflected in the regulations, which are to be followed at international level.

International governance of biotechnology requires effective governance for sustainable development. Sustainable development is a holistic approach where biotechnology is looked from different angles, like environmental, social, economic, legal and ethical considerations. The basic issue for developing countries is economic and legal, and that is reflected in the international conventions like Convention on Biological diversity and the Cartagena Protocol. Some fundamental issues for developing countries that directly influence the sustainable development and the use of biotechnology are illiteracy, poverty and overpopulation. That these are basic issues for the developing countries have also been well recognized at United Nations level, as seen in the various programs of many of the United Nations.

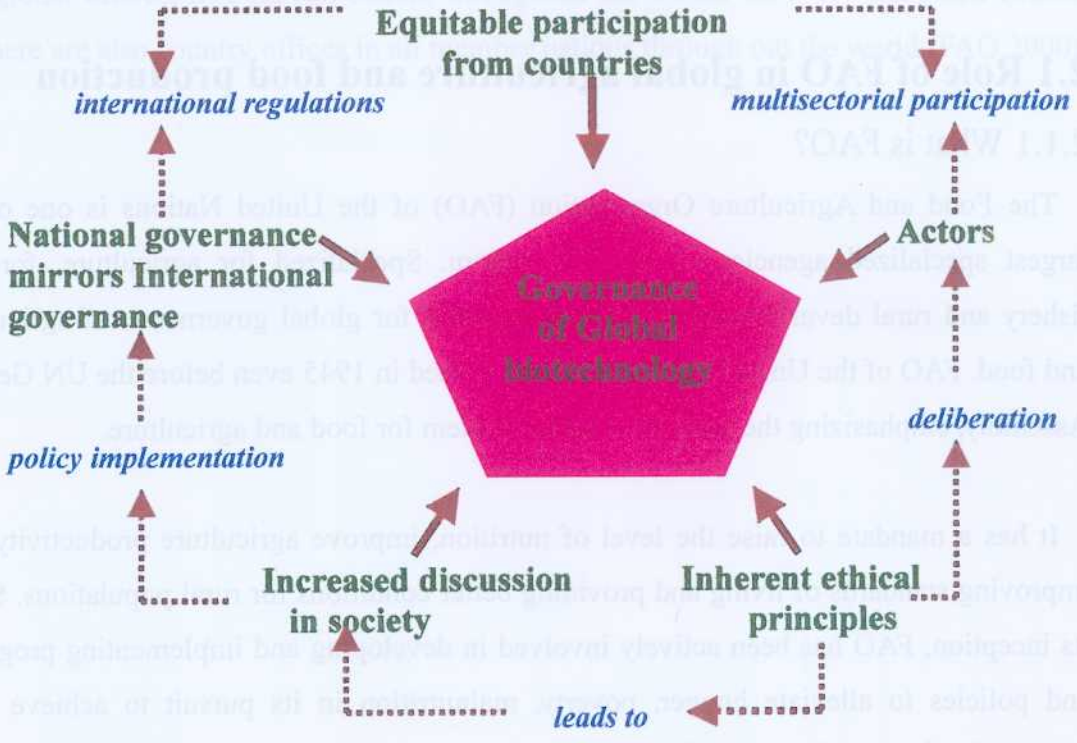

Figure 2: Inter-relationships between some components of the hypotheses