Global Institutionalization of governance of biotechnology and universality of ethical principles.

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When Karl Herkley coined the term 'biotechnology' he referred to methods and techniques that permit products to be produced from the raw materials with the aid of living organisms, without defining how and what could be the products of technology. 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. Several international agencies have defined biotechnology according to 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 1992), 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). 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.

When we talk about biotechnology, it is important to remember that biotech revolution is broader than genetic engineering. It is not limited to our ability to decode and manipulate DNA, but underlying science of biology. Any findings and advances in genetics eventually affect a number of other related fields including molecular biology, population genetics, medical genetics, behavior genetics, anthropology etc. Therefore governance of biotechnology is a critical and difficult question with an added challenge of difficulty of controlling and prediction aspect of the technology and its implications on life and living organisms, biological and beyond.

Governance

Marshall Nirenberg, the scientist who deciphered the genetic code famously said, "we are apt to learn to move genes around long before we can know it is safe to do so". The safety is not only biological and genetic, but also social as we can see it is effecting trade and politics at global level, as well as affecting the lives of individuals and society and changes in the environment. Safety of technology can only be acquired through ethical governance and firm regulations, and it is not limited to implementation of legal procedures to solve problems. 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). Governance is described in different aspects, based on the institutional framework in which applied, like economics and corporate, environmental, developmental strategies, and ethical perspective. There are different levels of governance and broadens from a community to nation and international

level and the role played by each actor in decision making process narrows as the level of governance broadens.

Ideals of good governance

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. Participation should not be paternalistic, as often viewed in medical ethics where patients are understood to be participated when informed. Participation means freedom of association and expression on one hand and an organized society on the other hand. 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. 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, aligning 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. 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 (Chadwick et al 2004). 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. If we think bioethics is love of life, as defined by Macer (1998) then each human being whether alone or with community does exercise bioethics in everyday practice in some ways even without realizing it. The philosophical discourses concerning politics and governance thus develop, broaden and flow from their ethical underpinnings.

Institutionalisation of global governance of biotechnology

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. Food and Agriculture Organisation of the United Nations (FAO) is the responsible body for governing the biotechnology applications in food and agriculture including fisheries and forestry all over the world with an aim of eradicating food insecurity and malnutrition from the world and sustainable development. 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. 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 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. United Nations Drug Control Program (UNDECP) is another program of the United Nations that looks after the medical technology and issues related to unethical production and use of drugs

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. 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). 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. 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. 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 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.

Balancing universal principles

Institutionalization of different aspects of biotechnology at global level has undoubtedly helped in providing more resolute answers to some of the problems arising because of globalization and help in highlighting significant problems of nations and their priorities in adopting and implementing various biotechnologies. The underlining act of the UN agencies to balance the interest of all the nations and their people whilst advising on appropriate technologies is delicate act and not necessarily always result in desired agreements and consensuses. To achieve a balance between values of different cultures and national priorities needed not only for the peaceful resolutions of the conflicts but also because there are no human rights without a basic moral consensus.

The role of United Nations in this balancing act is crucial but a 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. Ethical principles may not be directly mentioned in the international policy guidelines but use of terminologies and mandate of the organizations are pillared on ethical principles, for example, mandate of FAO and policy documents mention appropriate advice to countries, which is based on balancing principles and hunger alleviation is based on ethical principle of beneficence. International ethical guidelines specifically mention about participatory approach in implementation of biotechnology, based on the ethical principle of respect for autonomy to make decisions. In the international debate on genetic engineering, underlying issue of safety of technology, quality assurance, management of risk is based on the ethical principle of do no harm, harm could be inflicted in terms of health, environment, economic and hurting cultural and religious values of people across the world.

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 and ethical

guidelines, which are to be followed at international level. For example, Universal Declaration of Human Rights formed the basis of constitutions of many nations and Nuremberg Code and Helsinki Declaration are the basis of code of medical ethics of many countries. In medical biotechnology, Human Genome Organisation (HUGO) ethics committee has been proactive in framing ethical guidelines on genetic research, and several countries and multinational companies follow these recommendations on conducting research, safety of technology and sharing of benefits among the stakeholders. Nevertheless when it comes to implementations of these guidelines, the priorities of nations and competitive nature of globalization does shadow the balancing act, as seen especially in implementing guidelines on food derived from modern biotechnology and trade of genetically modified food and the trade related aspects. The labeling of GM food has been contentious between USA and Europe, which has also been over shadowed by rejection of GM food by the European public and some European countries declaring their boundaries as GM free zones.

Globalisation and political demands of biotechnology.

Globalization is the process of continuing integration of the countries in the world. 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) and it has necessarily become integrated to the global governance of biotechnology.

Civil society, science, politics and industry all have a political interest in the governance of biotechnology, especially in harvesting genetic knowledge, its industrial application and its therapeutic potential. Sometimes those interests overlap and sometimes they are completely incompatible and the governing systems have to find ways of negotiating and bringing a basic consensus and hopefully resolving. However, The issues for consensus are not necessarily always based on ideologies and ethical values of the governments, but also what market led globalization where economic value plays higher role than the moral values of the people. Arguably economic implications and benefits do influence the choices we make at personal and broader levels; and our needs are the basis of our choices, as also seen by adoption of GM technologies especially in the developing countries although there is still a resistance to direct application of the two approaches commonly seen, US liberal approach of the USA or very restrictive approach of European countries. However, the legitimacy of policy process itself can be questionable if the regulatory balance is not right as seen in the public debates on GM food across the world where it has been debated as an election issue by political parties (Bhardwaj 2001). Following the experience of GM foods and crops, and the political upsets we can say that regulatory policies need to be adapted in a way which deal with both the concerns of people and the industry and to compete effectively in the global biotechnology markets.

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). 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. These areas of policies signify an important aspect of the rich genetic resources available in the developing countries and the lack of technologies, economic and human resources to harness them. We can say that these changing faces of governance systems, from a political process to participatory approaches in policy from the beginning are also shaping ideals of global ethical values and new ethical principles are sought to accommodate wider values that are at stake. The concept of benefit sharing emerged with a flush of patent applications on genes and genome sequences. Benefit sharing and intellectual property rights are now adopted as ideals in the ethical guidelines in biotechnology. There is a need for 'value-led globalisation' rather than economics led globalization.

New technologies and new governance
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 public participation in the GM debate in developed countries of the world actively influenced the norms of medical ethics as well. We can say that for the three years more developments have taken place in medical biotechnologies than in agriculture biotechnologies. One reason could be the 'failure of governance systems' and political structures to be unable to develop regulatory policies that have an impact on consumer confidence, parameters of ownership and define cost-benefit balances.

The ethical concerns of genetic engineering led ordinary public to become more aware of the governance of technologies and the role and strength of other stakeholders in the governance of technologies, although there have been strong criticism of some of the medical biotechnologies such as cloning and stem cell research, arguably they have different impact on globalization process than GM technologies, because of no direct trade benefits and difficulties in implementation of easy access to technologies. Nevertheless, with the development of new dimensions of research in medical technologies, such as development of biobanks and genetic databases, serious concerns are raised on the issues of governance of these technologies with regard to protection of human rights and other fundamental concerns such as confidentiality and respect for privacy of information, along with the legitimacy and validity of scientific research. In the international governance of medical technologies, new ethical principles such as solidarity and equity are sought along with ownership of genes and right to information (Chadwick 2003).

Conclusion
Ethical assessment of technologies is challenging and problematic concept and developments in technologies will inevitably give rise to ethical challenges. It becomes more problematic especially when it comes to genomics and the use of new technologies especially when the prospects lie few generations away. New genetic technologies pose challenges for ethics, as there are not only developments in technologies but also in the potential uses of technologies and future opportunities. Technologies themselves make us to rethink our own theories and methodologies. It is not alone a question of maximizing benefits and reducing harm we also need to lay foundations of good governance structures for the future scenarios that can be predicted with the state of the art of technologies.

Reconfiguration of present governance systems or construction of new governance systems for ethical regulation of technologies is broader issue, but international agencies such as the UN are still perceived by most public opinion as the only source of international legitimacy (Macer 1997) . Therefore the role of UN in the international debates on biotechnologies can't be ignored, but the challenging task is in the efficiency in decision making as a single international political institution. Global institutionalization of governance of biotechnology can be said as a balancing act of different cultural values, ethical principles, interests of stakeholder and political realms in which humanity can be better organized.

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