Quadrant II – Transcript and Related Materials

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Unit: 10 -Applications of Genetic Engineering

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Notes

Modern biotechnology has a great impact on medicine and agriculture. It is important to see the benefits and risks in an international way because the world is becoming smaller and ever more interdependent. Generally, most people in industrialized countries perceive more benefit than harm from science and believe that improved quality of life depends on scientific information.

Genetic engineering is one element of biotechnology and involves design of the DNA or an organism. Genetic engineering may be perceived as a technology that can bring many benefits, and it is also often perceived as a technology associated with many risks, and most people have both these feelings about it. **Bioethics** is the study of ethical issues associated with life, including medical and environmental ethics. It looks at profit and risks, and also at balancing pursuit of individual autonomy with the duties of justice.

The word Bioethics consists of two parts derived from Greek: Bios meaning life and the adjective ethics meaning good or bad, right or wrong. Ethics is the philosophy behind moral or the theoretical basis for moral (moral derived from the Latin word moris meaning manners). Based on this, bioethics should deal with ethical problems of life and also of death since death is a function of life. Ethics deals with values and bioethics should therefore deal with values related to life and life processes.

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

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

Bioethical principles and biotechnology:

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

Human beings regard themselves as the most intelligent species, hence hold the liberty, right and authority to manipulate and use the nature according to their needs. The principle of autonomy is most controversial in applying biotechnology; and it is sometimes rather applied as principle of respect for autonomy. Proponents of genetic engineering usually try to debate autonomy as an ideal that centres on using human beings' capacity for deliberating about technology and then reflecting on its implications on life.

The biosafety guidelines are developed to contribute to ensuring adequate level of protectioj in the fields of safe transfer, conservation and sustainable use of biological diversity and reduce risks to human health. The Cartagena Protocol on Biosafety to the Convention on Biological Diversity has been designed to cover the transboundary movement, transit and handling of all living modified organisms.

The NIH, USA specify the practices for constructing and handling of recombinant DNA molecules, organisms and viruses, etc. These guidelines require approval and clearance from NIH or other Federal agency.

Biosafety during Industrial Production:

Many processes have the potential to generate Biohazards. Inhalation appears to be the most significant mode of entry of microbes into the body, Most reported health problems are associated with downstream processes, and the risk of allergic reaction is the greatest after the product is more concentrated. An effective monitoring strategy should involve environmental assessment of emissions at all stages of manufacturing process, and critical assessment of the biosafety performance of process equipments.

Biosafety Guidelines in India:

The MOEF gives the rules and procedures for manufacture, import, use, research and use of GMO made from such organisms under the Environment Protection Act, 1986. The DBT implements the research and development experiments utilizing the GMOs and recombinant DNA products, while MOEF implements large scale commercial use of these. The salient features of the guidelines are as follows:

1. Organization involved in research is required to set up an Institutional Biosafety Committee (IBC) having a DBT nominee. IBC will be nodal point for interaction of the organization with the government. IBC will provide half yearly reports to RCGM.

2. RCGM reviews the approval of ongoing projects on GMOs.

3. The MOEF has an internministrial committee called GEAC, which has subject specialists as members, and is the competent authority to decide on the large scale use of GMOs.

4. The guidelines recognize four levels of risk in case of experiments with microorganisms, based on pathogenecity of the microorganisms, disease of epidemic causing strains in India.

5. Four biosafety levels are recognised and containment facilities for each level are recommended for necessary safeguards.

6. All procedures should be scrutinized and checked. Controlled release of GMOs should be done. Planned field experiments with transgenic plants will be permitted only after evaluation according to the guidelines.

Biosafety Programme:

The main emphasis is given to facilitate the implementation of biosafety procedures, rules and guidelines under Environment (Protection) Act 1986 and Rules 1989 to ensure safety from the use of Genetically Modified Organisms (GMOs) and products thereof in research and application to the users as well as to the environment. A three tier mechanism comprising Institutional Biosafety Committees (IBSC) at the Institute/ company; the Review Committee on Genetic Manipulation (RCGM) in the Department of Biotechnology; and the Genetic Engineering Approval Committee (GEAC) in the Ministry of Environment & Forests (MoE&F)for granting approval for research and development activities on recombinant DNA products, environmental release of genetically engineered (GE) crops and monitoring and evaluation of research activities involving recombinant DNA technology has been established. Applications in pharma/ agriculture sectors for import/ export/ transfer / exchange of GE materials including GE seeds, conduct of pre-clinical toxicity studies, evaluation of pre-clinical study reports and recommendations to DCGI for appropriate phase of clinical trials of new drug(s) or similar biologics, confined field trials on GE crops etc., are examined by the RCGM and appropriate decisions are taken. RCGM has taken several policy

decisions on biosafety research on agricultural/ bio-pharmaceuticals / industrial products. (https://dbtindia.gov.in/regulations-guidelines/regulations/biosafety-programme)

For Biosafety Guidelines in India, please visit: https://dbtindia.gov.in/guidelines-biosafety