Nuffield Council of Bioethics: Consultation on Emerging Biotechnologies

1. How would you define an 'emerging technology' and an 'emerging biotechnology'? How have these terms been used by others?

Emerging technologies are innovative technologies arising from existing technologies and have a substantial impact on the social and economic parameters of the world. Emerging Biotechnology are innovative technologies (within biotechnology) which will improve the quality of life by improving health, developing new materials and increasing food production when compared to current standards. They have the potential to create a new industry.

One does not find much use of these words in the Indian context. The department of biotechnology, Government of India states that Biotechnologies is one of the emerging technologies but does not define what an emerging technology is. In one of the articles, Emerging technologies are defined as those technologies that may play a major role in the development and growth of any country. (reference: http://EzineArticles.com/4455397)

2. Do you think that there are features that are essential or common to emerging biotechnologies? (If so, please indicate what you think these are.)

Some of the common features of emerging Biotechnologies are;

1. These technologies are working on challenging global issues which would be difficult to solve using current traditional technologies (such as synthetic biologists are envisioning creating bacteria with artificial chromosomes to enable them to harvest sunlight into fuel)
2. Innovative application of existing knowledge.
3. Drawing expertise from a range of disciplines including engineering principles. (Multidisciplinary in approach).
4. Have a direct impact on human welfare.

3. What currently emerging biotechnologies do you consider have the most important implications ethically, socially and legally?

- **Synthetic Biology:** The ability to play god.

- **GMOs:** GM Seeds and Crops in view of their safety and impact on human health and environment are still being in doubt. Small land holding farmers in India find it viable to harvest and replant the seeds and are therefore not willing to pay for GM seeds year after year from seed companies.

- **Regenerative medicine** using stem cells.

4. Are there examples where social, cultural and geographical factors have influenced the development of emerging biotechnologies (either in the past or currently)?

Stem Cells Research in India
When it comes to stem cells research, religious, cultural and political circumstances are not in conflict in India. There has been a growing interest from private companies and government bodies as stem cell therapy is looked as having a great potential to emerge as a therapy for cardiovascular disorders; neurological disorders; burns and wounds; osteoarthritis; osteoporosis; bone, cartilage and liver disorders; congenital abnormalities; and neoplasms. Over 40 institutions, hospitals and companies are involved in stem cell research in India. It is reported that more than 90 programs have been implemented on various aspects of embryonic, iPS and adult stem cells.

Bt Cotton case study in Gujarat, India
The case of Bt cotton in Gujarat, India is as an example of how public policy sometimes might become less effective when large-scale violation of ethical and scientific norms takes place with positive business outcomes. Entrepreneurial spirit has created a unique case of farmer participatory research wherein farm crosses are being made between Bt cotton varieties and other released varieties. New production cycles are being created by farmers who have extended the life of the crop from six months to nine months to reap advantage of continuous flowering and thus higher yield. This happened in an unauthorised manner, with full public knowledge and despite complaints by the inventor of the Bt Cotton Varieties about the other Seed Company having 'stolen' their Bt gene.

(SOURCE: Agricultural biotechnology in India: ethics, business and politics.
Authors: Anil K Gupta and Vikas Chandak, Published in Int. J. Biotechnology, Vol. 7, Nos. 1/2/3, 2005).

5. Are there examples where social, cultural and geographical factors have influenced public acceptance or rejection of emerging biotechnologies?

India is interested in promoting GM crops to raise crop productivity levels to feed its growing population, minimize use of pesticides and improve the incomes of the farmers. However, GM Crops are yet to take a larger foothold in India. Traditionally, farmers are known to harvest and replant their seeds and are not willing to pay for seeds year after year from seed companies. Since some of these GM crops are sterile, (which means that farmers need to keep buying the seeds from seed companies that produce them), GM crops have not picked up in a big way.

From the consumer point of view, there have been concerns about the safety of genetically engineered foods. The field trials of GMO aubergine or eggplant in India have been put on hold until further studies can prove the crop's safety.

http://www.suite101.com/content/gmo-eggplant-will-not-be-grown-in-india-a200573#ixzz1OUxg3Ad0

In India, Embryonic Stem cell research and "therapeutic cloning" are not of serious religious concern. Therefore there has been no rejection of these technologies. Indian scientific community upholds the view that if embryonic stem cell research can find relief for incurable diseases, it should be encouraged.

6. Are there examples where internationalisation or globalisation of research, markets and regulation have influenced the development of emerging biotechnologies?

Internationalisation of research is significantly influencing the development of emerging technologies in India. An example is the collaborative work between the Kyoto University's Institute for Integrated Cell-

Material Sciences (iCeMS) and the Institute for Stem Cell Biology and Regenerative Medicine (inStem) in Bangalore.

The two labs have joined up to leverage upon each other's strengths to cover the fields of single-molecule imaging, disease model research and stem cell research. They hope that their joint work will greatly enhance the understanding of the forms and functions of cellular meso-architectures, possibly leading to the discovery of new drugs and treatment.

Nichi-In* Centre for Regenerative Medicine (NCRM) in Chennai, India is an Indo-Japan joint venture institute carrying out research, training and clinical applications-protocol development in regenerative medicine, with emphasis on Stem cells, Progenitor cells and autologous adult cells with regenerative capability to take them to clinical application. The institute has started providing Autologous NK cell based immuno-cell therapy (AIET) for cancer and providing stem cell isolation, enrichment and expansion services to partner hospitals in India for various diseases. The AIET which is in clinical practice in Japan since 90s for more than 15 years is being applied in India through NCRM. http://www.ncrm.org/

7. How have political traditions (such as liberal democracy) and political conditions (e.g. war) influenced the emergence of biotechnologies?

With the Indian economy growing, funding for science and technology has also seen a rise. Since Biotechnology has been recognised as a sunrise sector in India, it has received greater attention in terms of funding. Political conditions have not influenced any change in funding pattern for this sector. The Department of Biotechnology, Government of India has been therefore liberal in terms of funding for research projects and institutes in stem cells and therapy. Stem cell research in both the public and private sectors has grown considerably over the past few years in India, where political conditions or faith has not hindered its expansion.

http://ezinearticles.com/?Biotechnology-Thrives-in-India&id=181768

8. Are there ethical or policy issues that are common to most or many emerging biotechnologies? Are there ethical or policy issues that are specific to emerging biotechnologies? Which of these, if any, are the most important?

The issues are Safety and Trust.

- Safety Issues refer to how safe the technologies when used in humans, on the environment and ecology.
- Trust Issues refers to false or exaggerated claims of cure or solving of a problem due to the application of the technology or product.

9. Do you think that some social and ethical themes are commonly overlooked in discussions about emerging biotechnologies? If so, what are they?

As India becomes a Global Centre for clinical trials, both for its own industry and contract research organizations working on behalf of foreign companies, Social and ethical themes have become part of the discussions on emerging biotechnologies in India. However, what is of concern is the general lack of faith in the integrity of the testing and approval process. Even if the ethical committee grants approval, suspicion lingers that the data they are presented with may have been tampered with. There

are also fears that agribusinesses can influence decision makers, who could, in turn, make science pliable.

10. What evidence is there that ethical, social and policy issues have affected decisions in (i) setting research priorities, (ii) setting priorities for technological development, and (iii) deploying emerging biotechnologies, in either the public or private sector?

India's research priorities in emerging biotechnologies have been based on solving the country's problems in terms healthcare and food production. India's commitment to biotechnology was first formally recognized with the creation of the National Biotechnology Board (NBTB) in 1982, with the brief to create a research infrastructure and identify priority needs as a platform for long-term expansion of the healthcare and agricultural sectors.

Research in Emerging biotechnologies in the private sector in India has been driven by the huge market potential in the healthcare and agriculture sectors. The Central and State Governments have also play an important role in shaping the market environment of emerging technologies such as stem cell science. Building on their experience with IT innovation, most State governments have strategies to attract biotechnology industry through policies such as tax credits, subsidized industrial infrastructure and state support for technology incubators. This has encouraged private companies to focus their research on emerging biotechnologies.

11. What ethical principles should be taken into account when considering emerging biotechnologies? Are any of these specific to emerging biotechnologies? Which are the most important?

The following principles should be taken into consideration when considering emerging biotechnologies. However, they are not specific to emerging biotechnologies.

- To respect the power of emerging biotechnology and apply it for the benefit of humankind.
- Accord highest priority on health, safety and environmental protection during the deployment of the technologies.
- Listen and respond to concerns of those who are worried about the implications of these technologies.

12. Who should bear responsibility for decision making at each stage of the development of an emerging biotechnology? Is there a clear chain of accountability if a risk of adverse effects is realised?

Since emerging biotechnology has a bearing on the public, the government (regulator), should bear the responsibility for responsibility at each stage of the development of the technology. As of now the chain of accountability is not clear in India.

13. What roles have 'risk' and 'precaution' played in policy decisions concerning emerging biotechnologies?

In India, risks and precautions have helped in setting up ethical guidelines and also on the types of research that can be undertaken in India. The Indian Council of Medical Research (ICMR) has come up with guidelines for Biomedical Research on Human Participants (2006). Likewise, the Department of Biotechnology and ICMR have come out with a *Guidelines for Stem Cell Research and Therapy.* The

guidelines propose a system of review and monitoring of the field, based on a National Apex Committee (NAC) for Stem Cell Research and Therapy and, at the institutional level, Institutional Committees for Stem Cell Research and Therapy. All research, including clinical trials, would require the prior approval of, and be registered with, the NAC. The regulatory agencies have also prohibited some areas of research including reproductive cloning, implantation of a human embryo into the uterus after *in vitro* manipulation and transfer of human blastocysts generated by somatic cell nuclear transfer (SCNT) into a human or nonhuman uterus.

Likewise, government of India has also set up the Genetic Engineering Approval Committee which regulates the use of GM crops so that the safety issues get factored in.

14. To what extent is it possible or desirable to regulate emerging biotechnologies via a single framework as opposed to individually or in small clusters?

Since ethics are universal and common, it would be better to regulate emerging biotechnologies via a single framework as opposed to themes or geographically.

15. What role should public opinion play in the development of policy around emerging biotechnologies?

Public opinion is crucial in the success of emerging biotechnologies because of their impact on human welfare and the ethical dilemmas that they might pose. The resolution of the issues requires a broad public discourse in order to consider the interest and ideas of all segments of society such as patients, religious leaders, health care providers, user community, environmentalists, consumers, legislators, and other groups who share an interest in bioethical issues.

16. What public engagement activities are, or are not, particularly valuable with respect to emerging biotechnologies? How should we evaluate public engagement activities?

Instead of leaving emerging biotechnologies only in the hands of the scientists, regulators and industry, engaging the public through the mass media would be particularly useful in democratisation of the science and decision making. Use of mass media is crucial in India considering that a substantial proportion of the population is illiterate. A consultative process involving the public, voluntary sector, researchers, media, etc could be the way forward.

17. Is there something unique about emerging biotechnologies, relative to other complex areas of government policy making, that requires special kinds of public engagement outside the normal democratic channels?

None.