This response was submitted to the consultation held by the Nuffield Council on Bioethics on Emerging biotechnologies between April 2011 and June 2011. The views expressed are solely those of the respondent (s) and not those of the Council.

Consultation on emerging biotechnologies

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

➔ There is no definition or classification of 'emerging technology' or 'emerging biotechnology' in use in Korea. Instead, the term 'new health technology' is used in the medical sector. According to the Korean Medical Law (Article 2 Clause 54) 'new health technology' is defined as a technology that the Minister of Health and Welfare (MoHW) requires to be checked for safety and effectiveness. Currently the words 'emerging technology' and 'innovation technology' coexist in academia.

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.)

➔ It depends how 'emerging biotechnology' is defined but general features are;

1) It has the innovative power to change an original paradigm.
2) It brings an increase of 'efficiency' or 'utility' in outcome, but in application the potential benefit or harm is difficult to forecast
3) It can be easily understood as it challenges traditional ethical beliefs.

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

➔ IVF (In Vitro Fertilization) which is used in Assisted Reproductive Technology or PGD (Pre-implantation Genetic Diagnosis). In addition there are genomics, Xenotransplantation, Neuroscience and Nanotechnology.

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

➔ The desire to carry on a family line leads sterile couples to use assisted reproductive technologies rather than adoption;

- ➔ Sensational life science stories in the media and excessive trust in science has led patients to have over expectations of stem cell procedures;
- ➔ Scientific experimentation without pragmatic considerations is driven by a results-oriented society;
- ➔ Commercialization of tailored medical services such as the emergence of a DNA test service.

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

- ➔ Indiscreet media exposure
- ➔ Excessive pressure on science development and the national interests arising from it
- ➔ Promotion of Jingoism

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

- ➔ There has been a legal dispute involving Advanced Cell Technology (ACT), a US company, over the use of embryonic stem cells in clinical tests. The Korean National Bioethics Deliberative Council regulates clinical tests under the Bio-ethics Law (Article 4.1 Clause 20) which allows the use of stem cell lines only for research purposes. International regulations such as those provided by ISBER or NAS have been introduced and there has been the movement of medical samples between countries.

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

- ➔ South Korea is very dependent on national regulation and control, thus, the emergence of biotechnologies is highly influenced by domestic policy and regulation.

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?

- ➔ Lack of scientific understanding among general public;
- ➔ Lack of communication among science and social policy makers;
- ➔ Lack of expertise among administration officials;
- ➔ Commercialization of research due to economic interest.

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

- ➔ Fairness in the sharing of benefits or social change;
- ➔ High ethical price e.g. negligence of life or the possibility of exploitation of women and embryos;
- ➔ Strengthened social trends e.g. neglect of the elderly and valetudinarianism.

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?

- ➔ Research funding and the number of medical procedures in assisted reproductive technology have been increased as part of a sterile couple supporting project (2010) which was set up to counter a low-fertility, ageing society;
- ➔ Due to the increase in national policy supporting projects in tailored medicine, the number of research projects on dielectric and cohort have increased;
- ➔ After enacting the Bio-ethics and Safety Law (2005), the number of research projects using adult stem cells has increased. Central or local government can now provide funds to promote research on adult stem cells.

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?

- ➔ General ethical principles include: respect for life and dignity, good deeds, justice, respect for autonomy, stewardship among managers and research integrity. Priorities depend on the technology. There has been no social consultation, but respect for a man's life and dignity seems to be the most important principle according to the Korean law.

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 realized?

- ➔ First stage: A professional group e.g. scientists;
- ➔ Second stage: Institutional Review Board or Research Ethics Committee/Independent Ethics Committee which is responsible for overseeing professional groups and associations;
- ➔ Third stage: policy decision makers, media and regulatory authorities who adopt and apply policies to society;
- ➔ Last stage: civic groups who are needed to monitor compliance;
- ➔ In Korea there is no clear chain of accountability managing the risk of adverse effects.

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

- ➔ If experts agree there is risk, this can influence and increase regulatory oversight and the creation of guidelines to protect against danger.

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?

- ➔ There should be a single framework to regulate emerging biotechnologies. Expert groups, research institutions, regulatory authorities, civic groups should voluntarily co-regulate from various perspectives.

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

- ➔ Public opinion is important. Public outreach should deliver information based on accurate facts and should guarantee democratic accountability.

16. What public engagement activities are, or are not, particularly valuable with respect

to emerging biotechnologies? How should we evaluate public engagement activities?

➔ Public hearings, symposia, open fora, public meetings for agreement. All are important.

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?

➔ It is based on scientific professionalism.
➔ It attracts social consultation regarding different ethical views.

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