

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.

RESPONSES TO THE NUFFIELD COUNCIL ON BIOETHICS: - INVESTIGATION OF EMERGING BIOTECHNOLOGIES:

Question 1:

The terms ‘emerging technology’ and ‘emerging biotechnology’ have been used in many different ways over many years. One of the earliest examples was Haldane’s wonderful essay *Daedalus*, the inspiration for Huxley’s *Brave New World*; numerous books and articles have been published since, all dealing with emerging biotechnologies, particularly involving the potential for genetic enhancement and similar approaches to the betterment of mankind. While entertaining, these exercises have been completely futile with respect to any serious discussion on bioethics. In the present context it will be vital to have a more narrow definition of emerging biotechnology which encompasses the principle that a field has developed to at least the stage at which there is evidence to suggest that, by experimental manipulation, it is possible to obtain fundamental changes in biological activity. It is futile to open up arguments about fields like human intelligence and behaviour at a time when molecular and cell biology are simply uncovering layer upon layer of complexity. Furthermore, there is no shortage of emerging biotechnologies which have reached the stage at which they are ready for debate regarding the ethical and social issues involved.

Question 2:

This is a critical question for the Council if its report is to be kept within a reasonable scope. In the very simplest terms an emerging biotechnology might be defined as an experimental system that has reached the stage where there is reasonable evidence that it can alter fundamental biological function in any living organism, either permanently or at least over a significantly long period such that it will alter the phenotype of that organism. While such technology could mediate its effect by changing the organism itself there is now clear evidence that such effects might also be obtained through significant alterations in the organism’s environment. It follows that emerging biotechnology directed at altering the environment has also to be discussed in the light of the possibility that it will have the potential to cause deleterious long-term effects on living organisms.

Question 3:

In the biomedical field the increasingly low cost of DNA sequencing is already beginning to evolve commercial practices involving the sequencing of individual genomes for advice about the risk of illness. And it has recently been announced that companies are being set up to measure the length of human telomeres for the same purpose. Given the state of the science this raises a number of social and ethical issues. The increasing ease of pre-natal detection of genetic disease by evolving technology also raises a wide variety of questions about the ethical status of genetic counselling, the question of whether there is such a thing as neutral counselling, and the process of counselling against a limited background of knowledge about the true risk for particular diseases. In particular, it is going to raise increasing problems about the severity of genetic disease and other traits and to what extent it is ethical to offer termination of pregnancy for relatively mild conditions. These problems have been around for a while but they are going to be intensified rapidly by new technology.

Somatic-cell gene therapy is now starting to be applied and at least in the USA there have been reports of the application of germ-cell therapy. With the rapid advance of biotechnology in this area this field is going to have to be re-looked at completely. Although the fields of stem cell therapy, therapeutic cloning and gene transfer between species for therapeutic purposes have been subject to a good deal of discussion from the ethical viewpoint, these fields are also moving so fast that they will require detailed reappraisal. Nanotechnology is still very early in development but may require appraisal within the foreseeable future. The development of genetically modified disease vectors, mosquitoes for example, will also require analysis from the biological, social and ethical view point.

Questions 4 – 6:

These issues seem to be rather closely related. The concept of ownership of the information obtained from the human genome project was a matter of intense social and political division until the two parties decided to call it a draw! This undoubtedly had an effect on the rate of the project and is still the cause of debate and some bitterness between the parties involved. The early attempts at somatic-cell gene therapy were carried out without due ethical discussion and caused widespread concern such that the field was undoubtedly held back for a long period of time. Social and religious issues regarding stem cell therapy have certainly hindered advance in this field in the USA although to a lesser extent in the UK.

On the international scene the introduction of biotechnology in the fields of human genetics into many developing countries has not been thought through adequately from the ethical point of view. There are issues at every level including the education of populations regarding genetic disease and factors such as consanguinity which is part of religious or social custom in so many countries with high frequencies of these diseases. Pre-natal diagnosis was banned for a long time in Islamic countries although they have recently changed their regulations but the situation in Buddhist societies is still very mixed. The

whole question of explaining the basis of genetic disease cannot be carried through using Western approaches; many societies have totally different views on disease and many of them are male dominated so that husbands refuse to accept their role in passing on these conditions, their marriages break up, there is a high rate of suicide. These problems need reviewing from the point of view of Western societies analysing these issues with its own beliefs and so on and trying to impose these on the developing world. All these issues have important implications for the introduction of genetic technology into poorer countries.

Another issue which has not been widely debated and which will become increasingly important due to biotechnological advance is the question of so-called biopiracy. There are several examples of companies moving into poorer countries to obtain DNA or other biological material looking for genes with commercial possibilities. The whole question of the ethics of ownership of DNA in this kind of circumstance requires further investigation and control.

Question 7:

Having attempted to introduce biotechnology relating to human genetics into the developing countries for many years I don't think political issues have played a major role in their acceptance or otherwise. Perhaps the major issue along these lines is that governments of poorer countries wish to understand the economic aspects of this type of work and how this affects their very limited health care budgets. The ethical issue here is to what extent the richer countries should be trying to push this new technology compared with more pressing public health matters that many of these countries are still facing. There are obviously practical problems helping countries like this if they are at war and spending a high proportion of their GNP as a result.

Question 8:

Many of these new technologies have in common a certain degree of therapeutic uncertainty and are being applied at a time when knowledge of their value is far too limited. This problem applies to most of the new technologies that I have mentioned in previous sections. The specific issues particularly relate to areas like the feasibility of a permanent alteration to the human or animal genome, cross-species genetic transfer, genetic modification of crops, genetic modification of insect vectors, and some of the newer approaches to so-called therapeutic cloning.

Question 9:

Yes. There have been many aspects of recent developments in this field that really have received very little study. For example, there have been limited discussions about the growing industry of so-called personalised medicine and whether it is appropriate to be starting to offer whole genome scans to people with our limited knowledge of their

significance. Have we really looked carefully at the effect this kind of information may have on people with a very limited knowledge of biology and with what apparently is a very limited access to appropriate and knowledgeable counselling? And, as mentioned above, have we really got to grips with the problems of trying to transfer Western views of pre-natal diagnosis and control of genetic disease on to societies with completely different concepts of disease, different religions, and totally different social customs? Have we really considered the ethical issues relating to genetic manipulation of disease vectors or crops as they relate to the developing world or the potential problems of biopiracy by industry? Another area in which discussion has been limited is the lack of follow-up on the report on research in primates published by the Royal Society and Academy of Medical Sciences a few years ago. It seems extremely likely that some of the techniques of modern biotechnology will be evolved in an invasive direction towards the central nervous system and there has been very little movement on behalf of government or other bodies since that report to further discussions on the ethical issues involved in this type of research as it is applied to primates. This may be an important area in the none too distant future.

Question 10:

One of the prime examples of course is the different attitude to work on the genetic modification of crops on the two sides of the Atlantic. This question emphasises the difficulties in deciding about the social and ethical issues involved in a field which has reached the stage of development at which there is still a certain amount of uncertainty about the safety, and balance between safety and benefit of a biotechnological development for the community. Although there was less public knowledge, the same kind of issue arose some years ago after the first attempts at human gene transfer therapy but the early work of the Clothier Committee and later government committees dealt with this very successfully despite the continued uncertainties.

Question 11:

I don't think the ethical principles that underlie emerging biotechnologies are really any different to those that we have faced in the past with new technology, certainly as they apply to the richer countries like the UK. But I do think we owe it to the developing countries to have much clearer insights into how these technologies should be applied in totally different environments to our own. I know the Council has reported on the conduct of research in the developing countries but I think, as mentioned in earlier sections, that the issues go much deeper than this.

Question 12:

This is a critically important question, given the speed of development of some of the modern biotechnologies. The best example I know of is the deep concerns that some of us felt in the

1980s when somebody in the USA attempted gene therapy rather prematurely; without permission from the local Ethics Committee the scientist performed the experiment in another country and it always seemed to us that this could happen in the UK at any time. The line of communication was from the scientists who understood the problem to the granting body, i.e. the MRC who set up an immediate Committee of Enquiry which led to the government setting up the Clothier Committee and hence developed a Standing Committee to cover developments in this field. The only criticism I have of this particular episode was that I don't think the media or the public had the faintest idea what was going on globally in a potentially difficult field. You don't want to set up further layers of bureaucracy to impede science but on the other hand I wonder whether one can always rely on scientists to set the discussions in motion as happened over gene therapy. It may be that we do need some kind of Standing Advisory Group to monitor these issues and to advise both government and bodies like yourselves about the need for action. It is a job that could be given to a body like the Royal Society which covers so many aspects of science; certainly I can't think of any line of command that exists for this rather important activity at the moment.

Question 13:

At least in my experience the questions of 'risk' and 'precaution' have been major factors in discussions that we had some years ago on subjects like gene therapy and embryo research.

Question 14:

As mentioned earlier, I think that the kind of monitoring body that may be required should be via a single framework. I only say this because so much of modern biotechnology covers several disciplines and putting together suitable small bodies to cover each one separately takes time and is often extremely difficult. A Standing Body with a membership with broad knowledge across several different fields might be much more reliable and effective. The argument for this way forward is based on how modern technology like the modification of insect disease vectors may impinge right across fields ranging from medicine to ecology and plant and insect biology. Most of modern biotechnology requires examination in many different directions.

Question 15:

This is a huge question which has never been adequately addressed. There is no doubt that the public should be involved in these ethical issues. I know that the Council has always tried to have a very broad membership with non-scientists and people representing the general public but the question of communication with the public is much broader than this. The mechanisms for interaction between science and the public are very limited, particularly in this country the level of scientific journalism is not very high, and the public are constantly

being bombarded with half-truths about the potential efficacy of the latest scientific breakthroughs. The BBC do a slightly better job but they dissolved the Science Council, at which scientists conferred regularly with programme directors, some years ago and this important avenue of communication no longer exists. The only way forward is for the evolution of better lines of communication between science and the media and hence the media and their readers, something which seems to be discussed regularly but the discussions don't lead to very much. I think your report should make a very strong plea about this deficiency.

Question 16:

I think I have covered this in Question 15. The only direct means of communication between scientists and the public are the various science festivals round the country or through bodies that encourage public lectures by scientists. Some of these are excellent and you should look at this year's programme for the Cheltenham Science Festival and the similar Festival at Edinburgh. There is a lot of good debate on controversial issues at these Festivals but there are too few of them. You might also enquire at the universities as to how many of them run public lectures or demonstrations each year. I think things could be improved along these lines but I still think that we need to do an awful lot to improve scientific journalism and the interaction between the media and scientists. The responsibility for this probably lies in bodies like the Royal Society.

Question 17:

I suppose what is unique about emerging biotechnology compared with other complex areas of so-called government policy making (I say so-called simply when viewing the current state of the Health Service and education) is its technical complexity and uncertain risk combined with its ability to alter the fundamental basis of living function. We have a parliament which is completely devoid of scientists and a House of Lords in which its members are, for the most part, too old to be conversant with what is going on in the biological or physical sciences, yet many of the new biotechnologies do have the potential for impinging on the lives and environments of the population at large. Therefore you are dealing with a very specific problem. As outlined in my answer to Question 14 I think that some kind of broad ranging Advisory Group is probably required, given the speed of development of the field. The current state of the Health Service illustrates how ineffective government can be in complex issues that require special knowledge. At the moment a mechanism for defining the control and ethical issues of rapid and unexpected developments in biotechnology is non-existent. It would be interesting to know how many of the topics that have been covered by the Nuffield Council have come from suggestions within the Council compared with requests from outside! The new President of the Royal Society would be well worth consulting on this issue.