

The Use of Transgenic Animals in Medicine

The report on the seminar held at the
Hanasaari Culture Centre in Espoo, Finland
8-10 October 2000

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EUROPEAN FEDERATION OF
BIOTECHNOLOGY

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EFB Task Group on Public Perceptions of Biotechnology is an independent European expert group with the aim to encourage the social debate and dialogue on issues on modern biotechnology. (www.kluyver.stm.tudelft.nl/efb/home.htm)

Finnish National Advisory Board for Biotechnology is an expert group on modern biotechnology and genetic engineering appointed by the Finnish Council of State.

Genetic Interest Group is a patient's interest group working to benefit all people affected by genetic disorders.

Juliana von Wendt Foundation for Research without Animal Experiments is a private foundation.

Summary

Conclusions

The themes of the seminar were discussed in plenary on the final day of the seminar and the participants unanimously agreed on the following conclusions:

- 1 Transgenic animals are developed and used for the generation of new knowledge applicable in biomedical research and for the resolution of health problems.
- 2 As with all biological and medical research, animals shall not be used if a scientifically valid alternative method is available. The development of alternative and refined methods shall be encouraged.
- 3 There are very few ethical and animal welfare issues uniquely created by the use of transgenic animals per se. However, their creation raises cultural and metaphysical concerns, which also need to be addressed.
- 4 There is a need for a reflexive national and international regulatory framework, which allows appropriate uses and scientific work to proceed, but which also recognises animal welfare issues and public concerns.
- 5 Research and development using transgenic animals should be conducted in a transparent climate encouraging openness and accountability.
- 6 Issues on transgenic animals need to be addressed on a case by case basis until it is clear that there are matters, which are generic.
- 7 Understanding of the issues inherent in the use of transgenic animals will be enhanced by active communication between stakeholders.
- 8 Communication on science is essential. Scientists, regulators and other stakeholders need to be actively engaged in dialogue with the public on issues dealing with transgenic animals.

Background

The use of transgenic animals for medical purposes is an area of intensive current research which is leading to many practical applications. These include the production and use of animal models for human diseases and gene therapy, animals for the production of therapeutic substances, animal cloning and animals for organ transplants.

However, the research and use of these animals remains controversial. Ethical and moral issues, animal welfare issues, patients' interests and equity as well as economic, commercial and regulatory issues all need to be discussed if these new emerging technologies are to be used in ways which are socially acceptable.

Aims

The aims of the seminar were the encouragement of a European dialogue and a mutual learning process concerning the use of transgenic animals for medical purposes; to increase the knowledge about these leading edge technologies; to identify some of the key areas of concern beyond the purely ethical issues arising; to identify ways of incorporating these into policy making decisions.

Format

The programme included two keynote addresses and an introductory session. The main part of the programme, however, consisted of discussions in small groups. Each discussion theme was introduced by a short talk in plenary followed by discussions in working groups. All working groups discussed the same themes. The discussions were led by a facilitator and the results reported back in plenary after each discussion. Finally all issues were discussed in plenary and eight conclusions were unanimously agreed upon.

Organisation and sponsors

The seminar was organised by the European Federation of Biotechnology Task Group on Public Perceptions of Biotechnology and the Finnish National Advisory Board for Biotechnology in association with Genetic Interest Group, Great Britain and Juliana von Wendt Foundation for Research without Animal Experiments, Finland.

The event was made possible by educational grants from the EFB Task Group on Public Perceptions of Biotechnology, the Finnish Ministry of Social Affairs and Health and Novartis Finland.

Determination of the programme and invited participants was the sole responsibility of the Organising Committee the members of which were Dr Jill Turner, The Medical Biology Centre, Queens University, Northern Ireland, Director Alastair Kent, Genetic Interest Group, Great Britain, Director Riitta Salmi, Juliana von Wendt Foundation for Research without Animal Experiments, Finland and Helena von Troil, Secretary of the National Advisory Board for Biotechnology, Finland.

Programme and Speakers

For details on the programme and speakers, please see annexes I and II.

Participants

The 32 participants were personally invited to reflect a broad range of sectors, interest groups and European countries. Different stakeholder groups such as patient organisations, animal welfare organisations, natural and social scientists, public authorities, companies and bioethicists were represented. A list of participants is in annex III.

Keynote addresses**Animals, publics and identities: uncertainty, ambivalence and policy making**

Dr Mike Michael, Department of Sociology, Goldsmith's College

The various ways in which we in the West relate to animals has a major role to play in how different constituencies come to perceive risk, uncertainty, ethics, benefits, values and forms of regulation and control. By importing some observations from the social sciences and the public understanding of science (PUS) we might begin to explore new ways of thinking about and discussing the issues around transgenic animals in medicine.

In traditional PUS the predominant approach is questionnaire study of public understanding, which aims to measure levels of scientific literacy. However, this approach really focuses on the extent to which lay people's knowledge falls short of accredited scientific knowledge. To have improved scientific literacy, is to be intellectually better equipped to contribute to the process of a liberal democracy to which scientific knowledge has become fundamental.

In contrast, the critical approach to PUS addresses the cultural context of the public understanding of science. In particular, critical studies focus on the understanding of what has been called 'lay local publics' – people in their everyday, local settings. Critical PUS considers both lay knowledge and scientific knowledge to be in large part 'local', that is structured by its respective local cultural and social conditions. In the clash between expert and lay cultures one key difference is that whereas local publics are often aware of the uncertainties of their knowledge, scientific actors often appear as if they are not. In such clashes, publics lose trust in scientific actors whose statements of fact do not take into account the uncertainties and contingencies that underlie those 'facts'. Critical PUS, in tracing these antagonistic relations aims to map the shifting patterns of trust, that is, of who is believed and therefore of what counts as reliable knowledge.

Now, both versions of PUS have a version of democracy associated with them. For traditional PUS this entails the education of the citizens so that they can contribute to democratic decision-making (referenda, ethics committees etc.). In contrast, critical PUS draws on a model of democracy where citizens are already knowledgeable – they possess local knowledge, but they also grasp intrinsic contingency and uncertainty of all knowledge. For critical PUS, this implies that scientific knowledge must be presented so that its uncertainties, the indeterminacies and the contingencies are transparent. To neglect this openness is to alienate those public constituencies that have their own situated knowledges about the event or phenomenon under discussion.

Does the fact that we are dealing with animals have implications for the sorts of interaction between scientific and public constituencies that are possible? The uneasiness that some people express regarding animal biotechnology is partly related to the fact that in the West our relationships with animals are highly complex. With technological innovations (e.g. butchery and freezing), animals have been increasingly commodified. On the other hand, the rise of mass transport, leisure time etc has facilitated various humane, even sentimental, valuations of animals. Further, it seems that animals have more recently become important foci for

people's social, moral and political activities. This is because in these postmodern times of moral, social and political ambiguity, animals serve as relative unproblematic 'subjects' of concern and care.

This complexity is not exclusive to our contemporary animal symbolism—arguably, our symbolic relations to animals have always been complicated. In light of this, we would expect animals to have no symbolic essence but serve as a sort of complex symbolic 'other' which plays a vital role in the symbolic construction of human identities. Some animals symbols epitomize the 'superiority of humans', others can present animals as icons of morality. Thus, insofar as we constantly contrast ourselves against, and identify with, animals, human identities are neither coherent nor homogenous. To reiterate, crucial to this process of the construction of human identities is the complexity, ambiguity, volatility of animal symbolism.

What are the implications of this symbolic complexity for the conduct of open dialogue between expert and public constituencies, especially when it comes to transgenic animals? While the 'mass of people' seems to take a cautious and 'reasonable' perspective on animal experimentation issues, we can also expect that such positions are highly complex and volatile because of the complexity and volatility of animal symbolism. This suggests that, in the policy-making process, we need to have in place a mechanism of constant review – an institutional reflexivity – that is sensitive to these shifts and ambivalences. But such a suggestion makes the very processes of policy making very difficult: How is it possible to make policy on the basis of such fluidity and ambiguity?

At one end of the spectrum we have recommendations which deny the public voice: it is not only impracticable to try to accommodate mass ambivalence but also the core of the debate, where the arguments are most refined, lies with those who have some degree of expertise. At the other end, public contribution is seen to be crucial: given the nature of modern science, for knowledge to 'be viable', it must be situated in, and compatible with, the appropriate social and cultural context. We are left with a very confusing picture. Basically, there are many different types of strategy in attempting to ensure the usefulness and reliability of scientific knowledge and technological innovation, not last that concerning the development and use of transgenic animals. But whatever consensus or agreement is reached on a technoscientific debate, there is always the danger that even the moderate, uncommitted publics will reject it as, depending on the circumstances, different symbolic aspects of animals become prominent.

It will be noticed that the foregoing points apply to general biomedical uses of animals. However, transgenics does raise some potentially unique issues. Insofar as transgenics characterises animals wholly in terms of their genetic make-up, it tends to dramatically reduce the variety of meanings can be attached to animals. By appearing to make animals utterly knowable (not least as genetic products), by removing their otherness, their symbolic richness is greatly decreased and we are left with far fewer resources for articulating our own social identities. Paradoxically we find, that the greater the apparent knowability of animals, then the greater the unknowability of ourselves. It might well be this peculiar symbolic dynamic that people find so threatening in the development of the new genetics in general and transgenic animals in particular.

May we use transgenic animals for medical purposes?

Dr Kenneth Boyd, Institute for Medical Ethics, Edinburgh University

The Moral Prism

“Ideally moral judgement might be a white light showing clearly what action would be best in any situation. But just as light coming through a prism is refracted into a spectrum of different colours, so our moral thinking shows us a range of different features, and attention can fasten now on one and now on another. And just as it is absurd to maintain that one colour in the spectrum is the only true, or even the truest form of light, so we must not make the mistake of assuming that one feature in the moral spectrum is the only true form of morality. The metaphor of seeing light refracted through a prism is only one way of affirming that there is always a number of features which can be seen in making a moral judgement: features which need to be distinguished, even if they also affect one another in ways that have to be specified.”

Dorothy Emmet, *The Moral Prism*, London: Macmillan Press, 1979

May...	Whom asked?	* higher powers * animals * ourselves
we...	Who are we?	* humanity * every rational being - that has a reason, - that can give a reason * linguistic/prelinguistic/intelligent/other animals

“...adult human activity and belief are best understood as developing out of, and as still in part dependent on, modes of belief and activity that we share with some other species of intelligent animal...and...the activities and beliefs of those species need to be understood as in important respects approaching the condition of language-users.”

Alasdair MacIntyre, *Dependent Rational Animals*, London: Duckworth 1999

use...	relationship	* moral community, reason givers * historical community, animal-users
may we use animals....		* I – thou never simply means, always same time an end * I – it means to “our” personal / communal / global ends * I – other ?
may we use transgenic animals...		* human interests never sufficient to outweigh animal interests * human interests always suffice to outweigh animal interests * human interests insufficient to outweigh some interests of some animals
....for medical purposes...		* objection to genetic modification: “playing God” hubris, responsibility, prudence * objections to genetic modification of animals: “commodification” risks to health and the environment transgenic animal wastage and welfare; reduction / refinement
		* applied / fundamental biomedical research * necessity * proportionate / disproportionate expectations * scientific and commercial interests

Tragic Choices

“Since the values endangered by any given approach vary, a society which wishes to reject none of them can, by moving with desperate grace, from one approach to another, reaffirm the most threatened basic value and thereby seek to assure that its function as an underpinning of the society is not permanently lost... a moral society must depend on moral conflict as the basis for determining morality.”

“Honesty ...has the remarkable quality that it is capable of being abandoned with regard to some questions without being destroyed elsewhere. Thus it can often be of service to the tragic choice by being neglected – indeed the usefulness of some allocation methods depends almost entirely upon the charade that they serve the purposes they say they do. But the trick of dishonesty depends on assumptions of honesty; when these are questioned, honesty serves as a powerful engine of attack on the allocation.”

G. Calabresi & P. Bobbit, *Tragic Choices*, New York WW Norton & Co, 1978

		* whatever method of allocating tragically source resources is chosen “the distribution of some goods entails great suffering or death”. * reaffirm the most threatened basic value * human health and welfare; present and future generations * animal interests and welfare: transgenic and other animals * honesty
The Moral Prism		* utilitarian calculations * compassion * justice or fairness * practical wisdom in context

Regulative Ideals

“These are concepts not realisable in particular instances but which have a role in setting standards for practical reason... To say that something is unrealisable is to speak with reference of a goal or standard which may be approached but cannot be attained. Nevertheless, practice may be orientated towards it.”

Dorothy Emmet, *The Role of the Unrealisable*, London: Macmillan Press, 1994

Procedural Ethics

Virtue ethics

Introductory Session

Pharmaceuticals from transgenic animals

Dr Bruce Whitelaw, Roslin Institute

Transgenics -the transfer of a gene into an organism has great power because of its specificity. The transferred gene can be derived from a variety of sources, including the species itself. However, the technique is not perfect - there is little control over the amount of DNA integrated or where and how it will be incorporated. Of the offspring that result only about 20% will be transgenic at best. Transgenics can be used to introduce traits into the host such as accelerated growth or disease resistance. The new trait will then have to be developed into designer herds using conventional breeding. The technique is likely to be used in agricultural applications because of the genetic lag that will occur whilst characterising the effect of the transgene before it can be incorporated into the elite herd. Transgenics will also be useful in developing bio-reactors for the production of therapeutically active proteins in milk. Examples currently in development include the production of antithrombin III (by Genzyme) which is currently in phase three clinical trials and alpha-1-antitrypsin (by PPL Therapeutics) which is in phase two. Cell nuclear replacement will potentially increase the efficiency of the process because it will enable precise insertion of single point mutations into the genome which will be valuable for the production of pharmaceuticals.

Alternatives to the use of animals

Prof Pirkko Vihko, WHO Collaboration Centre

Cell cultures have been used to replace animals in a variety of situations - such as the production of monoclonal antibodies and recombinant proteins. The production systems include bacterial cells, yeast and insect cells. Animal and mammalian cells are needed for the production of more complex proteins. Cell culture makes it possible to produce large quantities of substances unobtainable by other methods. Cell cultures have research applications in functional studies of isolated genes, mutational analyses and structural studies. They can also be applied in diagnostics in generating antigens for antibody production. A wide range of proteins can be produced by cells cultured in bio-reactors. In some aspects of drug research animal use can be replaced by mass production of cells and proteins.

Xenotransplantation and transgenic pigs

Dr Dan Tucker, Imutran Ltd

Xenotransplantation could meet the gap between the need for organs and the supply available from humans. Potentially

there is an unlimited supply of organs that will be available in optimal condition and specified to meet patients' needs. In the long term there is the prospect of lower health care costs, even allowing for the need to maintain patients on immunosuppressive drugs.

Challenges to successful xenotransplantation are to establish the long term graft function and a tolerable immunosuppressive regime. Avoiding the transfer of xenogenic agents will also be crucial. For a variety of reasons pigs make the most appropriate organ source.

Imutran's research programme aims to produce physiologically normal pigs with functioning gene transfers in sustainable animal lines. These pigs will have defined health states (i.e. qualified pathogen free). Pigs are housed in special units with high regard to their welfare. They are physically, physiologically and behaviourally normal.

Central to the success of the project will be establishing risks (if any) associated with Pig Endogenous Retro Viruses (PERV) in respect of individual patients receiving transplants and possible population risks. To date experiments in primates and epidemiological studies have indicated no evidence of risk.

Life revisited

Dr Kirsi Sainio, University of Helsinki

That human tissue is able to renew has been known for a long time. Stem cells have the capacity to self-renew and do differentiate into a variety of cell types. There are three types of stem cells; embryonic stem cells, adult germ line stem cells and organ specific stem cells. Stem cells from adult tissues have a restricted ability to differentiate, whilst those from early embryos are totipotent.

If the mechanisms for controlling the differentiating ability of stem cell can be understood then there is the potential for developing treatments for a range of disorders including Parkinson's disease, Alzheimers, diabetes and congenital heart disorders. To do this will require research using human tissues and early embryos. Use of embryos will necessitate the recollection of complex ethical issues, but assuming these can be resolved there is considerable potential for treating any diseases which result from the lack of a tissue specific cell type.

Discussions

Discussion 1. Patients' Interests

Introduced by Andrew Blake - Seriously Ill for Medical Research

The post genomic era is likely to see a rapid increase in the use of transgenic animal models which help give a basic understanding of how genes and proteins are involved in human disease.

These techniques have never been available before and are giving patients suffering from any of the 5000 single gene caused disorders some very real hope and often for the first time.

The use of transgenic animal models of human disease has produced rapid progress and the movement of knowledge of genetic diseases to the point where human based work is possible.

The potential benefits of using transgenic animal models is undeniable. But is it ethical? Well I believe it would be unethical not to use transgenic animal models to try and alleviate human suffering. Alternatives to animals are complementary to animal based research but not a replacement for it. There is a strong need to communicate the real role played by animals in the creation of knowledge about human disease.

Discussion

Against the background of the need to find effective treatment for human diseases the following diverse points emerged:

Ethics is the framework for debate by all stakeholders and not only the preserve of professional ethicists. Animals have a long history in medical research and though mistakes may have been made in general it may be possible to create guidelines for the acceptable use of animals. The extent to which animal use is already regulated is largely unappreciated by the general public and it is important to create a climate of understanding which ensures that animals are not used when science can create an alternative. However, the judgement is also made in a climate in which the impact of the disease on the patient is fully recognised. Increasing knowledge of genetics highlights the genetic similarity that exists between humans and animals and an undue objectification of animals leads to an unbalanced research effort.

However, in severe disorders most patient groups have few problems with the use of animals in research because their illness is severe, drawn out and potentially fatal. The development of transgenic techniques will potentially speed the research process. But the notion of "severe" disease is not objective and decisions are tinged with ambiguity as to how conclusions are reached and by who.

Progress is generally achieved through a case by case approach, with the public expressing different attitudes in respect of diseases of children (where high levels of support for animal use are recorded) compared with AIDS (where perhaps prejudices about it being "self inflicted" or fear arising come into force). In other words, a different set of

moral values come into play. Evaluating the costs and benefits of intervention is an imprecise science. For example, end points in establishing pain in research animals involve measurers which may have a questionable link to the animals experience. Further research is needed on this and other topics where cost/benefit questions are raised. Guiding principles in R & D ought to be to the protection of the vulnerable (not forgetting humans) and the reinforcement of the "3Rs" - replacement, reduction and refinement where animals are involved. Ultimately, the decision as to what is acceptable will be a political one, with a universally acceptable framework being an unattainable goal. Factors in the equation are the severity of the disease, the proportionality of the response, protection of the vulnerable and minimising the impact on the animals involved.

Discussion 2. Animal welfare issues

Introduced by Dr Elizabeth Jenkins, the Fund for the Replacement of Animals in Medical Experiments (FRAME)

The vast majority of animals used in research are rodents. As a consequence of the use of genetic engineering methods the production of transgenic mice has increased significantly. The welfare of these rodents has to be considered. Currently used methods include the creation of pseudopregnant states in immature females and the vasectomy of males. Also the efficacy of microinjection methods can be as low as 5%. In the production of transgenic animals all animals have to be genotyped and marked regardless of whether they are transgenic or not. Marking methods include the use of tattoos and toe amputation.

Important animal welfare questions to consider include the direct harm done to animals, consequences of the deliberate introduction of adverse affects in transgenic mice and the possibility of unsuspected effects associated with foreign DNA introduced into the animal's genome.

All problems in connection with the use of transgenic animals cannot be avoided but have to be identified in order that procedures can be developed to reduce them.

Discussion

Problems cannot be avoided but must be assessed and evaluated with end points which minimise established animal welfare costs. Points to be addressed are general to the welfare of all animals used in research as well as issues possibly specific to transgenic animals - such as the methods used for altering the eggs, the increasing numbers of animals being used and the wastage that results from procedures with a low success rate in terms of the proportion of animals which incorporate the transgene. New technologies (e.g. nuclear replacement) may increase precision and reduce the numbers of animals involved.

In most respects the ethical and animal welfare issues that occur with transgenic animals are not unique but arise with animals produced by other methods, such as, the creation of disease models through artificial stimulation or mutation. From a patient perspective one central issue is the actual potential benefit to humans. Research using animals will lead to the development of treatments involving, for example, bio-reactors which might show marked improvement in the

efficiency of production systems. This raises the question of the intrinsic value of animals - a concept incorporated in Dutch law. Consideration of this issue may lead to pressure for the development of alternatives to animal use and consideration of novel ways of doing scientific research.

Animal based research should be undertaken in a transparent way, with sanctions (whether legal or commercial) for those who transgress accepted boundaries. Animals do not have rights as such but humans have a moral responsibility to ensure their welfare and avoid unreasonable exploitation. If research indicates a greater capacity for "thought" than is currently estimated to be the case in animal species then this may call for a re-evaluation of the approaches deemed to be legitimate in research.

Discussion 3. Regulatory issues

Introduced by MEP Astrid Thors, European Parliament

At the level of the European Union, parliamentarians have debated a number of relevant issues, most recently including the legitimacy of techniques for IVF and the morality of research using early embryos and techniques involving nuclear replacement, but not the issue of transgenic animals as such. The political process, in theory at least, focuses on what is desirable and what is possible. External factors play a significant role in the latter - for example, the possible enlargement of the EU in 2004 will make animal welfare issues difficult to debate in the period that follows as the CEEC countries will need a period of time to catch up with current practices within the EU.

Another issue is the question of the tolerable level of uncertainty, given that nothing can be said absolutely to be safe, what is acceptable when applying the precautionary principle on and in this context? The only predictable thing about EU decision making processes is that they are unpredictable. To influence the outcome of the debate there is a need for stakeholders to be actively involved in the debate in establishing the appropriate use of transgenic animals in research and development and where if anywhere new regulation is appropriate.

Discussion

There is significant value placed on diversity within the EU, making harmonisation difficult, even if some would see it as desirable. Even if the theoretical good of harmonisation can be agreed on, the problem of deciding where common ground can be established remains. Before seeking harmonisation a long process of education is needed if mutual understanding and respect are to be ensured. Once this has happened the question then arises as to when the appropriate point to legislate is given that the scientific possibilities are changing very rapidly and legislation, once enacted, tends to fix issues in a way that is difficult to modify.

On the other hand, flexibility can lead to inconsistency. Legislation with a "sunset clause" built into it may be a way forward in so far as it would establish a fixed point at which a decision could be made and by which time protagonists and antagonists would know they needed to make their case for continuation or repeal as appropriate. Seeking public endorsement should use a variety of methods, such as consensus conferences and citizens juries to involve all stakeholders in establishing the boundaries to probity. Those on whom the consequences of regulatory decisions impact should have a right of appeal.

The idea of proportionability with the "3Rs" as guiding principles is central to the decision making process. Ethical review committees have a key role in stimulating either practice. However, new practices in the development of transgenic animals will raise new questions - for example in respect of the integrity of animals developed for research purposes. A case by case approach will be essential until a consensus emerges as to the generalisability of issues generated by the accumulation of experiences in practice. There is unavoidable tension between those who advocate a "no, unless..." approach, who would not allow developments without explicit permission to proceed and those who would advocate a "yes, provided..." approach which assumes that things will be permitted unless they are expressly prohibited providing certain basic requirements have been met.

Annex I – Programme

Sunday 8 October 2000

18.00 Get together party with optional sauna and light buffet

Keynote speech
Animals, publics and identities: uncertainty, ambivalence and policy making
Dr Mike Michael, Dept. of Sociology, Goldsmith's College

12.30 - 13.30 Lunch

Afternoon session

Chairperson: Prof Richard Braun, EFB Task Group on Public Perceptions of Biotechnology

13.30 - 15.30 Discussion 2: *Animal welfare issues*
Speaker: Dr Elizabeth Jenkins, FRAME

15.30 - 16.00 Coffee

Monday 9 October 2000

Morning session

Chairperson: Dr Marja Simonsuuri-Sorsa, National Advisory Committee for Biotechnology

09.00 -10.00 Introductory session:
Animals for the production of therapeutic substances
Dr Bruce Whitelaw, Roslin Institute

Alternatives to the use of animals
Prof Pirkko Vihko, WHO Collaboration Centre

Xenotransplantation
Dr Dan Tucker, Imutran Ltd

The prospects of using stem cells
Dr Kirsi Sainio, University of Helsinki

10.00 - 10.30 Coffee

10.30 - 12.30 Discussion 1: Patients' interests

16.00 - 18.00 Discussion 3: *Regulatory issues*
Speaker: Ms Astrid Thors, Member of the European Parliament

19.00 Buffet dinner and keynote speech
May we use transgenic animals for medical purposes?
Dr Kenneth Boyd, Institute for Medical Ethics, Edinburgh University

Tuesday 10 October 2000

Chairperson: Prof Richard Braun

09.00 – 10.30 Reporting and general discussion

10.30 – 11.00 Coffee

11.00 – 12.00 Key conclusions and forward planning

12.00 - 13.00 Lunch and end of meeting

Annex II – Speakers

Mr Andrew Blake is the founder and director of Seriously Ill for Medical Research (SIMR). SIMR is a voluntary patients group formed to give patients input into the ethical debates on the use of animals and the use of genetic technology in medical research.

Andrew suffers from Friedreich's ataxia, a genetic disorder of the central nervous system. The disorder affects every part of the body except the brain. Andrew started showing the early symptoms of the disorder at 11, was diagnosed at 14, and been wheelchair-bound since he was 17.

Dr Kenneth Boyd is Research Director of the Institute of Medical Ethics and Senior Lecturer in Medical Ethics, Edinburgh University, Medical School. He is chairman of the Boyd Group, a UK forum on the use of animals in biomedical research. He is the author of a variety of publications, including *Lives in the Balance* (with J A Smith, Oxford UP) and *The New Dictionary of Medical Ethics* (with R Higgs & A J Pinching, BMJ Publications).

Dr Elizabeth Jenkins was awarded a Ph.D in molecular biology from the University of Nottingham in 1977. Since 1998, she has been employed by FRAME (Fund for the Replacement of Animals in Medical Experiments) investigating the use of transgenic animals in medical research. This includes research on welfare problems in the production and use of transgenic animals, their refinement and alternative systems for replacing *in vivo* studies.

Dr Mike Michael is a Senior Lecturer in Sociology at Goldsmiths College, University of London. He started off as a social psychologist but gradually became a sociologist, specialising in science and technology studies, and especially the public understanding of science. He has written on identity and the role of everyday technologies in social processes. More relevantly, he continues to work on how people come to assess scientific knowledge (e.g. on genetics), and has explored the assumptions underlying sociological studies of public understanding of science.

Dr Kirsi Sainio has a Master of Science degree in Cell Biology from the University of Jyväskylä and a Ph.D from the Medical Faculty at the University of Helsinki. Currently she is a senior scientist at the Institute of Biotechnology in Helsinki and Docent in developmental biology at the Faculty of Science, Department of Animal Physiology. Kirsi Sainio has published 28 original articles and 6 review articles in international pre-reviewed journals.

MEP Astrid Thors, who has a degree in law, is a Member of the European parliament since 1996, where she works in the ELDR-group, the group of European liberal parties. Astrid has been politically active since she was a schoolgirl and she has held numerous positions in her political party organisation, the Swedish people's party.

Dr Dan Tucker has a PhD degree from Pembroke College, Cambridge, the title of his thesis being "*In-vitro* Studies of Transgenic Pigs as Potential Organ Donors in Xenotransplantation" and he has received several academic awards. Currently is Head of Veterinary Services at Imutran Ltd, part of Novartis Pharma AG which is a world leader in the field of xenotransplantation research and development.

Dr Bruce Whitelaw has a PhD degree from the University of Glasgow and is currently a Principal Investigator at the Roslin Institute. He is a molecular biologist with an interest in the control of gene activity and has 18 years of research experience, 14 of which has been with transgenic animals. He was involved in the first study which confirmed the potential for producing human pharmaceuticals in transgenic sheep milk. Currently he is involved in projects designed to refine the use of transgenic animals by increasing the reliability, versatility and control of transgene expression.

Professor Pirkko Vihko is both a medical doctor and PhD. She is currently professor in biochemistry at the University of Helsinki and professor in medical biotechnology at the University of Oulu. Pirkko Vihko is also since 1996 director of the World Health Organization Collaborating Centre for Research on Reproductive Health which functions in connection with the University of Oulu.

Annex III – List of participants

Ms Sirpa Aalto, The Finnish Association for Organ Transplant and Kidney Patients, Finland
Mr Andrew Blake, Seriously Ill for Medical Research, United Kingdom
Dr Kenneth Boyd, Edinburgh University, Institute for Medical Ethics, Scotland
Prof Richard Braun, EFB Task Group on Public Perceptions of Biotechnology, Switzerland
Dr Nik Brown, University of York, Dept. of Sociology, United Kingdom
Prof Heikki Hokkanen, University of Helsinki, Agricultural Zoology, Finland
Dr Markus Idvall, University of Lund, Dept. of Ethnology, Sweden
Dr Piia Jallinoja, University of Helsinki, Dept. of Sociology, Finland
Dr Brigitte Jansen, European Academy for Environment and Economy, Germany
Dr Elizabeth Jenkins, FRAME, United Kingdom,
Dr Paula Junnilainen, Prov. State Office of Eastern Finland, Finland
Mr Alastair Kent, Genetic Interest Group, United Kingdom
Ms Janne Kuil, Dutch Society For the Protection of Animals, Netherlands
Dr Pekka Kurki, National Agency for Medicines, Finland
Ms Hannele Leiwo, Gene Technology Board, Finland
Dr Mike Michael, Goldsmith's College, United Kingdom
Prof Pirjo Mäkelä, Gene Technology Board, Finland
Dr Matti Poutanen, Institute of Biomedicine, Finland
Dr Kirsi Sainio, Biotechnology Institute, Finland
Ms Riitta Salmi, Juliana von Wendt Foundation, Finland
Dr Irma Salovuori, Gene Technology Board, Finland
Prof Laurence Simonneaux, ENFA, France
Dr Marja Simonsuuri-Sorsa, Ministry of Education, Finland
Dr Pirkko Skutnabb, Ministry of Agriculture and Forestry, Finland
MEPAstrid Thors, European Parliament, Finland
Dr Dan Tucker, Imutran Ltd, United Kingdom
Dr Jill Turner, Queens University, The Medical Biology Centre, Northern Ireland
Mr Ilkka Vass, Finnish Heart and Lung Transplant Ass. SYKE, Finland
Dr Bruce Whitelaw, Roslin Institute, United Kingdom
Prof Pirkko Vihko, WHO Collaboration Centre, Finland
Dr Hanna-Marja Voipio, University of Oulu, Laboratory Animal Centre, Finland
Ms Helena von Troil, National Advisory Board for Biotechnology, Finland