International Conference of the Council of Europe on Ethical Issues Arising from the Application of Biotechnology

Oviedo (Spain), 16-19 May 1999

PROCEEDINGS

Part 1: **General introduction**
Reports of sessions
General report

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FOREWORD

The holding of this International Conference of the Council of Europe on ethical issues arising from the application of biotechnology was decided by the Committee of Ministers of the Council of Europe in reply to Recommendation 1213 (1993) of the Parliamentary Assembly of the Council of Europe on the developments in biotechnology and the consequences for agriculture (see Appendix I of this document).

The organisation of the Conference was entrusted to the Steering Committee on Bioethics (CDBI) of the Council of Europe who decided to set up a Working Group responsible for the Organisation of the Conference (CDBI-GT-TECH).

The CDBI-GT-TECH was composed of:
Dr Octavi Quintana-Trias (Spain), Chair
Dr Stefan Winter (Germany)
Prof. Boris Youdin (Russia)
Dr Paul De Greeve (The Netherlands)
Dr Monika Mörtberg-Backlund (Sweden)
Dr Fabio Terragni (Italy)
Dr Maurizio Salvi (European Commission)

The objectives of the Conference were:

1. to identify ethical issues in relation to biotechnology from a multidisciplinary and multicultural perspective, with consideration to its social implications.
2. to promote open public discussion on ethical issues in relation to biotechnology.
3. a. to identify appropriate ways to deal with ethical issues in biotechnology, and
   b. to provide elements for a decision as to whether there is a need for action, such as a harmonised approach at international level, which could result in a possible new convention or other appropriate instruments.

In accordance with the objectives of the Conference, it was decided that the proceedings will be published in two parts:

- **this first part contains the report of each session of the Conference (environment, food, human health, animal welfare, research, industry, north/south, public perception/media), which summarises the issues and the proposed solutions presented during the Conference. It contains also the general introduction and the general report of the Conference. This document will be used by the Council of Europe as a basis for decision on a possible action in the field of biotechnology. All reports published in this document have been drafted after long concertation and dialogue, during and after the Conference, between the chairman, the rapporteurs of the sessions and the general rapporteur.**

- **the second part of the proceedings contains the contributions in extenso of the speakers.**

PROGRAMME

Chairman of the Conference: Dr Octavi Quintana-Trias (SP)

Sunday 16 May 1999

Opening of the Conference

- Mr Sergio Marques, President of the "Principado de Asturias"
- Ilmo. Sr. d. Gabino De Lorenzo Ferrera, Mayor of the City of Oviedo
- Mr Fernando Fernandez Noval, Delegate of the Spanish Government
- Mr Hans Christian Krüger, Deputy Secretary General of the Council of Europe
- Mr Walter Schwimmer, Vice-President of the Parliamentary Assembly of the Council of Europe

General Introduction
Prof. Jean-François Mattei (Parliamentary Assembly of the Council of Europe)

Monday 17 May 1999

ENVIRONMENT

Chair: Prof. Jaroslav Drobnik (CZ)
Rapporteur: Dr Piet Van Der Meer (NL)

- Fish farming
  Dr Matthias Kaiser (N)
- Genetic diversity in potato
  Prof. José Esquinas-Alcázar (FAO)
- Transgenic maize
  Rev. Dr Michael J. Reiss (UK)

FOOD

Chair: Dr Blanca Fernandez (SP)
Rapporteur: Dr George Zervakis (GR)

- Modified soya
  Prof. Emilio Muñoz (SP)
- Transgenic salmon
  Prof. Roger Straughan (UK)
- The ethical challenge of biotechnology in food engineering
  Prof. Dietmar Mieth (G)

HUMAN HEALTH
(Applied research not addressed by the Convention on Human Rights and Biomedicine[1])

Chair: Dr Marcelo Palacios (SP)
Rapporteurs: Mr Joze V. TRONTELJ (SL) and Sir Dai REES (European Science Foundation)

- Xenotransplantation
  Mr Gian-Reto Plattner (Parliamentary Assembly of the Council of Europe)
- Vaccines in plants
  Dr Emilio Mordini (I)
- Latest developments in the use of stem cells
  Dr Margarita Salas (SP)

ANIMAL WELFARE

Chair: Mr Gianni Tamino (European Parliament)
Rapporteur: Dr Paul De Greeve (NL)

- Transgenesis in pigs
  Prof. Louis-Marie Houdebine (F)
- Cosmetics – in vitro toxicology
  Prof. Horst Spielmann (G)

Tuesday 18 May 1999

RESEARCH

Chair: Prof. Boris Youdin (RUS)
Rapporteur: Dr Hans-Jörg Buhk (G)

- Monoclonal antibodies
  Dr Coenraad Hendriksen (NL)
- Human genome – comparative genome analysis
  Prof. Judit Sandor (H)
- Dolly
  Prof. Peter Sandoe (DK)
- Patenting in scientific research
  Prof. Darryl Macer (New Zealand)

[1] Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (ETS No. 164) of the Council of Europe (opened for signature on 4 April 1997).

INDUSTRY

Chair: Ms Paula Martinho Da Silva (P)
Rapporteur: Dr Monika Mörtberg-Backlund (SW)

- Oil seeds to replace mineral oil
  Prof. Sten Stymne (SW)
- Sweetener production with recombinant micro-organisms
  Dr Enrique Roca (SP)
- Dialogue with the society
  Dr Lise Kingo (DK)
- The moral agenda of VirtuBioBuss: biotechnology and business ethics
  Dr Christien Enzing (NL)

NORTH/SOUTH

Chair: Dr Linda NIELSEN (DK)
Rapporteur: Dr Julian Kinderlerer (UK)

- Vegetable oils
  Dr Albert Sasson (UNESCO)
- Neem
  Dr Vandana Shiva (India)
- Bioprospecting : linking biotechnology and biodiversity conservation
  Dr Ana Sittenfeld (Costa Rica)

Wednesday 19 May 1999

PUBLIC PERCEPTION – MEDIA

Chair: Prof. Alain Pompidou (European Parliament)
Rapporteur: Dr Fabio Terragni (I)

- Eurobarometer
  Prof. John Durant (UK)
- The Swiss referendum on biotechnology
  Prof. Dr Richard Braun (CH)
- The media and biotechnology: the case of cloning
  Prof. Dorothy Nelkin (USA)
- Public perception: question of values
  Prof. Gilbert Hottois (B)

Biotechnology: the point of view of a citizen
Prof. Jose Antonio Marina (SP)

European legal overview
Mr Carlos De Sola (Council of Europe)

Summary of the work and conclusion
General Rapporteur: Prof. Enric Banda (European Science Foundation)

Closing speeches

- Dr Benigno Blanco, Secretary of State of Environment (Spain)
- Prof. Jean-François Mattei, Parliamentary Assembly of the Council of Europe (France)
- Dr Elaine Gadd, Vice-Chair of the CDBI (United Kingdom)
- Dr Octavi Quintana-Trias, Chairman of the Conference (Spain)

GENERAL INTRODUCTION
Prof. Jean-François MATTEI
(France, Parliamentary Assembly of the Council of Europe)

Ladies and Gentlemen,

At the start of this international conference on the ethical issues arising from the application of biotechnology, I wish to thank the political and the institutional authorities who have made this gathering possible, the participants and also the organisers, particularly those in the Council of Europe who have trusted in me.

The conference's theme is of the greatest importance. In a few months' time we will begin a new century, a new millennium. I am fully aware that this is a terribly unoriginal thing to say by way of an introduction to our proceedings, but I nevertheless yield to the temptation of doing so, as - coincidence or not - our civilisation is also at a turning point. These changes can probably be ascribed to the simultaneous occurrence of two very importance events: the end of a fool's game of a century and the advent of a scientific revolution.

The end of a fools' game of a century during which our existence was governed by the vain clash of two ideologies, which resulted in our losing our traditional values and seriously impoverishing our faculty of imagination. When historians look back at this century they will probably perceive it as one of particularly lacklustre thinking, unlike the two centuries which went before it. And with the collapse of the ideologies, as both show themselves incapable of organising a world fit for humankind, humanity finds itself naked, stripped of its points of reference. The human race has never been so vulnerable as at the end of this century.

But as the century draws to a close, the third great social revolution of modern times is taking place. In the wake of the agricultural revolution and the industrial revolution, we now have the scientific revolution. Over the past fifty years we have made greater progress in terms of knowledge than in fifty centuries. This new knowledge makes humankind more powerful than ever before. The contrast between vulnerability and power is striking. Thanks to the knowledge revolution, the human race is destined to rebuild itself on the ruins of this century which has proved a disappointment. And it is this rebuilding process and the attendant emergence of an ethic which may begin to form a new human being.

Our new knowledge places us in new situations where we have to make new choices. Making a choice amounts to exercising a freedom, and new choices are synonymous with new freedoms. Availing oneself of a freedom means assuming a responsibility, and so we find ourselves with new responsibilities. In using the terms "freedom" and "responsibility", I am naming two essential foundations of human dignity. And it is clear to see that this new knowledge raises questions about our concept of human dignity. The most important stage, at the heart of the whole process, is that of making a choice, of asking oneself ethical questions. What attitude, what conduct, should be adopted? We can of course question ourselves as individuals with our own philosophical, moral and metaphysical beliefs or engage in a debate with our conscience. It is such individual choices that give a direction to our lives. This is what

Max Weber called the belief ethic. However, individual choices affect other people and have implications for the future. The notion of the other is already present in Kant's injunction that we do not do to others what we would not want to have done to us. And Jonas makes mention of the time element in his "Responsibility principle": "Ensure that the way you act is compatible with the preservation of a genuinely human life on earth". Broaching questions of temporality and alterity necessarily brings us to the issue of responsibility. This is what Weber called the responsibility ethic. We need common rules in order to live together because we are responsible not only for ourselves but also for others and for the future.

So far the future has been decided through the subtle interplay, varying with time, of knowledge and power. At times those in power have been opposed to knowledge (there is no need to mention Galileo); at others they have made use of it (as they have of genetics at certain periods). Knowledge may well have been countered or exploited by those in power, but in other eras - and probably in our own - knowledge has imposed itself on power, and the weaker the power is and the more enfeebled its convictions are, the more knowledge has done so. Knowledge then becomes an alibi. Politicians no longer cite Socrates or Plato, but seek to justify their decisions by claiming them to be scientifically or statistically proved. They rely on experts and surround themselves with Nobel Prize winners. We had an illustration of this in 1992 at the time of the Rio summit. Immediately after the summit a number of scientists launched what is known as the Heidelberg Appeal: "… We forewarn the authorities in charge of our planet's destiny against decisions which are supported by pseudo-scientific arguments or false and irrelevant data." One must of course trust in science, technology and industry.

The reaction was not slow in coming. A few days later, a counter-appeal was issued by scientists and intellectuals who, describing themselves as thinkers and activists in favour of sustainable development, spoke out against those who sacrifice Man to nature and against a scientific imperialism which asserts that humanity can be saved through science alone. It is hardly surprising that we are in a state of crisis which shows that science is no longer sufficient and that politics is failing to assume its full responsibilities.

The situation just described has led to the emergence of a third player alongside knowledge and power - the will. That is to say public opinion which is now discovering that the physical world is finite and is finding its confidence sapped by serious problems. Contaminated blood supplies, growth hormones and Creutzfeld Jakob's disease, prions and bovine spongiform encephalopathy, perhaps genetically modified organisms: all this is leading to a more general crisis, that of democracy. Citizens want to have their say. Representative democracy is gradually giving way to opinion-based democracy, and the outcome is a questioning of authority and doubts about progress. Nowadays, there is strong pressure for society to exercise control over science. There have always been movements against progress - 19th century romanticism was already a backlash against the world then being built - but it is now clear that public opinion will no longer tolerate being dictated to.

This tendency affects all fields of human activity. Medicine and biology are naturally in the front line, because the questions raised concern life, death, suffering, people's differences and their destinies. This has opened up the vast sphere of bioethics, involving issues such as organ transplantation (is the human body common property?),

medically assisted procreation (the right to a child, which may transform children into objects), pre-natal diagnosis with the excesses to which it may give rise - prescriptivism and eugenics - and in the background the question of the place of the disabled and of other vulnerable people in our society, predictive medicine and the prospect of the need to decide between determinism and freedom, and, lastly, gene therapy and the possibility of changing the very essence of human beings. For more than fifteen years texts on these subjects have been drawn up by one country after another, by UNESCO, more recently by the World Health Organization and, naturally, by the Council of Europe, with its Convention on Human Rights and Biomedicine; attempts have also been made to define common rules.

However, alongside biomedicine another source of problems compels recognition: application of biotechnology. From a semantic point of view, it is not uninteresting to note that the fashion for all things "bio" is also invading our vocabulary. We have had bioethics, biomedicine, a few neologisms, a few pleonastic expressions, and now we have biotechnology, or the technological exploitation of living processes, with all the artificiality that that entails.

Two background debates are going on concerning these technologies. Firstly, it is claimed that biotechnology is about to revolutionise medicine, the pharmaceutical industry, the environment and agriculture, although not everyone is in agreement as to the scientific and technical consequences. Some people think that things are going too fast, whereas others believe that inactivity and a wait-and-see attitude are dangerous, because progress is of benefit to humanity if kept under control and domesticated.

Secondly, since the advancing secularisation of society is increasingly going hand in hand with a pagan reconstruction of the sacred and also with a new rhetoric - a balance between faith and reason - the very substance of ethics is determined by the image which we have of ourselves as human beings and the ideal of humanity that we are pursuing. In science's case it is a matter of avoiding any form of rational conceit; in that of religion, there is a need to guard against another mortal conceit, that of unthinking belief.

That is the background to this conference, which can be said to pose three initial questions: identification of genes, appropriation of genes, use of genes. It is necessary to take stock of the situation, to establish a number of guidelines and to devise possible solutions permitting a consensus on these matters.

Identification of genes

From blue algae to *homo sapiens*, genetics has unravelled the strands of DNA and deciphered the code, showing that all living things have a genetic code. It has shown the universality and unity of the living world. The question of humankind's place in the universe, and, furthermore, in the hierarchy of living things, is now posed in different terms. The fact that the human race is capable of changing living organisms, and therefore has the power to change itself, does in fact raise questions. As genetics has moved on to isolate genes, to identify them and to track down those which are good and those which are less so, it has begun to pursue another objective, an objective which poses two problems: firstly, the relative importance to be given to genes in relation to their environment, since the omnipresence of genetics now seems to be making people overlook the reality of environmental influences; secondly, genetic recombination, in all its variety, and the way we humans influence this process.

A further problem is the selection and the elimination of genes, preferably in order to keep those which are good and eliminate those which are less so. A great deal is at stake here: although nature exerts a selective pressure on genes, might it not be possible that human selection of genes will in turn bring pressure to bear on nature? The equilibrium of ecosystems is easily broken. What is at issue here is biodiversity versus bioselectivity.

However, the possible appropriation of genes raises even more questions than their identification. We know that the question whether a patent can be obtained for living matter poses problems. The debate - in fact a clash of different cultures - is not yet closed. Much has been said about the need to distinguish discovery from invention. "Discovery" means learning about something so far entirely unknown but which already existed. An invention is the fruit of human intelligence and innovation and enriches the human heritage. To what extent is it possible to stake a claim to living matter which, by nature, already exists? Is it possible to have an exclusive right to exploit part of the living world, part of the common heritage which has its basis in the universal nature of living things? Don't living things belong to the whole human race? Since they are universal property, it seems unacceptable that anyone should have exclusive rights to them, especially since the confiscation of knowledge is a form of confiscation of the future. It establishes another form of organised dependence in economic, agricultural and industrial terms. However, where the three traditional criteria for granting a patent are fulfilled - namely that the object should be new, involve inventive activity and be susceptible of industrial application - patentability becomes logical and acceptable.

The European Directive on the legal protection of biotechnological inventions of 6 July 1998 shows a real change of attitude in this respect. And yet the problem still exists. Some people perceive the law as neutral and independent, in particular with regard to ethics, but it is not. Granting a patent is in itself already an economic incentive. As a doctor and a geneticist, I personally find it difficult to accept that gene sequences may now be covered by an industrial patent (a problem which I shall come back to in greater detail during the workshops). I feel the same way about the fact that the tests used to detect a predisposition to breast cancer are now the monopoly of Myriad Genetics in Salt Lake City. I do not think it is possible to become the exclusive owner of a gene sequence. It is understandable that a technique may be patented, that a patent may protect all uses of that technique, but certainly not that a patent may cover a gene sequence itself.

The result may be the monopolisation of an entire category of living material of human origin, and I deliberately use the word human because another problem arises here. The question of the patentability of genes gives new force to the debate on where the frontier between human and non-human lies, since human and non-human gene sequences may be so similar as to engender confusion. Is a human gene fundamentally different from a non-human gene? Should the rules for material of human origin differ fundamentally from those for other material, or should they be the same for all living matter? Genes will be used to create transgenic plants, which can be patented, or transgenic races of animals, likewise patentable. In all logic, the same should therefore apply to human material, beginning with modified embryo stem cells, and why not tissue, organs and entire transgenic human beings?

Use of genes

This brings us to the question of the use of genes, posed firstly in traditional terms, that is to say above all as a question of common sense, of generally accepted principles whereby use of genes is admissible if it has a curative effect, but not if it causes illness. According to this line of reasoning, the end justifies the means, the end being human good health. Anyone can see that such reasoning has a perverse effect if taken to extremes. However, let us accept it nonetheless in the case of biotechnology. Moreover, it has to be said that, where it is a question of introducing genes into cells in order to produce substances with a therapeutic effect, such as insulin, the growth hormone or interferon, the word therapy acts as an "open sesame". Then the technique is hailed as the birth of a new form of pharmaceutical industry, and draws no serious public criticism. If erythropoietin is today under fire in the media, this is not because it is a product of biotechnology but because it has been diverted from its medical use as a means of cheating in sports events.

Nor has there been much criticism of the idea of introducing genes into plants or animals for therapeutic purposes. It is a well known fact that plants are used for such purposes, and over the three days of this conference we shall be talking about tobacco and haemoglobin and plants with a vaccinating effect. Use of transgenic animals - colourfully referred to in the media as walking pharmacies - is also well accepted provided the ethical rules on animal welfare are respected. Production of albumin or of coagulation factor VIII in cow's milk, and more recently of anti-thrombin III in goat's milk, likewise does not meet with any disapproval; nor does genetic modification of pigs with a view to xenotransplantation. Even the cloning of animals did not cause any serious public dissent. The uproar began only when it became clear that adapting the techniques in order to clone human beings was possible, if not imminent. The statements made by certain scientists, who attempted to reassure people by explaining that there was no cause for concern because the technical difficulties remained too great for the process to succeed, failed to dispel the fears. The public instinctively understood that this is a field where technical or economic arguments against using a method are valueless, as, once those arguments have been overturned, one finds oneself disarmed, having already conferred legitimacy to the technique in principle.

Here it is indeed the metaphysical aspect of the question which prevails over all other considerations. What is at stake is the singularity of human beings, the freedom to be oneself not a copy of someone else. There is also the temptation for immortality. In these circumstances the simple rules of ethology laid down by Konrad Lorenz become applicable to humans. Human beings react when the limits beyond which they feel threatened are exceeded, when the end does not seem to be justified, when they feel that, instead of making use of progress, they are being used by it. In just a few years, things have changed considerably, as can be seen from the example of genetically modified organisms.

When all is said and done, the issue is quite simple. The controversy - one might almost say the outrage - about genetically modified organisms can be explained by the fact that one public health crisis has followed another. The situation provides a perfect illustration of everything I have said so far. The scientific community is under suspicion, the politicians have been discredited, and the public is in a position where it can make demands. Assuming that GMOs (genetically modified organisms) are not dangerous, what we have here is a case of once bitten, twice shy.

That being the case, all one can do is pose the necessary questions, without neglecting any aspect of the issue. Firstly, what are the real priorities here?

Is the end being served a noble one - that of feeding the planet? Does it serve lesser objectives, such as improving certain plant characteristics or making a profit?

As to the methods, is it justifiable to make use of genes conferring resistance to antibiotics, when it is widely known that such resistance is one of the health problems of modern times? Such an approach flies in the face of common sense. Similarly, using BT toxin to eradicate the European corn borer appeared to be the perfect solution, except that, as was to be expected, some of these insects have now developed a resistance to the toxin, and this resistance is probably a dominant genetic character; as a result the US Environment Protection Agency's recommendations are rendered obsolete.

A situation of this kind would necessitate a relentless search for a new toxin every year. Would that be at all reasonable?

Thirdly, open implementation and assessment of these techniques entail risks for cultivation, given the possibilities of gene flow, a risk for consumption; a risk in terms of social implications. It is therefore understandable that there should be such a fierce debate on the subject, revolving around two main concerns - health security and social acceptability - which I now wish to address.

Health security is a general concept having its origin in the problems posed by use of health and food products liable to cause environmental damage. Health security is now perceived as something to which citizens have a right and which states have a duty to ensure, just as they ensure civil and military security. Although the public may sometimes oversimplify matters - as when, on the subject of mad cow disease, people assert that a herbivore was made into a carnivore because cattle were fed with meat meal, and scientists know how inaccurate that assertion is - public opinion is a reality which cannot be ignored, especially since, although its expression may be clumsy, the public fully understands that technical progress is never devoid of risk. The simple fact is that it is all the less willing to accept a risk which is not absolutely essential. Furthermore, the scientific experts working on GMOs concur that additional research is needed to identify the potential long-term risks.

Hence the problem of social acceptability. This is primarily a question of freedom of choice, of the economic implications, of the impact on employment and on new forms of solidarity - it is therefore a question which is posed in terms of individual freedom and choice of the kind of society one wishes to live in.

The public regards interference with individual freedom as even more reprehensible than inadequate health security. Rejection of genetically modified organisms is, first and foremost, a refusal to allow other people to take control of the content of our dinner plates: eating is a personal act, which has to do with individual freedom, and consumers are reasserting their right to know in order to be able to choose; hence the demand for openness, for information, for traceability and for suitable labelling. Some countries have already understood this, as have some of the mass marketing networks.

For a choice of kind of society underlies these concerns.

This is a choice which raises a large number of economic questions: what are its implications for employment? and for farming? Can we accept the technology of the "terminator" gene, which renders seeds sterile and therefore prevents farmers from saving seeds from one season for sowing in the next, resulting in *de facto* dictatorship by those holding the industrial and commercial monopoly on seeds?

From the standpoint of solidarity, the questions raised are of equally crucial importance. How will the relationships between North and South be affected? Where will developing countries which cannot afford the technology stand? Can GMOs really help to reduce undernourishment, which today affects 800 million people world-wide? Could they guarantee a safe, secure food supply for a planet which in 25 years' time will have 9 billion inhabitants?

In fact, with regard to all these questions, there is often a striking contrast between the rhetoric and the little that is actually done to help the poorest countries. Is it not true that the first to benefit from the improvements are the farmers of the industrialised world? And is there not a growing gulf between the industrialised countries and those still seeking to develop their economies? An even greater cause for concern is that some genetic innovations result in the development of substitutes for products which had so far only been obtainable from the developing countries. Therefore, although progress is the official agenda, things are very different in reality and in some cases the situation is completely nonsensical. The sometimes irrational, but often well-founded reactions of a disenchanted society seeking a new meaning to existence should therefore come as no surprise.

I wish to conclude by bringing five matters to your attention: the constancy of humankind, the humanisation of the world, the ethical debate, the decision-making process needed and what is at stake in our proceedings.

First, humankind's constancy throughout history.

One is struck by the fact that today's scientific revolution is merely updating the ancient myths, bringing within reach the wildest dreams which human beings have always carried deep inside themselves. Cloning is the myth of immortality, or else the modern version of the myth of Narcissus, of love of oneself. Making it possible for women to have children alone, to reproduce themselves, revives the legend of the Amazons. Genetics' potential role in satisfying the desire for the perfect child brings to mind the story of Pygmalion shaping Galatea according to his wishes, whilst the fact that certain things are genetically preordained is reminiscent of Oedipus and his inescapable fate. Even interspecific genetic manipulations make one think of the mythical centaur. No, human beings have not changed with the passage of time. The new Prometheuses of the modern age still aim to equal the gods, to become the masters of the world.

Paradoxically it is because the human race gives the impression that it is capable of mastering the world that the world is becoming more human. Humankind's relationship with the world is changing, particularly in the two fundamental spheres of space and time. Space is a fast-shrinking commodity on earth as the planet becomes a global village, and if Dolly the cloned sheep raises the spectre of human clones, if GMOs point to a denatured world, it is because the human being has become the

measure of all things. The same applies to time. All humans now think in terms of their children, of the future generations from whom they hold today's world in trust.

In adopting a new set of values, humankind is becoming aware of the need for a meaning to existence and for an ethical debate. Make no mistake about it - the revival of philosophy is more than a passing fashion. It is a sign of a need, which neither science - in some cases a source of worry - nor political ideology, which has no more hopes to hold out, can satisfy. But philosophy teaches people to think; it rarely teaches them to live. Hence the need for an ethical debate, to find a maxim which can rule our conduct. However, that entails a process of reasoning and argumentation. Argumentation does not mean no longer thinking for oneself; on the contrary, it means looking within oneself to find solutions valid for others, bridging the gap between individual thinking and otherness.

It is this absolutely essential process which must be followed before any decision is taken.

The decision process is becoming more and more difficult. Henceforth politicians will increasingly be required to take hard decisions based on weak scientific evidence, whereas, traditionally, things were the other way round - the scientists produced hard evidence, and the politicians held weak opinions. Faced with uncertainty, we now have no choice other than to apply the famous principle of caution. However, unless we are prepared simply to leave things as they are – but this would be fatal - we must not forget that uncertainty is part and parcel of decision-making, since if there was no uncertainty society would have no need of decision-makers. It is by recognising the risk that we will be able to progress from a risk that is acceptable to one that is accepted, because it is managed in a culture of caution. The more uncertainty that surrounds us, the more the role of decision-maker becomes necessary. The greater the uncertainty, the more the decision-making process must be formalised and subject to public debate, the more the approach adopted to arrive at a decision must be open, coherent and clear. Otherwise, the decision-makers run the risk of wittingly sacrificing humankind and human health on the altar of economic competitiveness. They would then lose all credibility and a crisis would loom. In this connection, the failure of the talks held in Cartagena in February 1999 on regulating trade in transgenic products is a continuing cause for concern. This is what is at stake in our common reflection. It is not easy to steer a course between the legitimate aspirations of consumers and the need for fair trade, but failure to respond to public concern would wear away support for the trade liberalisation process. We must therefore identify the ethical issues, bring together the elements on which a decision can be based, and define common guidelines. We must strive wholeheartedly to do this, in order to improve our lives together and build a society which reflects our concept of humanity. We must attempt to improve our understanding of the world, as that is the only way of making it a fairer world, and therefore, quite simply, a more human world.

"ENVIRONMENT" SESSION
Dr Piet VAN DER MEER (The Netherlands)

Introduction

The session was introduced with three case studies presented by Dr Matthias Kaiser, Prof. José T. Esquinas-Alcázar and Revd Dr Michael J. Reiss. (More detailed summaries of the presentations are given in Annex I.)

Dr Kaiser presented a case study on the application of gene technology in relation to fish farming. As a start some ethical problems with the current application of fish farming were elaborated as well as the potential benefits of fish farming as a form a sustainable food supply. Subsequently, the status of the application of gene technology in relation to fish farming were discussed, focusing on the application of transgenic salmon with increased growth. In the final part of his presentation Dr Kaiser presented some ethical issues arising form the application of gene technology in this context, in which several different considerations were discussed, such as the "Playing God" consideration, the application of the Precautionary Principle, the role of participatory decision making and the potential contribution to sustainable food production. As a possible way to address these issues, Dr Kaiser underlined the importance of drafting positive development goals, safety assessment, compliance with existing ethical codes, monitoring and labelling, stressing that it is not the technology as such that should be the focus of the attention, but the resulting products.

Using potato as an illustration, *Prof. Esquinas-Alcazar* discussed the links between biodiversity, biotechnology and ethics. Biodiversity is key to the potential for mankind to address future challenges in food supply, health care and environmental protection. Biotechnology is a tool which makes use of biodivesity. Whereas biotechnology shows us what we can do, ethics tells us about what we should do with technology. The use of agricultural biodiversity and the application of biotechnology have to be seen in the context of addressing the problem of hunger in the world and achieving food security. Attention has to be given to ethical aspects such as interdependence between nations and generations. Prof. Esquinas-Alcazar emphasised the need to: promote access to genetic resources, information and technology, harmonisation of benefit sharing between gene-rich and technology-rich countries to address the needs of developing countries and poor farmers, conserve genetic and cultural diversity in order to remain able to adapt to future environmental changes and human needs and keep options open for future generations. As a possible way forward in addressing future challenges, Prof. Esquinas-Alcazar recommended more transparency in decision making, more information to the public, monitoring to serve all stake holders, effective regulations, and mechanisms for accountability. He also noted the work of the FAO and the role of the UN system in this context.

Revd Dr Reiss presented a case study of genetically modified maize. After placing the production of maize in its context, i.e. one of the major crops that feeds the world population, a number of reasons were discussed why gene technology is currently applied in maize. Those reasons are among others to obtain: resistance against the corn borer, herbicide resistance, male sterility and increases in nutritional value. The issues of insect and herbicide resistance were further elaborated. Insect resistance ('Bt maize') is pursued because currently a substantial part of the maize crops is lost due to infestation by the corn borer. Because the use of chemical pesticides has environmental

and financial implications and because the application of alternatives such as biological pest control has been demonstrated not to be sufficiently effective, a novel strategy is followed by introducing the Bt gene in maize. The results of three years of crop production on large scale in the US have shown significant increases in yield, in reduction of pesticide use and in contamination with hazardous compounds such as aflatoxin. Following a discussion of the reasons behind the developments of transgenic maize, Revd Dr Reiss presented and discussed a number of ethical concerns raised over the past years. Those concerns included: the application of gene technology is unnatural, it is unsafe for consumption, it is bad for the environment and some people simply do not want it. In concluding, Revd Dr Reiss stated that although none of the concerns raised would lead to the conclusion not to develop this alternative strategy in food supply, they certainly warrant adequate mechanisms for safety assessment, monitoring and clear labelling.

Discussion

Following the three case studies, the participants and the speakers exchanged views on the following two topics:

1. Which ethical issues related to biosafety can be identified in the field discussed in this session?
2. How can these issues best be addressed?

While reading the following report of the discussion, it should be recognised that the term "ethical issue" was used in the debate in many different ways. Ethics is a dynamic concept which can vary from person to person, from culture to culture and which can change over time. It was pointed out that in countries where the shelves of supermarkets are less full, an ethical debate may have a different starting and endpoint.

1. Identification of ethical issues related to biosafety.

From the discussions it became clear that ethical issues play a role on two different levels: on a general level dealing with the more fundamental question of applying biotechnology as such, and on a ‘case by case’ level, assessing the applications of biotechnology in the different fields.

Fundamental questions

In addressing some more fundamental questions, discussion focused on the justification to apply or not to apply biotechnology.

Arguments against the broad use of biotechnology referred to the ‘unnaturalness’ of combining genes from a different origin and to the issue of the right to "Play God".

Although some participants pointed out that man has been modifying organisms since the beginning of agriculture, it was generally recognised that not everything that can technically be done, should be done. In this context, the right of farmers and consumers to choose between non-genetically modified products and genetically modified products was underlined.

Arguments in favour of the use of biotechnology focused - among others - on the need to improve, increase and secure food supply in the world. It was pointed out that world wide every 2 seconds a person dies because of lack of (good) food, and that in the next century food production has to increase 60% in order to maintain the same level of food supply of today.

With reference to agriculture and fisheries, some participants stressed that the main problems in agriculture today are caused by a too small genetic basis for agricultural crops and underlined the importance of maintaining sufficient genetic diversity of agricultural crops and rotation of crops, regardless whether the crops include or do not include genetically modified crops. Similarly it was stated that the current problems in fisheries are caused by the way men has exploited the seas over the past centuries.

While recognising that current hunger in the world could to a large extent be addressed by a change in distribution of todays' world food supply, it was underlined that the growth of the world population will soon lead to situation where the current world production of food will not be sufficient, even with changes in distribution. In addition, the way food is produced has reached and crossed the limits of the carrying capacity of the environment. Applications of biotechnology - although not a panacea for all (future) problems in the world - can be one of the tools to address the problem of food supply in the context of sustainable land use.

Case by case assessments of applications of biotechnology.
The issues discussed included:
· The Precautionary Approach
· Monitoring.

The Precautionary Approach.
While there was general appreciation of the importance of the Precautionary Approach, there was considerable debate on the question how to apply that approach in practice. Dr Kaiser addressed this in his presentation, underlining that the Precautionary Principle does not imply a zero-risk ideology, and that it does not imply action upon merely speculative harm scenarios.

It was generally recognised that further work on how to apply the Precautionary Approach in practice in the different fields. Important aspect of this are the question of the burden of proof and the question how to deal with scientific uncertainties. One way of addressing uncertainties can be monitoring.

Monitoring
There was general recognition of the importance of monitoring of the impacts of the introduction of genetically modified organisms. Some discussion took place on the question of what to monitor and how. It was recognised that it is difficult if not impossible to monitor for unexpected effects.

Further work is needed to assess the potential and limitations of monitoring.

2. How can ethical issues best be addressed?
An important element in the discussions as to how to address ethical aspects was that current safety assessments should be broadened to Risk/benefit assessments.

Risk/benefit assessments can be carried out in terms of environmental risk/benefit but can also have a broader scope such as the impacts on socio-economic fields. In this context the question of the acceptability of risk was discussed. Whose benefit and whose risk are involved?

Many participants underlined the importance of broadening current risk assessment to encompass a risk/benefit assessment, including an assessment of the consequences of not applying biotechnology.

Annex
(Report of Dr Van Der Meer)

Brief report on the three presentations of the session 'Environment'

Transgenic Maize - Revd. Dr Michael J. Reiss

After placing maize in the context of the world production of food and feed (annually 135 million hectares / 590 million tons harvest in 1996) the author describes a number of different types of genetically modified maize applied or developed currently.

Focusing on the two important ones - resistance to insect attack and herbicide tolerance - the author describes the reasons for developing these genetically modified maize varieties as well arguments raised against the application of such varieties.

The author describes the expected benefits of these applications. In both cases those varieties were developed with a view to reducing the need to use in chemical pesticides, which is important in terms of environmental protection and in terms of food prices.

Next, the author presents a number of concerns raised against to the application of genetically modified (maize) varieties, such as:
· transgenic maize is unnatural and people do not want it;
· transgenic maize is unsafe for consumers and for the environment.

These concerns are discussed in clear detail and placed in the context of potential adverse effects of non-genetically modified maize and in the context of not applying this type of varieties. The author underlines that cost/benefit analysis is an important issue.

The author concludes that there is still a huge gap between those underlining the demonstrated or expected benefits and those warning for undesirable environmental, ethical or social side effects.

In describing a way forward to bridge this gap, the author underlines that consumer choice and monitoring for long term effects is important.

Fish-Farming - Dr Matthias Kaiser

Before discussing the application of modern biotechnology in fish farming, the author first discusses the ethical issues arising from fish farming.

The author underlines that among experts there is widespread agreement that some forms of traditional fish-farming do not raise any ethical problems.

The author first focuses on the concerns raised in relation to the more 'intense' forms of fish farming:
· environmental degradation because of their discharge of substances such as nutrients and chemotherapeutants in the water;
· increase of outbreak and spread of diseases in the species;
· it is not energy-efficient
· escaped fish threatens the genetic variation of the wild stocks.
· competion for the use of valuable areas of the coastal zone.

In the next part of his presentation, the author addresses the ‘other side of the coin’, the positive potential of the industry and its prospect of becoming a sustainable source of food. In view of the expected global population growth there arises the need for increased food production. Given that world fisheries face the acute threat of over-fishing already at present rates, and that agriculture faces the problem of soil erosion and severe limitations on the amount of land usable for agriculture, aquaculture is a possible contributor to the world food demand.

While many experiences with fish farming, in particular shrimp farming, have been negative in terms of the environmental costs, there are other examples which apparently show that fish farming can be practised with significant lower environmental costs.

In the third part of the presentation, the author focuses on the application of modern biotechnology in fish farming, such as transgenic species for human consumption; DNA vaccines for fish species; New composition of fish diets; Transgenic fish as bioreactors and producers of insulin; DNA analysis of fish for determination of the genetic stock structure.

The author describes several cases and presents some of the expected benefits and some of the concerns raised against these applications, in particular in the case of the transgenic salmon with growth enhancement.

In addressing the ethical considerations, the author focuses on environmental considerations, leaving animal welfare issues aside. The author takes a number of general principles related to sustainable fish farming as a starting point to discuss some of the ethical concerns raised in relation to the application of biotechnology in fish farming.

As to the more fundamental rejection of the application of gene technology, the author states that there are no ethical arguments applying to a certain technology per se, and that we are left an ethical evaluation of the possible consequences of a biotechnological intervention, i.e. a case by case evaluation.

In a making case by case evaluations, the author warns that we should be aware that any such assessment is thoroughly infected with scientific uncertainty.

There are two considerations of ethical importance for such management of uncertainty. The first is the Precautionary Principle. Basically a precautionary approach implies among other things the following: The burden of proof rests with the party planning an environmental intervention and the standard of proof should be commensurate with the potential risk to the environment.

The Precautionary Principle does not imply a zero-risk ideology, nor does it imply action upon merely speculative harm scenarios. The second strategy for ethically adequate management of uncertainty is related to the process of evaluation and negotiation. A weighing of possible risks and benefits.

Decision making on possible releases and marketing of genetically modified fish should be based on involvement of all concerned parties and interest-groups, and should be sufficiently open to allow a wide participatory process and public debate.

Genetic Diversity of Potato - Jose T. Esquinas-Alcázar

Starting point of the author's presentation is that the conservation and sustainable use of genetic resources is not a purely technical matter, but has strong socio-economic, political, cultural, legal and ethical implications which may affect the economies of countries and the future of humanity.

The potato famine being a good example in case. The ultimate cause of the disaster was the narrow genetic base of the tubers sown in Ireland. To solve this problem, the technique of plant breeding was applied to the resource base of the local varieties of potato in its centre of diversity in the Andes, with the aim of developing new varieties for Ireland with a wider genetic base.
More recently, using biotechnologies, the genes of wild species of potato have been used to improve the varieties of this crop. More modern technologies including genetic engineering have even allowed the incorporation of genes from other species.

The author addresses a number of general issues related to the topic of maintaining a sufficient level of genetic diversity in which biotechnology can be used:
· Interdependence between genetic resources and technology
· Interdependence between individuals within agricultural systems
· Geographical Interdependence between countries and regions.

"FOOD" SESSION
Dr George ZERVAKIS (Greece)

Final report based on the presentations " **Modified Soya**" by Prof. Emilio Munoz, "**Transgenic salmon**" by Dr Roger Straughan, and the public debates which followed them.

Modified Soya

The case of the modified soya represents an indicative example of a modern biotechnological application in the agrofood sector. It concerns the genetic modification of the soya plant for obtaining resistance to the non-selective herbicide Roundup (Soya Roundup Ready). The genetically-engineered soya bean was modified in a single gene controlling the production of a specific enzyme which is responsible for the sensitivity to the herbicide glyphosate (commercial name: Roundup).
The product was developed by Monsanto (which is the same firm that produced the Roundup herbicide) and its commercial application since 1996 was met with success in the United States and Argentina. Recently (1997) it was one out of five genetically modified crops obtaining sale approval in the European Union, after the enforcement of a thorough regulation mechanism (Directive 90/220/EEC).

However, the introduction of genetically-engineered agricultural products in Europe has raised severe reactions from the public as well as sound debates in the media and among parts of the market chain. The modified soya case is by no means different and can not be sorted out from the general arguments which prevail and concern relevant biotechnological applications and the socio-economical issues pertinent to their use. In an attempt to approach this topic, the following points have to be made clear:

- The term "biotechnology" does not refer (contrary to the popular belief) to a novel scientific (and many times obscure or threatening) field, but to the combined application of various technologies originating from several disciplines aiming to arrive at a specific research and/or economic result. Such integrated methodologies were used from the ancient times to successfully convert primary agricultural products into food (e.g. wine production or bread manufacturing). Hence, biotechnology can be referred to as an evolutive rather than a revolutionary technology.

- During modern times, the cultivation and breeding of plants is bound with procedures like the detailed monitoring of useful characters, screening and selection of biological material with valuable traits, and intraspecific or even interspecific hybridisation to yield varieties (which contain large parts of "foreign" genome) grown all around the world. In contrast, genetic engineering techniques permit identification and transfer of the much sought-after properties, by incorporating only their encoding genes. Therefore, the controlled introduction of a very confined part of the genome from another organism does not seem to present a greater potential "threat" to the host or the environment than breeding or natural recombination. Nature maintains a highly conservative trend as concerns maintaining and using molecules.

- Along the same line of argumenting were the reports of the US National Academy of Sciences and the US National Research Council concluding that "no conceptual

distinction exists between genetic modification of plants and micro-organisms by classical methods or by molecular techniques that modify DNA and transfer genes". These two Bodies together with OCDE, UNIDO, the International Council for Scientific Unions seem to have arrived at an agreement stating that the new biotechnological techniques do not require a new regulatory paradigm. This of course, have not prevented the existence of serious criticisms even from supporters of the safety of such technologies, which questioned the value of some risk assessment experiments. Therefore, it is of primary importance to plan and carry out appropriate and well designed experiments of this type, with emphasis on issues such as the possibility of transgenic movement by outcrossing into wild relatives of modified cultivated plants.

The core of the debate for searching a regulatory paradigm is still the product regulation, following either a "vertical approach" or the "horizontal approach" to risk assessment. In the USA the procedures for risk assessment are not based as many think exclusively on the "vertical approach", but instead agencies like EPA and USDA apply "horizontal approaches". In Europe the regulation is more complex and the introduction of genetically modified organisms (GMO's) is covered by Directive 90/220/EEC. This Directive regulates releases of GMO's to the environment either for experimental purposes or for marketing, and although the initial procedure is common for both cases (an application providing all necessary risk assessments to a competent authority of the member State), in the case of the release for marketing a consent is issued stating that the GMO can be marketed throughout the EU in accordance with the marketing consent.

As concerns the safety of genetically modified food, the European Union has issued the regulation 258/97/EC that covers novel foods and ingredients, and replaced the Directive 90/220 which until then authorised marketing of foods containing GMO's. The regulation 258/97 follows the principle "one door/one key", introduced a mandatory pre-market safety assessment for novel foods, and stated that the environmental risk assessment should be included in the initial assessment. It also covered the labelling issue by introducing provisions for all products derived from or containing GMO's. At this specific point, the regulation draws heavily on the World Health Organisation definition of substantial equivalence and places emphasis on the novel food content of key nutrients and toxic substances than of degraded DNA fragments and associated proteins.

In an attempt to summarise the benefits from the use of the herbicide resistant soya (Roundup Ready Soya, RR soya), the following arguments could be outlined:

i. Monsanto developed the first of a new series of products in respond to the needs of a new agriculture which is expected to result in a proliferation of the production streams.

ii. The RR soya has obtained marketing consent in both the USA and the EU following complex, but distinct, regulatory frames.

iii. The combined use of RR soya and Roundup will lead to reduced levels of herbicide application, which apparently results to less detrimental effects on the environment. In addition, Roundup is a biodegradable compound with a short life-span into the soil or underground waters; hence it is unlikely that weeds could develop any type of herbicide resistance.

iv. The new genetically modified crops (such as RR soya), will allow the use of non-selective and broad-spectrum herbicides (such as Roundup) after sowing, at lower concentrations, directly on the plants and only when the weed pressure really demands them.

v. The RR soya in conjunction with Roundup promotes conservation tillage practices, which in turn favours the judicious application of herbicides and reduces soil erosion. Results from opinion polls among USA farmers are in agreement with the previous statement, and showed that the majority of the participants were satisfied with the use of this genetically modified crop.

At the other end, a number of causes have formed the basis for serious criticisms from various organisations which question the application of biotechnology in the agrofood sector:

i. The new technology is being exploited to increase the multinational companies profit at the expense of farmers. Monsanto, in particular, through its active participation in the "Terminator" project (which resulted in the production of crop seeds that do not germinate in the second generation) develops novel and ambiguous products that bring vast amounts of money to its bank accounts.

ii. The excess use of the herbicide Roundup is rendered quite possible, taking into account the resistance of the RR soya, which will be followed by negative environmental consequences.

iii. There is a serious risk for the development of herbicide resistance in weeds, either through the direct transmittance of the respective genetic trait from the genetically modified plants to weeds or through selective pressure activated by the anticipated excess use of Roundup.

iv. Monsanto, like other companies, has focused its market campaigns only to farmers (which form its direct clientele), and omitted other significant elements in the food chain. It is essential to establish and maintain a communication with all the members of the market in order to avoid disputes caused by lack of information.

v. Many outcries are attributed to the issue of food-labelling which in the case of the modified soya is problematic, since such products are widely distributed throughout the world, they are usually manufactured as blends with conventional soya, and they are principally used as additives to many other goods. Hence, uniform labelling of the end product presents serious difficulties.

Transgenic salmon

Aquaculture is the controlled and planned production of aquatic bio-products for future harvest and has been practised by humans since the ancient times. During the last decades, the importance of this activity has risen significantly and today more than a

quarter of the total world supply of food fish derives from fish farming. However, as traditional methodologies of aquaculture are progressively abandoned in favour of more intensive growing schemes, much debate arises from the application of modern biotechnological techniques.

Biotechnology and more specifically genetic engineering produce transgenic fish that contains novel information in their genome. The new gene may originate from the same/homologous species, from another kind of organism (animal, plant, microbe), or it may be a product of in vitro synthesis. The use of transgenic techniques is easier for fish than for land animals because of external fertilisation, which include the already applied methods of microinjection into the fertilised egg and electroporation; those led to the production of the first transgenic fish in the mid-1980's and facilitated the subsequent fast progress in the genetic modification of these organisms.

Especially as regards the case of salmon, it is currently the only fish product on the market with inserted antifreeze agent and a growth hormone gene. Moreover, research is actually progressing towards the development of DNA vaccines (gene therapy applied to fish), transgenic manipulation of vegetable sources for improving the fish diet, and transformation of fish to bioreactors capable of synthesising human medicine.

Although, the application of biotechnological techniques is expected to produce a series of novel improved fish products which will confer to the market diversification and to cheaper prices, a significant amount of moral concerns have been expressed. The public attitude towards genetically modified food is outlined in relevant Eurobarometer's surveys showing people's unease and anxiety for "unnatural" technologies, especially if their products originate from transgenic animals.

The genetic modification of animals, and in this particular case the transgenic salmon raise a number of moral concerns and ethical issues that could be summarised as follows:

i. Unnaturalness.
This term is associated with the crossing of species boundaries by genetic engineering in such a way that it could not conceivably occur in a natural process. For salmon, there is a tendency to concentrate upon transferring genes deriving from the same species (autotransgenic fish). In either case, it remains doubtful whether outcrossing by incorporating foreign genes is a "sin" from the ethical point of view.

ii. Genetic modification of the "telos" of an animal (i.e. transformation of its essential nature).
Despite the fact that most of the domesticated animals have been in the past seriously affected by selective/conventional breeding and their "telos" has changed, fish have retained most of their natural characteristics (although they were integrated into fish-farming practises) and therefore any biotechnological intervention might provoke more radical consequences to their existence.

iii. Blasphemy.
The widespread concern of "playing God" and the religious dimension of unnatural form part of the most significant views expressed against the application of genetic engineering technology (of course, it does not particularly apply to transgenic salmon). Clearly, the ethical requirement to allow the consumers the freedom of choice is essential, as is the issue of labelling and the provision of appropriate information on such type of food.

iv. Safety.

The issue here, although not strictly a moral one, has to do with responsibility and justifiability, i.e. who ought to take the responsibility for this justifiable level of risk which every application of modern technology includes.

Especially in the case of the transgenic salmon, fears expressed are related with the escape of transgenic fish in natural habitats, the delivery of the incorporated genes on to wild relatives, and the possible health risks to consumers which are associated to potential allergic reactions from food containing growth hormones. Of course one could add several other concerns (which however exist in conventional fish-farming too) like that intensive aquaculture practises promote environmental pollution and degradation, increase the outbreak and spread of diseases, uses up valuable fish recourses from fisheries, etc.

v. Animal Welfare.

This subject has been associated in the past with intensive farming practises; nowadays genetic modification favours even more intensification and results to significant stress on animals. Transgenic salmon is no exception, since greater disease resistance leads to more dense growing in fish farms, whereas growth enhancement contributes to a reduction in overall fitness. Furthermore, the issue of stress has been shown to apply equally well to fish as to mammals, and high stocking densities may restrict their normal movement and social interaction. Therefore, the welfare of fish is ethically significant and as such will be treated by consumers for whom this is an important moral concern and who do not wish to see a further compromise in the living conditions of salmons as a result of genetic modification.

General remarks and conclusions

Distinctions between natural and unnatural concerning GMO's seems rather artificial and in many cases is scientifically unsound. Environmental issues arising from the application of such methodologies must be handled with sound risk assessment analysis and continuous monitoring of risk indicators for a reasonable period of time. Decisions at a political level could promote R&D and biosafety actions suitably incorporated into funded Programmes, since until now scientists have been rather reluctant to embark on such type of research. Protocols and methodologies concerning biosafety, monitoring and risk assessment issues should be agreed upon, because serious criticisms were expressed even from supporters of such technologies on the value of some experiments of this kind. Probably, this subject needs to be addressed at the frame of an international Conference.

Undoubtfully, a very important aspect for evaluation when introducing innovative applications in any society is public perception. In the case of biotechnological products, the popular attitude is rather negative, since most people seem to think that unknown is associated with danger of some kind. These feelings are probably related with the cultural (=religious?) belief that "whatever disturbs natural processes or initial state of nature is malicious".

Noteworthy is the difference in people's attitude towards biotechnology and their moral concerns, e.g. in the United States introduction of new technologies precedes risk estimation and monitoring in contrast to what is actually happening in Europe. Therefore it is of imperative importance to organise debates taking into serious account the public perception (as relates to novel food from biotechnological applications) in conduction with the interests of all parts of the market chain (especially consumers) to avoid disputes

caused by lack of information. Since public opinion is the key element for the spread of biotechnological applications, people expect to be provided with safer, tastier, more nutritious and cheaper food (by far advantageous over the conventional product), and to cover any supply shortages in third-world countries.

In general such issues are complex, and for those consumers who do not have fundamental objections to genetically modified food products, any rational decision about whether they would buy them or not depends on weighting the possible risks against the benefits in the light of their own system of values.
Clearly, the ethical requirement to allow the consumers the freedom of choice is essential, as is the issue of labelling and the provision of appropriate information on such type of food. Labelling should be enforced in a uniform way in all countries, despite the fact that for some cases uniform labelling of the end product presents serious difficulties.

There are numerous other points on which a relevant debate could be based on, some of them being highly controversial. Hence, very essential questions to be further raised are whether the commercialisation of modified or transgenic products is presently needed in view of the potential danger of over-production, and if all socio-economic factors have been carefully evaluated before the appearance of such products in the market.

Last but not least, legislation should take into account the cultural and social values of the individual regions, and include the word “pro-active” in its dictionary. Each case should be examined separately as regards the issues of ethics and safety regulations, and an evaluation of the estimated cost versus the benefit of use should be assessed for each product under examination.

"HUMAN HEALTH" SESSION
Mr Joze V. TRONTELJ (Slovenia)
Sir Dai REES (European Science Foundation)

1. Xenotransplantation (Mr. Gian-Reto Plattner)

The current state of the art in *xenotransplantation* (i.e. transplantation of animal organs to human patients for the purpose of treatment) was briefly reviewed. The increasing shortage of human organs for transplantation is the main reason for the interest in this controversial field. Another reason is the economic interest, since xenotransplantation could create a multimillion-dollar market. However, all xenografts of whole organs to date have been clinical failures. There has been some clinical success with cells or tissues, but even this has been limited. Acute or even hyperacute rejection of grafted organs and tissues presents the main problem. It is hoped that genetical modification of donor animals would reduce immune reactions. Another potentially serious risk, which is difficult to assess, is the possibility of transfer of pathogens, which may lead to new viral diseases, possibly even resulting in epidemics or pandemics. Present public acceptance of xenotransplantation is poor, and the cost of development of this method of treatment would be high. These difficulties are serious and the progress in this field is bound to be slow.

Thus the main ethical issues of xenotransplantation presently include:

- Serious risks for both the recipient and for the society. This degree of risk should require informed consent not only by the recipient but also by the society.

- Very high cost of development of xenotransplantation as a standard method of treatment. It is questionable if investment into xenotransplantation would be the right use of the limited resources for public health.

The following suggestions as to how to deal with these issues were proposed:

- To impose a moratorium for as long as needed to resolve the main biological problems. Such a moratorium is actually already in place in the U.S., while a *de facto* moratorium has been introduced by the Parliamentary Assembly of the Council of Europe. Stringent regulation is needed at all levels, including measures for close, life-long monitoring of already tranplanted patients, in order to allow for timely discovery of developing infection. The creation of "xeno-havens", where illicit procedures would be allowed, must be prevented. However, a distinction could be made between the more and the less risky transplants, e.g., whole organ grafts as compared to cells or tissues.

- Alternative solutions to the shortage of human organs for transplantation are possible and are cheaper. Many more donors can be recruited if the public is properly educated and efficient mechanisms are in force.

- The worst possible outcomes as consequences of introducing xenotransplantation on the one hand and of rejecting it on the other should be compared and long-term choice should be made on the basis of this consideration.

- The principal decision of how and when to proceed with the actual introduction of xenotransplantation into clinical use should not be left to doctors, patients, scientists or companies: it is for the society to decide. Even then, utmost caution will have to be exercised to minimise the risks. It must also be realised that xenotransplantation cannot solve the problem of lack of organs for transplantation.

Unfortunately, prohibitions cannot assure that some overambitious scientists will not proceed with human experiments in this field in secret. It was suggested that mechanisms should be put in place to deal with possible epidemics of xeno-zoonoses resulting from irresponsible clinical trials.

In discussion, it was said that introduction of xenotransplantation would decrease people's readiness to donate organs. One expert suggested that it would be best if the dead body became property of the State. Organ donation after death would then simply become citizens' duty. This view was not shared by others who felt that organ removal should not even become a matter of presumed consent. As the outstanding example of Spain shows, people can be motivated to volunteer to donate organs after their death, and the gap between the need and the supply can be made smaller.

A question was raised whether patients with terminal illness could be used in phase one xenotransplantation clinical studies. Their short life expectancy would reduce the risk to society of spread of possible infection. However, such patients would have little chance to benefit and would have to bear a heavy burden of surgery followed by immunosuppressant therapy. Such experimentation would be ethically unacceptable.

Some people feel that it is unethical to use animals in this way. However, such views cannot be logically defended as a general policy. Individuals' value judgement cannot apply to the whole society. Disturbed identity perception could also be a difficulty to some recipients of animal organs.

2. Vaccines in plants (Dr. Emilio Mordini)

The biotechnology of introducing vaccines into edible plants is at an early stage, but there have been two recent reports on the first phase 2 clinical trials, one using potatoes to carry vaccine against a virus causing respiratory infections and another one with antibodies against dental caries incorporated into tobacco. Other studies are in progress, e.g. using bananas as GMOs carrying vaccine against some microbes causing diarhoeal diseases in children. The expected advantages of such vaccines include greater safety and lower price, as well as simple transport and handling without need for refrigeration. All of these would make such vaccines particularly suitable for poor countries. Furthermore, they may in the future reduce the need for antibiotics (against which bacteria are becoming increasingly resistant), help fight zoonoses and even be used to control reproduction of wild animals.

Among the ethical questions raised is the need to address health problems in developing countries in a more systematic way. Providing good drinking water and better sanitation is the obvious alternative to expensive development of genetically engineered vaccines against diarhoeal diseases. Other questions concern safety. Is the oral route really safer compared to the standard parenteral administration? Could it not lead to allergy against important kinds of food? To address a major health problem (e.g. high child mortality), which has its important social dimensions and background, with just a single technological solution is probably questionable strategy. It can only

work if combined with long-term commitment to promote other components of health care and the general development of the country.

Other ethical issues include the need to conduct clinical trials in children and in developing countries - with possible risks to them - and obtaining ethically valid informed consent in local populations with different value systems. Biosafety of producing more complex GMOs, e.g. bananas with up to 5 or more different vaccines may also be an issue. New regulations in legislation on food products should be devised.

3. Latest developments in the use of stem cells (Dr. Margarita Salas)

Human embryonic stem cells have recently been obtained for the first time. This is a major scientific and technological achievement, likely to open new avenues in research of embryonic development, and to answer a number of questions regarding cell and tissue differentiation and organogenesis. It may lead to increased understanding of certain abnormalities leading to infertility, pregnancy loss and birth defects. Furthermore, it may offer new possibilities of research with ultimate applications in clinical medicine, e.g. development of new drugs, transplantation therapies, and treatment of diseases due to dysfunction of certain cell systems, such as Parkinsonism or juvenile diabetes.

The next step envisaged is combining this technique with cloning by nuclear transfer from adult somatic cells in order to obtain cell cultures suitable for transplantation. A further development may be the production of telomerase, an enzyme that prevents chromosome shortening during cell divisions. This may result in new knowledge about the processes of ageing and possibly in discovery of ways of slowing them down.

The important ethical question is that procurement of embryonic stem cells involves destruction of embryo, which to many is ethically unacceptable. The Oviedo Convention prohibits the creation of embryos for research. The same prohibition is in place in the U.S., but it affects only research institutions funded by public money. For this reason, human embryonic stem cells are only obtained in privately funded research projects. They can be used, however, also in publicly funded institutions. It seems likely that most research on human stem cells will be done in the U.S., due to stricter rules in Europe.

Is there a need for European legislation in these areas? Naturally worldwide regulation cannot be implemented. However, the discussants felt that at least some European policy should be developed.

One expert suggested that in Europe, a possible source of embryonic stem cells could be provided by the stored surplus embryos which would ultimately be destroyed anyway. Another expert commented that there would be few surplus embryos if only such number was produced as would be used for fertilisation.

Embryos produced by cloning using nuclear transfer from adult cells would be required for treatments with transplantation. That, too, is presently impossible in Europe, and a moratorium is in place in the U.S. A possible way to avoid the creation of cloned embryos would be to reprogram adult cells. This possibility is currently examined.

Patenting may seriously affect research in this area. One expert mentioned a sum of 1 million US$ which would have to be paid just to continue his work on a cell line produced by himself, which was found to have been patented by a company some time before.

The ethical issues in this field of biotechnology are highly contentious, and, due to the novelty of the dilemmas presented by the new developments, both ethical standards and public opinion are still evolving. Ethical values have changed in the past and will presumably continue to do so in the future. The present generation should not make value judgements on behalf of the unborn future generations. Nevertheless, we should abide by the presently valid ethical standards, particularly at the forefront of scientific and technological developments.

SUMMARY OF THE ETHICAL ISSUES

1. Xenotransplantation

1.1. Issues which require the implementation of presently accepted ethical principles with no need for new ethical judgements:

> Xenotransplantation is to be regarded as a last resort to be used when other possibilities are exhausted, such as measures for prevention of organ failure and increase in supply of donor organs, when the present serious technical obstances have been fully overcome, and patients have given informed consent in full knowledge of the possible serious complications.
>
> Measures should be taken to prevent scientific and commercial opportunists from proceeding prematurely with further experiments with human beings. People (not even terminally ill people) are to be used as guinea pigs in view of the serious complications associated with tissue rejection.
>
> In view of the risk of infection and consequent epidemics, informed consent is required from society as a whole and not merely the individual concerned. This is to be understood to mean full democratic consent on the basis of full technical information and not merely »no dissent«.
>
> A legally binding moratorium should be in place until the conditions above are met.

These recommendations can and should be implemented through proper democratic processes.

1.2. Issues which require further ethical evaluation.

Further public debate might be required on such aspects as “the identity problem” of individuals dependent on transplanted organs from non-human animals. Perhaps this is linked to the problem of “naturalness” which crops up in other areas discussed in this Conference. The usual Animal Rights issues require attention. In view of the long lead time even before experimental trials are resumed, they should not be decided by us now on behalf of future societies.

2. Vaccines in Plants

2.1 Issues which require the implementation of presently accepted ethical principles, with no need for new ethical judgements :

Problems to be resolved include legal regulation (as foods or as medicines?), education (can the people concerned understand that a food is a medicine and thus give informed consent for a trial?), and policy (how is informed consent to be defined for trials in the Third World, especially involving children?). Some (but not all) of these problems might be ameliorated by extracting the immunogen from the plant source and using it conventionally.

Problems need to be resolved in hazard definition and risk management, and indeed some risks might be unacceptable without attention to local infrastructure. Vaccination could be counterproductive in conditions of poor hygiene and especially without clean water supplies. Removing one organism can create a niche for another, and such risks increase considerably when a single plant is used as a vector for multiple vaccines.

Attention needs to be paid to the ethics of using Third World populations for trials to produce medicines of benefit to the First World. Development must proceed with clear prospects for benefit of the local population, without excessive commercial exploitation.

These recommendations can and should be implemented through proper democratic processes.

2.2. Issues which require further ethical evaluation.

None.

3. Latest developments in the use of stem cells

3.1. Issues which require the implementation of presently accepted ethical principles, with no need for new ethical judgements:

None.

3.2. Issues which require further ethical evaluation.

A new general problem arises in this area, namely the ethics of using sensitive human material as a research tool. A number of ethical positions are still under debate, particularly the ethics of experimentation with human stem cells, whether ethical priority should be given to the use of somatic cells where possible, from what embryo sources is it legitimate to take these cells – embryos created for the purpose and/or embryos discarded from in vitro fertilisation.

All these issues are special cases of the larger question of the extent to which the scientist has ethical liberty to use human germ line material as a plaything (“playing God”).

It is important that the fruits of research should be protected for the benefit of humanity, and that any commercial exploitation is for public good as well as giving fair return on financial investment.

"ANIMAL WELFARE" SESSION
Dr Paul DE GREEVE (The Netherlands)

General introduction

In Europe legislation aiming at the protection of laboratory animals has been issued on an international as well as on a national level.

The **first** European legislative document, the Convention for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes, was opened for signature in 1986 by the Council of Europe.
The leading principle of the Convention reads as follows: *while accepting the need to use animals for scientific and other purposes, everything possible should be done to limit the use for with the ultimate aim of replacing experiments, in particular by alternative methods.*

The **second** European document is the EC Directive for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes (86/609/EEC) which was inspired by the above Convention. However, the spirit of these two texts appears to be different in that the Convention gives priority to important principles (animal rights, mankind's needs), whereas the main concern of the Directive is to harmonise the national laws in order to avoid any distortions of the internal market.

Both legislative documents contain several provisions aiming at the **R**eplacing, **R**educing and **R**efining animal experimentation according to the 3R principle of Russell and Burch.

With respect to this principle special attention should be paid to two provisions:

Article 6 of the Convention:

An experiment should not be performed if another scientifically satisfactory method of obtaining the use result sought, not entailing the use an animal, is reasonable and practically available.

Article 23 of the Directive:

The Commission and Member States should encourage research into the development and validation for alternative techniques witch could provide the same level of information as that obtained in experiments using animals but which involve fewer animals or which entails less painful procedures and shall take steps as they consider appropriate to encourage research in this field. The Commission and Member States shall monitor trends in experimental methods.

Following the rules of the Convention and the EC Directive, Member States have implemented these and other provisions into their national legislation. However, it has become clear that some provisions are not been interpreted in the same way. The question is whether any "action" should be undertaken aiming at the "harmonisation of interpretation" of the legislative provisions.

With a view to addressing this question two case studies were presented as a basis for discussion: 1. Transgenic pigs and 2. Cosmetics – in vitro toxicity.

Transgenesis in pigs

Introduction

Prof. Houdebine presented a case study of the transgenesis in pigs. He informed the audience in detail for what purposes transgenic pigs are created, how they are created and underlined the great advantage of the application of biotechnological techniques.

Two ethical issues were identified by Prof. Houdebine:

- the use and sacrifice of a large number of animals and
- the suffering resulting from the surgical embryo transfer into recipient females.

Prof. Houdebine argued that the 3R principle appears to be respected not only for ethical but also for practical reasons:

Reduce:

by improving the efficiency of transgenesis techniques: in vitro by generation of embryos, use of ES cells and chimera after gene transfer, cloning of embryos after gene transfer, construction of more efficient expression vectors using insulators or homologous recombination.

Refine

by analysing the protocols to retain only the most relevant (with the contribution of local ethical committees).

At the end of his presentation he addressed the two attitudes towards the development of transgenic animals: the “no unless“ approach and the “yes, but” approach.

He argued that none of these approaches seems to be appropriate to take into account the reality in its entirety. However, the “yes, but” approach seems the best attitude for the experimental work, because of the limited number of animals involved. In addition, these experiments are carried out to get knowledge and not entirely directly to make profit. A reduction of animal welfare might be accepted on a case by case basis if transgenic animals are used for an improvement of human health, until an alternative method is available.

Discussion

Among others, questions have been asked dealing with relevant topics.

- the principle of proportionality. It was argued that, when designing an animal experiment, the prospected benefit should be weighed against the suffering of the animals; the so-called cost-benefit analysis.
- genetic modification affecting behaviour of animals. Is there a danger that the animals will be affected to a degree, so that it cannot be found out whether the animals suffer or not?
- is there not a limit to the degree of pain and other suffering that the animals should be allowed to experience in the name of research, even in research aimed at cuning or alleviating human diseases?
- the Council of Europe should guarantee that the inherent value of the animal will be taken into account.

- with respect of the production of antibodies: could transgenic plants be used instead of transgenic animals? It was argued that this is not possible due to the complexity of antigens.
- the impact on the welfare of transgenic animals. It was argued that a healthy animal will be a happy animal and that, fortunately, there will be always some uncertainty about the effect. In that respect the question was raised:
- how to proceed if the result/effect of the biotechnological technique cannot be foreseen. How to deal with the uncertainty?
- an ethical assessment of animal biotechnology should not be reduced to animal health and welfare.

Other relevant checkpoints are:

- the research aim: should be substantial, realistic and morally acceptable
- animal integrity: modifying the genetic make of animals requires good arguments.
- alternatives and 3R principle: to avoid "me too"research
- public concern: openness and democratic control; safety: risk assessment.

Of course, some of these checkpoints are complex and difficult to apply but that does not mean that we should not try. However, this not only task for research groups or local ethical committees, but it is a challenge for the Council of Europe to make efforts to harmonise moral codes/regulations concerning animal (and plant) biotechnology in Europe.

Concluding remark of the rapporteur

It can be concluded that there is a considerable ethical gap due to the fact that there is a fundamental difference in the approach to animals in the different European States.

Cosmetics - in vitro toxicology

Introduction

Prof. Spielmann stated that the ethical issues related to the use of animals for the safety testing of cosmetics have been solved by the above mentioned legislation.

Due to public pressure, the European Commission placed the testing of ingredients and finished products under a ban. According to the 6th Amendment of 14 June of the European Cosmetics Directive 76/786/EEC, animal test for ingredients and combination of ingredients **after 1** January 1998 was forbidden. However, due to the absence of internationally validated alternative methods, the ban has been postponed until 30 June 2000.

The current situation with regard to the safety testing of cosmetics is as follows:

- it is generally accepted that consumer protection has a higher priority than animal protection.
- the development of safer and more effective new cosmetic ingredients is beneficial for the consumer.
- despite a high priority in funding the development and validation of in vitro toxicity tests, only a limited number of toxic endpoints can today be assessed by in vitro methods.

In addition, a strong plea was held for putting into practice the 3R concept by

- refining experimental techniques,
- reducing both the suffering and numbers of experimental animals by a.o.using more humane endpoints, and by applying modern biostatics to reduce the number of animals required.
- replacing the animal experiments by in vitro methods.

Following an overview of the toxicological tests for safety assessment of cosmetic ingredients, the results of the joint ECVAM/COLIPA validation project as well as the ongoing activities of ECVAM with respect to the development relevant in vitro toxicity tests were mentioned.

At the end of his presentation, Prof. Spielmann strongly argued that the EU Commission and the cosmetic industry must give the highest priority to the funding of the development and validation of in vitro toxicity tests.

Identification of the ethical issues

According to Prof. Spielmann there are two positions**:**

- according to the opinion of the animal welfare movement, cosmetic products are not essential for human life. As a consequence animal testing of cosmetic ingredients and finished products should be banned.
  Prof. Spielmann argued that a large number of cosmetics labelled as "produced without the use of animals" are for sale, in other words, the principle of the freedom of choice has been respected.
- According to the point of view of the cosmetic industry and the consumer it is justified to continue to conduct research to find new cosmetics because human health is more important that animal welfare.

Discussion

There was support for the point of view of the animal welfare movement that it is ***not*** justified to use animals for the safety testing of cosmetics.

Beside several requests for clarification, no questions were asked concerning the ethical issues mentioned above.

"RESEARCH" SESSION
Dr Hans-Jörg BUHK (Germany)

Monoclonal antibodies - Dr Coenraad Hendriksen

The technology to produce monoclonal antibodies (Mabs) started in 1975. For this purpose an antibody-secreting lymphocyte was fused with a plasmacytoma cell resulting in immortalised, antibody-secreting hybridoma cells. The predetermined specificity of Mabs is the reason for their widespread use as research tools and for medical purposes (diagnostic, prophylactics, and therapy). There are two possible approaches for Mab production: (i) by *in vitro* culture of hybridoma cells and (ii) *in vivo* from the ascites of mice upon intraperitoneal injection of the hybridoma cells. Approximately 2.6 million mice are used each year for Mab production according to a report of 1991.

In vivo Mab production compromises the well being of the animals. The intraperitoneal injection of hybridoma cells and of a growth primer lead to pain. The induction of ascites fluid causes adverse pathophysiological effects including intra-abdominal tumour growth and respiratory distress. The tremendous impact of Mabs for scientific and medical purposes can be seen as balancing the animal welfare requirements, although many have their moral concerns.

Tumour growth and induction of ascites is inherent to *in vivo* Mab production. The way forward is the improvement of *in vitro* production techniques of Mabs.

Improved *in vitro* production techniques have been developed in the recent years. Mainly two types of techniques are available; (i) low cell density culture methods; and (ii) high cell density culture methods. Mabs produced *in vitro* are of equal quality to Mabs produced *in vivo*. *In vitro* production of Mabs is almost as cost-effective as *in vivo* production. But a limited number of hybridomas don't grow or don't produce Mabs *in vitro* because of cell culture problems.

During some congresses and workshops it was concluded that scientifically acceptable *in vitro* methods have become practically available. In some European countries (UK, NL, CH, D) *in vivo* production has been prohibited except under exceptional circumstances, in others the use of animals for ascites production is limited. Many of the member states (e.g. B, DK) of the Council of Europe lack restriction in this use of animals. Ascites can still be purchased from commercial companies in these member states.

It is concluded that there is neither a moral nor any other justification for the continued use of animal for *in vivo* **production** of Mabs unless under exceptional circumstances. Strategies are suggested to replace *in vivo* production by *in vitro* Mab production:

(i) support of *in vitro* Mab production (technical training, technical support),

(ii) legislative provisions by the individual member states, thereby harmonising legislation in Europe.

Furthermore, labelling requirements for *in vivo* Mabs and a publication policy requiring them to indicate the method of Mab production which would facilitate *in vitro* Mab production.

Reasons were discussed as to why researchers are reluctant to replace *in vivo* production of Mabs. The reasons mentioned are plausible regarding Mabs produced by researchers in their own facilities. However, they are less convincing with regard to production tourism. The answer to the question why a researcher would by-pass restrictive regulations by sub-contracting ascites production to European countries

lacking prohibitive regulation (e.g. BE, DK) or non-European countries needs further explanation. Scientific or economical advantages of *in vivo* produced Mabs would drive such activities.

Dolly - Prof. Peter Sandoe

Cloning is a term with different meanings. Cloning is sometimes used synonymously for both, genetic engineering and molecular cloning. Cloning in a genetic sense means the production of genetically identical individuals. This is a very common technique for the propagation of e.g. plants. The asexual multiplication of organisms leads to clones: cutlings of plants, parthenogenesis of insects, etc.

Cloning is also a technique which has grown out of cell biology. Embryo splitting, a technique dividing an embryo into two parts at a stage where all the cells of the embryo are still identical, is a technique used for animal breeding. More advanced forms of cloning involve nuclear transfer. Cells of an early embryo are not yet differentiated and can serve as a normal nucleus of a pre-embryo when transferred to an enucleated and unfertilised egg. The egg contains the substances to undertake the necessary reprogramming of expression of the genome in order to induce a restart of the embryonic development.

The new thing about cloning of Dolly is the fact that the cell from which she originated is a differentiated somatic cell. Culturing the cells in media with an extremely low serum concentration did the reprogramming of the expression of the genome. The lesson to learn is: cell differentiation is not an irreversible process.

The main interest of the company involved in the creation of Dolly is to create genetically identical individuals from a genetically modified and phenotypically characterised animal. Thus, with one genetically modified founder animal a whole stock of bioreactors can be bred and maintained. With the aid of cloning genetical modification can be carried out *in vitro* on a cell line. When the cell line has been checked for the wanted genetic modification one cell can be turned into an animal by means of the cloning technique. This technique promises to be much more precise and efficient than injecting DNA directly into a one-cell fertilised egg. There is no indication that animal cloning as such is more worrying than the creation of genetically modified animals.

Four ethical concerns regarding both, animal cloning and genetically modified animals, are specified as follows:

(1) animal and human welfare,
(2) scientists should not play God,
(3) animals should not be treated as mere means,
(4) the genetic integrity of animals should not be violated.

The main disagreement in the current debate is between the view that only *animal and human welfare* are relevant concerns, and the view that the *other concerns* mentioned do also matter.

Three possible interpretations of the "*playing God*" objection are discussed. According to one of the interpretations animal biotechnology involves greater risks. In cases where the risk to animal and/or human well being outweighs the expected benefits then animal biotechnology should not be used. But this concern is captured by the welfare-based approach. It is concluded that the "*playing God*" objection does not introduce an independent concern regarding biotechnology.

The concern that *animals should not be treated as mere means* is against the whole idea of animal use, and not specific for animal biotechnology. With the assumption that in principle the use of animals is accepted, this concern is not of specific relevance for animal biotechnology.

The concern that *the genetic integrity of animals should be respected* does not stand up to close scrutiny. During evolution (in history, today, and in the future) the genetic structures of given populations of species change continuously. The claim that the present genetic make-up is special or a "final" development seems completely arbitrary. The capability for adaptation of the genetic structure is a prerequisite for the survival of a species. If the phenotype of an animal is going to be changed abnormally animal integrity might be a concern. Nevertheless, the net result in terms of harm and benefit is better covered by the *animal welfare* approach.

Finally it is concluded that the welfare approach is an advantage for the ethical assessment of biotechnology**.** The same kind of assessment as that for other kinds of animal use should be used. To decide whether there is an ethical problem one should look for the same symptoms in all cases: abnormal behaviour, physiological stress-reactions, health problems, etc. In that sense there is nothing special about biotechnology compared to other "animal welfare issues".

A further important point is made that despite any complications and controversial issues the welfare approach is already at work. It is the basis of the regulations and recommendations issued by the Council of Europe and the EU.

Human Genome - comparative genome analysis - Prof. Judit Sándor

The presentation aimed at demonstrating that legal and ethical interpretation of genetic discoveries would require a broader inventive policy based attitude.

Based on the size of the human genome it is estimated to contain 80 – 100 000 structural genes. The objective of the Human Genome Project is to determine the nucleotide sequence of the entire human genome. By comparison of the nucleotide sequence of an individual to the reference data genetic disorders and genetic predispositions can be recognised.

Even though the Human Genome Project cannot be used directly to improve the patients health, the information gained will not only increase our knowledge on human genetics, but also will lay grounds for the development of new strategies of medical treatment including drugs with an optimised design for specific groups of patients. Distinction between genetic anomaly and illness has not always been made; therefore a specific evaluation of the impact on the individual's health is sometimes difficult.

People have been segregated based on race, religion and nationality. Segregation by race has its targets on the phenotype of the individual. The phenotype of an individual is an expression of its genotype. With the emergence of human genome mapping and human genome sequencing segregation is possible not only via the phenotype but in much greater detail directly on the basis genotype data.

Genetic discrimination is potentially harmful. If some genetic characteristics are regarded as inferior to the others the social position of the individuals who carry these genes may be affected. In the view presented this threat may become reality only if additional conditions are present, only when the dominant social and health policy is based on genetic reductionism. Genetic reductionism is a paradigm that is based on the misbelief that individuals can be reduced to their genes.

Identity has been elaborated as an aspect of human dignity with regard to cloning and genetic engineering. It is not evident whether personal identity constitutes human dignity.

Genetic testing and screening undermine the right to privacy, that is the control over someone's own personal information. An individual's control over its personal information should be guaranteed.

Genetic testing and genetic screening are efficient tools to detect the predisposition for and the cause of genetic disease. Genetic disease requires different ethical

considerations from non-genetic disease. They are in principle irreversible. Genetic anomalies may be inherited by the offspring and the late-onset of disease with the threat of developing symptoms affects the individual's life.

Genetic data is more than common health care data; it can also be used for specific personal identification. Specially designed confidentiality regulation is required, and also the individuals own access right should be reaffirmed. Individuals should have the "right to know" but also the "right not to know". Genetic testing and screening are likely to affect not only the tested patient, but also influence other family members e.g. in their life-style, family planning and health insurance. With regard to the existing regulations on human rights and the principles of medical ethics the need to extend this to the principle of privacy on ones own genetic data (privacy of information, relationship) was pointed out.

It is concluded that concerns about the human genome analysis have been raised on the wrong assumption that genetic based health-care policy will follow eugenic patterns. The commercialisation of genes as a result of the Human Genome project is another fear.

Human genome analysis and screening can give rise to the development of predisposition-based pharmaceuticals and medical treatment, and to an individual (genetic) based health-care policy with a positive impact on the quality of the life of the individual.

Patenting in scientific research - Prof. Darryl Macer

Patenting is a system of intellectual property protection designed to reward inventors. An invention must be novel, non-obvious and useful in order to qualify for a patent. Industrial competitiveness leads to secrecy; research results may not be published. A patent guarantees the publication of results for use in future developments. Patents can generally be sought either on products or on processes.

Logical steps of a process claimed as inventions that are clear to workers in that field are not inventive in the patent sense. If a protein sequence is known, than the corresponding DNA sequence will not in general be patentable. Natural products may loose their novelty and non-obviousness in the patent sense, if progressive details of a molecule or a sequence have been published.

An invention must also be commercially useful. A new use may be allowed a new patent; e.g. oligonucleotide probes used in genetic screening. Longer DNA sequences as they are used to detect marker sequences spread through the genome are another example. The Oncomouse was patented as a model for a particular human disease.

The two basic approaches to applying patent law to biotechnology are explained, (i) the normal patentability criteria (novelty, non-obviousness, utility, and recognised depository), and (ii) specific exclusion of certain types of inventions. The exclusion of animals in Denmark's national law to patenting is based on ethical issues.

Some ethical arguments that are commonly expressed when supporting patenting of biotechnology inventions are listed as well as arguments against patenting.

Patenting is believed to reward innovation. The successful modern democratic systems and the Asian economic systems recognise property rights in invention. Property rights are not absolutely protected in any society because of the principle of justice, thus, for the sake of "public interest", "social need", and "public utility", societies can confiscate property.

There is an existing legal concept, that things, which are of a high scale international interest, should become the cultural property of all humanity. The human genome, being common to all people, has shared ownership, is a shared asset, and therefore the nucleotide sequence data should be open to all for a reasonable price. As an alternative to patenting of discoveries from the human genome property rights similar to the variety rights regarding new varieties of plants have been suggested.

It is concluded that the most rapid progress in research will be obtained if the scientific results are shared within the scientific community. It is unethical to withhold information that could provide medical therapy. New foods or medical therapy should be available to all without discrimination.

"INDUSTRY" SESSION
Dr Monika MÖRTBERG-BACKLUND (Sweden)

Background

The use of biotechnology for industrial purposes has a very long history. For thousands of years man has used microorganisms for the production of food (bear, wine cheese and bread) and health care products. It was, however, first during the 19th century that we began to understand the importance of microorganisms and during the 20th century that we learned how to control them in different processes. During the last decades rapid developments in genetic engineering and cell biology have given us powerful tools for development of new services, products and processes in several fields. This "modern" biotechnology has a potential to improve life quality and environment but also it also gives raise to a lot of questions and public concerns.

The case studies selected under Industry illustrate with special focus on the role of biotechnology some central challenges, that the development within the industrial sector is facing today. Industrial development is expected to contribute to economic growth and employment, to consider the global situation and create new jobs for developing countries, to contribute to a sustainable development and to ensure the production of safe high quality products.

Summary of case studies

Oil seeds to replace mineral oil (Prof. Sten Stymne)

There is a strong incentive from a political and socio-economical point of view to increase the amount of agricultural products used for non-food purposes. The surplus production in agriculture in the industrialised countries is a substantial economic burden as well as an obstacle to free trade between nations. Since it is political unacceptable to radically reduce the agricultural sector, actions have been taken by the European Union and United States to promote non-food use of farm land. However, in most cases where conventional agricultural products are cultivated for non-food purposes, the market prices for these products are, at the best, equal and in many cases much lower than for commodity products for food purposes. The low price for agricultural products for non-food purposes is due to the competition from the dominating low priced raw materials used today, mineral oil and forestry produced material.

The main raw material today used in chemical industry is mineral oil with a global annual consumption of about 200 million metric tonnes. The world market prices of crude mineral oil is about one half to one fifth of the production costs of starch and vegetable oils. However, the chemical processing of the mineral oil to the final product is costly. Therefore the agricultural products may compete with mineral oils in the chemical industry if their cost/performance is such that it minimise the further processing to the final product.

By conventional plant breeding and mutation breeding it has been possible to radically alter the fatty acid composition of the oil in a few oil crops and thereby creating oils with distinctly different properties from the original quality. Genetic engineering opens the possibility to alter the chemical composition of the agricultural products in a way that is not possible with conventional plant breeding. Genetic

engineering makes it possible to introduce novel fatty acids in the crop oil, thereby creating oil qualities which cannot be found in commercial crops or obtained by chemical modification of the oils from those crops.

For food purposes the cloning of genes involved in the synthesis of highly polyunsaturated fatty acids from microorganisms is far advanced. The really great impact of genetic engineering of oil in agriculture is, however, likely to come from the development of oil qualities designed for different industrial applications like paints, lubricants and plastics. Over thousand of different unusual fatty have been characterised in seed oils from wild plant species. Many of these are highly interesting for the chemical industry. Today there is little doubt that the genetic ” tool box” for producing unusual fatty acids in high quantities in transgenic plants will be available in a few years time.

The use of genetic engineering to obtain agricultural crops for non-food purposes makes it is possible to optimise the performance of the product for the chemical industry and at the same time retain the same production cost as commodity agricultural products. This will increase the demand for agricultural products and consequently increase world market prices also of commodity products, thereby help restoring the profitability of agriculture. In addition to this, it will also have significant beneficial environmental impact by replacing fossil material with renewable biomaterial and replace hazardous organic chemical processes in industry with enzymatic ”zero by-product” processing in plants. There are, however, also concerns of negative impacts on existing economies and of health and ecological risks associated with the development of this technology.

Fears are expressed that the application of this new biotechnology in agriculture could lead to that the third world are further deprived of agriculture markets. Due to surplus production of agriculture products in the world, the only competitive agriculture sector for the tropical countries (of which many belong to the third world) is today the unique tropical plant products. Genetic engineering of plants could achieve product qualities in temperate crops that previously was only found in the tropical agriculture plants. It is, however, the authors firm believe that the third world, in the long run, will benefit significantly from the technology. Two main reasons for this opinion are presented. Firstly, the expansion of the non-food sector of the agriculture production will decrease surplus and increase world market prices and thus give opportunities to countries with good agriculture potentials but with no markets to develop their own agriculture sector. Secondly, the production from the engineered plant does not differ from conventional agriculture practice. Thus, if genetic engineering moves the chemical factory into the plant, it can be multiplied without the heavy investments in capital and human resources needed for a conventional chemical factory. Today there are, however, very little resources spent for improvement of tropical crops by genetic engineering.

There are also concerns that the production of specialised oil qualities for chemical industry from transgenic plants will, will be controlled by a few multinational companies by patent protection and that the plants will only been grown on contract basis leading to limitations of individual farmers freedom to operate. According to the author, it is doubtful that this will be regarded as negative by the farmers, since contract farming often is giving higher and more secure economic return than producing for the commodity market.

There are certain potential ecological and health risks associated with genetic engineering of oil quality. Some of the products that will be produced are antinutritional and possibly also toxic. It will therefore be essential that transgenic crops yielding products with negative effects on human health are only grown where there are regulations, infrastructure and education levels to ensure that these plants can be grown without risks of contaminating the food chain.

The ecological risks of producing antinutritional or toxic compounds in transgenic plants has not yet been investigated by researchers. The difference with the transgenic plants compared to the naturally occurring toxic plants will be that some of the former plants is perceived as edible by the wild life and may suddenly become toxic. However, this risk can already now be minimised by not using wild life preferred crops to produce potentially toxic compounds. Further, it is possible, by genetic engineering to introduce divergent seed colour and bitter tasting compounds, like tannins, in order to aid animals to differ these seeds from the edible varieties.

Sweetener production with recombinant micro-organisms (Dr Enrique Roca)

Xylitol is a very effective sweetener used in the food industry. In the case study presented by Dr Roca a process for production of xylitol based on fermentation of plant material with micro-organisms was described. In one series of experiments genetically modified organisms (GMO) were used in order to increase the yield of the product. However, their stability was very sensitive to the conditions under which the fermentation was performed. The fermentation process could instead be optimised using non-modified microorganisms by change of temperature, dilution rate, substrate and by the use of an immobilisation process.

On the basis of these experiments it is concluded that there is a need to consider the alternatives to the use of GMO. By developing recombinant tools a need is also created to use modified organisms. The best practice would instead be to use a step by step approach, considering the best overall solution for each case.

Dialogue with the society (Dr Lise Kingo)

In this case study the company Novo Nordisk has been selected as an example to illustrate a model on how companies can create a dialogue with the society.

Novo Nordisk is a multinational company represented in 61 countries. More than 14,000 people work for Novo Nordisk and in 1997 the company had a net turnover of 1,632 million DKK. The business comprises health care products and enzymes for industrial applications.

Novo Nordisk produces insulin, human growth hormone, human factor VIIa and a wide range of industrial enzymes with the help of genetically modified micro-organisms (GMOs) and the company is also involved in developing transgenic animals. These techniques are considered by the company as tools to reach the goals of finding better ways to fight disease and to provide sustainable biological solutions to industry. However, it is also realised that these techniques can be controversial and that there are groups in society that deem them as unnatural, immoral and too dangerous.

During 1997 Corporate Management of Novo Nordisk initiated a cross-organisational project called ”Values in action”. The aim was to review the company’s awareness, attitudes and actions in relation to three focal areas of finance, environment and social concerns. A bioethics and environment task force group was formed with the purpose

of strengthening the company's way of handling bioethical and environmental issues and ensuring that they are integrated into the managerial decision-making process.

For Novo Nordisk bioethics encompasses all ethical issues related to the use of life science technologies for the development and production of biotechnological and pharmaceutical products including clinical testing of pharmaceutical products, access to genetic resources, conservation of biodiversity, patenting, labelling, animal welfare and the safe use of biotechnology. The company has commissioned an independent third party to review its management practices in regard to bioethical issues. The report was available as a part of the 1998 Environment & Bioethics Reports at the Oviedo conference.

According to Novo Nordisk the Environment & Bioethics Reports can never replace two-way communication. The company's experience is that direct face-to-face dialogue with the interested parties is the best way to discuss environmental and bioethical issues. These issues are therefore highlighted in courses held internally. The company is also open to visits from schoolchildren and students and the staff appears at conferences, meetings and courses to discuss the environmental work performed in the company. Over the eight last years, Novo Nordisk has held annual "environmental visits" where leading NGO representatives are invited to discuss issues such as genetic engineering, patenting, animal experimentation etc. as well as visiting the research and production facilities. Customers, investors, academia, the authorities and the media are also important dialogue partners for the companies. A systematic dialogue with the company's stakeholders is an important part of the business. It is concluded that transparency and interaction with the society is crucial for the biotech industry's future and therefore the industry must learn to handle bioethics issues.

The Moral Agenda of Virtubiobuss: biotechnology and business ethics (Dr Christien M. Enzing)

Severe discussions in the management group of Virtubiobuss, a biotech company active in the field of diagnostic kits and therapeutics, has led to a decision not to produce a new set of diagnostic kits. This the starting point for this case study which summaries the result of a study on how biotech companies think and act in relation to the ethical aspects of biotechnology.

Ten biotech companies were interviewed in the study. They included both so-called dedicated biotech companies specialised in development and production of high added value biotech products such as pharmaceuticals, tools in plant breeding etc. and traditional food and pharmaceutical companies that use biotechnology as an important tool in R&D and production.

The result of the study showed that the companies devoted a lot of attention to ethical issues. One company had an ethical audit and another one had an ethical advisory board. Others would ask experts in certain cases for advice. When asked for examples of specific decision making on ethical issues, almost all companies could mention examples.

The moral agenda of companies is made up of three ways:

1. New issues are raised as a direct reaction to the activities of the two other groups of actors in this field: government and the public. For instance, national or EU regulation

or when activities of social groups directly concern the companies activities or products.

2. Issues which are raised as an indirect effect of the activities of the two groups. For instance, formulating an ethical code or setting up a professional code.

3. Issues are brought forward because the company has the opinion that it has a social responsibility in relation to its processes and products. For instance it can include responsibility with respect to sustainable development or cultural assets.

The paper focuses on the part of the moral agenda that results from the interaction between the companies and the public. The result of the study shows that the companies consider information on production technologies important, using the moral concept of a ”right to know” of the consumer to receive information. Half of the studied companies declared that a ”dialogue” or ”transparency” in their ethical code as one of the important principles of the company. However, it is shown that this positive attitude to information and communication is in sharp contrast with everyday practice. The conclusion of the study is that the companies have a communication problem in that they are not able to organise the interaction they want.
On the other hand the public does not trust companies as reliable source concerning information about biotechnology (Eurobarometer,1997).

The public distrusts the information of the companies not because the information is considered not correct but companies are distrusted because they are companies. Distrust can not be simply overcome with better information. It can only be overcome by ”better” companies. The companies must be better in a virtue-ethical judgement i.e. the company judged as such without looking at the intentions or the results of the company. Virtue ethical judgements are about the company you are, irrespective of your intentions and of your results. Companies can also be interpreted from the point of view of the company as a social institution. In this contractarian point of view the company is an institution for mutual advantage, reputation is a basic asset for those who govern it. But reputation can only build up by means of a set of general ethical commitments on values that can be verified on acts and results. This makes the company accountable to the public. Trust is the basic concept and it needs commitments on values and procedures.

In both Virtue-ethical and contractarian views ”more information” is not the solution to overcome distrust. From a virtue-ethical point of view companies can only improve the way they are viewed upon, through working on their own values and norms without other goals than to clarify them for themselves. From a contractarian point of view clarifying is not enough. Companies should also communicate and discuss their corporate values and norms with the public.

Biotech companies are recommended to make their own moral codes more explicit in a transparent way being open to dialogue with concerned stakeholders, such as consumers, citizens and environmental groups, the scientific community, regulatory bodies and the media. Intermediate organisations like EuropaBio or the national biotech industry organisations are recommended to play an active role in this communication process. In order to overcome strict virtue-ethical judgement of the public companies should start open communication processes with consumer organisations, environmental organisations and other issue group. Another possibility is

to invite consumers´, patients´, environmental or other issue-organisations in the company and to start a low profile interaction.

Discussion

In the discussion that followed the oral presentations of the case studies questions of who is controlling the technologies, what the choices are, who will benefit and who is at risk were addressed. The right of the public to know and to chose, if big companies can be trusted to protect the rights and health of citizens and how companies can create a dialogue with the public were other topics that were discussed.

Concerning the case study on oil seeds to replace mineral oil ethics and justice between the developed and developing countries were discussed. Coconut and coffee were mentioned as examples of products where tropical countries have been deprived of their markets for agricultural products. According to professor Stymne the case where oil seeds replace mineral oil is different because in this situation the application of a new technology has a potential to make agricultural profitable for countries without market for their agricultural products. By production of non-food agricultural products new markets will appear which will lead to increased prices of commodity products. This applies both for tropical countries as well as for eastern part of Europe.

Another issue which was brought up in connection to this case study was land use. It was discussed how much land would be needed in order to replace mineral oil with oil seeds in the described application and how in the future limited land resources should be divided between food and non-food production. Prof Stymne pointed out that there were no exact calculation to estimate this need but at present starvation is not a problem of land use, instead it is a distribution problem. The production of non-food agricultural products gives a possibility for farmers in developing countries to develop a profitable economic activity. It was also commented that the replacement of mineral oil with oil derived from plants besides introducing renewable raw materials also has the advantage of resulting in biodegradable final industrial products, contributing to a cleaner environment and sustainable development.

The control of the technology, information to the public and who will provide the seeds was also discussed. The concern was expressed that the distribution of seeds would be controlled by patent protection by a few multinational companies. On the other hand it was pointed out that companies need to get money back from their investments in research and development, and that patents are valid for a limited period of time before they expire.

In connection to the case studies on industry's dialogue with the public and the moral agenda of companies it was questioned whether the driving forces for companies in creating a dialogue with the public are based primary on concerns about bioethics or about business. In the following discussion the need for companies to gain confidence from the public was stressed. An example from Denmark pointed out the need for industry to build alliances with academia and the public and to create fora where business ethics and basic moral values can be discussed. The participation in such processes could help companies not only to increase their awareness of and insight into these issues but also to gain confidence and social acceptance among the public.

Conclusion

Public acceptance based on confidence and trust is crucial for the future of the biotech industry. Only information is not enough to overcome public distrust and to gain acceptance for the development and application of new technologies. Companies need to discuss bioethics and their basic moral values in an open and transparent communication process with external stakeholders. The public and the private sector as well as different interest groups need to interact and to participate in an active dialogue in order to ensure that the rapid developments in biotechnology can be accepted by the society.

"NORTH/SOUTH" SESSION
Dr Julian KINDERLERER (United Kingdom)

It was recognised that the session could in no way cover the many issues that arise when considering the ethical issues that arise from the application of biotechnology in relation to developing and developed countries (North — South). It had been decided that there would be three case studies that highlighted particular issues and which enabled a limited but informed debate.

Introduction

This session was not the only one that raised issues important when ethical issues linked primarily to the 'North — South' debate. It is therefore deemed important to include some introductory paragraphs that highlighted the many contributions from a host of sources that arose during the meeting.

The use of modern biotechnology within those countries that are in the 'industrialised north' will inevitably have an impact on the economies and science in the countries of the 'developing south'. In this context, south must be used to denote most of Africa, Asia and South America. However, agriculture in these countries may be industrialised and there remain agricultural practices in industrialised countries that many associate with subsistence agriculture. In contrast to the cost of infrastructure needed for most new technologies, Biotechnology may have relatively low entry-barriers, so that the introduction of the capacity to develop new products may be much easier. This session aimed to explore issues that will arise from the impact of modern biotechnology in those countries that have not had the industrialisation of agriculture to the same extent as exists in most of Western Europe. Amongst many other issues, this will involve the introduction of new products in the 'north' which supersede economically important products in the 'south' as well as the introduction of new products. It will involve the search for new 'genes' either through the use of traditional knowledge or through prospecting for new and scientifically unexplored plants and microorganisms.

It is possible to look at the same use of the technology in very different ways; for example, some may see commercial exploitation as empowerment. The identification of plants containing genes that may be exploited for many uses, including pharmaceuticals, is seen by many as providing the gene pool needed for improving marketable products, and by others as piracy. The use of traditional knowledge to identify new commercial opportunities is seen by some as normal commercial practice, by others as theft. Modification of plants so that crops currently important in the 'south' lose commercial significance is seen by many as a continuation of traditional economics, by others as a challenge to individuals already on the breadline who require compensation for their loss of livelihood. The use of indigenous knowledge to develop new products or a search for new genetic material is biopiracy to some, bioprospecting to others.

The short life of patents on products or processes and the requirement for disclosure are forgotten in the argument against the protection of intellectual property arising from biotechnology. This dichotomy in our appreciation of that offered by biotechnology

requires that sharp lines are drawn so that all feel that the technology (if used) is capable of benefiting them and that there are systems in place for the protection of all.

The insistence on the safe use of modern biotechnology and the 'precautionary principle' in industrialised countries where there is already more than enough to eat is be felt by many to be an expensive luxury. They argue that this cannot be sustained when there is a desperate need to provide food and to ensure its efficient and safe distribution. This does have an impact on those in the 'south' who might consider either that the 'north' is less concerned at their safety or choose not to eat rather than allow something considered not safe for a European or North American environment to be used.

The dumping of unwanted products that may not have been tested adequately or that are not approved in the industrialised countries is already seen as a problem, and many fear that modern biotechnology will increase this practice. There is also a fear that the 'industrialised' countries may choose to test new products on those in the 'south' before its use in their own sophisticated and litigious backyard. There is good evidence, some presented in this session, that access to new products may be blocked, possibly on a large scale by abuse of intellectual property systems.

The introduction of modern biotechnology products might result in changes in agricultural practice (including a change in the use of chemicals) or the loss of economic sustainability as new products enter the market. These will result in changes in social structures which might sequentially affect the types of agriculture and needs for distribution of foods and food products.

The monopoly control of chemicals used in agriculture and of seeds that allow plants to resist these chemicals might be exploitative and place a strain on the economy of developing countries. Intensive agriculture may result in the use of a particular variety of plant (or animal) which may lead to the loss of other varieties. Use of a small number of varieties may cause problems when a significant part of the total area planted is uniformly susceptible to a pest or environmental hazard. "One of the main causes of genetic vulnerability is the widespread replacement of diverse varieties by homogeneous modern varieties"[1].

Although modern biotechnology is often seen as providing a means for integrating the process of agriculture, many in the non-industrialised countries view the technology as providing:[2]

- Diseases free planting material. Tissue culture techniques are used in laboratories to allow the micropropagation of plant material, which is free of disease and can be provided to farmers. This technology is not only important for crops traditionally cultivated using vegetative propagation (banana, potato) but also coffee, cocoa, oil palm and sugar cane.

[1] Background documentation prepared for the International Technical Conference on Plant Genetic Resources, Leipzig, Germany, 17-23 June 1996, Food & Agriculture Organisation, Rome, 1996

[2] Joel Cohen, Cesar Falconi and John Komen (May 1998) "Strategic Decisions for Agricultural Biotechnology: Synthesis of Four Policy Seminars" ISNAR Briefing Paper 38. [International Service for National Agricultural Research, Laan van Nieuw Oost Indië 133, 2593 BM The Hague, PO Box 93375, 2509

- Biocontrol agents that are not integrated into the plants, but may be used directly.
- Diagnostics and vaccines for livestock diseases. “Diagnostic tests and rDNA vaccines for rinderpest, cowdriosis (heartwater), theileriosis (East Cost fever) and foot-and-mouth disease” have been developed.
- Plant varieties that offer disease resistance, either through traditional breeding and selection techniques or through the introduction of genes from other organisms.
- However, many regional crops have importance on a world scale because of the provision of particular chemicals. The possibility of modifying common commodity crops grown in temperate climates to produce higher value chemical products may have devastating impacts on the original products and producers

Case Studies

The session attempted to consider many of these issues through three detailed case studies. The first examined changes in the quality of a product by looking at **Vegetable Oils** *derived from transgenic and non-transgenic oilseed crops: Achievements and possible substitutions”* (Albert Sasson). This provided a detailed examination of many oil seed crops, particularly those important in the South, including palm, palm kernel and coconut. Professor Sasson discussed the changes to ‘Northern’ crops that might modify the market for these crops, and therefore indicated the likely impact of biotechnology on the livelihood of those involved in their production. The need for fats and oils was analysed and Professor Sasson identified a change to less saturated fat, and hence towards oils derived from plant material. “Coconut was, from 1914 to the end of the 1950’s the world’s leading oilseed crop…… coconut oil is threatened with extinction at the dawning of the 21st century….. it is crucial for some small Pacific States, whose economy partly depends on coconut oil.” Palm oil production is increasing at a greater rate than for any other oil. Palm Kernel oil has become an important competitor for coconut oil, but it too is produced (albeit more commercially) in the developing ‘south’. This demand for short chain fatty acid oils (lauric) is likely to be met in the future from modified crops grown in temperate climates, which will have an impact on southern economies. Even with these new varieties, Professor Sasson suggested that

- World demand for fats and oils will remain high.
- World production is increasing, but stocks will remain insufficient and the balance between production and consumption will be precarious.
- Asia shows the highest potential for the increase in demand, because of an increase in expectation.
- Europe will have to adjust to the new agricultural common policy and world-trade regulations and decide about developing its oil production.

It is possible to modify plants to produce wanted oils in three ways, using traditional methods as had been used to reduce erucic acid in oil seed rape, chemical modification and transgenesis. The case study highlighted Prof. Sasson’s view that there were few ethical issues raised by the production of new variants of plants for the production of oils. The oils were seen as pure chemicals, without genes or proteins, hence without problems.

In a different session of this conference, Prof. Sten Stymne reported on *Oil seeds to replace mineral oil.* He suggested that the extra costs that might be needed for identity preservation for crops in which the oil has been changed might increase the cost of these beyond that which is commercially viable. "The really great impact of genetic engineering of oil in agriculture is likely to come from the development of oil qualities designed for different industrial applications like paints, lubricants, plastics etc…". He further suggested that it might be possible to domesticate a few wild plant species with interesting oil qualities in order to have them produce oils at commercially acceptable prices but unless genetic engineering is used this is too difficult and will take too long. The risks associated with changing the oils are significant, both to health and the environment. "[I]t will be essential that transgenic crops yielding products with negative effects on human health are only grown where there are regulations, infrastructure and education levels to ensure that these plants can be grown without risks of contaminating the food chain". There will also be ecological risks if we change the oils produced in common crop plants, many of which will be toxic to birds and other wildlife. Animals and insects that recognise plants as safe and suddenly the plants are changed so that they are no longer safe are certainly a major hazard to wildlife. Prof. Stymne is concerned that agriculture is best served by identifying the risks and minimising them before commercial production is allowed.

Dr Vandana Shiva looked at the industrialisation of a traditional product in her paper on **Neem.** The paper represented a very detailed examination of indigenous knowledge 'pirated' for pharmaceutical products that might be important in the 'North'. "Even the processes that have been patented are only minor modifications of processes that have been used for centuries to prepare extracts". The name of the tree means "that which get rid of disease" and the neem plant is often called the 'village pharmacy'. Presumptions that Western exploitation of the plant were advanced relative to the use in India were seen to be arrogance and demonstrated a lack of understanding of the culture and traditions of the population from whom the indigenous knowledge had been taken. There is a need for cultures to respect one another

Dr Shiva was concerned that the use of the active constituents of the neem tree in the US has not resulted in any return to those who have used it for centuries. The intellectual property of the indigenous users has been stolen by US companies who claim "these large scale extraction processes constitute a genuine innovation". Dr. Shiva identified a number of issues

- *Resource piracy* in which the biological and natural resources of communities are freely taken without recognition or permission
- *Intellectual and cultural piracy* "in which the cultural and intellectual heritage of communities and the country is freely taken without recognition or permission and is used for claiming … patents[,] and trademarks.
- *Economic piracy* in which the domestic markets are 'destroyed'.

Dr Shiva asserted that there "is an urgent need to evolve a legal system to protect the indigenous knowledge of the communities and our biodiversity in order to prevent such piracy through patenting". Cultural differences are important and need to be based on mutual respect, "not predation by the economically powerful".

The third paper in the session related to **Bioprospecting: linking biotechnology and biodiversity conservation**. In this paper, Dr Sittenfeld identified the methods by which Costa Rica has protected its biodiversity through using bioprospecting to incorporate two goals:

- "The sustainable use of biological resources and their conservation; and
- The scientific and socio-economic development of source countries and local communities"

Dr. Sittenfeld agreed with Dr. Shiva that there must be regulatory systems and appropriate frameworks in place to ensure the fair use of material. She identified a necessity to involve "governments, intermediary institutions, private enterprise, academia and local communities and entities" as essential to ensure equitable exploitation of resources. This contribution discussed the mechanisms by which the authorities in Costa Rica have attempted to work with international companies to 'harvest' their genetic resources. However, "it is still nearly impossible to control the illegal transfer of genetic material". "Authorised access permits" are tools to operate a regulatory regime, but do not guarantee good practice. The "real challenge for bioprospecting activities is to find ways to capture part of the financial revenues for the source country and to be able to transform those benefits into socioeconomic development and better living conditions".

The most telling point in Ana Sittenfeld's paper was that the "value of raw materials obtained from biodiversity is low, the transformation into products is a long and expensive process that requires tremendous contributions from science and technology." The economic impact of bioprospecting should not be over-estimated: modern bioprospecting can only complement other activities designed to improve standards of living and conservation of biodiversity". Joint ventures with companies were seen to be important if resources are to be exploited in a reasonable manner that allows a return to all that contribute.

Discussion

The discussion that followed the case studies was lively, primarily addressing the issues raised by the three speakers. The main issues raised included:

There is a conflict between the ethical systems of the 'North' that stress the rights and needs of individuals and the communitarian views put by Dr. Shiva which stressed the values of those in 'southern' less developed communities. Dr. Shiva, in answer to a number of questions, indicated that individuals in a community are ingenious when not being robbed, and will look after themselves and their communities. The ethical systems are difficult to reconcile. Transfer of the fruits of indigenous knowledge to those who actually provide the information is not happening in the view of many of the speakers; there must be something in place to ensure that patenting does not remove rights held through indigenous knowledge.

The relationship between the World Trade Organisation (WTO) and the protection of natural resources identified in the Convention on Biological Diversity (CBD) has to be clarified. In the view of many of the speakers, it was important that the CBD took precedence. Many spoke of the need for a new legal concept of sharing and solidarity

rather than the individual rights conferred by patenting. Dr. Shiva asserted that Biopiracy represented a concept of the ‘enclosure of the intellectual and biological commons’ — that which used to be shared has been changed as patents have been extended from the inanimate to the living world.

Conclusion

The main issue that arose in the debate was the cultural difference between North and South and the need to balance the rights of individuals to exploit property and the rights of communities to retain there traditional knowledge.

"PUBLIC PERCEPTION-MEDIA" SESSION
Dr Fabio TERRAGNI (Italy)

Introduction

Recombinant DNA technology raises public controversies and problems in public acceptance. In the 25 years of its history, the focus of the related public concerns shifted from the technique itself to the risks into the laboratory, from the deliberate release of genetically modified organisms into the open environment to the ethical implications of genetic diagnosis and therapy, from the rights and welfare of transgenic animals to the safety and ethical issues surrounding genetically manipulated food. Notwithstanding the change of the core of the public concerns, the social discomfort regarding genetic engineering and biotechnology is still alive and in some cases grew up to dangerous levels (close to terrorism and boycott). Public institutions should take their responsibility in managing the conflict and addressing the public fears, starting from a deeper understanding of which are the roots and the reasons of the social conflict on genetic engineering.

Eurobarometer - Prof. John Durant (UK)

The persistency of the social unease about biotechnology is confirmed by the several public opinion polls supported by the European Commission (*Eurobarometers on Biotechnology*). In the last Eurobarometer survey (1996) most of the previously observed trends have been confirmed, the first one regarding the fact that Europeans on average are less optimistic about the impact on their life of biotechnology and genetic engineering than about other strategically significant technologies. Moreover the term «genetic engineering» seems to be associated with a more negative perception than « biotechnology». Such superficial index of public evaluation of biotechnology varies considerably from country to country, with northern countries generally tending to be more critical than southern ones. Interestingly, the level of support is hardly directly proportionate to engagement and even to knowledge; even if the countries with higher levels of knowledge (possibly related to the degree of industrial development) show greater involvement in biotechnology, they are not the same with the higher support! Knowledge plays a modest part in determining attitudes towards science and technology, and in part reinforces pre-existing attitudes, giving the chance to express a more definite opinion. This seems to be confirmed by the observation that national public opinions of countries where a hotter public debate on genetic engineering occurs (generally more informed and with a higher degree of knowledge) show a stronger polarisation between supporters and critics. Anyway, the general level of knowledge remains considerably low and the «menacing» imagery seems to be associated also (but not only) to a low scientific education.

About the sources of information (and trust), previous results have been confirmed too: for most Europeans, the medical profession is the preferred source of reliable information about medical biotechnology whereas environmental and consumer organisations are the preferred sources of reliable information about agricultural and food biotechnology. This pattern shows that the European public discriminates between sources of information on the base of the specific issue involved.

Regarding general attitudes, a majority of Europeans doubt the sufficiency of current biotechnology regulations and believe that public consultation is desirable. A surprising result regards regulation: most Europeans would like to see biotechnology regulated by international organisations, such as the United Nations and the WHO; this may reflect

both a lack of trust in national institutions and/or a recognition of the international nature of the matter involved.

About specific applications, Europeans display widely differing attitudes towards different areas of application of biotechnology, with medical applications receiving more support, agricultural applications receiving intermediate levels of support and animals applications receiving least support. This pattern strongly suggest that the European public is not fairly described as «anti-biotechnology», but is more appropriately keen to judge specific applications on their individual merit. The reasons of the support or the rejection of a specific application has been explored, and it appears that perception of usefulness and moral acceptability are strong predictors of support, whereas perceptions of risks are only weak predictors. This seems to work in all the investigated countries and for all the considered applications and is a remarkable outcome, with important implications for policy making: indeed biotechnology regulations have generally been based mainly if not only on the scientific/technical evaluation of the risks, but this will hardly reassure people, more swayed by moral considerations. Of course, the regulation should not follow the public perception, but not considering at all which are the public concerns could weaken public institutions credibility. Indeed, the most striking result of this last Eurobarometer on Biotechnology probably regards the role of the perception of usefulness and moral acceptability of specific applications in triggering their social acceptance, and it seems to evoke the old debate on the so called *fourth hurdle*: a consideration of the moral and social balance as an additional criterion of evaluation of new product and technology.

A final remark can be added, about a possible comparison with the US and Canada. The European public opinion does not behave differently from the Americans on issues such as genetic testing, but is much more opposed to biotechnological food. Probably this is due to a menacing imagery present in the European Union (and ignited by recent food scandals such as those on the mad cow disease – BSE - and the dioxin chickens in Belgium), because there are no major differences regarding the level of knowledge.

The Swiss referendum on biotechnology - Prof. Dr R. Braun (CH)

Anyway the recognition of the considerable social diffusion of public concerns and fears should not bring to conclude neither that they must be taken as a ground for political decision nor that they are not modifiable. The recent experience of the Swiss referendum on biotechnology (GPI: *Gene Protection Initiative)* testifies the concrete existence and persistence of a critical public opinion but also the possibility to publicly support the reasons of scientific research in the field of genetic technology. The referendum demanded for three bans: no transgenic animals should be allowed; the release of genetically modified organisms should be banned; the patenting of transgenic plants should be forbidden. The promoters of the referendum, mainly environmental groups, based their requests primarily upon the hypothesis of considerable risks for the environment and the human beings; but before the public consultation they progressively shifted towards ethical objections. The opponents, mainly university and industrial researchers, entrepreneurs in biotechnology, doctors and farmers, organised demonstrations and public information initiatives focusing their arguments upon scientific evidences about risks, the socio-economic usefulness of biotechnology and its products (in particular reference to illnesses and sick people), the quality of university teaching and the fear to further isolate Switzerland. During the five months of a hot campaign most of the public opinion, initially supporting the GPI changed its mind and finally only a 33% of those who participated to the vote (41% of registered citizens) were in favour of GPI. This is the result also of a direct assumption of responsibility by the scientific community itself that accepted to take the worries of the public

seriously and to confront their views in a public arena, bringing back fears and concerns to their scientific and socio-economic reality.

The media and biotechnology: the case of cloning - Prof. D. Nelkin (USA)

Taking seriously the public concerns implies a structured effort directed not only to photograph the pattern of public reaction to genetic engineering and biotechnology but also to understand and to explain the possible reasons of this very specific phenomenon. An interesting insight can be offered by a detailed analysis of the behaviour and the role of the media, often cited as amplifiers of both the not rational fears and the excessive expectations of biotechnology. Dorothy Nelkin, Professor of Sociology at New York University, referred to the media coverage of Dolly, the cloned sheep and now a true international star (the recent birth of her three lambs appeared on newspapers of all the world).

As public perception, the media seems to be less influenced by the scientific details than by the robust images associated to genetic engineering; moreover they help to create the beliefs and assumptions underlying personal decisions, social policies and institutional practices. Nelkin affirms that, consequently, Dolly is not only a lamb but also a Rorschach test and a symbol: so the media response to its production, reflecting the futuristic fantasies and fears usually surrounding genetic research, can reveal a lot about the social implications of biotechnology. The enormous media coverage of Dolly shows a clear fascination with cloning, immediately transferred to human beings. The first reactions anyway were mainly anxious, reflecting more general concerns such as the so-called «genetic essentialism», a deterministic tendency to reduce personality and behaviour to genes. This concept may help to explain why geneticists and their works are sometime seen as a possible menace: acquiring the power to control the hereditary information they could determine the human future. And any mayor outbreak in genetics may be perceived as a further step in this direction. Such control can bring to cloning humans, «violating the sanctity of human life», giving birth to «sexless, soulless creatures», assuring immortality and allowing to dream the resurrection of the dead.

An overall evaluation really far from the one by the scientists and researchers active in the field or directly involved in the treated experiments. Their opinion, supporting the usefulness of cloning animals and even human cells, emerged and has been published, but the scientific-technical details have anyway been given a lesser importance than symbolic associations. Such links recalled social problems and tension, clearly independent from cloning and more generally from science, but anyway present and important in shaping social sensitivity. It is the case of the interpretation of cloning as a threat to the role of the male in reproduction. Or, jumping into the general fears about science and its progress, the concerns about the commodification of the body (a process changing the perception of our body) and the increasing socio-economic power of the biotechnology firms. Even if the extreme supporters of human cloning did it, it is difficult to dismiss these concerns simply as a product by anti-science or new Luddites movements. They are more widely diffused and seem to be triggered by the symbolical and evocative power of cloning and of Dolly as an icon for the exploration of identity, heredity, destiny and the social meaning of science. In this sense, Dolly can be judged as a spectacular beast capable to evoke for some euphoric fantasies and for others horrible nightmares. She offered both a business opportunity, based on the complete control over animal bodies, and the spectre of technical decisions that will turn bodies into intentional products: a step toward a definitive association of science to commercial interests.

Summarising, Dolly can be seen as a symbol of the struggle between technological changes and moral tenets. It is not fair to dismiss such media speculations about science simply as a product of public ignorance and media sensationalism. Media disseminate their narratives, contributing to shape the way people think to technology, but they take these images form society itself. «Far more than a biological entity, Dolly is a cultural icon», she conveys meanings that extend well beyond the single experiment and its practical implications: «she provides a window on popular beliefs about human nature and the social order, on public fears on science and its power in society, and on concerns about the human future in the biotechnology age».

Public perception: question of values - Prof. G. Hottois (B)

What we see as a simple sum of individual choices in reality is a composed phenomenon both at social (heterogeneity of modern societies) and at individual level (where we can find at work a variety of references). And there is an intrinsic ambiguity in the term: apparently describing a passive process, in reality it is a kind of active even if unconscious evaluation process, strictly dependent by the cultural frame of the individual and of society. Moreover we usually cannot handle the public perception but only its partial representations, through surveys and polls. This should bring us to be cautious in analysing and evaluating the public perception, focusing on its two main components: the factual one, based on the information over science and the technology involved, and the judgement based on the individual and social values. About the first component, we must remember the poverty of scientific information and the need for a proper education as a pre-requisite for a scientific culture; this last point being more important for a democratic approach to the social dimension of science and technology than the establishment of ethical committees trying to impose a common right and moral (national institutions should invest on wide education and training). About values, we should be still more cautious, because of the complexity and the confusion surrounding this concept. The strategy of the supporters of values *in* se, absolute and transcendent, is hardly acceptable, because it refuses to recognise the historic and cultural nature of values. All the values emerging from the analysis of the public perception of biotechnology should always be put in relationship with the more consistent bases of our democratic civilisation: the culture of human rights (including multiculturalism) and the role of research and techno scientific development.

Discussion and conclusions

It appears clearly that the evaluation and management of the very specific pattern of the public perception of biotechnology and genetic engineering is not a simple issue but a delicate task not to be left to the interested parties but to be handled by public institutions, both at national and at international level.

A particular feature of genetic manipulation, compared to other technologies, at least in Europe is its «bad reputation». It seems to be due to its real ethical implications and to its symbolic and cultural content, not always based on scientific and technical grounds. Moreover, the acceleration to scientific developments in the field of biotechnology brings to a condition where technical progress and capabilities are considerably faster than our adaptation capacity.

Some experiences demonstrated that political decision making about biotechnology can overcome the criticism and the opposition of part of the society, but cannot solve the social conflict, probably destined to persist and, if not properly treated, to burst out in relation to specific applications, products and processes. If a mature democracy implies the respect also of the view of the minority, how the human rights culture and the multicultural perspective can be preserved and coupled to the freedom of research?

The first thing could be to guarantee information: scientific and technical information (and the capability to use them, i.e. education and training), but also transparency and openness about processes and products than can be reputed objectionable for any reason. This can be considered a target also for National and European Parliaments and their *technology assessment* offices, that should also try to set the agenda of discussion and decision making about biotechnology over a rigorous work trying to avoid the bottlenecks and the urgencies due to the media coverage. A better-informed public debate is a common aim, even if it does not grant *per sè* a higher social acceptance of biotechnology. This aim should lead the actions and the policies of national and international institutions: a deep respect for public opinion means listen to, answer to, provide the public with the needed information and techno-scientific frame for evaluation, trying to avoid a paternalistic professional debate on bioethics (a public trust towards institutions and the scientific community must be recovered, because it happens that scientists are perceived as a lobby) and supporting a bottom-up approach to what can be considered as ethically relevant.

GENERAL REPORT
Prof. Enric BANDA (Spain)
European Science Foundation

Thank you Mr Chairman, ladies and gentlemen. I should start by thanking the Council of Europe and the Chairman of the Conference for the invitation to act as General Rapporteur and that this gives the European Science Foundation the opportunity to combine forces with the Council of Europe. At a time when for a growing number of topics affecting science and society no organisation can claim exclusive ownership, I believe that such collaborations and partnerships are extremely important. Therefore, thank you on behalf of the European Science Foundation. Of course, I also have to thank my compatriots the hosts of this meeting - the city of Oviedo and the Principado de Asturias.

I should also state at the outset that in writing my report, I have been enthusiastically assisted by the Rapporteurs of the different sessions. Without them, I could not possibly have reported. However, of course I assume full responsibility for any omissions or distortions in what I am about to say. Necessarily, my report will be rather short but I will try and cover some of the main issues raised during the Conference before coming to some conclusions and recommendations.

Now, let me remind you of what the objectives of the Conference were.

- To identify ethical issues in relation to biotechnology from a multidisciplinary and multicultural perspective, with due consideration to their social implications.

- To promote open public discussion on ethical issues in relation to biotechnology.

- To identify appropriate ways to deal with ethical issues in biotechnology, and, to provide elements for a decision as to whether there is a need for action, such as a harmonised approach at international level, which could result in a possible new convention or other appropriate instruments.

From the outset, speakers and participants have highlighted the complexity of the matter. However, complexity should not prevent issues being addressed that are important for the future, as each generation should pass on to the next generation a world at least as good as the one they inherited. As outlined by Professor Mattei in his opening speech, we face a collective task of defining the rules that will allow us to live together.

Many crosscutting ethical issues have been raised by the various speakers and participants. What follows is a non-exhaustive summary of the meeting's wide-ranging debate.

Ethics, even if the word is in the title of the Conference, have been referred to in a number of different ways reflecting that ethical perceptions differ from individual to individual, country to country and over time. We actually witnessed in one session two perceptions, two different attitudes which come from different conceptions of ownership. I mean community ownership versus individual ownership. This has been enlightening but it is only an example of how we hold different perceptions.

Playing God has been an expression used by many in terms of modifying nature beyond the sphere of traditional human activity. However, the expression might also be taken as indicating that we care for and act creatively in nature.

Unnaturalness has been referred to as the incorporation of foreign genes, i.e. crossing species boundaries or modification of the essential nature of organisms. Participants felt that this was generally acceptable as far as plants are concerned and reasonably acceptable for animals. A diversity of opinions was expressed, however, in relation to humans, though there are fewer ethical objections to the modification of somatic cells and tissues rather than germ cells where the changes could be propagated through generations. The accelerated pace of technological change adds considerably to the ethical hesitations in this whole area, since the public needs time to adjust to new ideas.

The *precautionary principle* has been a recurrent subject for debate. Although the definition was well established (at Rio) the application in practice remains controversial and is used in a variety of ways.

Human health has been discussed in relation to a number of issues. Xenotransplantation, with all its associated problems raises ethical issues due to the severe risk not only for the recipient but more especially for society. Would a world-wide moratorium be appropriate? If so, should research be allowed? A de facto moratorium has already been introduced by the European Parliament, and in the USA the NIH has prohibited within its programmes the transplantation of chimpanzee organs into humans. Future activities with regard to xenotransplantation should include studies and public debate related to the problem of human identity. Stem cells present the problem of using sensitive human material as a research tool. Should priority be given to the use of somatic cells where possible? From what embryo sources is it legitimate to take these cells - for instance, embryos created for that purpose and/or embryos discarded from in vitro fertilisation? Vaccines from plants do not seem to pose new ethical issues although a number of technical problems remain unsolved.

Safety has been discussed mainly in terms of dealing with uncertainty and acceptability. Risk benefit analysis should include the evaluation of the consequences of not applying biotechnology. Safe versus not safe is not the issue but rather the key question is, is it safe enough? In this sense further R&D in this field is necessary.

Monitoring of biotechnological developments and activities has also been discussed with delegates recognising that risk assessment in this area cannot be an exact science because of the large number of variables involved and the lack of scientific information about much of the interaction of living species with one another within a particular environment. Any use of a modified organism should be monitored so as to be able to report on any predicted effects that do not occur and on any unexpected events that do occur. It was recognised that the probability of many unexpected events is very low, and that monitoring for an effect that is unknown and extremely rare is extremely difficult. Monitoring should be independent, and not carried out by those that perform the risk assessment. The monitoring system should be validated so as to ensure consistent standards.

The debate about *animal welfare* has concluded that there is a considerable variation across Europe due to the fact that there exist fundamentally different approaches to animals in the different European States. Ethical issues cannot be reduced simply to issues of animal health or welfare but must include consideration of whether the research aim is sufficiently substantial to justify the use of animals. Animal integrity is a further ethical consideration. Modification of the genetic make-up needs good arguments and the search for alternatives should be pursued. The principle of reduce, refine and replace should be fully applied. There was considerable scepticism whether the use of animals could be justified in the testing of cosmetics. Also, the case of monoclonal antibodies showed how *in vitro* production using biotechnology is now practically as reliable as *in vivo*. The current lack of harmonisation threw up the prospect of scientific tourism by which researchers might seek to by-pass restrictive regulation, and this was a matter that needs further discussion.

The *environment* has been recognised to be endangered by most human activities, biotechnology being no exception. The conservation of biodiversity was considered to be an important ethical priority and an essential part of the promotion of sustainable development. It was argued that public institutions should pay attention to those aspects of public protection with which the market would not spontaneously concern itself.

Industrial activities have been debated leading to a general view that an improved dialogue involving the various stakeholders, notably society, is essential if the prevailing atmosphere of public mistrust is to be dispelled. The moral agenda of companies, the conference believed, should be generalised and made public. It was felt that companies, or their activities, were not trusted by the public which should be of concern to companies. Full impact assessment of companies' activities should be required. Partnership between industry and the academic world, the public and private sectors, is fundamental and would be beneficial to all.

Intellectual property rights have been discussed by the participants who recognised the need for social benefit from a product as well as the private right to profit from an investment. The patenting of living organisms remains a controversial issue and the ethics of it have still to be properly addressed.

Food aspects of biotechnology have also been debated by the participants who highlighted the cultural aspects that lead to different attitudes and perceptions. Biotechnology could not be seen as the panacea for all problems of food supply, which has to be placed in a broader context of sustainable food supply.

The mapping of the *human genome* has been seen as introducing a danger of unfair discrimination with the emergence of the definition of genetic identity. Genetic testing and screening raises problems with privacy, which should be guaranteed. This affects not only the individual concerned but also family members.

Conclusions and recommendations

- Most ethical issues raised apply to many areas of biotechnology. Some of these are specific to biotechnology, others are of broad application, but interestingly enough, have been highlighted and reinforced by biotechnology.

- The ethical issues need to be addressed at three different levels: individual, society and environment.

- Biotechnology has created a public nervousness if not social alarm. Therefore there is a need for international (European and world wide) action and agreement to deal with the following items among others:

1. It is urgent to establish a solid basis for overall impact evaluation including a risk/benefit analysis and an evaluation of the impact of not using biotechnological applications. This calls for the promotion of intensive interdisciplinary R&D.

2. Monitoring has to be carried out in a transparent and independent way and comply with internationally accepted standards. The role of the Council of Europe may be to assist in the process of acceptance.

3. Aware of the high speed at which developments in the field of biotechnology proceed it is urgent to promote dialogue among the key actors (producers, consumers and society at large) as a way to help keep in step technological development and public opinion. Future generations can be considered as absent stakeholders. Perhaps the Council of Europe could take the initiative of developing the concept of an "ombudsman" to represent the interests of future generations.

4. There is also an urgency to determine as precisely as possible how to apply the precautionary approach in practice. International understanding is needed in this respect. The Council of Europe is urged to act in this direction.

5. The right of the consumer to be informed and to choose is recognised. It is therefore urged that public information and public debate be promoted by public and private sectors as a way to secure that society and technological developments do not drift apart. Communication between science and society should be enhanced so that society understands the goals of biotechnology but also for the scientist to understand the concerns of society.

CLOSING SPEECH
Prof. Jean-François MATTEI
(Parliamentary Assembly of the Council of Europe)

I should like to add my own thanks to those just addressed to you, Chairman, for organising this meeting, to the whole organising committee and to everyone who took the trouble to attend and to express their views.

Now that I have the floor, I have two problems: the first is that it is now late, and a lot has already been said. It would be difficult to continue the debate for much longer. The second, as was made clear in a slide shown to us this morning, is that I must decide whether to address you in my capacity as a doctor, or as a politician. I fear for my credibility if I speak as a politician, and perhaps my words will be listened to if I speak as a doctor. Yet it is as a politician, representing the Parliamentary Assembly, that I am here, speaking on behalf of all the Members of the Assembly who have participated in this work, especially Mr Plattner, whose Assembly role in the sphere of ethics is an important one.

In practice, it is the politician who has to speak. There are ultimately three attitudes which could be adopted in the face of the problems which have been described to us.

The first is to do nothing, allowing market pressure alone to achieve a kind of balance between supply and demand. In my view, this would be a cowardly and hypocritical position to take. Cowardly, because doing nothing means letting people do what they want; hypocritical, because unless society lays down rules, the strongest will prevail.

The second is to decide to call a halt to research in a given field. I can understand some individuals taking this line, obeying their own conscience, but I am not sure that this squares with humankind's design. The human race has a constant need to know more about what it is, where it came from and where it is going, and it is impossible to imagine a life in which it is forbidden to try to find out the whys and the wherefores. On reflection, it is not knowledge which is dangerous, but the use to which it can be put. So deciding to stop research is not the right solution.

The third, in contrast, is to attempt to lay down rules, which we must do. This is where politics really has a role to play, although political action is very often criticised, or even denigrated.

So what is politics? A probable definition, expressed in very simple terms, is that it is what organises relations between human beings and society. Before determining the political action to take, however, we have to answer two questions: which human beings and which society? We have seen over these three days that we agree about human values, human dignity and the meaning humans strive to find for their life. It is very important to try to organise society, for a society has a value only insofar as human beings attach a value to themselves - and when I refer to society, I mean the word in its broadest sense, in not just societal, but also environmental, terms.

This debate between human beings and society is ethics, deliberation, argumentation and, finally, political decision. This decision involves at least three kinds of significant difficulty.

Firstly, a system based on morality needs to be avoided, but at the same time moral values need to be brought back into public debate, and the difficulty of striking a balance is clear.

Also, it needs to be clearly understood that what is moral is not necessarily lawful, and what is lawful is not necessarily moral.

Lastly, of course, an attempt needs to be made to strike the best possible balance between respect for each individual and the requirements of the community.

This all takes time, and politicians in our national parliaments do not always have the necessary freedom. This is why the Parliamentary Assembly and the Council of Europe seem to be the ideal places for giving thought to issues of this kind and for taking this kind of action, for the pace is less frantic here. Questions can be tackled in a very different way from that adopted in our national parliaments, where splits and party rivalries play a much greater role and sometimes make our debates less sincere.

I shall conclude by saying that I have, in this meeting room, felt that we all have something in common, going beyond our differences: all of us are convinced that there is something greater within all human beings, outside their control, beyond their grasp, transcending them, something which believers call the soul, but to which non-believers refer as the spirit, intelligence or reason. Whatever we call it, this dimension beyond the human grasp has a mystical value, and we must take as our common reference point this mystical aspect of the human being, which justifies our search for common solutions. This certainly falls within the tradition of the Council of Europe, which upholds human rights, helps to safeguard freedoms - especially freedom of choice - and defends democratic societies, more than in that of the European Union, initially an exclusively economic organisation, and, although it is expanding its remit, still insufficiently concerned about rights, especially in the health and social spheres. What is more, fifteen countries are not representative of the whole continent, and the voices of 41 carry much more weight and are stronger and more consistent than those of 15 countries. I therefore pledge to do all that I can to fulfil my wish for the Parliamentary Assembly to embark on detailed discussions in an attempt to persuade all the states to consider these difficult issues on which our human future depends.

CLOSING SPEECH
Dr Elaine GADD
(Vice-Chair of the CDBI)

As you have said, this conference had its origins in the Recommendation of the Parliamentary Assembly, and the CDBI was very honoured to be asked by the Committee of Ministers to undertake the organisation of this conference. In turn, on behalf of CDBI I must thank Mr Quintana and the organising Committee for all the hard work in putting together such an excellent and thought provoking range of speakers. We must also thank the Secretariat of the Council of Europe, in particular Madame Laurence Lwoff for her very hard work in bringing this to a successful conclusion. And not only on behalf of CDBI but I am sure on behalf of you all, I must thank the authorities of Oviedo, of Asturias and of Spain for the excellent hospitality they have afforded us this week. Oviedo has a very special significance to us as members of the CDBI as it was the place in which, as you have heard, our Convention on Human Rights and Biomedicine was opened for signature some two years ago

It is clear from the discussions we have had today that the CDBI's work on bioethics and human rights is far from over and there are many important issues that we may need to consider in the future.

In Professor Mattei's opening speech, he highlighted the issue that biotechnology may raise not only for human rights but also in the other areas which our speakers have so ably illustrated in the case studies of this conference.

We have also heard of the amount of work the Council of Europe has been doing in these areas, for example on the protection of animals and on the environment. As well as the public debate that we have had, I think we also need to publicise the work that has already been done and promote it to ensure reaching a wide audience. It is also clear that those of us who come from the different groups, from the Bioethics Committee and the environment and animal protection groups, need to work together to produce a response that is coherent to the challenges of biotechnology.

In the Convention on human rights and biomedicine, we highlighted the importance of public debate and this conference has been an illustration of how to take that forward. I am very grateful for the lively contributions from many members of the audience that we have had and sorry that we have not had time to hear from more people and at greater length. But even if we were here ten times as long, I think we would still only be beginning to explore the ramifications of the issues that we have raised.

It is clear that further work in these areas is needed, but I think although our rapporteur has put together an excellent conclusion from this conference, it's perhaps not a consensus on exactly what the Council of Europe should be doing in these fields and it is a matter on which all of us need to reflect very carefully.

We have also heard of the role of the other bodies; the EU, the FAO, the World Trade Organisation, to merely illustrate the bodies that could be involved, and we need to ensure that we work with those bodies in a manner which is complementary; we

need not to duplicate work but to ensure that the ethical issues are addressed, that they are addressed in an effective manner and also in an efficient manner.

As the Parliamentary Assembly recognised in their opinion so long ago, this conference is only at the start of a process of taking this work forward. I think it has been an excellent basis from which we can build, and the Council of Europe as an organisation which covers the whole of Europe from East to West is clearly going to play an important role in addressing the issues raised by biotechnology.

I am sure that I can speak for my colleagues in CDBI in saying that we look forward to play our role in that process.

Thank you.

Appendix I

RECOMMENDATION 1213 (1993) [1]
of the Parliamentary Assembly of the Council of Europe
on developments in biotechnology and the consequences for agriculture

1. Biotechnology which in a sense has a history as long as bread making and brewing can be defined as the use of biological organisms, systems and processes in industrial, manufacturing and service activities. The elucidation of the nature and functioning of the nucleic acids (DNA and RNA) in the 1950s has paved the way for the manipulation of the building blocks of living organisms so that cells or molecules can be altered. The gene pool available for "crossing" has been widened far beyond the limits of sexual compatibility.

2. Biotechnology's application in the agricultural sector (including forestry and fisheries) has resulted in the production of new animals which could not have been bred with traditional methods and the creation of new pest resistant and other genetically modified plants. The use of tissue culture has permitted the rapid regeneration of cells into identical full sized plants and animals (clones). Some of the new animals and plants have already been patented.

3. Biotechnology can be used to promote contrasting aims:

i. to raise agricultural outputs or reduce inputs;

ii. to make luxury products or basic necessities;

iii. to replace chemical herbicides and insecticides or target them more efficiently;

iv. to upgrade pedigree flocks and herds or expand indigenous stock in developed countries;

v. to upgrade plants for industrial use;

vi. to convert grain into biodegradable plastics or into methanol for fuel;

vii. to hasten maturity in livestock or prevent sexual maturation in locusts or in farmed salmon;

viii. to produce more nutritious and better flavoured foods or diagnose tests for bacterial contamination;

ix. to engineer crops for fertile temperature zones or for semi-arid regions;

x. to fight viral epizootic or build up populations of endangered species;

xi. to reduce production of "greenhouse gases" or utilise them in food production;

xii. to clone meat animals for particular markets or form embryo banks to maintain genetic diversity.

4. The Assembly is convinced that biotechnology offers the agricultural sector (including forestry and fisheries) important new development perspectives for plant and animal breeding, for the production of food as well as non-food products (energy, pharmaceuticals, medicine).

5. Biotechnology can also be misused, for example for the production of new diseases or for the creation of animals or plants which could have unwanted negative effects on specific ecosystems. The altering of genes and cells and the manipulation of life processes of animals can also result in unnecessary suffering and thus violate animal welfare regulations.

6. The Assembly is of the opinion that the manipulation of genes and life processes must be subjected to a careful monitoring by the application of appropriate policies in order to detect inherent risks, avoid harmful aspects and promote promising developments.

7. The Assembly recalls the responsibility of developed countries towards the developing countries and, in this context, supports the respective engagements stipulated in the Biological Diversity Convention adopted at the United Nations Conference on Environment and Development in Rio de Janeiro.

8. It has taken note with satisfaction of Recommendation No. R (92) 9 of the Committee of Ministers to member states on the potential ecological impact of the contained use and deliberate release of genetically modified organisms and of the decision to organise a pan-European conference on this theme from 24 to 26 November 1993 in Strasbourg, which will bring together top-level ecologists and scientists.

9. The Assembly, recalling its Recommendation 870 (1986) on the biogenetic revolution in agriculture - a blessing or a curse, recommends that the Committee of Ministers:

i. extend its work on bioethics (that is the systematic study of human conduct towards life, examined in the light of ethical values and principles) to include issues related to the production, release, use and trade of new or modified living organisms, animals and plants or food and non-food products, and work for a European harmonisation of legislation in this field;

ii. invite the European Community and the European Patent Office to take part in this work;

iii. initiate the work by convening a European conference with representatives of all relevant professions and interest groups concerned to examine the scope and main content of European concerted action and use the experience already gained in the Council of Europe's work on bioethics;

iv. organise, on the basis of the pan-European conference mentioned above, a second European meeting bringing together the representatives of the world of science and ecology as well as the representatives of all the professions and interest groups involved;

v. promote the setting up of national committees to analyse bioethical aspects regarding the use of biotechnology in the agricultural field, in particular with regard to field research. Such bodies could also give advice on the monitoring of new developments, on necessary policy reforms, on measures to be taken to preserve biodiversity and could be the national bodies of a European network co-operation;

vi. draw up a European convention covering bioethical aspects of biotechnology applied to the agricultural and food sector.

10. Furthermore, the Assembly asks the Committee of Ministers to call on governments of member states and the Commission of the European Communities:

i. to increase and co-ordinate European research and development in the field of biotechnology, giving priority to research of existing natural biodiversity and the sustained development and exploitation of these resources;

ii. to deploy all necessary efforts towards ratifying the Biological Diversity Convention concluded in Rio de Janeiro at the occasion of the United Nations Conference on Environment and Development;

iii. to give special emphasis to biochemical engineering and its potential applications for the pharmaceutical industry in general and for the production of new vaccines and disease-resistant plants in particular;

iv. to encourage the creation of new enterprises to exploit inventions in biotechnology and adopt a regulatory framework for their operation;

v. to pay special attention to the need for better and more information to the public through the organisation of information activities and exhibitions and through appropriate labelling;

vi. to strengthen training programmes on biotechnologies and their applications in the field of agriculture, forestry, fisheries as well as food and non-food production and processing;

vii. to accept the concept of "farmers' rights" as resulting from the United Nations Food and Agriculture Organisation's (FAO) resolution, adopted in November 1989, as well as to encourage the implementation of the project on an "International Code of Conduct for Planned Biotechnology" drawn up by the FAO;

viii. to take action to protect biodiversity and ecosystems from all possible negative influences that biotechnological inventions might cause and to use biotechnology in preserving biodiversity;

ix. to adopt a cautious policy with regard to the granting of patents for biotechnological inventions and applications so as to take due account of ethical considerations and environmental safety concerns;

x. to implement technology assessments for biotechnology inventions as a precondition for further research and development and to work for the setting up of an international biotechnology assessment office;

xi. to encourage the inclusion of bioethics in the training of specialists in the field of biotechnology and favour the development of professional ethical norms for work regarding biotechnologies and their applications - including the setting up of professional bodies at institutional, national, European and international levels;

xii. to associate the non-governmental organisations concerned with these activities.

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1. Assembly debate on 12 May 1993 (34th sitting) (see Doc. 6780, report of the Committee on Agriculture, Rapporteur: Mr Gonzalez Laxe).
Text adopted by the Assembly on 13 May 1993 (36th Sitting).

Appendix II

LIST OF PARTICIPANTS

CHAIRS, RAPPORTEURS, SPEAKERS TO THE CONFERENCE

Chairman of the Conference
Dr. Octavi QUINTANA-TRIAS, Institut National de la Santé, Alcala 56, E - 28071 MADRID, Spain

Opening of the Conference
- Mr Sergio MARQUES, President of the "Principado de Asturias"
- Ilmo. Sr. d. Gabino DE LORENZO FERRERA, Mayor of the City of Oviedo
- Mr Fernando FERNANDEZ NOVAL, Delegate of the Spanish Government
- Mr Hans Christian KRÜGER, Deputy Secretary General of the Council of Europe
- Mr Walter SCHWIMMER, Vice-President of the Parliamentary Assembly of the Council of Europe

General introduction
Prof. Jean-François MATTEI, Deputé des Bouches du Rhône, Membre de l'Assemblée Parlementaire du Conseil de l'Europe, Hôtel de Ville, F - 13233 MARSEILLE Cédex 01, France

ENVIRONMENT SESSION

Chairman
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Rapporteur
Dr. Piet VAN DER MEER, Ministry of Housing, Special Planning and the Environment, PO Box 30945, NL - 2500 THE HAGUE, The Netherlands

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Prof. José ESQUINAS ALCAZAR, F A O, Viale delle Terme di Caracalla, I - 00100 ROME, Italy

Revd Dr Michael J. REISS, Reader in Education and Bioethics, Homerton College, Hills Road, UK - CB2 2PH CAMBRIDGE, United Kingdom

FOOD SESSION

Chairperson
Mrs Blanca FERNANDEZ-CAPEL BANOS, Calle Pedro Antonio de Alarcon 89, E - 18003 GRANADA, Spain

Rapporteur
Dr George ZERVAKIS, Dr, Head at the Institute of Kalamata, National Agricultural Research Foundation (NAGREF), Research Center of Kalamata, Lakonikis 85, GR - 24100 KALAMATA, Greece

Speakers
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Dr Roger STRAUGHAN, Dr, Reader in Education, University of Reading, Department of Humanities, Bulmershe Court, GB - RG6 1HY READING, United Kingdom

Dr Dietmar MIETH, Professor, Social Ethics, University of Tübingen, Center for Ethics, Replerstr. 17, D – 72074 TÜBINGEN, Germany

HUMAN HEALTH SESSION

Chairman
Dr Marcelo PALACIOS, Chairman of the International Society of Bioethics (SIBI), Honorary Member of the Parliamentary Assembly, Sociedad International de Bioética, C/Maternidad 2, Atico, E - 33207 GIJON (Asturias), Spain

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Speakers
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Dr Margarita SALAS, Centre de Biologie moléculaire "Severo Ochoa", Universidad Autonoma, E - 28049 MADRID, Spain

ANIMAL WELFARE SESSION

Chairman
Mr Gianni TAMINO, (M.E.P.), Office 8G210, Rue Wiertz, B - 1047 BRUSSELS, Belgium

Rapporteur
Dr Paul DE GREEVE, Dr, Senior Veterinary Public Health Officer, Inspectorate for Health Protection, Commodities and Veterinary Public Health, General Inspectorate, P.O. Box 16.108, NL - 2500 BD THE HAGUE, The Netherlands

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Prof. Horst SPIELMANN, Direktor u. Professor, Head of ZEBET, Bundesinstitut für gesundheitlichen Verbraucherschutz und Veterinärmedizin (BgVV), Diedersdorferweg 1, D - 12277 BERLIN, Germany

RESEARCH SESSION

Chairman
Prof. Boris YOUDIN, Vice-Director of the Institute of Human Studies, Russian Academy of Sciences, Volkhonka 14, MOSCOW 109842, Russian Federation

Rapporteur
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