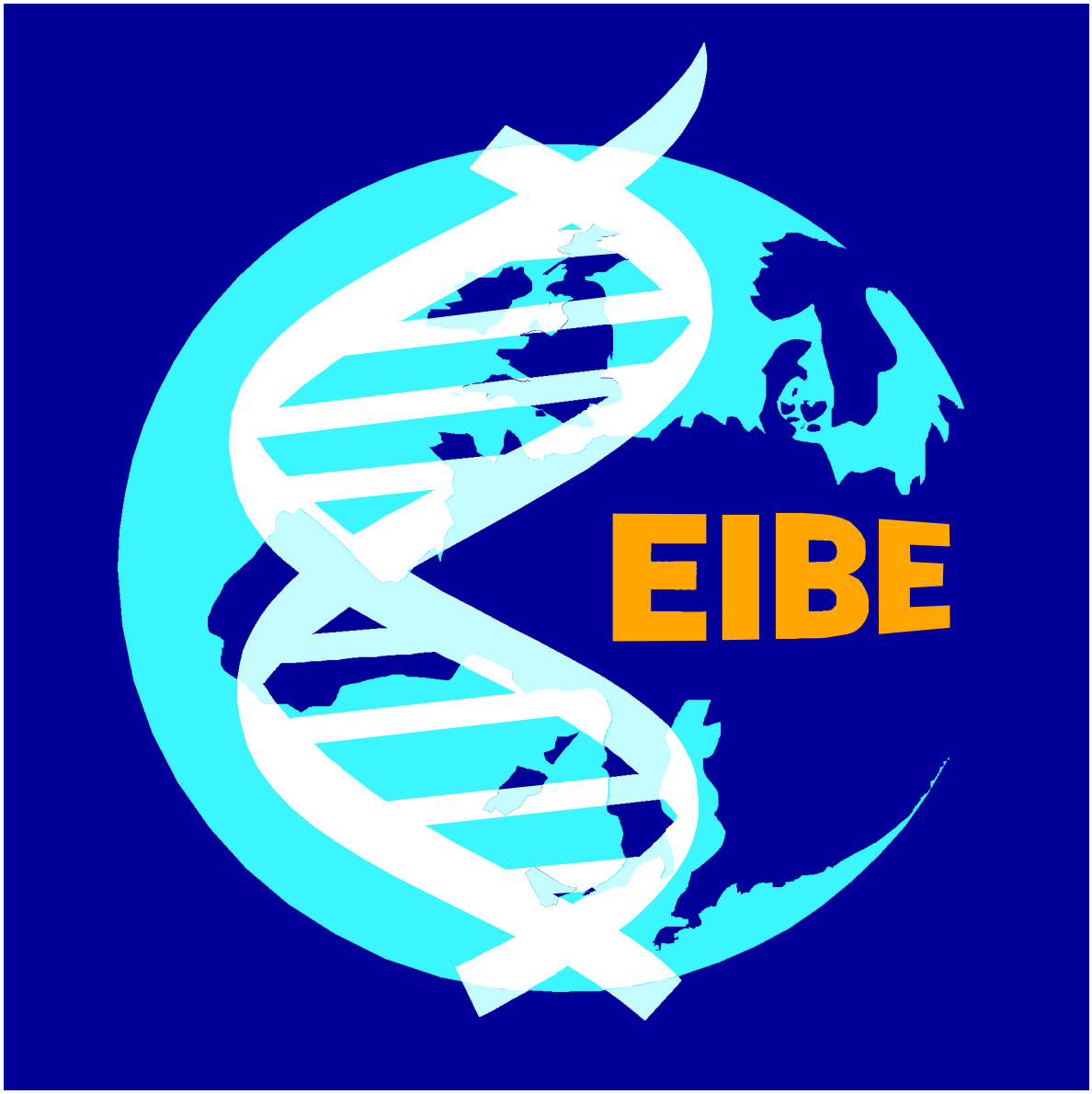

A Model European Council

A debate about preimplantation genetic diagnosis

Unit 12

European Initiative for Biotechnology Education

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A Model European Council

A debate about preimplantation genetic diagnosis

Unit 12

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Introduction

Advances in the biological sciences are occurring at a tremendous pace. The social, political and ethical issues generated by some of this work are hardly discussed before new techniques become common practice. This unit is about debating one of these issues. It is now possible to select an embryo that is not only free of certain genetic defects but that has characteristics parents might prefer. Where does one draw the line?

In this simulation of a meeting of the Council of Ministers of the European Union, students will be asked to put forward the points of view of the different countries. This is a role-play, it is important that participants represent the points of view of their governments not their own. We have supplied some background material to help ministers prepare for the meeting. It is highly recommended however that participants do as much research as possible of their own. This will motivate them to take an active part in discussions and will bring them up to date with recent developments. They should for example be able to answer the following questions:

1. Is genetic screening of foetuses allowed in your country? If yes, what use is made of it?

2. Is *in vitro* fertilisation (test tube babies) allowed and/or practised in your country?

3. What is the present state of the law on abortion?

4. Who decides on ethical issues arising from modern genetic diagnostic techniques? If there is a committee does it only have a consultative role or does it have any statutory powers?

The political background information shows that a general consensus is developing in Europe with regards to IVF and PGD. If teachers feel that the pan-European situation is not sufficiently varied to stimulate debate then they could work with their "ministers" to establish a more radical, more controversial stand for each country.

Proposed timetable for the running of the simulation.

1st session (45 minutes)

- Present the game and stress the fact that it is a role-play.
- Present the background material.
- Distribute the roles of the different Health ministers. If there are too many students then it possible to set up two groups or allocate a scientific advisor to each "minister" or set up a group of journalists, etc.
- Distribute the material necessary for each minister to prepare for the sitting of the council of ministers.

2nd session (90 minutes)

- The role-play proper. The meeting of the council of ministers that must end with the adoption of a final resolution.
- The final resolution must be very carefully worded, with every phrase carefully weighed, so that it could be used to judge real situations.
- This session should be a sufficiently long time after the 1st session for the students to be able to find and assimilate the necessary information.

3rd session (45 or 90 minutes)

- A look again at the philosophical questions brought out by the debate.
- These questions will obviously be the bio-ethical questions of the debate itself but could also be questions about the processes of judgement and decision making, or about the essence of democratic debate, or law and legislation, etc.
- One period could be used to collect and classify the questions and the second to try to clarify the most important.
- This session could take place in one 90-minute block or two separate periods with the first animated by the teacher and the second by a visiting "expert".

Scientific background

★ ★ ★ ★ ★ ★ ★ ★ ★ ★ ★ ★ ★ ★

Infertility

Around 10% of all couples in the western world are medically classified as being infertile. In some European countries couples are officially classified as being infertile if, after one year of trying, they fail to conceive. We are not absolutely certain but some studies point to an increase in infertility over the last 50 years. The conclusion one draws depends very much on the factors one looks at. Several reasons have been suggested for this possible increase in infertility.

- The number of active sperm cells in semen is going down so there is a lowering of the quality of semen. Some people suggest that this is due to an increase in the levels of oestrogen compounds in the environment. A small Danish study has shown that farmers using organic farming methods have semen of a higher quality (greater sperm count) than the average Danish male.
- In females the single most important cause of infertility is due to the blocking of the oviducts (Fallopian tubes). It is known that *Chlamydia*, a sexually transmitted disease, is often the cause of this blockage.
- Another factor influencing fertility is the age of couples when they start a family. With more people in higher education it is becoming common to put off having children until studies have been completed. Often couples are in their mid-thirties before they try to have children and it is known fact that the ability to conceive diminishes with age.

Medically Assisted Procreation (MAP)

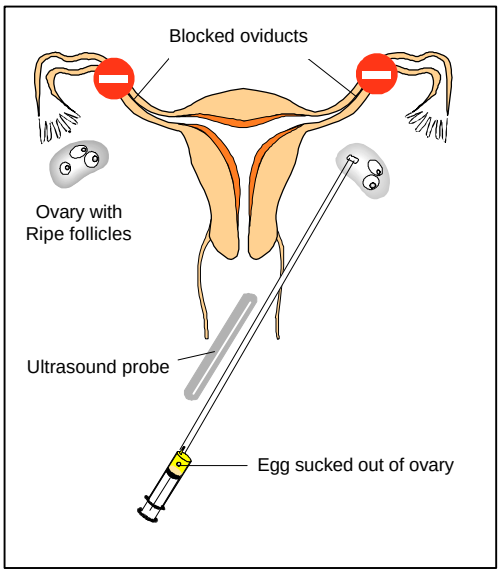
The term MAP covers any sort of medical assistance that helps a couple to conceive. There are three different ways that modern medicine can intervene:

- **Hormone treatment**
  In females around 4% of fertility problems are due to an imbalance in the hormones FSH and LH. Treatment with these hormones helps in 70 to 80% of cases. (A detailed account of the activity of these hormones can be found in any biology textbook dealing with the human reproductive process) There is a suspicion that this treatment could cause cancer so in some countries the number of attempts using this method is restricted to 3.

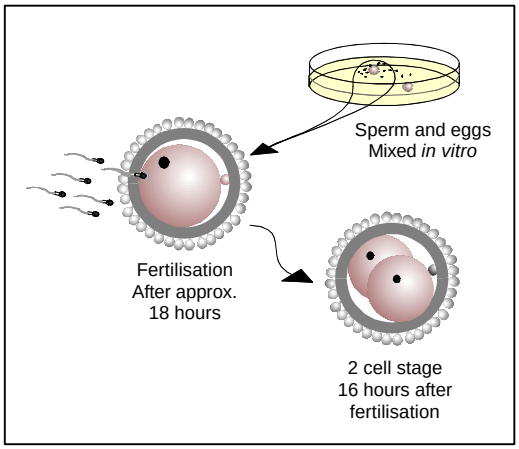
- **Artificial insemination.**
  Healthy semen contains 60 to 80 million sperm cells per cm^3 and each ejaculation releases about 4 cm^3 of semen (240 to 320 million sperm). A man is defined as being infertile if semen contains less than 5 million sperm per cm^3 or his sperm cells show less than 20% of normal movement. Artificial insemination (with donor sperm) is an option for couples where the male partner has such low quality semen. Semen collected by hospitals for donation is subjected to a strict quality control. Donors must not have any history of genetic disorders in their families and they must be fit and healthy. A couple choosing to use donor sperm are not allowed to know the origin of the sperm but they are allowed to match the physical characteristics of the donor to that of the male partner (eye colour, skin colour, racial type, etc.) The number of children any one donor can father is limited. For example the number of children is limited in the UK and USA to 10, in the Netherlands to between 25 and 32, in Sweden and Spain to 6 and in Denmark to 20. Recently the term artificial insemination has been widened to include the process of microinjection. In this procedure a man with a low sperm count can have one of his sperm cells injected *in vitro* directly into an egg of his partner. It is even possible to use immature sperm cells removed directly from the testes. In this latter case there is some doubt about the fitness of the immature sperm cells, as they have not passed through the natural selection procedure of development that weeds out weak and defective sperm.

- **IVF - *in vitro* fertilisation.**
  IVF was first developed to help women with blocked oviducts. The process starts with a treatment of FSH, often supported with

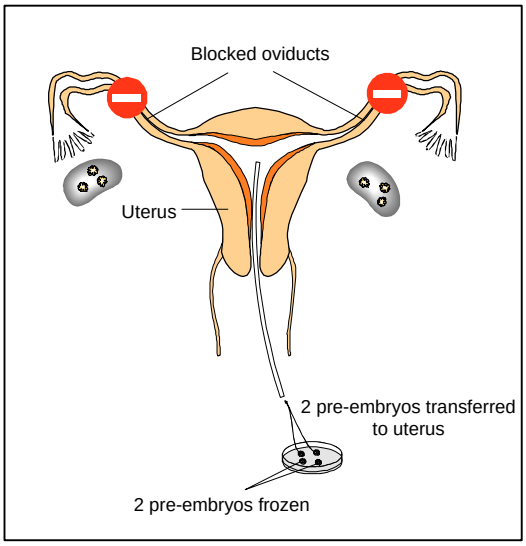
other hormone treatments, so that the woman will produce more than one egg at ovulation. Using ultrasound scanning these mature eggs are sucked out of the ovary.



These eggs are then mixed with sperm cells that have been selected to be active swimmers. Within 16-20 hours it is possible to see if the eggs have been fertilised as the nuclei are visible and the fertilised egg takes on a swollen appearance. The first cell division comes around 16 hours after fertilisation and successive divisions occur at approximately 16-hour intervals.



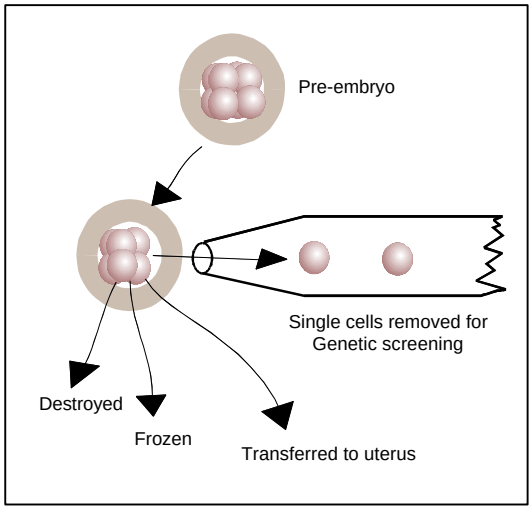
After 2-3 days the embryos will have developed to the 4-8-cell stage. Two of the developing embryos are then put into the woman's uterus and within 12 to 14 days tests will show if the treatment has been successful.



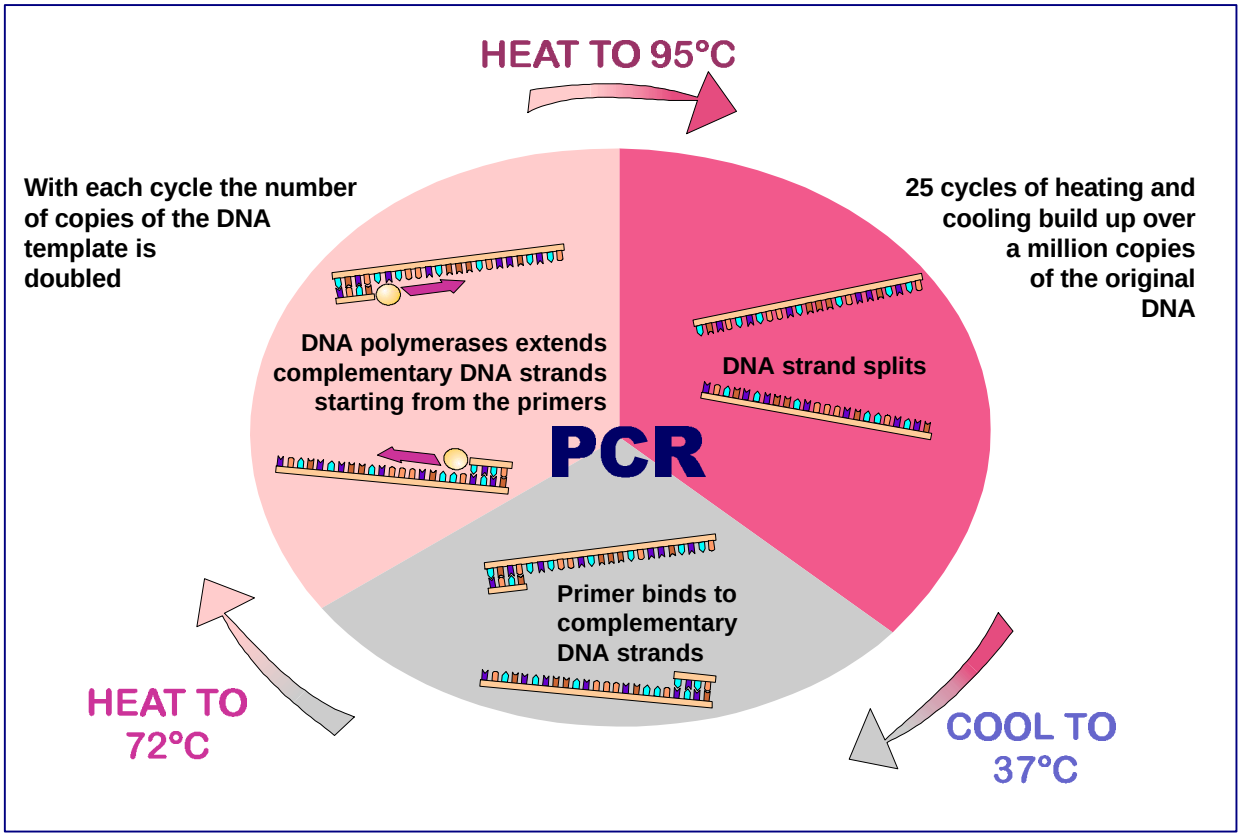
(Egg donation. It is possible for women going through this treatment to donate any unused eggs to women who are sterile)

Preimplantation genetic diagnosis (PGD)

This involves genetic screening of an embryo before it is transferred into the uterus of the mother. At the moment it is only possible to screen using the polymerase chain reaction (PCR) for single gene conditions.



In PGD two cells are removed from the embryo at the 8-cell stage and the DNA is used for PCR analysis.



In this process the DNA from the embryo cells is mixed with short pieces of DNA (primers) that match a small region of the DNA in the gene(s) to be screened. The process then amplifies the DNA of these genes. The small pieces of DNA can then be separated into bands using gel electrophoresis. The DNA fingerprint produced can be used to determine the nature of the gene. By testing for the presence of DNA found only on a Y chromosome this test can also be used to determine sex. One example of the use of this technique is found in the newspaper articles given later - a woman with a dominant gene for colon cancer had an embryo, selected so as not to contain the cancer gene, implanted in her uterus. Another possible use would be to select a female embryo when there is a risk of a male embryo having a gene for a sex-linked disease such as haemophilia. Today this is still a fairly costly procedure which gives rise to serious questions as it can be considered as “opening the way to eugenics” (See Unit 4 - Issues in Human Genetics for a discussion on eugenics). There is a risk that this technique could be used for selecting embryos on the basis of purely subjective criteria such as size, sex, hair colour or character.

Sex selection

Another method for choosing the sex of the embryo is expected in the near future. Research is being done to develop a procedure to separate X and Y carrying sperm. The question that has not yet been answered is, "Will the process be safe?" as the procedure involves marking the sperm with a dye and then running them through a "selector machine". Artificial insemination will then be possible with this selected sperm to determine sex.

Political background

The Council of the European Union

The Council Headquarters, Brussels

Members ministers of the 15 Member States

Presidency from 1 July 1995 rotates every six months in the following sequence: Spain, Italy, Ireland, the Netherlands, Luxembourg, the United Kingdom, Austria, Germany, Finland, Portugal, France, Sweden, Belgium, Spain, Denmark, Greece

The Council of the European Union, usually known as the Council of Ministers, has no equivalent anywhere in the world. Here, the Member States legislate for the Union, set its political objectives, co-ordinate their national policies and resolve differences between themselves and with other institutions.

It is a body with the characteristics of both a supranational and intergovernmental organisation, deciding some matters by qualified majority voting, and others by unanimity.

Its democratic credentials should not be in doubt. Each meeting of the Council brings together Member States' representatives, usually ministers, who are responsible to their national parliaments and public opinions. Nowadays, there are regular meetings of more than 25 different types of Council meeting: General Affairs (Foreign Affairs ministers), Economy and Finance, and Agriculture meet monthly, others such as Transport, Environment and Industry meet two to four times a year.

In 1994, the Council held around 100 formal ministerial sessions during which it adopted about 300 regulations, 50 directives and 160 decisions.

The presidency

The Presidency of the Council rotates between the Member States every six months: January until June, July until December. The Presidency's role has become increasingly important as the responsibilities of the Union have broadened and deepened. It must: arrange and preside over all meetings; elaborate acceptable compromises and find pragmatic solutions to problems submitted to the Council; seek to secure consistency and continuity in decision-taking.

Decision-making

The Treaty on European Union based the Union's activities on three 'pillars' and established that mainly decisions should be taken either by qualified majority voting or by unanimity.

Pillar One covers a wide range of Community policies (such as agriculture, transport, environment, energy, research and development) designed and implemented according to a well-proven decision-making process, which begins with a Commission proposal. Following a detailed examination by experts and at the political level, the Council can either adopt the Commission proposal, amend it or ignore it.

The Treaty on European Union increased the European Parliament's say through a co-decision procedure, which means that a wide range of legislation (such as internal market, consumer affairs, trans-European networks, education and health) is adopted both by the Parliament and the Council.

In the vast majority of cases (including agriculture, fisheries, internal market, environment and transport), the Council decides by a qualified majority vote with Member States carrying the following weightings:

Germany, France, Italy and the United Kingdom	10 votes
Spain	8 votes
Belgium, Greece, the Netherlands and Portugal	5 votes
Austria and Sweden	4 votes
Ireland, Denmark and Finland	3 votes
Luxembourg	2 votes
Total	**87 votes**

When a Commission proposal is involved, at least 62 votes must be cast in favour. In other cases, the qualified majority is also 62 votes, but these must be cast by at least 10 Member States. In practice, the Council tries to reach the widest possible

consensus before taking a decision so that, for example, only about 14% of the legislation adopted by the Council in 1994 was the subject of negative votes and abstentions.

Those policy areas in Pillar One which remain subject to unanimity include taxation, industry, culture, regional and social funds and the framework programme for research and technology development.

For the other two pillars created by the Treaty on European Union - Common Foreign and Security Policy (Pillar Two) and co-operation in the fields of Justice and Home Affairs (Pillar Three), the Council is the decision-maker as well as the promoter of initiatives. Unanimity is the rule in both pillars, except for the implementing of a joint action, which can be decided by qualified majority.

Co-operation in Justice and Home Affairs aims to achieve the free movement of persons inside the Union; promote measures of common interest in the fields of external border control, asylum policy, immigration policy; and fight against terrorism, drug trafficking and other serious forms of international crime.

European council

Since 1974, Heads of State or Government meet at least twice a year in the form of the European Council or 'European Summit'. Its membership also includes the President of the Commission. The President of the European Parliament is invited to make a presentation at the opening session.

The European Council has become an increasingly important element of the Union, setting priorities, giving political direction, providing impetus for its development and resolving contentious issues that have proved too difficult for the Council of Ministers.

The European Council submits a report to the European Parliament after each of its meetings and an annual written report on the progress achieved by the Union.

Legislation

Community law, adopted by the Council - or by the Parliament and Council in the framework of the co-decision procedure - may take the following forms:

regulations: these are directly applied without the need for national measures to implement them;

directives: bind Member States as to the objectives to be achieved while leaving the national authorities the power to choose the form and the means to be used;

decisions: these are binding in all their aspects upon those to whom they are addressed. A decision may be addressed to any or all Member States, to undertakings or to individuals;

recommendations and opinions: these are not binding.

Organisation

Each Member State has a national delegation in Brussels known as the Permanent Representation. These delegations are headed by Permanent Representatives, who are normally very senior diplomats and whose committee, called Coreper, prepares ministerial sessions. Coreper (from the French "Comité des représentants permanents")meets weekly and its main task is to ensure that only the most difficult and sensitive issues are dealt with at ministerial level.

Coreper is also the destination of reports from the many Council working groups of national experts. These groups make detailed examinations of Commission proposals and indicate, among other things, areas of agreement and disagreement.

The work of the Agriculture Council is prepared by senior Brussels-based representatives of Member States meeting weekly in the Special Committee on Agriculture.

The Secretariat-General provides the intellectual and practical infrastructure of the Council at all levels. It is an element of continuity in the Council proceedings and has the custody of Council acts and archives. Its Legal Service advises the Council and committees on legal matters. The Secretary-General is appointed by the Council acting unanimously.

Adapted from material on the European Commission web site at:: http://europa.eu.int

THE RESOLUTION

Debate material

The European Commission Proposal to be considered by the Health Ministers of the Model European Council

The European Commission:

- aware that medically assisted procreation (MAP) using *in vitro* fertilisation techniques is being used on an ever increasing scale, and that *in vitro* fertilisation procedures produce more embryos than are needed for medically assisted procreation.
- concerned that it is technologically possible to genetically engineer the human gametes used in MAP and that genetic engineering of the germ-line would change human hereditary characteristics of future generations.
- recognising that this procedure requires the fertilised eggs to develop, in vitro, to a multicellular stage where the removal of cells for genetic screening will cause no harm to the embryo
- having regard to the fact that genetic screening of this type (preimplantation genetic diagnosis - PGD) has already occurred in the selection of embryos free of life threatening hereditary diseases, is gravely concerned that this technique of PGD is open to the worst abuses of eugenics

The European Commission would like the European Council to consider the following resolution.

THE EUROPEAN COUNCIL OF MINISTERS

1. Accepts the present use of MAP in helping infertile parents to conceive.
2. Notes that MAP has been invaluable in alleviating the suffering of couples that have not been able to conceive in any other way.
3. Emphasises that MAP must not be extended for other purposes without careful consideration and stresses that limitations on its use must be clearly defined.
4. Stresses the need for the current prohibition on manipulating the genetic structure of a human embryo to remain and insists that there should be no manipulation of a human germ-line at any stage (including manipulation of gametes).
5. Feels that it is not ethically defensible to alter the human hereditary characteristics of future generations.
6. Calls upon member states to consider carefully the use of MAP techniques associated with Preimplantation genetic diagnosis (PGD) given that this technique is not used to overcome infertility but to select embryos that are free of genetic disorders.
7. Calls upon member states to recognise that because artificial selection of human beings is not ethically defensible, this technique must only be considered in exceptional cases to alleviate extreme suffering and death.
8. Calls upon member states to establish regulatory bodies whose function it is:-
   i) to define the limitations of the use of PGD
   ii) to grant or refuse permission for the use of PGD in any treatment

Debate material

The positions of the different governments

BELGIUM

At the present there is no official national ethics committee. In 1976, an ethics commission was created within the FNRS (Fonds National de la Recherche Scientifique). This commission was given two tasks

- To give opinions on the various questions of medical ethics
- To encourage and organise work groups for discussing matters of medical ethics

Belgium also has a considerable number of ethics committees that can be divided into two principal types

- Institutional committees (University or hospital ethics committees)
- Problem based committees (medical research protocols, procreative medicine, etc)

In 1983 the Committee of medical Ethics of the FNRS examined the ethical aspects related to *in vitro* fertilisation (IVF), including research on human embryos. Some of their most important guidelines were:

- Each research project involving human embryos must be examined separately and must clearly mention why relevant information cannot be obtained in an animal model.
- Research embryos cannot be replaced in humans except if the aim of the protocol was to enhance the chance of implantation in the uterus.
- Modifications of the human genome and cloning of embryos cannot be accepted as research projects.
- Research embryos cannot be cultured in vitro beyond day 14.

Medically assisted procreation (MAP) programmes exist in all Belgian University Hospitals and in some community hospitals. Some of these have clinical research protocols aimed at improving the success of these procedures. For example the Centre for Reproductive Medicine of the Vrije Universiteit Brussel (VUB) carries out research in:

- Freezing of fertilised oocytes.
- Assisted fertilisation procedures of the oocyte by microinjection of a spermatozoon in the perivitelline space.
- Preimplantation genetic diagnosis.
- Diagnosis of hereditary diseases by biopsy of embryos prior to implantation was successful in the mouse for certain diseases. If applicable to the human, this procedure could be used in conjunction with selective placement of unaffected embryos and could be an alternative to prenatal diagnosis by chorionic villi sampling or amniocentesis.

Each research protocol requires approval by the University and/or Hospital Ethical Committee. Before there can be research on supernumerary embryos the agreement of the concerned couple must be obtained.

DENMARK

Abortion is legal in Denmark, as is medically assisted procreation. Denmark allows preimplantation genetic diagnosis, under certain conditions. Firstly the germ line may not be altered. The technique can only be used if there is a known risk of the child inheriting a serious hereditary disease, thus obviously excludes hereditary disorders, like baldness. The fertilised eggs without the disease in question can then be implanted in the usual way. The unused embryos can be frozen for up to 5 years. This technique can only be used in sex selection if there is a risk of a serious sex-linked hereditary disease. Experiments, which involve clones, changing the germ line or allowing embryos to develop in the uteruses of other species are also forbidden.

The process of medically assisted procreation is also controlled, embryos must be destroyed after 14 days, and cannot be frozen for more than 5 years. If the couple separates, the embryos must also be destroyed. According to new legislation passed in May 1997 eggs must either come from the intended mother or from another woman enrolled in a fertility programme. In this latter case the identity of the donor must be kept

secret which may cause problems due to the possibility of inherited diseases.

In short, medically assisted procreation is legal, if it is helping a couple to have children. Preimplantation genetic diagnosis is also legal, as long as it is only used to help a couple have a child free of a disease that runs in their family.

FRANCE

The President of the Republic established the National Consultative Ethics Committee for Life Sciences and Health (CNESVS) in 1983. It is the task of this committee to comment on the ethical problems involved in biological, medical and health research which may arise for individuals, social groups or society as a whole. Since its establishment, the CNESVS has issued several statements and recommendations relating to research on human embryos. These may be summarised as follows:

- It is not possible to preclude any *in vitro* research on embryos but research projects must be submitted to the CNESVS for comment.
- No human embryo may be produced exclusively for research purposes.
- Embryos used for research should not be implanted.

The development of the embryo is a continuous process even though it is possible to recognise various developmental stages (3rd day: protein synthesis begins; 7th day: implantation in the endometrium; 14th day: formation of embryo structures). For this reason it is not possible to ascribe an ethical significance to any stage of development.

The research work in this field may be carried out only by approved centres which are not identical with centres for *in vitro* fertilisation.

Gene transfer in human embryos using viral vectors should be forbidden to avoid the risk to modify the genome of germ cells.

A total independence must exist and be clearly be seen to exist, between Medical teams involved in the terminations of pregnancies and the teams involved in the use of embryos and foetuses for research.

In 1986 the committee recommended a 3 year moratorium research activity aimed at genetic diagnosis before the transplantation of an embryo. The committee still recommends not undertaking preimplantaion genetic diagnosis. Nevertheless, it said its attitude could change in the light of new knowledge in the field. The CNESVS is a moral authority and its recommendations have an important influence on doctors and scientists.

A government advisory group came to similar conclusions in a November 1991 report with the added statement that the consent of donors should be obtained before supernumerary embryos are used for research.

In November 1992, a series of laws on ethical aspects of biomedical research and practice were submitted to Parliament. The laws were approved and sent to the Senat for ratification. A commission of the Senat is still considering them and they have not yet been discussed in plenary session. They are:

- No embryo should be conceived *in vitro* without a parental project.
- In case of embryo preservation, at the end of the legal limit for storing embryos both members of the couple must give their permission before these unused embryo can be used for scientific research.
- All research projects on human embryos should be submitted to the National Commission for Medicine and the Biology of Reproduction and Prenatal Diagnosis, and authorised according to conditions defined in a decree. Every year the Commission will publish the list of centres where research on embryos is carried out.
- The commercial and industrial use of embryos is forbidden.

GERMANY

The Embryo Protection Act of 13 December 1990 was designed to outlaw certain practices, such as surrogate motherhood, and to secure protection of the embryo against manipulation. In the act an embryo is defined as "a fertilised human egg capable of development, or any cells separated from the embryo that are capable of developing into an individual".

Certain activities in medically assisted procreation are prohibited in the Embryo Protection Act. Violations, or attempted violations, of these prohibitions are considered criminal offences. The non-respect of some prohibitions can incur a maximum penalty of 3 years imprisonment or a fine. These prohibitions are:

- Creation of human embryos specifically for research purposes.
- *In vitro* fertilisation of a greater number of egg cells than is necessary for a single course of medical treatment within one monthly cycle.
- The use of human embryos for any form of research. This includes research into techniques to preserve embryos if these embryos are not intended for re-implantation.
- The artificial penetration of an egg with a sperm cell except with the aim of bringing about the pregnancy of the woman from whom the egg cell has been taken.

The non-respect of the following prohibitions is punishable by 5 years imprisonment or a fine.

- Alteration to the genome of human germ-line cells, if these cells are to be used for fertilisation or if in any way these cells are to be transplanted in a human embryo, foetus, or human being.
- The cloning of embryos.
- The creation of chimeras.
- The creation of hybrids, combining animal and human gametes.

Guidelines of the Federal Chamber of Physicians "Concerning the Use of Foetal cells and Tissues (1991)" covers problems not dealt with in the Embryo Protection Act.

- Cells and tissues may be taken from live foetuses when the foetus or the mother derives immediate benefit. (e.g. pre-implantation genetic diagnosis)
- Cells and tissues may be taken from dead foetuses for experimental or therapeutic purposes but all such experimental or therapeutic research must be submitted first to an ethical committee for approval.
- If a woman is considering an abortion her decision must be her own and she may not be offered or given any privilege which might encourage her to undergo an abortion or give her consent to the use of the foetus.
- For the collection, storage and distribution of foetal tissue the guidelines propose the establishment of regional tissue-banks.

Ethical committees exist in all regional Chambers of Physicians and at the medical faculties of universities. The Code of Ethics of the German medical profession obliges doctors to seek advice from one of these ethical committees before doing research on live human gametes and live embryonic tissue.

GREECE

Law (N.1609) was voted by parliament in 1986 and became part of the penal code.

According to article 2 of the law, it is not unlawful to terminate a pregnancy, provided there is consent of the pregnant woman, the procedure is performed by an obstetrician with the participation of an anaesthetist in an organised hospital unit and, in addition, at least one of the following conditions applies:

- The embryo is less than 12 weeks old.
- There are indications, based on prenatal diagnosis, that the embryo to be born will suffer from a serious abnormality and the pregnancy has not passed the 24th week of gestation.
- The life of the pregnant woman is endangered or there is danger of serious damage to her physical or mental health. In this case a certificate by a medical specialist is required.
- The pregnancy is the result of rape or incest.

As far as artificial human procreation is concerned, there is no explicit legislation governing the newer reproductive techniques. However, law N. 2071 of 15/7/92 allows for the establishment and operation of units of artificial fertilisation by presidential decree. These units must operate in specifically organised public hospitals, private hospitals or private clinics. Artificial insemination (using husband or donor sperm) has been performed

for over 20 years in the private sector. *In vitro* fertilisation was introduced in 1984 and the first twin children were born in 1986. Ever since, *in vitro* fertilisation has been performed to a growing extent in the private sector, under no state control. The attitude of doctors and lay people towards artificial procreation is positive. The church has not taken an official position, but is positive towards tissue and organ transplantation.

IRELAND

Here is Ireland's point of view about genetic engineering and specially on MAP and PGD

As Ireland is a very conservative country it is very restrictive on all these techniques.

The facts are as follows:

- MAP is allowed in Ireland: however all fertilised eggs must be implanted, you are not allowed to discard or store embryos.
- Neither PGD nor abortion is allowed in the Republic.
- You are allowed to travel to other countries for abortions.

Ireland has a sophisticated support system for handicapped children and in particular for those self-help groups dealing with Down's Syndrome. Ireland is of course against artificial selection of human beings and manipulation of gametes

ITALY

In Italy there has not yet been any legislation with regards to bioethics and the control of modern genetic techniques for human beings.

A National Bioethics Committee was founded in March 1990 with the role of evaluating scientific developments in function of human freedom and dignity, and to formulate suggestions for adequate legislation. To date they have published guidelines on:

- Human seminal fluid collection and treatment for diagnostic purposes.
- Prenatal diagnosis.
- A human embryo's identity and statute.

In the latter of these the committee clearly defines what they believe to be ethically acceptable with regards to medically assisted procreation and preimplantation genetic diagnosis.

They were unanimous in condemning as ethically unacceptable:

- The production of human embryos for experimental, commercial or industrial purposes
- The multiple production of human beings - cloning from the embryo
- The creation of chimera
- The production of human-animal hybrids
- The use of animal as surrogate mothers for human foetuses

They were unanimous that the following were ethically acceptable:

- Therapeutic interventions on the foetus with the aim of safe guarding life and repairing problems
- Experiments on aborted foetuses

There was concern but no unanimous disapproval of:

- Unjustified suppression and manipulation of embryos
- Preimplantation genetic diagnosis with intent to discriminate and suppress specific embryos
- In-vitro fertilisation to produce embryos that are not intended for re-implantation

A part of the committee was in favour of:

- Medically assisted procreation (MAP)
- Preimplantation genetic diagnosis (PGD) to identify embryos that have grave malformations or genetic diseases
- The use for experimental purposes of embryos produced by IVF and shown by PGD to be unacceptable for implantation that have been abandoned by the parents
- The use for research purposes of embryos from IVF programmes that have not reached the stage of development when they could be implanted.

MAP techniques are allowed and practised, and in vitro fertilisation clinics do exist. Genetic screening is also allowed and used to diagnose

serious diseases so as to facilitate treatment.

Law 194 (May 22, 1978) on abortion allows the interruption of pregnancy within 90 days for certain reasons – health, economic and social conditions, serious disease. After 90 days abortion is only possible if there is a risk to the life of the mother.

LUXEMBOURG

In Luxembourg there are still no corresponding laws nor has any debate taken place, since here there is scarcely any research. The government is at present guided by French laws. When there is a ruling for the whole of the European Union, Luxembourg will put it into effect without delay.

In general, Catholic Luxembourg has major ethical reservations on this kind of problem. The Luxembourg government accepts MAP in principle, however, as long as it is only applied in order to help infertile couples. But even here there must be clear guidelines. Thus Luxembourg only wants to permit MAP in the case of couples consisting of a man and a woman who are both living, who are of fertile age, who are either married or have lived together for at least two years (to guarantee a certain stability in the relationship) and both of whom have been informed in detail about the risks of MAP and agree to it.

Luxembourg doesn't wish to permit MAP in the case of single women who have passed the stage of menopause, homosexual couples or "post-mortem" implantation.

It is strictly against any alteration of the gamete cell whatsoever, and also against any manipulation of the embryo after fertilisation.

The use of PGD must be very strictly regulated in order to prevent any form whatsoever of eugenics being practised. Luxembourg wants to allow the non-acceptance of an egg cell only when it is a case of preventing serious illness - and of course, these illnesses must be precisely defined. Under no circumstances can this lead to artificial selection. The use of PGD reminds Luxembourg strongly of Nazi practices.

To sum up, MAP without PGD is a very useful thing but with PGD so many risks are involved that the use of PGD must be very strictly regulated.

THE NETHERLANDS

In Holland abortion is legal up to 3 months of pregnancy. Local ethics committees however have to give their permission on a case by case basis.

In vitro fertilisation (IVF) is allowed and practised for couples that cannot conceive in any other way. Even injecting the sperm into the egg, as long as the sperm comes from a normal ejaculation, is permitted for *in vitro* fertilisation. There is a moratorium, however, on the use of immature spermatocytes extracted by aspiration from the testes.

Preimplantation genetic diagnosis was first used in 1997 to detect a single gene disorder. A government commission is studying the idea of general screening of embryos produced by IVF, especially when the eggs are taken from older women. The commission should publish its conclusions in the autumn of 1997.

The government is not in favour of any form of prenatal gender selection especially when discrimination against one sex or the other is involved. Even when sex related genetic diseases are concerned it is felt that the procedure is not sufficiently safe.

Medical research with human embryos may be carried out with embryos younger than 14 days.

PORTUGAL

Though most of the population is catholic not many are churchgoers.

In Portugal 98% of couples use contraception and abortions are permitted though the emphasis is on preventive medicine. The abortion law has recently been revised to extend the legal period for abortions to 22 weeks after conception. Abortions are not paid for by the state and are only allowed under specific circumstances such as; as a result of rape, if the embryo is not viable, if the mother's life is threatened by the pregnancy, if there is a malformation of the embryo, etc.

Amniocentesis has been available since 1974, it was initially only performed in the later stages of development but since 1984 it has been offered at much earlier stages. Genetic screening is only allowed to detect disease and all results are

covered by medical secrecy.

Medically assisted procreation (MAP) is readily available and frequently used for couples who cannot conceive in any other way. Preimplantation genetic diagnosis (PGD) of embryos produced by *in-vitro* fertilisation is allowed for the identification of genetic diseases at the request of the parents.

Amniocentesis and MAP procedures are free if performed in a public hospital and subsidised by the government if done in private hospitals.

There is a national ethical committee considering the use of modern genetic diagnostic techniques for human beings and each medical centre has its own ethical committee to carefully study each individual case.

SPAIN

Spain is the country in the European Union with the lowest birth rate. Legislation about Medically Assisted Procreation (MAP) and Preimplantation genetic diagnosis (PGD) was passed by the Parliament in 1988 and 1996.

MAP is allowed and can be paid for by the National Health System when a single woman or a couple is infertile. The unused pre-embryos are frozen for a maximum of 5 years. They must be kept for at least 2 years in case the pregnancy fails and new pre-embryos are needed for a second attempt.

The pre-embryos can not be used in another woman without the couple's consent. The pre-embryos can be used for research, without procreation purposes, with the couple's consent.

PGD is allowed only for diagnosis of precise hereditary diseases or to evaluate the viability of the pre-embryos. It is not allowed for selection of individuals for specific characteristics or race.

Human cloning it is not allowed.

SWEDEN

Sweden is cutting its budget in every aspect like other EU countries. Sweden uses medically assisted procreation (MAP) but it is not always paid for by the state any many couples have to turn to private centres where costs can be SEK 20 000 to 30 000 for each attempt. If further processes like preimplantation genetic diagnosis (PGD) are used then about 10 eggs should be fertilised and screened. The unused embryos are frozen for one year to see if pregnancy has been successful. PGD is only allowed to screen for diseases that produce a severe handicap or early mortality. Sex selection *per se* is not allowed but the sex of the embryo will be considered for serious sex-linked hereditary diseases.

Abortion in Sweden is legal up to the 12th week of pregnancy. After that there has to be a good medical reason for an abortion to be permitted.

UNITED KINGDOM

The world's first baby conceived by *in vitro* fertilisation - IVF - (Louise Brown) was born in the UK in 1978. As a result of this birth and other developments, the UK Government commissioned the Warnock Committee Report in 1984, which conducted a wide-ranging consultation exercise before the passage, in 1990, of the Human Fertilisation and Embryology Act. Under the Act, three main areas of activity are regulated and monitored by a statutory body, the Human Fertilisation and Embryology Authority (HFEA). These areas of activity are:

- any fertilisation treatment which involves the use of donated eggs and sperm (e.g. donor insemination), or embryos created outside the body (IVF). These are 'licensed activities';
- storage of eggs, sperm and embryos;
- research on human embryos.

The HFEA is an independent body with 21 members, representing a broad range of views and experience: medical, scientific, social, legal, lay and religious. It is funded partly by the taxpayer and partly by licensed centres that carry out the medically assisted procreation (MAP). A major function of the HFEA is to inspect and license centres. It also has several other responsibilities, including:

- the publication of a Code of Practice giving guidance to centres on how they should carry out licensed activities;
- keeping a confidential register of information about donors, patients and

treatments;

- explaining its role and the services which licensed centres provide;
- giving advice and information to licensed centres;
- providing information and advice to people seeking fertility treatment, to donors, to people who may need to store their sperm, eggs or embryos for medical reasons and to the general public;
- keeping the whole field of fertility treatment and research under review and to make recommendations to the government if asked to do so.

Abortion has been legal in the United Kingdom since 1967. It can be conducted in a National Health Service hospital or an approved private hospital or nursing home. It is available free-of-charge to a woman if there is a risk to her life or mental or physical health, or if there is a substantial risk of handicap in the child. The time limit on abortions is dependent upon the viability of the foetus. Initially, this was fixed at 28 weeks gestation. It is now 21 weeks.

IVF and artificial insemination (AI) are restricted to centres licensed by the Human Fertilisation and Embryology Authority. The HFEA issues a Code of Practice that licensed centres must follow by law. The Code of Practice is amended regularly. Many factors must be considered before IVF and similar treatments are offered to people in the UK. Of paramount importance is the welfare of any child who may be born or who might be affected by the birth, and the commitment of people seeking treatment to having and bringing up a child or children. Various types of counselling must also be offered to those seeking treatment or wishing to donate eggs or sperm.

Regional Health Authorities in the UK have control of their own budgets. Some provide free treatment, but in other parts of the country IVF/AI is only available from private (fee-charging) clinics.

There are detailed rules in the Code of Practice regarding the taking, production, storage, transport and use of gametes and embryos. For instance, there are age limits on donors (18-35 for women and 18-55 for men). In addition, all donors must be screened for medical disorders, including HIV. There is a statutory maximum storage period for embryos of 5 years. For sperm it is until the donor reaches 55 years of age. Those consenting to the storage of their embryos or gametes can request a shorter period. Donors must also specify the precise use of the materials and state what is to be done with it if they die.

PREIMPLANTATION GENETIC DIAGNOSIS (PGD). Currently (June 1997), this has not been done to any great extent in the UK. There are three centres specially licensed by the HFEA to carry out such work, which is limited to screening for serious life-threatening conditions such as cystic fibrosis and Duchenne muscular dystrophy. Sex-selection for non-medical reasons is forbidden.

The HFEA is currently working with the Advisory Committee on Genetic Testing to establish a Code of Practice for PGD. This should be published late in 1997.

Debate material

Every child a perfect child? *By Gail Vines*

(New Scientist 28.10.95)

MEDICAL history could be made early next year. A couple from the north of England are hoping that their embryos, conceived by in vitro fertilisation, will be the first to be screened for a gene that could cause cancer in later life. Only those deemed not to have inherited the gene will be transferred to the woman's womb.

Preimplantation screening was first used in 1990, and involves the genetic analysis of a single cell taken from an eight-cell embryo, when it is just a few days old. Until now, it has focused on gene mutations that invariably cause severe disease in childhood or early adulthood, such as the genes for Duchenne dystrophy and cystic fibrosis. Two factors make cancer genes different. First, they do not always cause disease. And even when they do, tumours may not appear until well into adulthood.

For many researchers, ethicists and patient groups, the extension of preimplantation screening to genes of this type lands the procedure in an ethical minefield. "How far do we go in pursuit of the perfect baby?" asks Bill Gullick, a professor of molecular oncology at the Imperial Cancer Research Fund's laboratory at Hammersmith Hospital in London. The problem with pressing ahead now, some observers argue, is that this debate is barely out of the starting blocks. And given the still-experimental nature of preimplantation screening techniques, there are fears that clinical practice may be about to run ahead of the technology.

The scientists involved – infertility specialist Robert Winston and embryologist Alan Handyside of the Hammersmith Hospital and geneticist Joy Delhant of University College London – deny that they are pushing ahead too fast. The northern couple's plight is extreme, they say, and preimplantation screening offers the only way out. "We are very carefully and gently developing a treatment," says Winston. "We are certainly not rushing into anything."

The woman suffers from an inherited form of bowel cancer called familial adenomatous polyposis (FAP), also known as adenomatous polyposis coli. People inheriting a single copy of the gene responsible have an 80 to 90 per cent chance of developing the disease by the time they are in their forties. FAP can be treated by removing the lower bowel but tumours often occur subsequently in other parts of the body, where they are usually lethal. Surgery to remove the woman's lower bowel created scar tissue that has blocked her fallopian tubes, leaving her infertile. IVF is her only hope of conception, and she does not want her children to inherit the cancer gene. "It seems a justifiable use of the technology," says Handyside.

Ethical confusion

The Hammersmith Hospital's ethical committee accepts this argument, and has approved the plan. But Handyside knows that the case creates an important precedent: it crosses a boundary, raising new ethical issues about how far parents should be able to choose the genetic characteristics of their offspring. It remains a grey area as to how severe and heritable a condition has to be to qualify for preimplantation genetic diagnosis, says Handyside. "We need to ask whether it is ethical to exclude embryos that may not develop the condition, or may develop it only in their forties or beyond."

This is where the problems begin. "No one has yet thought much about preimplantation genetic diagnosis for cancer predisposing genes," says Theresa Marteau of the-Psychology and Genetics Research Group at the United Medical and Dental Schools at Guy's Hospital in London.

Marteau's research shows that there is little consensus on screening for genes that predispose to cancers later in life. She has surveyed doctors, scientists and members of the public, asking them under what conditions they approve of screening. The study revealed wide differences in opinion. Fewer than half the people surveyed felt that testing for cancers that would develop in a person's early thirties should be available. But a substantial minority was in favour.

Even this study is of dubious relevance to the debate on preimplantation screening, however, as the questions were framed in terms of prenatal diagnosis. This raises the issue of aborting genetically "defective" foetuses, rather than the potentially less emotive disposal of unwanted embryos before implantation. While pro-life activists typically oppose both, many people will possibly draw a distinction between the two.

Scientists on the front-line of this debate are still divided over what is acceptable clinical practice. Peter Braude, professor of obstetrics and gynaecology at the United Medical and Dental Schools at St Thomas' Hospital in London, sees little problem screening for predispositions which are "genuinely medical and potentially lethal". He predicts that "the furore will be over whether parents can select embryos for things like blue eyes and blond hair".

But other experts think it is difficult to draw the line even for medical conditions. I would be anxious if people began to screen embryos which had only twice or four times the average risk of developing a particular cancer," says Angus Clarke, clinical geneticist at the University of Wales in Cardiff.

"We are trying to get some discussion going on these issues" says Gullick. "What if a gene conveyed only a 5 per cent increase in the risk of breast cancer? Where is the cut-off?" Winston says he would only consider

preimplantation genetic diagnosis in cases where there is a greater than 50 per cent chance of developing a cancer that is likely to spread or to occur in several organs. But unless such questions are widely debated now, Gullick argues there could be "inappropriate use of the technology that queers the pitch for everything else".

Preimplantation genetic diagnosis is still far from routine. Only 16 centres world-wide perform the technique, which so far has resulted in just 3 live births.* In Britain, only the Hammersmith team is licensed by the government's statutory body – the Human Fertilisation and Embryology Authority (HFEA) – to offer the treatment.

Technical difficulties

Not surprisingly, given the technique's relative novelty, there are concerns about the accuracy of preimplantation genetic diagnosis. Yury Verlinsky, director of the Reproductive Genetics Institute in Chicago, says that preimplantation screening sometimes gives an embryo the all clear when it carries a defective gene. There have been several "false negatives" with the subsequent births of babies affected by genetic disease, he says.

Disorders such as FAP, which is caused by a single copy of a mutated gene, have proved particularly tricky to diagnose from a single embryonic cell. Because the amount of DNA available is minute, researchers use the polymerase chain reaction (PCR) to make multiple copies of the DNA segment that may harbour the disease gene. Unfortunately, PCR is vulnerable to contamination. The results can go awry when a stray bit of DNA gets into the sample being analysed.

Recently, another problem has emerged. Because we inherit two copies of each gene, one from each parent, the PCR must copy both to be sure of detecting an inherited disease. But sometimes the PCR misses one of the copies – a phenomenon known as allele dropout – allowing a genetically abnormal embryo to slip through. Researchers have also discovered that up to 15 per cent of early embryos have a couple of cells containing only half the normal complement of genes. If embryologist by chance analyse one of' these "haploid" cells, they have up to 50 percent chance of missing any disease gene.

Delhanty is trying to solve these problems, and Handyside says that the northern couple will not be treated until she has succeeded. One idea is to take two cells from the eight-cell embryos. "It would be unlucky if both were haploid," says Delhanty. To get round allele dropout, the researchers are trying to multiply the whole genome before zeroing in on the region that may contain the disease gene. They also aim to add other tests to check that the PCR has amplified DNA from both parents.

Error rates for preimplantation genetic diagnosis of cystic fibrosis run at 4 per cent or below, and Handyside estimates that the error rate for FAP will be somewhere in the region of 2 per cent. Braude believes that preimplantation screening should ideally move into the clinic only when it is as accurate as prenatal techniques such as chorionic villus sampling, which can be used in the eighth week of pregnancy and has an error rate of about 1 per cent. "It seems unclear whether the science and techniques of preimplantation genetic diagnosis are well enough developed to actually be able to provide the couple with what they think they are getting," says Richard Nicholson, editor of the Bulletin of Medical Ethics. Handyside disagrees, arguing that the key is to explain carefully the limitations of preimplantation embryo screening. He says that many patients are happy to go through the process simply to reduce the risk of bearing a child with a cancer-predisposing gene.

What the northern couple's case underlines most clearly, however, is that guidelines for the preimplantation screening of genes of this type need to he debated now, before they are laid down by default on the basis of previous clinical practice. In Gullick's view, this debate cannot be left to scientists. "That should happen through some form of political process," he says. Currently, the HFEA has no plans to stimulate public debate on the topic. But Marteau has a clear suggestion about what should happen next. In July, the House of Commons Select Committee on Science and Technology recommended establishing, a Human Genetics Commission to discuss the issues thrown up by advances in genetic screening. This body could lead the debate, says Marteau.

The government should respond to the committee's report within the next few weeks. What is needed, argues Alistair Kent, director of the Genetics Interest Group, an umbrella body for organisations that support people with genetic conditions, is a commission with real clout. "It must have the power to police and enforce its recommendations," he says.

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* By May 1997 this number was already in the hundreds

Debate material

The new eugenics

By Jacques Testart[1]

The ability to select and grade human embryos, brought about by the alliance of medically assisted procreation (MAP) with diagnostic genetics, has created entirely new conditions in the quality control of children. It enables parents and doctors to refuse the low-grade handicaps that used to be tolerated in conventional antenatal diagnosis (AND) screening. The same diagnosis reached by AND requires more circumspection than one made by preimplantation genetic diagnosis (PGD) in a newly fertilised embryo:
AND involves a single fetus which the parents already think of as their baby, whereas PGD is based on a multiplicity of eggs carrying relatively low emotional weight and as yet isolated from the mother's body.
Embryo multiplicity is the corner- stone of a successful MAP programme and the motor of the new eugenics: in AND, the worst was weeded out; in PGD the best is planted in. AND could assess only one potential infant per couple per year; PGD can assess several dozen, with predictable impact on the abnormality tolerance threshold, given that most couples aim to have only a small number of children. No longer is it a matter of accepting or rejecting the birth of a child with such and such characteristics; the infant "elected" for birth by PGD is the one with the most favourable characteristics in the pool of potential children. The list of physical traits with known gene codings will inevitably lengthen until it encompasses everything that defines the singularity of an individual, yet with no concept of how much this singularity owes to deviation, or of the boundary between deviation and disease.
To guard against eugenic abuse, it has been proposed that lists of handicaps be drawn up to justify the use of PGD. This presumes a precise definition of abnormality (by whom?) and of its various "intolerable" manifestations. Such a verdict amounts to the labelling with consensus effect of "abnormal" individuals as non- human, when in fact, despite medicine's best efforts, a number of them will always continue to exist.
An inventory of the unwanted is neither desirable nor achievable; at the same time, an inventory of couples at risk of producing "unwanted" children and thus potential requesters of PGD would need to be infinite, since some major handicaps, e.g. trisomy 21, can occur in any family.
Once PGD becomes available, it is hard to see how it cannot be offered to couples already producing multiple embryos in a MAP programme (the annual test-tube embryo count in France is 150,000). The definition of these "sterile couples" is extremely loose, just like that of the "serious handicaps" that PGD aims to prevent, while embryos can already be readily obtained from normal fertile couples by uterine lavage following intercourse rather than by in-vitro fertilisation. Thus, except by arbitrarily defining a level of intolerable risk, nobody is likely to be refused access to PGD; the benefits of multiple indicators for potential infant selection will rapidly become universally available. It is worth noting that in AND there is no restriction on genetic diagnosis; only the act of termination is regulated. In PGD, MAP almost always provides an excess number of embryos; selection is thus implicit in the diagnostic process, meaning that it is the access to the diagnosis itself which ought to be regulated.
Given current attitudes and legislation, PGD carries no in-built brake upon its use comparable to the role played by termination in AND, with its attendant physical and mental stress. It is naive to assume that acceptable limits will somehow loom into view as PGD develops; the "perfect child" fantasy has no limits. We have become committed to an irreversible process without having reached answers as to possible outcomes. The aim is clearly not to create monsters of perfection, since this would be open to two major criticisms: absence of the therapeutic justification essential to any medical proposal, especially when it runs counter to conventional thinking; and irrelevance in terms of the market that develops around every biotechnology, as there is no

popular demand for such a construct, despite "super-infant" headlines in the media. In fact, the new eugenics will simply select future generations by applying the predictions of the new genetics regarding individual characteristics. But the ability to discover and select potentials for excellence will introduce as yet unsuspected social hierarchies of biological characteristics. Thus a health hierarchy will be set up between, say, one individual embryo, fetus or person at 78% risk of heart disease and 59% risk of asthma versus another individual with risks of only 8% and 13%, respectively, thereby inaugurating a revolution in ethics. To date, it has been impossible to grade and quantify differences in genetic inheritance; a particular blood group determined for the purpose of transfusion, or a tissue group determined for organ transplantation, define different but equivalent states. Now, however, we have entered an age in which a prior pre-disease grading in terms of statistical risk can stratify the population along health lines, with potential impact on their status and prerogatives in areas such as education, employment, insurance, procreation etc..
Incorporation of embryos into this creeping health hierarchy will convert the egg, as some doctors have already proclaimed, into "the smallest patient", i.e. an object of medical attention before any intimation of disease. "Treatment", in this case, will consist, first, in eliminating the great majority of eggs, and second, in engineering a propitious environment for those that are spared.
Two dimensions are almost entirely absent from current discussion of genetic intervention in human procreation.
Gene therapy for serious disease is likely to be achieved, hopefully in the near future. But this is designed for individuals already born and possibly for foetuses, but not for the fertilised egg. "Germ cell therapy" is a non sequitur: as eggs can be obtained simultaneously in large numbers, at least half of which will be devoid of the disease in question, it would be nonsensical to correct a gene defect in one egg when there are normal alternatives available with which to initiate pregnancy.
The danger, at embryo level, lies not in gene manipulation but in gene purification, i.e. in selecting rather than correcting. In their defence, geneticists often argue that genetics does not have the wherewithal to practise eugenics, claiming that in the final analysis its competence is limited — while at the same time giving us almost daily demonstrations of its awesome power. To be sure, we have not yet reached the time when robots will be reading reams of genetic characteristics from individual embryonic cells supplied by millions of potential parents, with the costs offset by demonstrable gains in public health. But how do we escape the conclusion, as of now, that acceptance of PGD as an idea implies acceptance of open-ended eugenics?

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[1] **Dr. Jacques Testart** is director of Gamete Maturation and Fertilisation Research at the French Institut Nationale de la Santé et de la Recherche Médicale in Clamart. After his early research on reproduction of domestic animals he pioneered human in vitro fertilisation techniques in France. He is author of various essays reviewing the ethical aspects of reproduction techniques in humans.

This article was taken from the book “Genethics” published by Ciba-Geigy Ltd.

Free copies of this book, which debates issues and ethics in genetic engineering, can be obtained from:
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The position of various European religions with regard to bioethic questions

	Organ transplants	Abortion	Surrogate motherhood	IVF - donor eggs or donor sperm	IVF - wife's egg and husband's sperm	Artificial insemination with donor sperm	Artificial insemination with husband's sperm
Catholic	YES	NO	NO	NO	NO	NO	NO
Protestant	YES	YES	NO	NO	Varies - depends on Church	Varies - depends on Church	YES
Orthodox	YES	NO	NO	NO	NO	NO	NO
Islam	YES	YES 90 days	NO	NO	YES	NO	YES
Judaism	YES	YES if the mother is in danger	NO	NO	YES in USA NO in Europe	NO	YES

Appendix 1

MODEL EUROPEAN COUNCIL 1996 – THE E.I.B.E. CONNECTION

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WHAT IS THE MODEL EUROPEAN COUNCIL?

The **Model European Council or MEC** is a student simulation of a full meeting of the European Council; for the past 13 years this has been organised and run by teachers of the nine **European Schools**.

These schools (the total student population is over 10,000) teach the children of European Union officials in such centres as Brussels and Luxembourg.

The annual simmulation alternates between the **Model European Parliament** and the **Model European Council**.

The role of each of the 15 EU countries at MEC is played by a European School delegation (large schools often send two delegations).

Each is composed of 7 members – Head of Government plus the Ministers of Foreign Affairs, Finance, Agriculture, Education, Transport etc. Total participation is about 220 (200 student politicians/journalists and 20 teacher advisors). The teachers' role is to prepare the students for the simulation – during the simulation they are essentially present as observers.

Topics discussed by the committees in the last session included:

- *Economic and Monetary Union of the EU*
- *Community Immigration Policy*
- *The Export of British Beef*
- *Women's rights*
- *EU policy in ex-Yugoslavia*
- *The safety of nuclear installations inside and outside the EU*
- *Admission to the EU of applicant nations (Turkey, Slovenia, Hungary, etc.)*

The simulation is a role playing exercise and the students argue the way they think the country they represent would argue; they do not put forward their own points of view.

Another feature of the Model European council is the presence of student journalists who produce three newspapers and run two press conferences at the simulation.

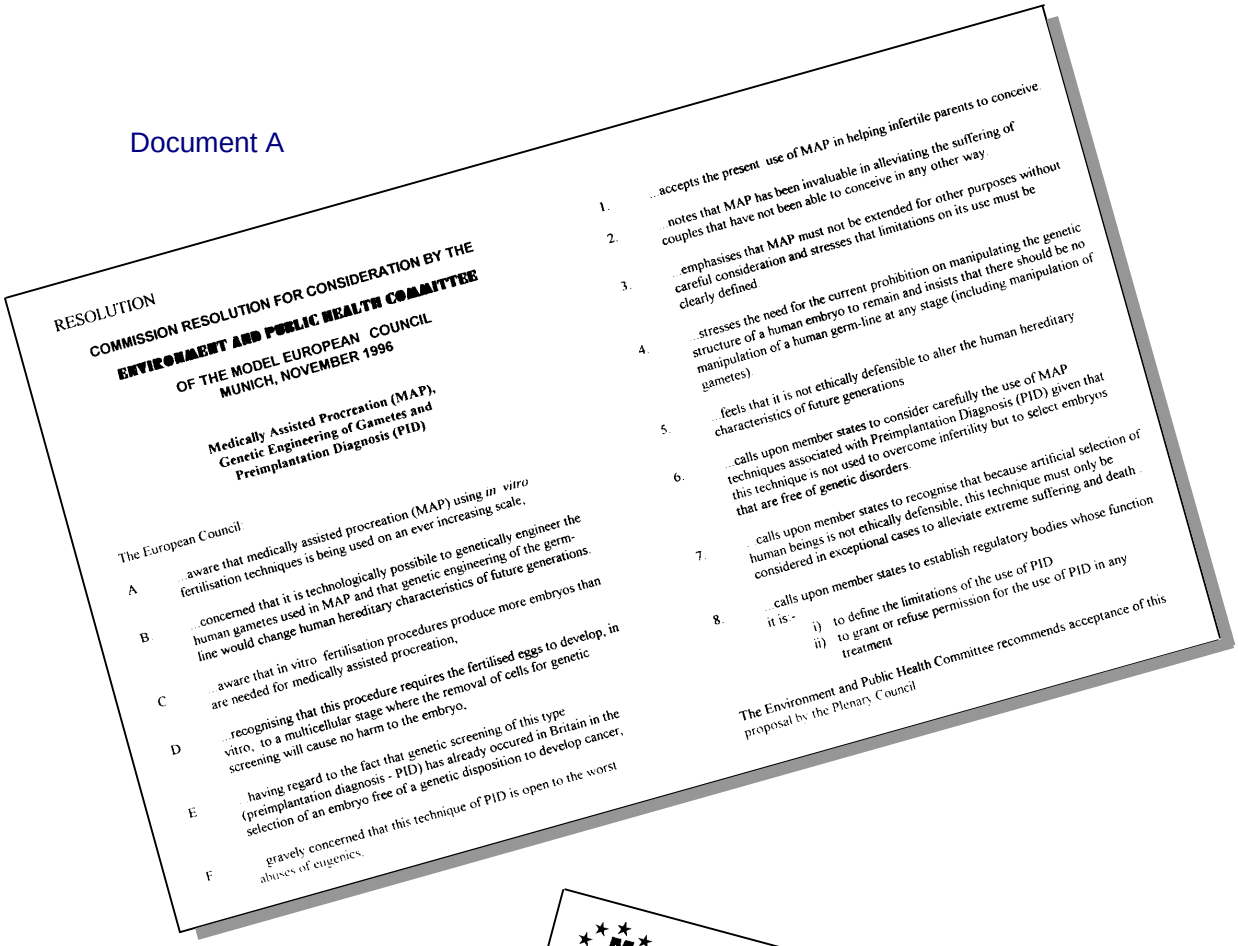
In **November 1996** a two day "M.E.C." was help in Munich. One of the Committees, the **Environment and health committee**, debated **a resolution drawn up by EIBE** in the summer (*Document A).*

The committee debate on this resolution was discussed by the 15 ministers (chaired by Ireland) for about 4½ hours and the **final resolution** (*Document B*) was approved by the plenary session at the end of the two day simulation.

Two EIBE members were present throughout the session in the role of **experts** and fielded technical questions from the committee.

Appendix 1

Document A



RESOLUTION

COMMISSION RESOLUTION FOR CONSIDERATION BY THE ENVIRONMENT AND PUBLIC HEALTH COMMITTEE OF THE MODEL EUROPEAN COUNCIL MUNICH, NOVEMBER 1996

Medically Assisted Procreation (MAP), Genetic Engineering of Gametes and Preimplantation Diagnosis (PID)

The European Council:

A ...aware that medically assisted procreation (MAP) using *in vitro* fertilisation techniques is being used on an ever increasing scale,

B ...concerned that it is technologically possible to genetically engineer the human gametes used in MAP and that genetic engineering of the germ-line would change human hereditary characteristics of future generations.

C ...aware that in vitro fertilisation procedures produce more embryos than are needed for medically assisted procreation,

D ...recognising that this procedure requires the fertilised eggs to develop, in vitro, to a multicellular stage where the removal of cells for genetic screening will cause no harm to the embryo.

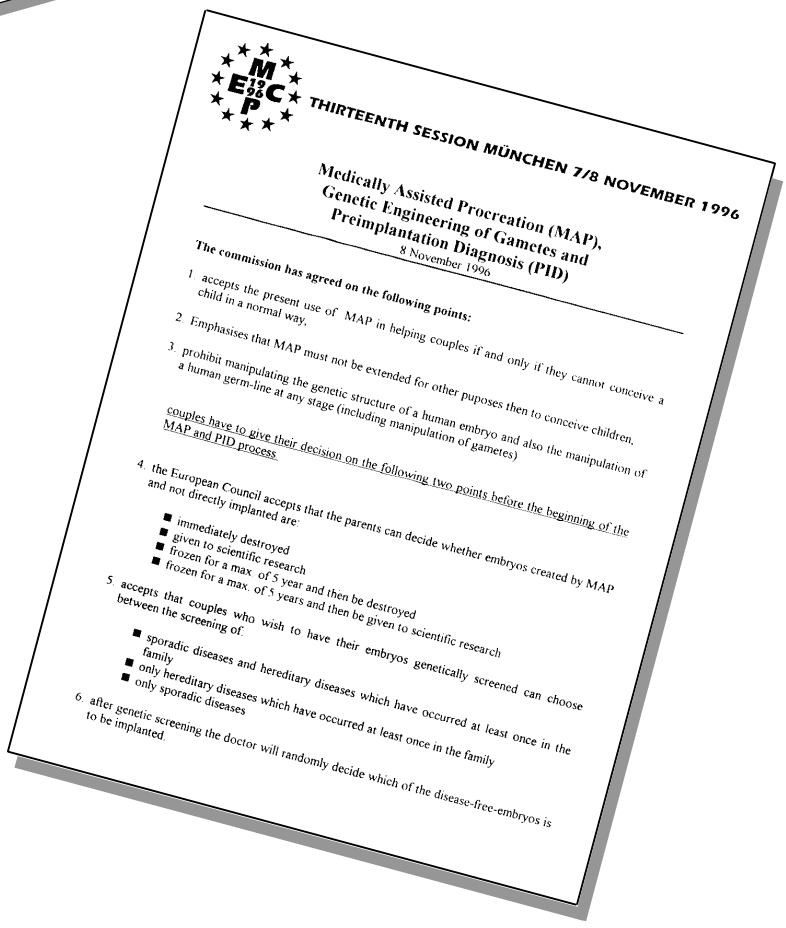
E having regard to the fact that genetic screening of this type (preimplantation diagnosis - PID) has already occured in Britain in the selection of an embryo free of a genetic disposition to develop cancer,

F gravely concerned that this technique of PID is open to the worst abuses of eugenics.

1. ...accepts the present use of MAP in helping infertile parents to conceive.
2. notes that MAP has been invaluable in alleviating the suffering of couples that have not been able to conceive in any other way.
3. ...emphasises that MAP must not be extended for other purposes without careful consideration and stresses that limitations on its use must be clearly defined.
4. ...stresses the need for the current prohibition on manipulating the genetic structure of a human embryo to remain and insists that there should be no manipulation of a human germ-line at any stage (including manipulation of gametes)
5. ...feels that it is not ethically defensible to alter the human hereditary characteristics of future generations
6. ...calls upon member states to consider carefully the use of MAP techniques associated with Preimplantation Diagnosis (PID) given that this technique is not used to overcome infertility but to select embryos that are free of genetic disorders.
7. ...calls upon member states to recognise that because artificial selection of human beings is not ethically defensible, this technique must only be considered in exceptional cases to alleviate extreme suffering and death.
8. ...calls upon member states to establish regulatory bodies whose function it is:-
   i) to define the limitations of the use of PID
   ii) to grant or refuse permission for the use of PID in any treatment

The Environment and Public Health Committee recommends acceptance of this proposal by the Plenary Council

Document B



THIRTEENTH SESSION MÜNCHEN 7/8 NOVEMBER 1996

Medically Assisted Procreation (MAP), Genetic Engineering of Gametes and Preimplantation Diagnosis (PID)

8 November 1996

The commission has agreed on the following points:

1. accepts the present use of MAP in helping couples if and only if they cannot conceive a child in a normal way.
2. Emphasises that MAP must not be extended for other puposes then to conceive children,
3. prohibit manipulating the genetic structure of a human embryo and also the manipulation of a human germ-line at any stage (including manipulation of gametes)

couples have to give their decision on the following two points before the beginning of the MAP and PID process

4. the European Council accepts that the parents can decide whether embryos created by MAP and not directly implanted are:
   - immediately destroyed
   - given to scientific research
   - frozen for a max. of 5 year and then be destroyed
   - frozen for a max. of 5 years and then be given to scientific research
5. accepts that couples who wish to have their embryos genetically screened can choose between the screening of:
   - sporadic diseases and hereditary diseases which have occurred at least once in the family
   - only hereditary diseases which have occurred at least once in the family
   - only sporadic diseases
6. after genetic screening the doctor will randomly decide which of the disease-free-embryos is to be implanted.

Appendix 2

MODEL EUROPEAN COUNCIL 1997

Introduction

After the success of the debate on IVF and PGD during the MEC '96 session in Munich, the organisers asked EIBE if it would assist once again with proposals for the 1997 MEC in Copenhagen.

Discussions were held in Luxembourg in September between EIBE members and students representing the European Commission and the proposals on the following pages were drafted. This time four proposals on biotechnological points were prepared; three for the Health Committee and one for the Environment Committee.

They were duly discussed at MEC '97, held at Eigtveds Pakhus, the venue for the actual European Council meeting hosted by Denmark as president of the EU.

Eigtveds Pakhus
Copenhagen

We feel that these proposals could be useful alternatives to the one on PGD presented in this unit. Teachers interested in using these proposals for a political simulation of a Modern European Council will obviously have to motivate their students to find the necessary scientific and political background information.

The topics covered in these new proposals are:

- Gene Therapy
- Cloning
- A *Chlamydia* Information Campaign
- Transgenic Plants

The Health committee discusses ***Chlamydia***

The final proposals from all the committees (including Health and Environment) were presented to the whole Model European Council during the closing plenary session.

M.E.C. in plenary session

If anyone has any comments or questions about any of the material in this unit please contact John Watson at:

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Appendix 2

MODEL EUROPEAN COUNCIL (MEC)

HEALTH COMMITTEE

Proposals by the Health Commissioner of the European Union (EU)

Gene Therapy

Preamble

- *aware of the potential of gene therapy in correcting the genes of a variety of disorders*
- *given the progress using gene therapy in the treatment of cancer*
- *aware that gene therapy can be used to correct problems in somatic and germ line cells*
- *recognising that it is easier to obtain sperm cells than egg cells*

The EU Commission makes the following proposals:

1. that the European Council encourage further work in somatic gene therapy;
2. that gene therapy on germ cells (in particular spermatozoa) be permitted because the correction of mistakes in germ cells is more cost effective than treating somatic cells;
3. that each member state establish its own regulatory body whose function it is to control the use of this technology according to the recommendations of the EU committee.

Appendix 2

MODEL EUROPEAN COUNCIL (MEC)

HEALTH COMMITTEE

Proposals by the Health Commissioner of the European Union (EU)

Cloning

Preamble

- *aware that certain techniques used in agriculture can be, and often are, applied to humans e.g. in-vitro fertilisation, surrogate motherhood etc.*
- *aware that various cloning techniques have been developed*
- *given that it is now possible to clone an adult mammal by taking a cell and using it to grow another genetically identical mammal*
- *aware that the technique of cloning is an efficient way to produce useful genetically modified mammals*
- *understanding that human tissue cloning is already used as an important tool in medicine*
- *concerned that the technique of cloning could be open to abuse*
- *accepting that the European Council in its conclusions to the meetings in Amsterdam in June 1997 prohibits the cloning of whole human beings.*

The EU Commission makes the following proposals

1. that the present use of cloning genetically modified mammals be accepted as beneficial to humans;
2. that further applications of this technique be accepted as beneficial (e.g. transgenic pigs for organ transplants, transgenic mice for disease models, etc).
3. that limitations on the use of cloning be clearly defined and that a regulatory body be established whose function it is:

    a) to define the limitations on the use of animal and human cloning;

    b) to grant or refuse permission for the use of animal and human cloning for any particular purpose.

Appendix 2

MODEL EUROPEAN COUNCIL (MEC)

HEALTH COMMITTEE

Proposals by the Health Commissioner of the European Union (EU)

Chlamydia Campaign

Preamble

- *aware of the general ignorance of Chlamydia as the EU's most prevalent sexually transmitted disease;*
- *noting that Chlamydia trachomatis is a common, often asymptomatic. disease which can lead to extra-uterine pregnancy and infertility in 10% to 25% of infected women;*
- *aware that newly developed screening tests could improve community-based screening for this infection;*
- *acknowledging that over 1 in 20 women aged 18-25 years may have an undiagnosed infection;*
- *given that information on Chlamydia infections is rarely, if ever, taught in schools or promulgated via the media*
- *noting that public awareness of this infection could substantially reduce its prevalence in society;*
- *realising that the cost of a public awareness campaign and the cost effectiveness of a screening policy must be evaluated;*

The EU Commission makes the following proposals:

1. that a limited-term Agency be established whose function it is to inform the EU public of all aspects of this infection through a publicity campaign "Europe against *Chlamydia*", and targeting young people in particular;
2. that the agency be composed of a representative of the Ministry of Health of each member state;
3. that each Minister of Health in each member state implement selective screening for *Chlamydia* infection, with anonymous automatic screening of all urine samples sent to laboratories for testing;
4. that condoms be made easily and cheaply available in shops, supermarkets and well known meeting places for young people, such as secondary schools, institutions of further education, youth clubs, etc.

Appendix 2

MODEL EUROPEAN COUNCIL (MEC)

ENVIRONMENT COMMITTEE

Proposals by the Health Commissioner of the European Union (EU)

Transgenic Plants

Preamble:

- *aware of the fact that the European Union has given permission to grow and market several transgenic crops*
- *given that, when this permission was granted, it was with the understanding that the growth of these crops would bring about a decrease in the amount of herbicides or insecticides used in agriculture*
- *understanding that with several years experience there is now a wealth of research data available*
- *concerned that because only a few companies are involved in producing these crops there are only a limited number of herbicide-resistant genes used;*
- *concerned that these herbicides are now occasionally found in drinking water;*
- *concerned that weeds tolerant to these herbicides are now being found in nature;*
- *aware that certain insects have become resistant to the insecticide genes introduced into crops*

The EU Commission makes the following proposals

1. that the release into the environment of genetically modified plants is reconsidered since it was agreed that the use of these crops would be monitored as more information became available
2. that the Environment Protection Agency in Copenhagen investigate the present use of transgenic plants and make a report with recommendations directly to this Council;
   - 2.1. that in this report a new risk assessment, in the light of recent research, reconsiders the ecological effect of releasing genetically modified plants into the environment;
   - 2.2. that this report look at ways of stimulating projects designed to improve **food quality** using transgenic techniques .