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THE GENE POLITICS OF THE EUROPEAN COMMUNITY

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Synopsis—More recently, the European Community (EC) institutions have taken a keener interest in the subject of genetic technology. In the following article the competences of the individual EC institutions and the whole dilemma of reaching decisions at EC level will be discussed first and then the individual proposals in the field of gene technology.

In the first part four Directive proposals are presented which are directly aimed at European legislation. The Directive proposals concern the use of gene technologically modified microorganisms in enclosed systems, the release of gene technologically manipulated microorganisms into the environment, the protection of employees against harm from biological substances at work, and the patenting of living organisms.

Part two deals with proposals in the field of human genetics. Of topical importance and the subject of controversy because of its openly eugenic aims is a planned EC research programme on the analysis of the human genome. Two parliamentary reports on the ethical and legal problems of gene manipulation and artificial 'in vivo' and 'in vitro' fertilization round off the gloomy picture of gene politics at EC level.

Synopsis—In neuerer Zeit nehmen sich die EG-Institutionen verstärkt des Themas Gentechnologie an. Im folgenden Artikel soll zunächst kurz auf die Kompetenzen der einzelnen EG-Institutionen und auf das Dilemma der Entscheidungsfindung auf EG-Ebene überhaupt eingegangen werden, ehe die einzelnen Vorschläge im Bereich Gentechnologie beschrieben und kommentiert werden.

Im ersten Teil werden vier Richtlinienvorschläge vorgestellt, die unmittelbar auf eine europäische Gesetzgebung abzielen. Die Richtlinienvorschläge betreffen die Verwendung von gentechnisch veränderten Mikroorganismen in abgeschlossenen Systemen, die Freisetzung gentechnisch manipulierter Mikroorganismen in die Umwelt, den Schutz der Arbeitnehmer gegen Gefährdung durch biologische Stoffe bei der Arbeit und die Patentierung von Lebewesen.

In einem zweiten Teil geht es um Vorschläge im Bereich der Humangenetik. Aktuell und ob seiner offen eugenischen Zielsetzungen umstritten ist gerade ein geplantes Forschungsprogramm der EG zur Analyse des menschlichen Genoms. Zwei parlamentarische Berichte zu den ethischen und rechtlichen Problemen der Genmanipulation und der künstlichen Befruchtung 'in vivo' und 'in vitro' runden schliesslich das düstere Bild der Genpolitik auf EG-Ebene ab.

After a long period in which developments in the field of basic research and its application, in particular in agriculture, have been carried out and gone unnoticed by the public at large, gene technology (GE) and the new reproductive technologies (NRT) are increasingly becoming the object of political debate. This is partly due to feminist and other critics of the technologies, but the drastic increase in possibilities of application has also created a need for political action. In many countries, legal foundations or recommendations for the experimental and industrial use of GE and NRT which prepare the way for broad application are presently being worked out. However many scientists, physicians, and industries speak out against a restriction of the so-called freedom of science and against binding legal provisions, they are nevertheless in favour of establishing a legal framework which they then can use to legitimize their research.

Many governments internationally have begun to draw up regulations on the totally unlegislated areas created by scientific development in GE and NRT. Likewise, the European Community is

now applying itself to this field. This move is prompted less by the view that the effects, for example, of releasing genetically manipulated organisms cannot be contained within national boundaries, than by the fact that it is in the interest of multinational companies; put differently they do not want to have to deal with legal situations that differ from country to country. The concern of the European Community Commission therefore is mainly focused on problems arising with regard to competition which can result from different national regulations, and on the disadvantages European companies might suffer when compared to USA and Japan. The European Community Commission proposes to create a European internal market to counteract this danger: an aim which is to be realized by 1992 through, as it is called, the 'harmonizing' of regulations between the 12 individual states.

I. THE POLITICS OF THE EUROPEAN COMMUNITY

What is European law?

The European Community can make recommendations to its Member States (which are not binding), and issue directives, which then have to be translated by the Member States into national laws. If the countries do not meet this obligation, the European Community Commission may file a charge against the relevant government at the European Court of Justice in Luxembourg. The Court then decides whether the national provisions on translating the European Community directives are adequate or not.

How is European law made?

A fundamental nexus in the creation of European law is provided by the elaboration of a proposal by the European Community - Commission. The Commission is an enormous bureaucratic apparatus with its headquarters in Brussels. It is composed of civil servants designated by its Member States who form the executive of the European Community.

After the publication of a draft directive by the Commission, the opinion of the European Parliament is sought. This process until recently has had a purely legitimating function: often when the Parliament requested an amendment to a certain directive, the representative of the Commission calmly announced that the Commission would not take this suggestion into account[1]. Only since the adoption of the Single European Act must Parliamentarians' opinions in certain fields, such as health, safety, the environment, and protection of the consumer, be included in a cooperative procedure with the Commission and the Council. In other words, Parliament can block decisions of the Council in these fields[2]. It also has the possibility, by means of a complicated procedure, to make amendments to Commission proposals for which an absolute majority is necessary. This is the sole possibility of exercising democratic principles with regard to law-making by the European Community. In other fields, such as economic, currency, and social policy, Parliament may only issue non-binding opinions.

The Council of Ministers decides after obtaining the opinions whether and in which final form a Commission proposal should be made into law. Frequently there are tough negotiations among Ministers according to their national interests, in which the Commission then plays the part of mediator. The result of these compromise negotiations as a rule reflects the lowest common denominator (i.e., a levelling of opinion at the lowest level).

Arriving at a common denominator means that the Council of Ministers, with the aid of the Commission (which acts as the executive) issues laws which then bind it in its further capacity as National Executive. The laws therefore are made by those who subsequently execute them.

In the case of unpopular decisions, the individual governments often refer to the anonymous European Community, thus concealing their own responsibility and complicity.

The consequences of European law for the Member States

European law prevails over national law. There are, however, different implementing regulations. Article 130r-t (Protection of the Environment) of the EC Treaty leaves it to the Member States to issue additional laws that go beyond the common protective measures (i.e., at question are minimal standards which do, however, require a unanimous vote among the members of the Council of Ministers). But Article 100a (Approximation of Laws for the Common Market) prescribes a binding single standard which no Member State may exceed in order to prevent distortions in competition. Legislation brought under Article 100a needs only a qualified majority of the members of the Council of Ministers to be implemented. Quite often, therefore, governments like to refer to lower European Community standards when they want to prevent or reduce stricter regulations in their own countries. In other words, there exists a tendency towards a shifting of power from democratically legitimated national decision-making structures (Parliaments) towards the European Community level, where democratic control mechanisms are practically nonexistent. An added complication is that precisely because of the remoteness and impenetratability of the decision-making processes, the public is totally inadequately informed on the activity of the European Community and therefore can scarcely build up any extraparliamentary opposition to its decisions.

II. INDUSTRY FRIENDLY DIRECTIVE PROPOSALS

There is a type of legally dry text which, on close reading, can be more exciting than a thriller. One's reading pleasure is only lessened by the fact that this is not fiction but threatens to become reality. The two proposals of the European Community Commission for Council Directives of 4 May, 1988 belong to this type of text. One is on the contained use of genetically modified organisms to the environment[3].

When reading thrillers we would never turn to the last page first; in the case of these documents, however, we can only recommend it. For at the end of the Directive proposal on release it says:

> This proposal has been discussed with the European Biotechnology Coordination group, composed of representatives from different European Industry's organizations: AMFEP, CEFIC, CIAA, EPPIA, GIFAP. The employees side, however, has not been consulted, (p. 58)

What are these two proposals about, which were agreed with the representatives of industry but otherwise formulated by excluding the public?

A. The Directive Proposal on the Contained use of Genetically Modified Microorganisms (GMM)

The first aim of this Directive proposal is unequivocally in the interests of industry: it is intended to hinder distortions in competition, which could arise through different regulations of the European Community Member States in this field. In countries in which a high standard of safety is legally prescribed, research (or production) is more expensive than in countries in which no or only very few rules exist. In fact, as the Commission says, national regulations vary greatly as the following summary of the Commission shows (1988: 3–4):

Legislation in the Member States of the European Communities

> Several Member States have been reviewing existing regulations and some have issued specific rules concerning the contained use of biotechnology.
>
> In *Belgium* a 'rDNA Advisory Committee' is in creation, in order to channel biotechnology-related issues to the competent authorities. There is no specific regulation in the field of

biotechnology but it is estimated that a number of existing rules will apply. These include systems of authorizations for production, and for liquid and solid waste transport, and disposal as well as legislation on worker protection.

In *Denmark* the Folketing adopted in May 1986 a bill on 'Environment and Gene Technology.' Concerning workers' safety an order on "Gene Technology and Working Environment" was issued in September 1987. Research can be carried out only in laboratories classified for this purpose by the National Labour Inspection, and each experiment has to be notified and registered. Production in industry must be previously licensed by the competent authorities. This involves the review of a risk assessment study and the approval of the containment and emergency measures proposed by the applicant.

In *the Federal Republic of Germany* the contained use of genetically modified microorganisms is subject to several provisions. Research activities are subject to guidelines; the disposal of liquid wastes from production and utilization of genetically modified microorganisms are subject to authorization, as is the establishment and functioning of industrial installations producing medicinal products or their intermediates using biotechnology.

The Association (Berufsgenossen-schaft) of the chemical industry has prepared a recommendation for accident prevention in laboratories and industrial installations using biotechnologies. The Minister for Social Affairs has given his agreement and the different associations will now implement these recommendations in their own sector.

In *France* there are guidelines for research with genetic technologies which provides for voluntary notification of certain high risk projects to a scientific committee (Commission de Classement). Industrial activities using genetically modified microorganisms are subject to the Law on 'Classified Installations for Environmental Protection' and at present must be authorized before beginning to work. An interdepartmental working group, meeting by initiative of the Prime Minister, is evaluating whether industrial activities should be distinguished on the basis of the microorganism used and submitted to declaration when using low risk microorganisms.

Greece has set up an interdepartmental Committee, the 'Ad-Hoc Committee on Biohazards' which is responsible for the coordination of biosafety activities in relation to research projects.

In *Ireland* a statutory Recombinant DNA Committee has been set up to receive and examine notifications for research projects falling within categories of high risk. The Committee also receives proposals for industrial large scale work and issues case by case recommendations to the local authorities on conditions to be met regarding the plant's design, the containment measures, and the safety of workers.

In *Italy, Spain, and Portugal* no specific guidelines or rules apply to the contained use of biotechnology; however, a number of existing regulations related to products are applicable.

In *Luxembourg* there are no specific laws with respect to biotechnology. At present, both laboratories and industrial installations using genetic technologies fall under the general rules for 'Classified Installations' where authorization is needed before beginning to work.

In *the Netherlands* guidelines have been set up for research and industrial production. Also, genetically manipulated microorganisms are regulated under the Nuisance Act

which requires a license for hazardous installations. The licence could specify the provisions to be adopted for containment and emergency response. The licence is given by the Community Council and is normally based on advice of the Recombinant DNA Committee.

In *the United Kingdom* the general requirements of the Health and Safety at Work Act and the Genetic Manipulation Regulations, issued under this Act, apply to researchers and industries using genetic technologies. Notification of activities is required, and Guidelines on Safe Work are issued by the Advisory Committee on Genetic Manipulation, while the Health and Safety Executive inspectors carry out active controls for enforcement. The Health and Safety Commission is planning to propose statutory notification for the large scale use and planned release of genetically modified microorganisms, because at present such notifications are on a voluntary basis.

During the course of the realization of the internal market (i.e., of the easing of international activities of firms) the Directive on the Contained use of Genetically Modified Organisms is intended to bring about a harmonization. This unification will—according to the text—be based on a high protection level and suggest a uniform safety standard for the whole Community. We will discuss below, however, how seriously the Commission takes this claim.

The initiative is questionable for other reasons too. The Commission wants to pass regulations, 'to ensure that the use of genetically modified microorganisms is undertaken with the degree of security (control) commensurate with the potential risk involved' (p. 2); and 'to limit their negative consequences for the health of the general population and the environment' (p. 10). But how can a danger be controlled or even just limited, when it cannot possibly be assessed in advance? That 'the precise nature and scale of risks associated with genetically modified microorganisms are conjectural' (p. 10), the writers of the Council Directive concede themselves in the next but one sentence. So what kind of safety do they intend offering us?

Their confidence in 'new scientific or technical knowledge relative to risk management (sic!) and waste disposal' (Art. 5, p. 10) does not seem daunted even after experiences with nuclear fission. Their concept of science becomes evident when they take connections apart and let the individual parts appear manageable. For example, genetically modified microorganisms, which are considered a minimal risk, are arbitrarily classified as Group 1 and all others as Group 2 (see p. 19)[4]. Further classification is undertaken on the basis of application in the nonindustrial (education, research, and development) and industrial field (production, including pilot plants). For the latter—apart from a general obligation to register 60 days before work commences—different provisions apply (Art. 6–8, pp. 16–17):

(a)For nonindustrial work with genetically modified microorganisms of Group 1 working reports need only be made available at the request of the supervisory authority.

(b)Work with genetically modified microorganisms of Group 1 on an industrial scale must first be notified by submitting certain information; it is not, however, subject to any permission, but can be initiated immediately.

(c)For genetically modified microorganisms of Group 2 an obligation to notify applies for nonindustrial use, which iscoupled with more comprehensive information. Unless the relevant authority raises any objection, work may begin after 15 days.

(d)Notification of work with genetically modified microorganisms

of Group 2 on an industrial scale is attached to even more comprehensive information, and the period of examination of the authority is 60 days in this case.

Member States are to nominate authorities to examine the notification and, if need be, demand further information or suggest other conditions for use. In this case the waiting period is extended until the demands have been met. National authorities should also 'carry out inspections and checks, and take all requisite measures with a view to preventing accidents or limiting the consequences of such accidents, including drawing up of external emergency plans' (p. 8). (One might ask what emergency plans have to do with preventing accidents.) They are also responsible for ensuring 'that all persons liable to be affected by an accident are informed in an appropriate manner of the emergency response measures and of the correct behavior to adopt' (Art. 11, p. 14). This is the only place where the population is mentioned: as potential victims of an accident. There is no question of a right of appeal by those living nearby, no public hearings are provided for. Instead the Commission plans to start a data bank available to Member States with a register of all accidents including the experiences gained as a result. And every three years there are to be reports from the Member States and the Commission, which can publish general statistical information, 'as long as it contains no information likely to cause substantial harm to the competitive position of a user'(p. 16).

Previous practice—an example from the FRG

On 31 August, 1988, the Trade Supervisory Office of Lower Saxony approved one of the largest and most controversial genetic laboratories in Europe exactly ten hours before the tightening of the legal authorization procedure for gene-technological production sites which prescribes a public hearing came into force. The US firm *Invitron* intends to manufacture active substances (biocatalysts) for the manufacture of medicines by multiplying animal cells enriched with human genetic information at Hannover's Medical Park. The plant was approved, although even ardent supporters of gene technology admit that 'an escape of individual cells from the plant cannot be prevented' (Professor Pin-goud, quoted in *Die Tageszeitung,* 9.9.1988): the spread of (retro-) viruses is still largely unresearched; in spite of vacuum and air filters tiny particles do manage to enter the environment: in spite of protective clothing an infection through very minor skin wounds or inhalation cannot be excluded.

Supervision of the lawful running of the plant is in the hands of the Trade Supervisory Office of the Federal Land, in which, however, there is no gene-technology expert. The employee most qualified to do check-ups, a chemist, had to admit: 'If *Invitron* deliberately evades check-ups, there's not really much we can do' (Dr. Franke, quoted from *Die Tageszeitung* of 9.9.1988).

But even if no breakdowns should occur during production, retroviruses nevertheless manage to get into the blood of those who use the manufactured drugs. The relevant purity criteria of the World Health Organization (WHO) tolerate a maximum of 100 Picograms of DNS per milligram of protein, which corresponds roughly to 50 times the amount of total genetic information of a human cell. The control of the cell lines used in the plant is in the hands of the Central Commission for Biological Safety (ZKBS), which is not bound by any law, and whose members are nominated by the Federal Minister for Health. At present, five of the twelve members of the ZKBS are employees of the chemical-pharmaceutical industry, while not one critical scientist belongs to it!

Since 1 September, 1988 the Federal Republic of Germany has prescribed a public hearing for the approval of gene-

technological plants. But if, as expected, the European Community Directive comes into force, then the Federal Government can (if Article 130r-t is applied) or *must* (if Article 100a is used) abolish public participation in the interest of harmonization. It is interesting that the German Federal Government through the Council of Ministers speaks in favour of the application of Article 100a. (Article 130s was voted for by members of Ireland, Denmark, Spain, Greece, and U.K.)

This example clearly shows the weaknesses of all attempts at regulation; they cannot guarantee safety and the supervisory authorities are either directly involved in the industry or not in a position to carry out adequate controls. The same problems arise in the case of release of genetically modified organisms.

B. The Proposal for a Directive on the Deliberate Release to the Environment of Genetically Modified Organisms (GMO)

The explanatory memorandum preceding this proposal states that, 'Public concern about genetic engineering is growing, and it is easy to imagine the public's response in case of harm to people or the environment caused by a GMO deliberately introduced in the environment' (p. 29). The introduction continues by saying that the increasing application of genetic engineering, protection of human beings and the environment is also urgently necessary. Only in the *actual text* of the Directive are the efforts at harmonization within the framework of realizing the internal market named as the prime motivation for regulation at the European level. For even in the area of the deliberate release of GMOs there are totally different national legal provisions, as the European Community Commission's survey of countries shows (pp. 27–28):

Legislation in the Member States of the European Community

> Several Member States have been reviewing existing regulations and generally assessing the risks to humans and the environment from the release of genetically engineered organisms.
>
> In the *Federal Republic of Germany a* general ban on the deliberate release of genetically modified organisms (GMOs) has been established. Exemptions are on a case-by-case basis, without any formal authorization procedures. The German authorities are currently deciding whether a legal framework is necessary to regulate the deliberate release of GMOs, taking into account a recent Bundestag report on the subject.
>
> In *Italy,* no specific regulation applies to the deliberate release of GMOs. A first proposal for release is being examined under pesticide legislation.
>
> In *the Netherlands,* regulations for environmental release are in preparation. At present, there is no ban on the release of GMOs; the Government allows experiments to proceed where adequate review has been provided.
>
> In *France,* the Ministry of Agriculture has established a commission (Commission de Génie Biomoléculaire) to examine case-by-case the deliberate release of GMOs.
>
> *Belgium* is covering GMOs under existing legislation, having gained some experience with a proposed release of genetically modified potato plants.
>
> *Luxembourg* is examining closely the deliberate release of GMOs. The possibility of ad hoc authorizations will be examined by the Ministry of the Environment.
>
> In the *United Kingdom,* guidelines for the deliberate release of GMOs were approved in April 1986. These guidelines, prepared by the Advisory Committee on Genetic Manipulation (ACGM) establish a framework for the case-by-case consideration of proposals by an expert national body and relevant governmental departments, and has set up a subcommittee to oversee individual

notifications. This scheme is at present voluntary, but the ACGM has proposed statutory notification for deliberate releases.

The guidelines, which will apply to organisms obtained through genetic manipulation, will cover releases to the environment in large scale and field trials under noncontained conditions. It is envisaged that when GMOs developed for release have been fully assessed by ACGM, HSE, and other relevant governmental departments, routine use will be exempt from the notification procedure.

In *Denmark,* the Danish Folketing adopted in May 1986 a bill on genetic engineering and other technologies, including agricultural and environmental uses of GMOs and products containing them. The provisions of the law state:

- release of GMOs may not take place even for research purposes; the Ministry of the Environment may approve such releases in special cases;
- applicant in these cases must, if so required by the Authorities, provide information and test results in accordance with certain guidelines, and at certain laboratories. The Ministry of the Environment may lay down detailed rules on the implementations of the approval arrangements;

The law covers:

- inspection, information on accidents, prohibition after authorization has been granted, imported substances, local authorities, and the possibility of appeal against decisions taken under the law.

Ireland has set up a Recombinant DNA Committee and an Institutional Biosafety Committee. Deliberate releases will require review and approval by these Committees, which will follow the OECD recommendations. In addition, provisions of a number of Irish laws are relevant in the cases of deliberate releases, including the Water Pollution Act, the Dangerous Substances Act, and the Destructive Insects and Pests Act.

In *Greece* there are no specific regulations in this field, but an 'Ad hoc Committee of Biohazards' has been set up with responsibility in the coordination of biosafety activities.

In *Spain,* no specific regulations apply to deliberate release of GMOs, but a committee is being set up to be responsible of these activities.

In *Portugal,* there are no specific regulations in the field but the Secretariat of State of Environment will be responsible for the subject.

Setting the fox to keep the geese

The European Commission uses the limited international experience in the field of release as an argument for proposing no general directives or testing requirements, but rather to set up a procedure of notification and acceptance or counselling per case, which corresponds to the OECD recommendations and is based on a dialogue between applier and authority. In their words (p. 30): 'The endorsement procedure has the advantage over an authorization procedure, that it leaves responsibility with the notifier' – but it also has the advantage for the appliers by granting them enormous discretionary scope.

Decisive for the field of application of the Directive is the narrow definition of GMO[5] and a whole list of exceptions:

*The regulations do not apply for the commercial circulation of products such as animal drugs, food, fodder, and their additives, cultivated plants and animals and materials and products reproduced therefrom (Art. 8, pp. 4–2). This restriction covers the majority of all conceivable releases and is justified on the grounds that there are already directives

for these products—which, however, have not so far referred to genetic manipulation.

*Also excluded is the transport of GMO (Art. 1.2, p. 37).

*If, on the basis of a successful experimental release or 'on substantive, reasoned scientific grounds, a notifier considers that the placing on the market and use of a product do not pose any risk to human beings and/or the environment, he may propose not to comply with one or more of the requirements' (Art, 8, p. 42).

*The applicant may also, by referring to his competitive position, request from the national authorities the concealment of certain information (Art. 17, p. 46).

The acceptance procedure differs according to the purpose of release: (a) If it serves research and development purposes, then the notifier must submit notification before the release to the national supervisory authority. Within 15 days the authority must inform the Commission, which then in turn informs the other Member States. The national authority must draw up a risk/utility evaluation within 90 days and then it either accepts the notification or demands further information or measures. The other Member States can also demand more comprehensive information and make proposals regarding permission, to which, however, the relevant authority is not bound (Arts 4–7, pp. 45–47).

(b) For the bringing into circulation of products containing or consisting of GMO (i.e., for the release for commercial purposes) the same procedure applies with the variation, that the other Member States may lodge a protest against the admission of a product within 60 days. If no agreement is reached between the relevant national authority and the other Member countries, then the EC Commission decides, after consulting an advisory committee[6]. This decision is then binding for all Member States (Arts 8–6, pp. 47–51).

There was a heated argument among the experts from the national ministries over the legal foundation of the Directive. If it were based on the regulations regarding the protection of the environment of the EEC Treaty (Article 130r-t), then the Member States would have the possibility of decreeing addition protective measures going beyond the Directive. However, within the Commission those powers who make the harmonization of provisions for the common market (Article 100a) the legal foundation have been able to enforce their will; (i.e., that there is a binding single standard beyond which no Member country may go). Thus, no member country may forbid, restrict, or prevent a product which answers to the provisions of this Directive.

A country can only temporarily forbid an already accepted product; after consultation with the advisory committee, the Commission then decides on its further utilization (Arts. 13–14, p. 45).

Confidentially expressed severe criticism from an environment ministry

In a confidential paper by the Federal German Ministry for the Environment the European Community proposal for the Directive was severely criticised: 'The procedure of registering or notifying oneself does not answer to the demands of safety for the environment' (Gen-ethischer Informationsdienst, No. 33, 6/88:2). This counters the European Community Commission's proposal that after presenting the prescribed information work can begin, (even with dangerous biological material as long as the authorities do not demand any further information), by stating that in the FRG authorization of each individual case is mandatory by law. In addition, participation of the public is also provided for. If the present Directive text is adhered to, then the FRG would be forced to revoke these achievements, and the consequences for Denmark, would be even more serious. If the European Community Directive came into force Denmark would have to withdraw its prohibition on the release of GMOs.

C. The Proposal for a Directive on the Protection of Workers Against the Risks Related to Exposure to Biological Agents at Work

In March this year the European Community Commission published a proposal for a Directive to regulate the protection of workers who handle biological agents[7]. It concerns jobs in research and development laboratories, isolation wards in hospitals, clinical and veterinary medical experimental laboratories, and commercial activities in which biological agents are involved, as long as they are not in the category 'contained use.' Previous legal provisions of the Member States are very varied in this field too, and in so far as there is any legal protection at all against biological agents, it is particularly inadequate in the field of biotechnology.

The Directive provides for 'the limitation of the number of workers exposed, the design of work processes, collective and personal protection, adequate information and training for workers, the use of bio-hazard signs and emergency procedures' (p. 11), and an obligation to report accidents. The notification of intended genetic manipulations or work with genetically modified biological agents of groups 2, 3, or 4 (see below) at least 60 days before commencement of work is also provided for (Art. 10, pp. 23–24).

Basically, all microorganisms including genetically manipulated microorganisms, cell cultures, and multicell human-endoparasites are defined as 'biological agents' (Art. 2a, p. 16). In addition, a classification is undertaken which must appear more than questionable:

(a) In Group 1 are biological agents which are 'most unlikely to cause human disease'; do not cause infection, and, are 'unlikely to spread in the community' (Art. 2b, p. 16).[8]

(b) Group 2 comprises agents which can provoke an illness in humans, 'rarely' cause an infection; they are 'unlikely to spread in the community and there is usually effective prophylaxis or treatment available' (Art. 2c, p. 16).

(c) An agent of Group 3 'may cause severe human disease and presents a serious hazard to workers. It may present a risk of spread in the community but there is usually effective prophylaxis or treatment available' (Art. 2d, p. 17).

(d) Group 4, finally, defines an agent 'that causes severe human disease and is a serious hazard to workers. It may present a high risk of spread in the community and there is usually no effective prophylaxis or treatment available' (Art. 2e, p. 17).

Groups 2, 3, and 4 are classified under the relevant degrees of safety, which contain more or less binding conditions.

As Group 1 is classified as nondangerous, it is not subject to any protective regulations.

This is not the only example where the application of protective regulations has been undermined to the point that only a mockery remains:

*"Also excluded is 'a biological agent which causes disease only in animals and/or plants and that there is no identifiable health risk to workers' (Art. 3.6, p. 19)."

*"Crews in airlines and maritime travel have no claim to protection (Art. 1.2, p. 16).

*"Protective measures shall not apply either, if 'the work activities involve only incidental exposure to biological agents' (Art. 3.7, p. 19).

Furthermore, all materials for which no definitive risk evaluation has yet been undertaken, but of which it might be suspected that. there could be a risk to health, are subject only to the requirements of safety degree 3.

After the restriction of the field of application, the provisions are then formulated so loosely that they open up enormous scope for interpretation: For the protection of workers, their exposure to biological agents is to be decreased to the level as low 'as is necessary in order to protect adequately the health and safety of the workers concerned' (Art. 4, p. 20).

And again the fox is set to keep the geese

For activities in which biological agents of Group 3 are deliberately involved, the employer is asked to keep a record of workers exposed, 'indicating the type of work done, and whenever possible the biological agent to which they may have been exposed, as well as records of accidents and incidents, as appropriate' (Art. 7, p. 22). To these records, which must be kept for 10 years, the physician, the health authority, and the employee concerned must have access.

The unspoken assumptions behind the concern about the health of workers are clarified by the demand that the state of the health of workers must be assessed *before* commencement of employment in order to introduce any special protective measures (Art. 12.2, p. 25): 'When appropriate, effective vaccines should be made available for those workers who are not already immune to the biological agent to which they are exposed or are potentially exposed' (Art. 12.3, p. 25). As the study of vaccines is itself the subject of—frequently militarily motivated—genetic research and still in its infancy, this regulation may—at best—be regarded as naive. But what is expressed in it is the individualizing of risks instead of the general reduction or avoidance of risks.

A new evaluation of risks—and thereby tighter security measurement—can only be demanded by the authorities or physicians *after* an employee has become ill. To prove what exactly caused the illness is extremely difficult and raises many new problems in relation to recognising work place associated diseases.

D. The Proposal for a Directive on the Legal Protection of Biotechnological Inventions (Patenting)

The Commission's draft on the patenting of biotechnological inventions[9] has quite obviously come about under pressure from multinational chemical and pharmaceutical concerns. These threaten to invest not in Europe but in the USA, where the Patent Office has already ruled plants and animals patentable and recently issued the first patent on an animal[10]. The European Community Commission itself justifies the enormous haste with which the Directive is to be translated into national law by the end of December 1990 by the considerable market volume, an estimated 40,000 million dollars.

In contrast to the 'European Patent Convention' of 1973, which explicitly excludes plants, animals, and biological processes from patenting, the Directive offers the possibility of the patenting of living organisms: 'A subject matter of an invention shall not be considered unpatentable for the reason only that it is composed of living matter' (Art. 2, p. 75). Ethical considerations have been swept away by real possibilities after only 15 years. Meanwhile it has become possible to cross biological barriers, producing a 'geep' out of a goat and a sheep, or a 'pomato' out of a potato and a tomato, to take human genes and let them function in an animal, or to insert animal genes into a plant. Biotechnology changes the very meaning of 'life' and makes the ownership of it a very profitable business. This business knows no bounds: the Directive does not exclude any form of life. Even in the 'patent-paradise' of the USA, human beings are excluded from patentability.

All biological classifications (such as species, genera, families, etc), with the exception of 'varieties,' are patentable (Art. 3, p. 75).

Parts of organisms such as genes, plasmids, cells, etc. are patentable, as well as their products (Art. 8, p. 76). A plant or animal can thus end up covered by a whole series of different patents, for each of which royalties have to be paid.

Not only is the end 'product' regarded as patentable, but also its manufacturing process, in so far as it comprises a biotechnological human intervention: 'A process in which human intervention consists in more than selecting an available biological material and letting it perform an inherent biological function under natural conditions shall be considered patentable subject matter' Art.

7, p. 76). Process patenting would make the current practice of plant and animal breeders illegal. They would be forced to get permission from and pay royalties to patentees for techniques that have previously been freely available. The consequences are obvious: only the big breeders would be able to pay this; this would cause further concentration within the breeding industry, would raise farming costs, and ultimately raise food prices. Since farmers would not be allowed to reuse patented seed, the common agricultural practice to use part of the harvest for next year's sowing would become illegal. This would not only bind the farmer further to the chemical industry (and drive out many of the small farmers), but would also destroy what is left of genetic diversity in Europe.

If that were not enough, the process patent applies not only to the end 'product,' but also to its offspring: ' . . . the rights of the patent shall not only extend to the product initially obtained by the patented process but also to the identical or differentiated products of the first or subesequent generations obtained therefrom' (Art. 12, p. 77) and the 'protection of a product consisting of or containing particular genetic information as an essential characteristic of the invention shall extend to any products in which said genetic information has been incorporated' (Art. 13, p. 77).

A licence 'shall not be available prior to the expiration of three years from the date of the grant of the patent or four years from the date on which the application for a patent was filed, whichever period last expires' (Art. 14.2, p. 78).

Last but not least, the Commission proposes to reverse the 'burden of proof: One who is accused of patent infringement has to provide proof of innocence while the accuser does not have to prove the other guilty (Art. 17, p. 84).[11]

The industry can be content with this Directive proposal. It meets the interests of the enterprises who aim at the broadest property protection possible, leading to characteristic patenting rather than product patenting.

There are differences between the European Patent Office (EPO), which inclines to product patenting (including plants and animals), and the European Community Commission. At the EPO, between 1985 and 1987 around 2600 gene-technological processes and products were registered. In summer 1988 the EPO approved the first application of a US company for a patent on plants. It involves a technique for increasing the protein content of forage crops and includes not only legal protection for the technique itself, but also for plants produced with the aid of this technique. Though the EPO has not yet granted a patent on animals,[12] its decision to accept a patent on plants opens the way for the general acceptance in Europe of patents on new forms of both plants and animals.

Within the Commission too there has been controversy between the representatives of industry (DG III Commission Department for Internal Market and Industry) and agriculture (DG IV Commission Department for Agriculture), which delayed publication of the text.

The consequences of patenting living organisms will affect not only breeders and farmers but also animals. Patenting leads to restricted information exchange among scientists and thus even more to the public. It will push for privatization and commercialization of medical research and services. It will enormously increase the drive to release genetically engineered organisms into the environment. Cloning will become more profitable. The dominance of the industrialized countries will be reinforced and any development of self-sufficient economies in so-called developing countries will be blocked.

At the beginning of 1988 the ICDA (International Coalition for Development Action) Seeds Campaign instigated a widespread campaign to prevent the patenting of living organisms. Together with GRAEL, they organized the conference

'Patenting Life Forms in Europe' on 7–8 February at the European Parliament in Brussels.

Meanwhile even the World Council of Churches has called on the churches to immediately undertake the necessary legal steps to prevent the patenting of living beings: 'The patenting of life forms is an attempt by the overprivileged to expand economic predominance and to bring the world economy under their control. Patenting serves only the interests of the ruling elite.' To regard animals purely as objects, exploitable for money, rests on the same 'attitude which is expressed in the enslavement of people, in racism and sexism' (quoted from *Gen-ethischer Informationsdienst,* No. 39, 12/1988: 21ff).

But outside the European Community too, efforts are being made to extend patenting law to living organisms. In Switzerland such a draft law—which incidentally is based on an initiative from Ciba-Geigy—is coming up for parliamentary discussion. Critics have however already announced that they want to prevent it with a national referendum.

III. EUROPEAN COMMUNITY PLANS IN THE FIELD OF HUMAN GENETICS

In the field of human genetics two proposals were recently under discussion within the European Community, one at the level of the Commission and the other within the European Parliament.

1. The Commission proposal 'For a Council Decision Adopting a Specific Research Programme in the Field of Health: Predictive Medicine: Human Genome Analysis', was discussed and adopted with minor amendments by the Parliamentary Committee for Energy, Research and Technology in January 1989, before it has been adopted by Parliament in March 1989. S. 171-12.

2. Two connecting reports from the European Parliamentary Committee for Law and Civil Rights: the first, The Ethical and Legal Problems of Genetic Manipulation', and the second, 'Artificial In Vivo and In Vitro Fertilisation', were discussed and accepted with minor amendments by Parliament in March 1989.

On the relevance of these proposals

As discussed above the reports and decisions of the European Parliament, in general, are not binding and therefore not very relevant. Since the adoption of the Single European Act, however, the Parliament does have the possibility of making amendments to the Commission's drafts. This means that the above three reports are of different degrees of importance. The two reports from the Committee for Law and Civil Rights are, at most, of interest as they may influence the discussion and opinion of the Parliament on the planned research programme of the Commission. The report by the Committee for Energy, Research and Technology, could alter the Commission's proposal, if it were voted for by a qualified majority of the Parliament.

On the content of these proposals:
1. On the proposal for a research program for the analysis of the human genome

As long ago as September 28, 1987, the Council of the European Communities adopted a Community framework program in the field of research and technological development for the year 1987-1991. In addition to 120 million European Currency Units (ECU) for the subsection biotechnologies, (i.e., gene technology in agriculture), 80 million ECU are also earmarked for the subsection 'health,' more exactly, for predictive medicine and novel therapies (1 ECU=approximately 1 US $)[13]:

> The development of predictive medicine and novel therapies will mainly be oriented towards better knowledge of the human genoma, immunity techniques, genetic engineering process aiming at re-pairing DNA defects (e.g., in congenital

> diseases of genetic origin), and development of diagnostic test kits (e.g., for AIDS).

With the research program for analysing the human genome only part of the above mentioned framework programme has been put in concrete form. The programme was to apply for a period of three years, beginning in January 1989 and was to be supported by 15 million ECU.

The program comprises: (a) the improvement of the resolution of the human genetic map (i.e., creation of a map of the human genome, consisting of DNA markers, which would enable researchers to locate genes easily and quickly; (b) the setting up of ordered clone libraries (i.e., of collections of ordered sets of DNA fragments which fully represent the DNA present in the entire genome, selected chromosomes or chromosomal fragments; (c) the improvement of advanced genetic technologies and, through a training program, the spreading of these advanced technologies throughout the Member States. Advanced genetic technologies are[14]:

> New biochemical reagents [. . .], improvement of methods for the detection and localization of genetic markers [. . .], development [. . .] of procedures for the transfection of chromosomes, development of model systems for the reproducible and stable expression of medically important genes.

The justification for this research program is illuminating. First of all it is ascertained that many illnesses widespread today have a genetic component, either in the form of an inherited 'single gene defect,' or in the form of an interaction of 'several genetic defects' with environmental factors, or in the form of anomalies in the number and structure of chromosomes. For example, sickle cell anaemia or certain immune deficiencies are considered single gene defects, and in the European Community Commission paper illnesses such as coronary artery diseases, cancer, stomach ulcers, rtheumatoid arthritis, diabetes, or even serious psychoses are listed as so-called multigene defects. The formulation is very revealing: environmental factors, social factors, etc., disappear totally behind the classification 'multi-gene defects' and therefore simply no longer exist.

'The aim of the program is by predicting risks, early diagnosis, prevention, improvement in prognoses, and finally therapy to contribute to combatting human illnesses based on genetic defects'[15]. Since it is extremely improbable that environmentally caused risk factors can be excluded—so the argument goes—it is important to learn as much as possible about factors of genetic predisposition and thus to be able to identify people or populations at risk. As they put it[16]:

> Most of the currently available tests are based not on identifying the abnormal gene(s) but on detecting the gene product; hence they are limited to some 200 disorders where a gene product or biochemical marker is known, a small number in comparison to the 4,200 known single gene defects [. . .]. Tests which directly detect the genetic lesion in the DNA overcome many of these limitations.

What is attempted here, with the aid of gene-technological procedures, is to expand the spectrum of ascertainable diseases firstly to less serious illnesses and secondly to predispositions and even susceptibilities. The evaluation of what is considered 'ill' or 'healthy,' what is to be classified as 'normal' or 'anomalous,' the evaluation of the degree of gravity of an illness is, however, bound to society's value judgements. An individual's perception of the gravity of an illness is to a considerable degree determined by how society treats it.

The classification 'normal gene'—'genetic defect' presupposes a standardization of the genetic constitution of human beings. The reduction of complex

interactions to one genetic component also leads to individualizing health risks. An individual (or even ethnospecific) genetic predisposition, and no longer the complex interaction of social and environmental factors, is said to be responsible for an illness. In this way individuals or even whole population groups are singled out. Will genetic or even 'gene-ethnic' predisposition be the catchword of the future?

Hopes have been expressed that the research program will lay the foundation for diagnostic applications in the field of 'single gene defects' and chromosome anomalies, for the identification of genes which are connected to an illness and finally for genetic therapy[17]:

> It is hoped that eventually it may be possible to correct a defective gene by inserting normal DNA directly into a cell.

The undaunted confidence in scientific-technical solutions to complex disease processes is the more remarkable given that gene therapy constitutes experimentation on living human beings with little prospect of success. A human being is perceived as a machine consisting of individual parts, whose cells and organs can each be corrected separately.

Throughout the research program the early diagnosis of genetic predispositions and genetic 'defects' and their early treatment is discussed. Such early diagnosis and therapy is only possible through invasive intervention in women's bodies. Obviously this does not pose any problems for the Commission, as not a single thought is wasted on the importance of these interventions for women. Moreover, this 'new type of predictive medicine' hopes

> to protect individuals from the kind of illness to which they are genetically most vulnerable and, where appropriate, to prevent the transmission of the genetic susceptibilities to the next generation.[18]

How, if the occasion arises, the transmission of genetic susceptibilities to subsequent generations is to be prevented is not clarified. Logically, there are only three possibilities: (a) the sterilization of the 'genetically susceptible,' (b) pre-implantation diagnosis, which would presuppose that either all human reproduction occurs via IVF, or that 'naturally conceived' embryos would be flushed out before they implant themselves in the woman's womb; or (c) surgical interventions in the germ cells—'gene therapy' as it is also called.

The Commission rejects the latter, as 'for ethical reasons, there must be a rejection of any possibility of modifying the genetic constitution of the human germ cells'[19]. The two other possibilities remain.

Apparently the Commission has not yet thought about these which, on the one hand, reflects how much gene technology is groping in the dark and, on the other hand, throws light on how little the practitioners and supporters of gene technology have thought about possible and long term implications.

A further role in the argumentation in favour of this project is played by questions about the competitive capabilities of the European Community. It is emphasized that the European Community must have an answer ready to corresponding research projects in the USA ('Mapping and Sequenzing the Human Genome') and in Japan ('Human Frontiers Science Program'), in order to develop, for example, new DNA probes or diagnostic equipment, as until now the European Community has been largely dependent on imports. The potential European market for DNA probes is estimated at 1–2,000 million ECU in the next decade. It is also argued that possibilities should be created for lowering health care costs. As is stated in the proposal[20]:

> Information about human genetic makeup will increase enormously in the course of mapping the human genome; simpler, faster and less costly

> methods of screening for genetic susceptibility to disease will be developed. This will provide the possibility of therapeutic intervention to prevent the manifestation of disease. As genes are identified which are associated with an increased risk of common diseases, such as heart disease, diabetes, and arthritis, population screening will become a possibility. In Western Europe, where there is a steadily ageing population and an associated ever-increasing cost of health care, the prospects both of cheaper testing and earlier intervention making possible a decrease in morbidity are very attractive ones.

More worrying than the sums which are to be invested in genetic research is the assurance with which a consensus on countless premises is presupposed, or things are presented as inalterable 'facts'—the results of scientific objectivity—and thus removed from any influencing control, which belongs in the realm of political, social decisions[21].

With the same apparent objectivity with which 'normal' and 'defective' genes are ascertained, a consensus is presupposed to the effect that it is impossible to undertake decisive alterations in products and production processes which destroy health and the environment. Rather it is argued that the only feasible and promising course consists in correcting apparently defective human genes. In this way both the responsibility and the risk are individualized: the individual is responsible for her/his defective genes and possibly their transmission to subsequent generations. Therefore she/he is also under the obligation—in the interests of a reduction in health care costs—to subject him/herself to the relevant screenings and 'therapies.' In the context of a labour market situation which is becoming tighter along with attempts to reduce costs in health care, it must be assumed that the interest of employers and insurance companies in the use of genetic mass screenings will increase.

It is a political decision to opt for the development of gene-technology rather than, for example, to seek to replace carcinogenic substances by harmless ones, or to replace allergy-inducing cleaning agents by biologically degradable ones, manufactured on a natural basis, or to reduce the injurious poisening of our food, or to undertake research into the effects of radioactive pollution, or to investigate the estimated 100,000 chemicals about whose environmentally destructive and health-endangering potential we know very little.

But according to the European Community Commission's proposal, what remains within the decision-making scope of 'the politicians' is solely the administration of the results of their proposed genetic research, such as the 'growing gap between diagnosis and treatment,' the possible use of data about the genetic constitution of people by employers and insurance companies, or that 'personal privacy must be weighed against general health care considerations'[22].

2. The opinion of the committee for energy, research, and technology on the Program 'Predictive Medicine'

The draft report of this Committee attempts to whittle the European Community program down to basic research into human genetic material and to situate it in a discussion with all social groups concerned. The vague term 'predictive medicine' is to be replaced by 'study of the human genome' as a medically meaningful application is not in prospect. Any previously formulated aim has been eliminated. Biotechnology is not to be more extensively applied, nor is the knowledge obtained to be channeled directly into risk prognosis, prevention, early diagnosis, prognosis, or treatment of hereditary diseases. Instead the draft shifts the discussion on the social effects of such research into the centre. An 'integrated European plan for the socially and ethically minded and responsible study of the human genome' is to be developed. Nonscientific organizations and public welfare associations of all types dealing

with this subject are to participate in elaborating this plan. Furthermore, a study of the history of eugenics and present-day eugenic trends along with proposals on how these trends can be effectively dealt with is to be financed within the framework of this programme.

Unfortunately no alternative was developed on which areas and with which aims medical research should be carried out This offers a typical example of European decision-making. The European Parliament chases after the submissions of the Commission with amendment petitions in the hope of being able to ward off the very worst with compromises. All we can hope for now is that out of ten steps in the wrong direction only nine will be made.

The German Parliament is shocked at the openly eugenic aims of the research program, and the Federal Government has announced that it cannot agree to this program because of serious ethical reservations regarding the eugenic trends contained within it. Because of these objections the Human Genome Program is to be modified. Revisions by the Commission are expected in the near future. It is likely that the openly eugenic formulation of the Program will be masked.

3. On the report on the ethical and legal problems of genetic engineering

As this report at best has an indirect influence on the debate in Parliament about the European Community Commission's research program and possibly the draft Directive concerning the release of genetically manipulated organisms, the differences between the previously discussed approach of the Commission to the research program and this one will be briefly sketched.

While the Commission proceeds with its research program according to the motto: *first* research at any price in order to create 'facts,' *afterwards* let the politicians consider how they can best administer the results of this research. The argument in the Report on Ethical and Legal Problems of Genetic Engineering is based on the standpoint of the politician emphasizing that the legislation must provide the basic conditions within which research can be carried out. To make it clearer and to repeat what we said at the beginning of this article: Members of the European Parliament are interested in obtaining more power with regard to the classical domains of a Parliament: legislation. But legislation at the European Community level (i.e., the formulation and adoption of directives), takes place largely by excluding Parliament, that is through the Commission, (which is also the executive) and the Council of Ministers, (consisting of the representatives of the individual national governments). Therefore at European Community level the usual minimal control through parliamentary democracy does not exist.

In contrast to the Commission's proposal, in which only the 'chances' (and not the risks) of human genetics are discussed, this report is somewhat more critical: the risks are weighed against the chances. For example, it is stated in the report that

> the prospect of a significant improvement in screening and preventive occupational medicine through genome analysis', may be counteracted by the possible pressures exerted by eugenics and preventive medicine, the application of genetic analysis for the purposes of social control and the selective breeding of whole social strata, the selection of embryos and foetuses on the basis of their genetic characteristics alone and the fundamental change in our society which these developments will produce.[23]

At first glance the above abstractly formulated principles on genome analysis in the EP-report seem different from the EC Commission document both in terms of language as well as content. For example, it is emphasized that 'the principle of a patient's right to self-determinationmust have absolute precedence over the economic pressures imposed by health care systems' [. . .]; that the'the establishment of individual gene record and their storage [. . .] must be prohibited'; and that 'the development of

genetic strategies for the solution of social problems is dangerous' . . .[24].

However, what happens to these abstract principles when they are concretized with regard to specific fields of application in human genetics becomes clear in the following examples:

Somatic gene therapy is basically approved, in so far as the scientific foundations for a gene transfer are correspondingly developed and the party concerned is comprehensively informed and her/his consent obtained. The concepts of illness and genetic 'defect' should be examined and a 'clear, legally regulated catalogue of indications' worked out for genetic 'defects' suitable for genetic therapy, in order 'to deal with the danger of defining as a medical disorder or genetic defect conditions which are merely deviations from the genetic norm[525].

In the field of the genome analysis of workers[26], it is demanded on the one hand, that genetic analyses for mass screenings and the selection of workers according to genetic criteria be prohibited. On the other hand, the right of each individual to be informed of previous analyses is emphasized as well as the right to protection of a worker's genetic data from misuse by third parties. Here too then, there is a 'yes' to genome analysis, flanked by the information of the party concerned, by data protection, and a vague drawing of borderlines with regard to genetic mass screenings.

The dubiousness of this position becomes clear. Attempts to prevent an 'overflow' of these technologies and their 'misuse,' without seeing that *any* use automatically implies misuse and that *any* attempt to draw 'clear and legally established borders' is doomed to fail.

The statements concerning diagnosis and therapy are most ambiguous[27]:

> procedures involving live human embryos *in utero* and *in vivo* or foetuses in utero for diagnostic or therapeutic purposes are justified only when their purpose is the welfare of the child concerned.

That prenatal diagnosis and therapy are only possible through an often dangerous surgical invasion of a woman's body is concealed behind the term *'in utero.'* This formulation hides the placing of the well-being of the embryo/foetus above the well-being of women, and that women are the crucial parties concerned.

But all the petitions for amendment which give precedence to the dignity, self-determination, and well-being of women, were rejected by the legal committee.

A newly proposed section was accepted demanding the setting up of an international commission to exercise a sort of democratic control over research programmes, aims, and results in the field of the study of the human genome. This commission is to be composed of members of the European Parliament, of the national Parliaments, and experts, and—this was the success of an initiative of the Greens—delegates from organizations representing the interests of those particularly affected as women, workers, consumers, the disabled, etc.

In all it is not surprising, in view of the vague formulations which offer sufficient scope for the various application of human genetics, that broad consensus was achieved. The representatives of the Commission present also largely agreed with the ethical principles and lines of argument.

No wonder, because ethical principles cost nothing, as long as no financial interests are affected. It is logical that an argument flared up within the Commission at the conclusion of the report as the interests of large firms are affected. The report ends with the demand, 'to prohibit the release of gene-technologically modified organisms, until the Community has issued binding safety regulations and calls on the competent committees to investigate whether in view of the biological residual risk, which is in the long run neither quantifiable nor

qualifiable, a total prohibition should not be pronounced.'[28]

4. On the report on artificial 'in vivo' and 'in vitro' fertilization

It is difficult to take a report which should really be called 'Encyclica on the Protection of the Family' seriously. Embryos and the family should be protected; the complex subject is more or less reduced to such pronouncements. The report emphasizes the dignity of every human being from the moment of conception and the right of the child to life and, in particular, to a family. Here family means the genetic mother and the genetic father. The creation of surplus embryos during in vitro fertilization should be prohibited. Heterologous intracorporal artificial fertilization (AID) and in vitro fertilization using donor sperm also should be prohibited. For Member States that will not recognize this principle, a series of conditions for semen and ova donations are specified.

The report recommends that artificial insemination and in vitro fertilization should be made available only to married couples or to heterosexual couples living together in a stable partnership. The fact that in vitro fertilization represents a risky intervention in the bodies of women, and does not offer much chance of success, does not seem to be understood by the Committee on Law and Civil Rights. The report takes up an unambiguous attitude towards surrogate motherhood. Any form of surrogate motherhood is rejected and the commercial procurement of surrogate mothers should be punished. Such enterprises or agencies should be prohibited.

IN CONCLUSION

Through research and legislation the European Community is preparing the ground for profitable biotechnological developments in Europe. But as the Human Genome Analysis Program illustrates, where profitability is not immediately available ethical arguments can have an impact. This leads us to conclude that the final outcome of how gene technology will be promoted depends upon the awareness and activities of critical forces in the European Community member states.

ENDNOTES

1. The European Community has only had a directly elected Parliament since 1979, with almost the sole task of codeciding on a small part of the European Community budget (the whole agricultural area is excluded).

2. For this, however, the European Parliament needs the support of the Commission or of a minority in the Council.

3. Commission of the European Communities: Proposals for (a) a Council Directive on the Contained use of Genetically Modified Organisms; and (b) a Council Directive on the Deliberate Release to the Environment of Genetically Modified Organisms. Com(88) 160 final-SYN 131, Brussels, 4 May 1988. The two proposals for Directives are each preceded by an explanatory memorandum. Direct quotations from the text of the Directives are indicated by the relevant Articles. Implementing provisions are contained in the relevant annexes.

4. Annexe I (p. 17) explains the criteria for the classification of genetically modified microorganisms of Group 1.

5. They are defined in Annexe I (p. 49) as follows: 'Genetically modified organisms are organisms which can be obtained by such techniques as recombinant DNA, microinjection, macroinjection, microencapsulation, nuclear and organal transplantation, or genetic manipulation of viruses.' The Commission explains (quoted from *Gen-ethischer Informationsdienst* No 32, 5/88:5): 'It does not include deletion, mutagenesis, conjugation, transformation, transduction, and all other processes, which are carried out under normal physical conditions and not by utilizing a genetically modified organism.'

With this reservation, the Commission retreats behind the definition used in the laboratory Directive.

6. This advisory committee is composed of representatives of the Member States and is headed by the representative of the Commission. It advises the Commission also on the implementation and realization of the Directive (Arts 19–20, p. 47).

7. Commission of the European Communities: Proposal for a Council Directive on the Protection of Workers From the Risks Related to Exposure to Biological Agents at Work, COM(88), 165 final-SYN 129, Brussels, 5 April 1988. The classification and manner of quoting corresponds to the above (see Note 3).

8. Annexe 1 gives a somewhat more precise classification only for genetically modified agents of Group 1 which are considered nondangerous; otherwise the text remains vague.

9. Commission of the European Communities: Proposal for a Council Directive on the Legal Protection of Biotechnological Inventions, COM(88) 496 final-SYN 159, Brussels, 17 October 1988.

10. In the USA, by 1986 1,200 patents had been granted for 'products' from 'animate nature'; 15 concerns hold over half these. One third of all patents be long to the five chemical multinationals: Upton, Sandoz, Royal Dutch Shell, Luprizol and ITT.

11. For years the women's movement has been campaigning for a reversal of the burden of proof in discrimination in the labour market. For a long time the Commission evaded drawing up a relevant directive and claimed legal obstacles. Now it has submitted a draft, which however only formally reverses the burden of proof, but de facto the woman must still first produce evidence of discrimination. We are therefore very surprised at the ease with which the Commission overcomes all legal obstacles in different situations!

12. This seems to be just a matter of time. The first patent on an animal was issued in April 1988 by the US Patent and Trademark Office for a genetically modified mouse. The novel breed of mice develop breast cancer and are 'produced' to study how breast cancer develops and to test new drugs and therapies that might be useful for the treatment of cancer in women. There is as yet no draft of this report and there will not probably be one in the foreseeable future.

13. Council Decision of 28 September 1987 on a Framework Programme of the Community in the field of research and technological development (1987–1991). Official Journal of the European Communities, OJ No L, 302, p. 6.

14. Proposal of the Commission of the European Communities for a Council Decision on a specific research programme in the field of health: Predictive Medicine: Human Genome Analysis (1989-1991). 1988. pp. 1 and 22.

15. Proposal of the Commission of the European Communities for a Council Decision on a specific research programme in the field of health: Predictive Medicine: Human Genome Analysis (1989-1991). 1988. pp. 3 and 22.

16. Proposal of the Commission of the European Communities for a Council Decision on a specific research programme in the field of health: Predictive Medicine: Human Genome Analysis (1989–1991). 1988. p. 8.

17. Proposal of the Commission of the European Communities for a Council Decision on a specific research programme in the field of health: Predictive Medicine: Human Genome Analysis (1989–1991). 1988. p. 9.

18. Proposal of the Commission of the European Communities for a Council Decision on a specific research programme in the field of health: Predictive Medicine: Human Genome Analysis (1989–1991). 1988. p. 3.

19. Proposal of the Commission of the European Communities for a Council Decision on a specific research programme in the field of health: Predictive Medicine: Human Genome Analysis (1989–1991). 1988. p. 10.

20. Proposal of the Commission of the European Communities for a Council Decision on a specific research programme in the field of health: Predictive Medicine: Human Genome Analysis (1989–1991). 1988. p. 9.

21. As a comparison: in its previous research programmes in biotechnology in agriculture, the EC has invested considerably more, as here the commercial interests can be immediately realized and they have quite different dimensions. BAP, the Biomolecular Action Programme (1985–1990) has been supported with approximately 55 million ECU by the EC; ECLAIR, the biotechnology-based, agroindustrial research and technological development programme, plans for 1988–1993 a budget of 152 million ECU, of which 80 million ECU will be provided by the EC; BRIDGE, the planned follow-on programme for BAP, is to be subsidized by the EC with 100 million ECU. BRIDGE is of particular interest, as within the framework of this programme research into gene transfers in animal cells is to be undertaken. The fact that the Commission emphasizes that BRIDGE and the research programme on the analysis of the human genome must be carefully coordinated, in order to avoid overlapping, shows yet again how little gene technology in agriculture can be separated from human genetics. The term 'biotechnology' threatens to obscure this connection.

It is also important to mention that the Commission of the European Communities has had a new advisory board on European industry since February 1984: IRDAC (Industrial Research and Development Advisory Committee). Within IRDAC, in which 15 representatives from industry and one trade union representative sit, a working group on biotechnology has been established as a 5th working group. IRDAC's working groups formulate opinions for the Commission which are as a rule used as the basis for the EC's research and development programmes. For example, the proposals of IRDAC'S Working Group 5 on building up a strong European bio-industry are to be found partly in the ECLAIR programme. And it is IRDAC's Working Group 5 that urges the same work protection provisions for working with genetically modified microorganisms to be laid down and for patenting laws to be revised and harmonized.

In IRDAC's Working Group 5 the leading European biotechnology firms are represented: the Danish *NOVO Concern, Unilever, Henkel, Hoechst, ICI, BASF, Shell,* and *Degussa.*

22. Proposal for a Council Decision adopting a specific research programme in the field of health . . . , pp. 9-10.

23. Report on the ethical and legal problems of genetic engineering (Doc. A2-327/88). 1988. p. 6.

24. Report on the ethical and legal problems of genetic engineering (Doc. A2-327/88). 1988. p. 8.

25. Report on the ethical and legal problems of genetic engineering (Doc. A2-327/88). 1988. p. 9.

26. This is the exact wording of the texts; there is just as little talk of *women* workers as there is of *women* politicians, etc; women exist only in the expression *'in utero'*.

27. Report on the ethical and legal problems of genetic engineering (Doc. A2-327/88). p. 10.
Report on the ethical and legal problems of genetic engineering (Doc. A2-327/88). p. 12.