EUROPEAN COMMISSION

Secretariat-General

"Ethics and Biotechnology"

Information dossier on

the **Group of Advisers on Ethical Implications of Biotechnology**

MAY 1994

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EUROPEAN COMMISSION

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PRESS CONFERENCE BY PRESIDENT DELORS AND MRS LENOIR (24 MAY 1994)

PRESS RELEASE - ETHICS AND BIOTECHNOLOGY

Biotechnology is a MAJOR CHALLENGE FOR SOCIETY. The debate is fuelled by excessive fears on the one hand and unrealistic expectations on the other.

Apart from its economic significance (almost 9% of the labour force and gross added value in the European Union), BIOTECHNOLOGY - as a tool for manipulating living organisms - presents a major socio-cultural challenge to Europe.

In medicine, biotechnology is revolutionizing our approach to disease (genetic testing) and its treatment (gene therapy). In agriculture, transgenesis (transgenic animals and plants) could well revolutionize the way we grow crops and breed livestock. And the application of biotechnology to the fight against pollution (using micro-organisms to dissipate oil slicks, for instance) opens up exciting new prospects for the environment.

This is why the recommendations of the WHITE PAPER on growth, competitiveness and employment give pride of place to the development of biotechnology, which is so rich in potential.

The Commission is fully involved in the biotechnology debate. A GROUP OF ADVISERS ON THE ETHICS OF BIOTECHNOLOGY was formed on 20 November 1991. Because it achieved so much during its first two-year term, the Commission decided to expand its role and increase its resources, in the light *inter alia* of the White Paper's recommendations. On 25 February 1994 new appointments were made and the Group now has nine rather than the original six members. Mrs Noëlle Lenoir, a member of the French Constitutional Court and President of UNESCO's International Bioethics Commitee, has been appointed chairperson.

The Group has a high profile. It has plans to step up its contacts with the general public and international organizations. Today's press conference should be seen as a first step in this direction.

Because of its terms of reference, the Group has a unique place in the European Union. It is closely involved, in a consultative capacity, in the elaboration of relevant Community policy but is completely independent. And it is able, at its own initiative, to examine any topic touching on biotechnology.

The Group's activities are consistent with the new approach to European integration introduced by the MAASTRICHT TREATY. It is particularly alive to the concerns of Parliament and the PEOPLE OF EUROPE. Its work is based on the principles of freedom and responsibility set out in the European Convention for the Protection of Human Rights and Fundamental Freedoms, which has been recognized as a source of Community law by the Maastricht Treaty.

Europe cannot be built on purely utilitarian foundations. Integration presupposes an ongoing social dialogue based on ethical and human values which are common to our cultures. The Group's task is to integrate these values into its reflections so that it can advise the Commission on initiatives to be taken in this key area.

PRESS CONFERENCE BY PRESIDENT DELORS AND MRS LENOIR

2.Press review

EUROPEAN COMMISSION

Secretariat General
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PRESS CONFERENCE BY PRESIDENT DELORS AND MRS LENOIR (24 MAY 1994)

PRESS REVIEW

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Ethik der Biothechnologie: EU-Berater legen Bilanz vor =

Brüssel (dpa) - In der Frage der ethischen Auswirkungen der Biotechnologie hat die Beratergruppe der Europäischen Kommission eine erste Bilanz vorgelegt. Wie die Vorsitzende des unabhängigen neunköpfigen Ethik-Komitees, Noelle Lenoir, am Dienstag in Brüssel sagte, gaben die Mitglieder Meinungen zur Verwendung des die Milchproduktion stimulierenden Hormons BST, zu aus menschlichem Blut gewonnenen Produkten und zur Frage der Patente in der Biotechologie ab.

Die Gruppe hielt die Verwendung von BST unter bestimmten Voraussetzungen für annehmbar. Bedingungen sei, daß die Behandlung der "Turbokühe" sofort eingestellt werden müsse, wenn es zu Entzündungen bei den Tieren komme. Das Niveau von Somazellen pro Milliliter in der erzeugten Milch dürfe nicht höher sein als in der mit traditionellen Methoden gewonnenen Milch. Die mit BST produzierte Milch sollte nach Ansicht der Experten für den Verbraucher gekennzeichnet sein.

Blutprodukte sollten laut dem Komitee nicht als normale Ware angesehen werden, und niemand solle zusätzliche Gewinne aus den Produkten machen. Bei der Patentierung von "lebendiger Materie" sieht die Gruppe keine grundsätzlichen ethischen Probleme. Patente von Techniken der menschenlichen Genmanipulation sollten aber verboten werden, wenn sie nicht klar für therapeutische Zwecke bestimmt seien.

Wie EU-Kommissionspräsident Jacques Delors am Dienstag sagte, hat die Europäische Kommission die Empfehlungen angenommen. Die neun Experten beschäftigen sich gegenwärtig mit den Problemen transgenetischer Tiere und der Gentherapie. Die Gruppe wurde 1991 gebildet. Die Zahl ihrer Mitglieder wurde Anfang des Jahres von sechs auf neun erhöht.

Sie besteht steht außer Genetikexperten aus Theologen, Profesoren für Ethik und Philosophie sowie Juristen. Ihre Aufagabe ist es, sich mit den Sorgen der europäischen Bürger und mit den Risiken der Einführung der neuen Techniken auseinanderzusetzen. Die Mitglieder sollen Ethik, Fortschritt und Fragen der Sicherheit gegeneinander abwägen. Delors verwies am Dienstag noch einmal auf die große wirtschaftliche Bedeutung des Sektors. Zehn Prozent der europäischen Industrieproduktion seien von den Auswirkungen betroffen.
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Bioethics group to examine prenatal tests, gene therapy
BRUSSELS, May 24 (Reuter) - A group advising the European Commission on ethical questions related to biotechnology will examine issues including test-tube babies and genetically engineered animals, the group's new chairwoman said on Monday.

Noelle Lenoir, a member of the French Constitutional Council, said the group would also debate gene therapy -- an experimental technique that involves inserting healthy genes into a body's cells to replace defective ones to cure diseases.

The nine-member group, which includes professors and scientists from across the EU, was created by the Commission in 1991 and is just beginning a second two-year term.

Lenoir said one of its priorities would be "prenatal diagnosis", including ethical questions related to the creation of embryos in a laboratory to implant into a woman's womb -- for example, whether parents should be allowed to select embryos by sex.

Some European countries permit such a selection to prevent the transmission of inherited diseases such as haemophilia, which is passed on only to males, she said.

Lenoir said the issue of genetically engineered, or "transgenic", animals involved the basic "relationship between man and animal".

She noted that the genetic make-up of pigs was being altered to help human beings -- for example, to create organs that can be transplanted into humans.

"Do we envisage the animal species in a completely utilitarian way or do we have another vision?", she said.

Lenoir said the group wanted to study gene therapy because the EU's European Medicines Agency would have to decide whether to authorise biotechnology products related to the procedure.

Commission President Jacques Delors said he had proposed the group be created as a way to get advice on sometimes uninformed and emotional debates about biotechnology.

"We who are in the middle of all the lobbies need to see things clearly," he said.
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EUROPE/ SCIENCES/ SOCIETE/ TECHNOLOGIES/ SANTE/ ENVIRONNEMENT
La Commission s'inquiète de l'éthique dans les nlles biotechnologies
BRUXELLES 24/05 (BELGA) = La Commission européenne, inquiète de des problèmes éthiques inhérents au développement foudroyant de la biotechnologie, a renforcé les effectifs du groupe de conseillers

pour l'éthique en matière de biotechnologie, qui est passé de 6 à 9 membres. Leur programme de travail touchera à l'avenir des questions aussi sensibles que la thérapie génique, le diagnostic prénatal et les animaux transgéniques, a indiqué mardi à Bruxelles la présidente du groupe, Mme Noëlle Lenoir, par ailleurs présidente du Comité International de Bioéthique de l'UNESCO.

Le nouveau groupe de conseillers, issus des secteurs scientifique, juridique, philosophique, théologique et politique, se réunira pour la première fois officiellement le 16 juin prochain à Bruxelles. Parmi eux figure notamment le Pr Gilbert Hottois, professeur de philosophie du Centre de Recherches Interdisciplinaires de l'Université libre de Bruxelles (ULB)

"La science va plus vite que l'homme et les problèmes (bioéthiques) renvoient à des questions de société à l'égard desquelles il faut avoir une attitude d'honnêteté", a notamment souligné la présidente du groupe, qui dressait devant la presse le bilan de deux ans et demi d'activités.

"Nous ne sommes pas un tribunal de la morale ou de l'inquisition, mais nous sommes là pour faire le point", a-t-elle ajouté.

Les conseillers devraient notamment approfondir la réflexion sur les problèmes de diffusion de la thérapie génique, une nouvelle technologie fort couteuse consistant à corriger une altération génétique (comme le cancer) par voie d'injection, a souligné Mme Lenoir.

Par ailleurs, le diagnostic prénatal et préimplantatoire, qui permet de sélectionner, en cas de fécondation in vitro, les embryons selon leur sexe est jugé défendable pour raisons médicales, notamment dans le cas de familles d'hémophiles, une maladie qui se transmet par les femmes et ne touche que les hommes, a souligné Mme Lenoir.

Les conseillers en bioéthique de la Commission devraient aussi étudié les problèmes posés par les animaux transgéniques, dont l'identité génétique a été modifiée, notamment pour servir de cobaye ou pour améliorer la qualité de la viande. Mme Lenoir a notamment cité le cas de porcs auxquels ont injecte des gènes humains pour en prélever ensuite les foies et s'en servir comme greffon pour des transplantations sur des êtres humains.

L'idée de la création d'un tel groupe est née à la suite de l'explosion de la centrale nucléaire de Tchernobyl. Une discussion vraiment scientifique sur les conséquences de la catastrophe s'est avérée impossible, chacun se contentant d'expliquer que ses produits étaient "sûrs", a expliqué le président de la Commission européenne, Jacques Delors. D'où la mise sur pied de ce groupe en novembre 1991.

Depuis lors, le groupe a notamment préconisé une limitation de l'emploi de la somatotropine bovine (BST), une hormone galactogène (accroissant la production de lait), au profit de la santé du consommateur et du bien-être des animaux. Il s'est aussi exprimé en faveur de l'interdiction de brevetabilité du corps ou d'éléments du corps humain.

Selon Jacques Delors, la Commission a repris dans les trois cas précités le point de vue exprimé par les experts.

"Tout le monde parle de biotechnologie, mais on vend beaucoup de contrevérités à cet égard", a encore souligné M. Delors, justifiant ainsi la nécessité, pour la Commission, d'un avis autorisé lui permettant de mieux informer le public et le monde politique.

"L'opinion publique doit être bien consciente des risques réels de la biotechnologie. C'est de cette manière que l'on pourra éviter un rejet infondé" des nouvelles possibilités qu'offre la science, a-t-il encore dit./. LVE (CET)

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UE-BIOETICA

COMISION EUROPEA ABRE DEBATE SOBRE ETICA Y BIOTECNOLOGIA EN UE

Bruselas, 24 may (EFE).- El presidente de la Comisión Europea, Jacques Delors expresó hoy, martes, la preocupación ética que tienen las instituciones europeas por la aplicación de la biotecnología dentro de la Unión Europea (UE) y el desafío socio-cultural que representa para sus ciudadanos.

El grupo de consejeros de la Comisión para la ética de la biotecnología, presidido por la francesa Noelle Lenoir, dio a conocer hoy los resultados provisionales de su análisis sobre las implicaciones éticas del uso de sustancias y técnicas sobre seres vivos para mejorar la producción agrícola o pesquera, o la terapia médica en humanos.

Este comité de expertos de carácter consultivo se formó en noviembre de 1991, a instancias del mismo Delors, tras el accidente nuclear de Chernobil, y a él pertenecen personalidades independientes del mundo de la ciencia, el derecho y la teología, entre otros campos, de toda la UE.

En una intervención ante la prensa, Jacques Delors insistió en que el desarrollo de la biotecnología ofrece un potencial considerable, que va más allá de su peso económico en la UE, donde representa el 9 por ciento de la mano de obra y del valor añadido bruto.

El desarrollo de este sector y sus implicaciones éticas también aparece en el Libro Blanco sobre la competitividad, el crecimiento y el empleo, en el que Delors subraya que es necesario aclarar las cuestiones morales unidas a ciertas aplicaciones de la biotecnología, en especial las relacionadas con la investigación biomédica.

Lenoir, que preside también el Comité de Bioética de la UNESCO, señaló que este grupo "es independiente y desde luego no somos ni un tribunal de la inquisición ni uno moral. Nos limitamos

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a informar a la Comisión de lo que hay, y sabemos que no tenemos ninguna legitimidad política".

Entre sus primeras conclusiones, el grupo de expertos se inclina, "en un plano ético", por la utilización de la hormona BST, siempre que se respeten la seguridad y la sanidad de los consumidores, el bienestar de los animales y se preserve la biodiversidad.

La BST, o somatotropina bovina, es una proteína hormonal hipofisiaria que estimula el crecimiento óseo y el anabolismo proteico, y también aumenta la producción de leche en los bovinos entre un diez y un veinte por ciento.

También han sometido a análisis la directiva sobre los productos farmacéuticos derivados de la sangre y del plasma sanguíneo (1988), que suscitó vivas críticas en Francia tras los casos de transfusiones de sangre contaminada por el virus que causa el síndrome de inmunodeficiencia adquirida (SIDA).

La presidenta del Comité señaló que en el futuro inmediato estudiarán cuestiones relacionadas con la terapia génica, los diagnósticos prenatales y de preimplantación de embriones, así como los animales transgénicos.

A los trabajos de este grupo han contribuido el jurista Marcelino Oreja, antes de su nombramiento como comisario europeo de Transportes, y el presidente del Comité Director de la Bioética (CDBI) del Consejo de Europa, Octavi Quintana Trias. EFE

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ue: bioetica, per delors centro dibattito su scelta societa'

(ansa) - bruxelles, 24 mag - circondato da gruppi di pressione, il legislatore europeo ha bisogno di un aiuto esterno indipendente per ''vederci chiaro'' soprattutto quando si tratta di dare una valutazione etica alle attivita' che scaturiscono dalla biotecnologia, ossia dall'applicazione dell' ingegneria genetica all'industria.

cosi', il presidente della commissione europea jacques delors ha presentato oggi a bruxelles il gruppo di consiglieri indipendenti che da due anni contribuisce con i suoi suggerimenti a sciogliere dubbi e a rispondere alle preoccupazioni etiche delle istituzioni europee. sono filosofi, giuristi, scienziati, medici, teologi, ai quali e' chiesto di individuare i problemi etici sollevati dalla biotecnologia, valutare gli aspetti etici dell'attivita' comunitaria e studiare l'impatto potenziale che queste attivita' possono avere sulla societa' e sugli individui.

un ruolo che secondo delors va rafforzato in quanto ritiene che la bioetica sia, nell'europa dei dodici, ''al cuore del

dibattito sulla scelta di societa'''. per il presidente della commissione bisogna ''lottare contro le false notizie'' e ''andare oltre la dimensione economica della biotecnologia'' che rappresenta ormai il nove per cento del prodotto interno lordo dell'unione. (segue).

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(ansa) - bruxelles, 24 mag - il gruppo di consiglieri, che ha un potere consultivo, si e' gia' pronunciato su problemi delicati: dai brevetti, per dare protezione giuridica alle invenzioni biotecnologiche, ai principii etici da rispettare per i prodotti derivati dal sangue o dal plasma umano e per un eventuale utilizzo della somatotropina bovina, l'ormone frutto della biotecnologia che e' ancora vietato nei dodici e che provoca l'aumento fino al 20 per cento della produzione di latte nelle vacche.

problematiche altrettanto delicate sono attualmente all'esame del gruppo di consiglieri. il gruppo sta ad esempio valutando quali principii etici vadano rispettati nella diagnosi prenatale, compreso l'impianto del feto nell'embrione, per evitare discriminazioni sul sesso del nascituro o sul diritto alla vita dei portatori di handicap. o ancora, quali sono i limiti invalicabili della terapia genetica, quando intervenendo sui geni per combattere una malattia si rischia di trasmettere la mutazione genetica alle altre generazioni.

il gruppo che ha un potere consultivo e' rinnovato ogni due anni. per l'italia e' presente attualmente stefano rodota', professore ordinario di diritto civile dell'universita' di roma e membro del comitato etico del consiglio nazionale delle ricerche. (ansa).

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(EU) UE/ETHIQUE: LE PRESIDENT DELORS ET MME LENOIR ONT PRESENTE LE PREMIER BILAN ET LES NOUVEAUX OBJECTIFS DU "GROUPE DE CONSEILLERS POUR L'ETHIQUE DE LA BIOTECHNOLOGIE"

Bruxelles, 24/05/1994 (Agence Europe) - Le président de la Commission européenne Jacques Delors et le nouveau président du "groupe de conseillers pour l'éthique de la biotechnologie" ont présenté ce mardi à la presse un premier bilan de l'activité de ce groupe ainsi que ses nouveaux objectifs. M.Delors a souligné les orientations générales et les raisons qui ont amené la Commission à créer cet organisme; Mme Lenoir a fourni des indications sur les travaux en cours ou envisagés.

Le groupe examine des questions qui sont au coeur de la destinée humaine et prendront de plus en plus d'importance à l'avenir, a déclaré M.Delors. Ni la Commission, ni le Parlement européen, ni le Conseil ne peuvent trouver dans leurs connaissances les éléments suffisants pour trancher certains problèmes fondamentaux; et pourtant, ils sont obligés à prendre des décisions. C'est pourquoi ils demandent l'avis de personnes particulièrement compétentes et totalement indépendantes, qui ne reçoivent aucune instruction; la Commission finance leurs travaux, et c'est tout. Chaque jour, ceux qui ont la responsabilité de décider se trouvent confrontés à des problèmes éthiques résultant des nouvelles sciences qui peuvent modifier la matière vivante: pour l'alimentation, l'environnement, la lutte contre les grandes maladies, etc. Ce qui préoccupe particulièrement M.Delors face à ces grands problèmes, c'est que "n'importe qui peut raconter n'importe quoi", ou par goût du sensationnel ou au service d'un lobby; il est absolument indispensable que les décideurs disposent d'éléments qui leur permettent de décider et d'informer objectivement l'opinion publique, en dehors des pressions des lobbies et d'une certaine presse.

Mme Lenoir a insisté sur le caractère libre et indépendant des travaux du groupe, qui peut entreprendre l'étude d'un problème aussi bien de son initiative qu'à la demande de la Commission. Un premier bilan est possible après le premier mandat de deux ans. Le groupe a exprimé trois avis, qui ont été entièrement suivis par la Commission. Par le premier, il a estimé qu'il n'était pas opportun d'introduire sur le marché la BST (hormone qui développe la production de lait chez les vaches); par le second, il a justifié entièrement la directive communautaire sur les produits dérivés du sang; par le troisième, il a soutenu fermement le projet de directive communautaire sur les brevets pour les produits issus de la biotechnologie, en estimant que le vide juridique est la pire solution. Ces trois avis ont impliqué l'examen de questions fondamentales telles que les relations de l'homme avec les autres êtres vivants; en même temps, le groupe a tenu compte des aspects économiques, de la concurrence internationale en matière de biotechnologie (surtout de la part des Etats-Unis et du Japon) et en général de l'équilibre à respecter entre les risques et les avantages.

Le groupe va franchir à présent une nouvelle étape. Grâce aux moyens accrus dont il disposera, il pourra notamment:

- s'ouvrir vers l'extérieur, dans le sens que ses interlocuteurs ne seront plus seulement les instances de la Commission mais aussi le Parlement européen, le Comité économique et social, les associations (dont certaines représentant les malades poussent en faveur d'une exploitation rapide des connaissances nouvelles, d'autres représentant les écologistes poussent dans le sens opposé);
- aborder aussi des "sujets d'anticipation" comme la médecine génétique, les "individus à risque", les plants transgéniques, etc.

La Commission a demandé au groupe d'étudier la question du "diagnostic prénatal" (qui permettrait aussi la manipulation de l'embryon). Le groupe examine en outre deux autres sujets: la thérapie génétique (modifications de l'être vivant pour éliminer les maladies héréditaires); les animaux transgéniques. En outre, il maintient à son ordre du jour la question des brevets sur les produits issus de la biotechnologie, qui, à son avis, reste d'actualité aussi longtemps que la Communauté n'a pas pris de décision (le projet est toujours devant le Conseil, après de très vifs débats au sein du Parlement européen).

Le groupe est actuellement présidé par Mme Lenoir, membre du Conseil constitutionnel français, et comprend huit membres: dr Anne Mc Laren (GB); dr Margaretta Mikkelsen (DK); prof. Luis Jorge Peixeto Archer (P); prof.Gilbert Hottois (B); prof.Dietmar Mieth (Al), M.Octavi Quintana Trias (Es); prof. Stefano Rodotà (It); prof.Egbert Schroten (PB).

BIOETHICS AND THE EUROPEAN UNION

BIOETHICS AND THE EUROPEAN UNION

3.a. Extracts from European Commission White Paper on "Growth, Competitiveness, Employment"

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EXTRACTS FROM THE EUROPEAN COMMISSION WHITE PAPER ON "GROWTH, COMPETITIVENESS AND EMPLOYMENT" (Dec. 1993)

B — Biotechnology and its diffusion

5.5. As a result of intensive scientific research and major discoveries over the past four decades in molecular biology, biotechnology has emerged as one of the most promising and crucial technologies for sustainable development in the next century. Modern biotechnology constitutes a growing range of techniques, procedures and processes, such as cell fusion, r-DNA technology, biocatalysis, that can substitute and complement classical biotechnologies of selective breeding and fermentation. This confluence of classical and modern technologies **enables the creation of new products and highly competitive processes in a large number of industrial and agricultural activities** as well as in the health sector. This would provide the impulse to radically transform the competitiveness and growth potential for a number of activities and open up new possibilities in other sectors such as diagnostics, bioremediation and production of process equipment (biohardware). In terms of the quality of life, we should not underrate the important **potential of biotechnology for improving the environment** by correcting pollution and for improving health by preventing or remedying illness or other physical problems.

The Community has taken a number of initiatives, on the one hand, to promote the competitiveness of bio-industries and, on the other hand, to ensure the safe application of biotechnology. It implies mainly funding of research and development and the putting into place of a regulatory framework.

5.6. Potential of biotechnology and similarities with information technologies

Reinforcing the potential of biotechnology are a number of features which biotechnology shares with electronics and information technologies: it is science-based, the scientific input being the most crucial element of the technology trajectory; the gap between developments in basic science and their research and development applications and even further downstream is small and diminishing; a very major and growing

stimulus can be expected for process equipment, instrument and engineering sectors; and finally **the impacts of the processes, techniques and hardware represented by biotechnology are across a number of sectors.**

The Community is highly competitive in these sectors which cover chemicals, pharmaceuticals, health care, agriculture and agricultural processing, bulk and specialized plant protection products as well as decontamination, waste treatment and disposal. These sectors where biotechnology has a direct impact currently account for 9% of the Community's gross value-added (approximately ECU 450 billion) and 8% of its employment (approximately 9 million). Beyond this, perhaps only modern biotechnology has the potential to provide significant and viable thrusts, compatible with CAP reform and not dependent on operating subsidies, to new energy/fuel and industrial outlets for agricultural raw materials. The important role of biotechnology in these sectors is likely to be to maintain employment by stimulating its productivity as well as to create highly skilled labour demand.

The following are two valid indicators of the potential of biotechnology: the pace of international innovative activity and the evidence of growth in output and value-added in products derived through biotechnology. Measuring innovative activity by patents filed for relevant products in the USA, the Community and Japan show that patents filed have increased from 1 100 per annum in the early 1980s to 3 350 per annum in 1990. In 1980 the Community was in a leading position, by 1990 the USA was filing 50% more patents than the Community. European Patent Office (EPO) statistics reveal a similar evolution: between 1980 and 1991 biotechnology patents filed with the EPO increased by a factor of 10, the most being filed by US-based companies.

Current global indicators of the growth prospects of the biotechnology industry are the following: in the USA the industry based on modern biotechnology had a turnover of over USD 8 billion in 1992, a growth rate of 28% with employment growing at 13%. It is estimated on the basis of the observed rates of diffusion of biotechnology that the US biotechnology industry's revenues will grow at an average rate of 40% to reach USD 52 billion by the year 2000. The current industry size in Japan is officially put at USD 3.8 billion and is estimated by the Ministry of International Trade and Industry to reach USD 35 billion by the end of the century. In the Community, despite the emergence of a significant number of firms and a substantial growth in markets, primarily of bio-pharmaceuticals, to over USD 3 billion, at the current rate of growth, the value of output and employment is about the same as that in Japan. It is therefore clear that by the year 2000 with an estimated world market of ECU 100 billion for the biotechnology industry, the Community growth rate will have to be substantially higher than at present to ensure that the Community will become a major producer of such products, thereby reaping the output and employment advantages while at the same time remaining a key player in the related research area.

5.7. Factors favouring growth, competitiveness and employment in the Community

The sectors with the greatest potential for the applications of biotechnology are amongst the most vigorous and competitive sectors in the Community with a long record of sustained growth, productivity increase, and highly competitive trade performance.

The Community firms in these sectors (chemicals, pharmaceuticals, agricultural processing) are leading firms at a global level with important capabilities in the domain of innovation.

Among other factors favouring investment in biotechnology in the Community are the strong science base and infrastructure, the availability of skilled labour, and the high quality of process engineering and production facilities.

5.8. Unfavourable factors

The key factors that may jeopardize a significant expansion of biotechnological applications in the Community are the following:

(i) In a domain where the technology trajectory is crucially dependent on basic science, the **public research and development expenditure in the Community lags behind.** For the 1993 financial year publicly financed US biotechnology research and development expenditures are set to exceed USD 4 billion; in Japan in 1991 they exceeded USD 900 million whereas the Community's and Member States' expenditures totalled around USD 600 million. The fourth research and development framework programme's proposes ECU 650 million in biotechnology over five years. Member States have also programmes devoted to R&D in biotechnology.

(ii) **Privately financed research and development on biotechnology in the Community has not compensated for the shortfall in public funding;** on the contrary, available indicators identify a delocalization — an investment outflow, largely net, from Community companies mainly towards the USA and Japan of USD 2.2 billion since 1984. In the most vigorous sector of biotechnology, biopharmaceuticals, in 1990 67% of patents were held by US-based companies and only 15% by Community-based companies. There exists the risk that the Community will be a leading future market for biopharmaceuticals but not a leading future producer. There is an evident feedback between technology diffusion and private investment.

(iii) Régulation concerning the safety of applications of the new biotechnology is necessary to ensure harmonization, safety, and public acceptance. However, the current horizontal approach is unfavourably perceived by scientists and industry as introducing constraints on basic and applied research and its diffusion and hence having unfavourable effects on EC competitiveness.

(iv) Technology hostility and social inertia in respect of biotechnology have been more pronounced in the Community in general than in the USA or Japan. It has become clear that these issues should be examined in greater detail in order to properly address these concerns. Supporting actions such as those under the Biotech programme and the creation of a group of advisers to look at ethical issues have been undertaken.

5.9. Conclusions and recommendations

The potential of biotechnology to dramatically impact on competitiveness is greatest in certain sectors of the Community chemicals, pharmaceuticals, process equipments and appliances, agriculture and agricultural processing. These sectors contribute importantly to value-added and employment. The observed international growth in output of between 30 and 40% in the most vigorous of the biotechnology dependent sectors and the associated labour-intensive service activities (e.g. research, health care) has the capacity to provide a valuable stimulus to employment growth.

The means to achieve a fuller realization of the Community's inherent strength in biotechnology are to be found in overcoming existing constraints by creating appropriate channels for biotechnology policy development and coordination and by acting on the following **recommendations.**

(a) Given the importance of regulations for a stable and predictable environment for industry and given that they influence localization factors such as field trials and scientific experimentation, the Community should be open to **review its regulatory framework** with a view to ensuring that advances in scientific knowledge are constantly taken into account and that regulatory oversight is based on potential risks. A greater recourse, where appropriate, to mutual recognition, is warranted to stimulate research activities across Member States. Furthermore, if the Community is to avoid becoming simply a market rather than a producer of biotechnology-derived products then it is vital that Community regulations are harmonized with international practice. The development of standards will supplement regulatory efforts.

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(b) The Commission intends to make full use of the possibilities which exist in the present regulatory framework on flexibility and **simplification of procedures** as well as for technical adaptation. To sustain a high level of environmental protection and to underpin public acceptance, it is important to **reinforce and pool the scientific support for regulations.** An advisory scientific body at Community level for biotechnology diffusion drawing on the scientific expertise within and at the disposal of the existing committees at national and Community level. An advisory body at Community level — scientific committee for biotechnology diffusion — could play a crucial role in intensifying scientific collaboration and in providing the needed support for a harmonized approach of the development of risk assessments underlying product approval. This body could also advise on the development of a further Community strategy for biotechnology.

(c) Since the Community is not matching efforts elsewhere in research and development expenditure, it needs to compensate for this through **focusing on the most vigorous biotechnology research and development domains and increased coordination** between the Community and Member States in order to avoid duplication, encourage collaborative research and improve efficiency of expenditure on research and development.

(d) The small and medium-sized research-oriented firms play an important role in biotechnology diffusion and the growth of this sector would substantially benefit from the creation of a **network of existing and new biotechnology science parks** in the Community linking together academic institutions, research laboratories and SMEs. This would create the possibilities for, on the one hand, greater educational investment in molecular biology and biohardware, and, on the other hand, the involvement of venture capital and other financial institutions. The Structural Funds could also play an important role.

(e) Member States should provide additional incentives to **improve further the investment climate for biotechnology** and to facilitate the transfer of applied research and development to the market place. These might include fiscal incentives respecting the existing Community guidelines that have a bearing on biotechnology innovation and investment.

(f) The commercialization of biotechnology will in certain areas require specific actions aimed at **further enhancing public understanding of the technology.** Member States should encourage interest groups to make objective information available and to encourage dia logue.

(g) It is necessary **to clarify further value laden issues in relation to some applications of biotechnology.** In view of this, the Commission will reinforce the role of the Group of Advisers on Ethical Implications of Biotechnology and other groups which examine in particular ethical questions related to biomedical research.

BIOETHICS AND THE EUROPEAN UNION

3.b. Communication "The Biotechnology and the White Paper" (June 1994)

BIOTECHNOLOGY AND THE WHITE PAPER ON GROWTH, COMPETITIVENESS AND EMPLOYMENT

PREPARING THE NEXT STAGE

Communication from the Commission to the Council, the European Parliament and the Economic and Social Committee

CONTENTS

INTRODUCTION

An innovative tool

The White Paper on Growth, Competitiveness and Employment acknowledged modern biotechnology as one of the fields offering the greatest potential for innovation and growth. Its application could be of particular benefit in areas such as healthcare, industrial chemicals, food and feeds, agriculture and environmental clean-up services. Moreover, the further development of biotechnology will require increasing investment in supplies, services and hardware. This would have a correspondingly positive effect on the employment situation.

A Community role

The European Community has been becoming increasingly involved in biotechnology since the mid-1970s. By funding research and developing a regulatory framework, it has sought to promote the competitiveness of bio-industries, whilst also ensuring the safety of man and the environment.
The Commission recognised, in its 1991 initiative, that biotechnology is a key technology for the future competitive development of the Community. As such, it will determine the extent to which Community industries remain world leaders in the development of innovatory products. Although the main responsibility for competitiveness rests with the firms themselves, the Commission also took the view that public authorities could help to stimulate competitiveness by adopting a consistent and supportive approach in relevant areas. This would entail the provision of financial support for basic and applied research and related infrastructure; the drawing up of a coherent regulatory framework, based on a number of defined principles (including protection of intellectual property); a renewed emphasis on education and training; the stimulation of technology transfer; and the facilitation of public understanding and consumer choice. A package of priority measures was subsequently approved.

A new impetus

The White Paper confirmed the outstanding promise of biotechnology in terms of growth, competitiveness and employment.

Taking account of the content and state of implementation of the 1991 package, it gave new impetus to achieving a fuller realisation of the Community's inherent strength in biotechnology and to overcoming existing constraints. Reinforcing conditions at both the R&D and marketing stages of biotechnology would increase its potential for employment creation. By taking a number of specific steps, Europe's competitiveness in this field will be further enhanced.

The present communication represents the Commission's response to the White Paper's recommendations, and its structure has been designed so as to follow the order in which these recommendations were listed. It is based on the premise that the White Paper's goals in relation to biotechnology can be achieved only through close cooperation between operators, users, Community Institutions, Member State authorities and interest groups. The Commission recognises the important interest of the European Parliament in developments in biotechnology and is ready to establish the necessary dialogue on biotechnological issues, in particular with the Parliament. It will also seek, as in the past, to organise round-table discussions.

REGULATORY FRAMEWORK

Introduction

Biotechnology involves the use of modern genetic engineering, which will affect many different products and processes. The Community's regulatory framework for biotechnology was designed, in the late 1980s, in order to provide the necessary legislation to ensure adequate protection of health and the environment, while at the same time creating the internal market for biotechnological products. It is based on a number of principles, adopted in 1991[1], which still retain their validity (see Annex 1 for details).

The Community is putting into place both "horizontal" and product legislation containing a specific environmental risk assessment of products containing or consisting of GMOs. (An overview of the state of play regarding current legislative activities is attached at Annex 1.)

This framework has been built upon the knowledge available at that time, when there was still considerable uncertainty as to safety and the risks involved in the application of modern biotechnology. The Community adopted legislation aiming at a broadly preventative approach as regards the use of modern biotechnology.

The White Paper concluded that the Community should be open to reviewing its biotechnology regulatory framework, in order that the full potential of modern biotechnology for jobs, investment and growth can be realised.

Following this commitment, the Commission, in consultation with Member State authorities, undertook such a review. Its objective was to ensure that the safety requirements and administrative procedures are appropriate to the risks for human health and the environment and reflect acquired experience, advances in scientific knowledge and established international practices. It also took account of the existing regulatory frameworks on modern biotechnology used by its main competitors, in particular the United States.

The way ahead

In carrying out the review, the Commission paid special attention to the wider range of knowledge and experience currently available, which has increased understanding of the risks associated with genetic modifications and increased confidence among scientists in the safety of genetic engineering.

Much use has now been made of the technology in research laboratories and industrial facilities worldwide. From this knowledge and experience, it may be concluded that the risks involved in the contained use of GMMs are substantially less than were once foreseen. For example, the potential for horizontal gene transfer resulting in novel and harmful properties being acquired by microorganisms has not

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been shown to present hazards to human health and the environment. There is a growing confidence that the GMMs used in research and in industrial production can be more precisely categorised, so that they are unable to survive except in the special environment of the experiment or process in which they are used. Experience has shown that the majority of genetic modifications in contained facilities can be done safely by applying good laboratory practice.

Worldwide, there have now been many deliberate releases of GMOs, mainly with a number of well-known crop plants. This has led to an improved understanding of the behaviour of these plants and their safety in respect of human health and the environment. So far, such releases have not given cause for concern, and evidence is accumulating to the effect that genetically modified plants do not differ from non-modified plants other than in the specific character conferred by the introduced gene.

As part of its broader reflections, the Commission acknowledged that the biotechnological regulatory framework is a factor impacting on industrial competitiveness, which confirms the need for balanced and proportionate regulatory requirements commensurate with the identified risks.

It also noted the results of surveys indicating the important role that the regulatory framework has to play in building public confidence in biotechnology. This shows the need for a predictable and adaptable regulatory system.

Taking these elements into account, the Commission confirms its earlier view that, in the future, the whole network of interrelated biotechnological regulations needs to ensure that oversight is always appropriate in relation to the risks involved, the building of public confidence and to the competitive development of the industries involved, while guaranteeing the protection of human health and the environment. On this basis, the Commission is of the opinion that the following two-track approach for the future development of the biotechnological regulatory framework should be applied:

- the exploitation of existing possibilities for revising measures/procedures/degree of oversight/requirements, through use of the "light" procedure of adaptation to technical progress (regulatory Committee procedure). (internal amendment)

- the bringing forward of amendments to existing legislation in order to incorporate changes which cannot be achieved by technical adaptation while leaving the basic structure of the framework intact (external amendment)

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The Commission examined the application of the two-track approach in greater detail for specific parts of the regulatory framework, considering each such part on its particular merits. It came to the conclusions outlined below.

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Directive 90/219/EEC on the contained use of genetically-modified microorganisms

The review indicated that extensive use was made during the late 1970s and the 1980s of genetically-modified microorganisms in laboratories and industrial fermenters, from which substantial experience was gained. This experience, together with the recommendations made by the OECD, forms the scientific basis of the Directive.
The Commission identified, on the basis of the substantially increased understanding of the risks associated with the use of GMMs in contained circumstances, as mentioned above, the following objectives for further action:

i) streamlining and easing of the administrative/notification/ consent requirements where this does not compromise safety;

ii) ensuring that the classification of the genetically modified micro-organisms and of the activities in which they are used are appropriate to the risks involved;

iii) ensuring that the conditions of use are appropriate to the risks involved;

iv) extension of the flexibility of the Directive so it can be more easily adapted to technical progress by regulatory Committee procedures.

In line with these objectives, this will mean that it will continue to make full use of the inherent flexibility of the Directive (regulatory Committee procedure), i.e. by:

- preparing a Decision redefining the risk categories of GMMs through the revision of Annex II;

- revising the guidelines for classification as established under Article 4.2 of the Directive as a result of the discussion undertaken for amending the criteria of Annex II (see above);

- further exploiting the possibilities to adapt safety assessment parameters, containment measures and required information for technical progress.

The increased knowledge and experience mentioned above also gives a clearer indication of the present administrative (notification) consent requirements necessary to ensure safety for the different risk categories of GMMs.

Taking into account the most up to date information, it may be concluded that the existing administrative arrangements may be lightened for activities presenting low risk to human health and the environment, without jeopardising existing safety standards. This would also allow a greater focusing of attention on higher risk

possibilities. However, as the Directive does not provide for such adaptations, a number of specific amendments must be introduced, as follows:

- replacing the consent requirements by record-keeping, or notification for information purposes, for certain low-risk activities;

- replacing the explicit consent requirements by implicit consent for certain higher-risk activities;

- reduction of time periods involved in implicit/explicit consent procedures;
- adapting the present risk classification system for GMMs, in accordance with new safety considerations.

- removal of the differentiation between activities in research laboratories and production plants.

The Commission will propose the possibility of adapting the definitions contained within the scope of the Directive via a Committee procedure, as is, for example, at present foreseen in the case of pharmaceutical legislation.

The Commission will conduct the necessary broad consultations with operators, users, Member State authorities and interest groups in order to propose amendments before the European Council to be held in Essen by the end of 1994.

Directive 90/220/EEC on the deliberate release of genetically modified organisms to the environment

The Commission has made a number of technical adaptations to the Directive to reflect the evidence acquired from the wide number of GMO releases in the plant area, which were shown not to pose any specific risks. These measures seek to improve uniform application, streamline and simplify the procedures and reduce the obligations on the notifiers while maintaining the appropriate protection of health and the environment. These activities are the following :

- A Commission Decision revising the notification information requirements of Annex II of the Directive, reducing them significantly for releases of plants (95% of releases) (April 94).

- A Commission Decision revising the Summary Notification Information format reducing the information required for plants (April 94).

- A Commission Decision establishing criteria for introducing simplified procedures under Article 6.5 (Oct. 93) for genetically modified plants.

- Preparation of a Commission Decision introducing specific simplified procedures for releases of plants (to be adopted by June/July 94).

The Commission concluded, on the basis of the progress made in adapting aspects of the Directive, that it is flexible enough to satisfy current needs for adaptation to technical progress and simplification of procedures. In the short term, it will fully exploit the existing possibilities in this area.

Biotechnology is a fast-moving and continually evolving technology, and the Commission recognises that there are aspects of the Directive that might be improved. It is not, however, possible at present to detail the precise nature of these improvements, as further experience is necessary in order to determine the right balance between the need for safety, public reassurance and the minimum restraint on industry and research work.

Hence, on the basis of future experience and scientific knowledge, the Commission will carry out a further review of the Directive during the first half of 1995. This review will assess the need for proposals in relation to:

- extending the flexibility of Directive 90/220/EEC, so that its scope and the procedures to be followed are always appropriate to the risks involved, and are easily adaptable;

- strengthening more uniform decision-taking between Member States in the case of research and development releases;

- introducing further opportunities for notifiers (industry and researchers), so that they can benefit more from the existence of a uniform Community system;

- facilitating the link between this Directive and product legislation.

Other legislation

The Commission has noted that, to date, one specific piece of product legislation, namely for medicinal products of biotechnology, is in force. As from 1 January 1995, this will be replaced by a centralised procedure which will result in a Community-wide marketing authorisation. This new piece of legislation is the result of a streamlining of existing marketing authorisation procedures so that patients can benefit from new innovative medicinal products simultaneously in all Member States, while at the same time safeguarding maximum standards of public health.

In respect of other product-based regulations which contain or will contain an environmental risk assessment similar to that in Directive 90/220/EEC, one other such piece of legislation (namely, additives in feeding stuffs) has been adopted - which will enter into effect as from 1 October 1994 - and a further two (on novel foods and seeds) are under discussion before the other institutions. The rapid adoption by the Council of this legislation, as an essential part of the overall framework, is seen as a matter of urgency. The Commission will continue to make efforts to arrive at this and to ensure its proper implementation, by drawing upon experience and knowledge already available.

It will, as a matter of urgency, make a proposal for an amendment to Council Directive 91/414/EEC on the placing of plant protection products on the market in order to complete the environmental risk assessment, already provided for in the Directive, with the technical complements which are necessary to cover adequately plant protection products containing or consisting of GMMs. A fast track procedure for certain low risk plant protection products, including biological plant protection products, whether derived from GMMs or not, will also be proposed.

In relation to the legislation to protect workers from the risks related to exposure to biological agents at work, the Commission will press Member States for a more rapid transposition.

The review again demonstrated the need for adequate patent protection for inventions, as an important condition for attracting investments in biotechnology. The Commission re-emphasises therefore that Community legislation, which has been under discussion since 1988 and 1990 respectively, in the area of intellectual property (patents for biotechnology inventions and plant variety rights) should be adopted as a matter of urgency. By doing so, an important gap in the regulatory framework will be closed.

The same applies to the draft modification of the seed marketing directives aiming at integrating the environmental risk assessment in the established variety acceptance procedure.

The Commission will seize opportunities - as is foreseen, at the end of 1997, for example, in the legislation for medicinal products - as regards further simplification and/or streamlining of procedures of the biotechnology regulatory framework as part of its general policy in this area as stated in the White Paper. An ongoing review of the biotechnological regulatory framework shall be carried out as new scientific knowledge and the emerging regulatory practice of major international competitors indicates that this is necessary or desirable.

STRENGTHENING OF SCIENTIFIC ADVICE

The White Paper recognised the importance of scientific advice available to the Commission, which is particularly relevant in the field of biotechnology with applications in a broad range of areas. At present, it is therefore assessing whether there is a need for reinforced scientific input to regulations, for example, in view of an appropriate implementation of product legislation containing a specific environmental risk assessment for products consisting of or derived from GMOs. This assessment will also take account of the work of existing advisory scientific committees at Community level and that carried out by a number of national advisory Committees on biosafety or genetic modification providing advice at national level. A meeting will be organised between the Commission and the chairpersons of these scientific committees to share experiences and to identify whether there are further needs in the area. A European Science and Technology Assembly is being set up to assist the Commission in the conception and implementation of all Community research and technological development policies, including those relating to biotechnology. This will further strengthen the links between the Commission and the research world.

RESEARCH AND DEVELOPMENT

One of the greatest resources for the European biotechnology industry is ready access to a well-established science base and a highly-skilled workforce. A recent survey of some 400 new biotechnology companies indicated that, generally speaking, they have grown up around areas of academic excellence. This vital resource of innovation and skills, much of it funded by governments, is also readily available to Europe's large pharmaceutical and chemical companies, either via strategic partnerships or directly-funded research. Experience, however, has shown that, despite this, Member States need to give greater recognition to the importance of the science base for biotechnology, as has been done elsewhere. Furthermore, increased coordination is needed between and within Member States' research programmes to minimise wasteful duplication and to maximise collaboration, with the aim of improving the efficiency of R&D expenditure.

Community initiatives

To these ends, the Commission has recently proposed considerably expanded research programmes activity within the area of Life Sciences and Technologies: biotechnology (552 MECU), biomedecine and health (336 MECU) and agriculture and fisheries (684 MECU) under the Fourth Framework Programme. This total proposed expenditure of 1572 MECU signifies an increase in budget of 741 MECU in comparison to the relevant programmes as included in the third Framework Programme.
The Commission realises that the European Union as a whole is not matching research and development expenditure made elsewhere. However, it is compensating for this by focusing on the most vigorous R&D areas and on increasing coordination between the Member States' and the Community's research programmes.

To improve these aspects, the three Specific Programmes in the Life Sciences and Technologies area propose three mechanisms:

- Areas offering the highest potential returns on R&D in the short to medium term will receive special priority for funding (concentrated financial support). This will often involve a multi-disciplinary and integrated approach.

- Areas which are strategically important, but where limited financial support is available, will be supported by the establishment of networks aimed at coordinating and building upon Member States' research programmes.

- Areas which are essential to the exploitation of the life sciences, but which may require special attention in respect of other factors such as socio-economic or ethical issues, will be addressed by horizontal activities. These will involve the key players and users in dialogue aimed at socially acceptable solutions and a well-informed public.

By the rapid adoption of the three specific programmes and through the implementation of the above mentioned mechanisms, the Commission expects to achieve a fuller realisation of the Community's inherent potential in biotechnology R&D.

BIOTECHNOLOGY AND SMES

As shown by previous major technological advances, small and medium sized enterprises play a vital role in the early stages of technological innovation and diffusion. This sector is growing, and a number of important firms have been established. In terms of numerical importance, SMEs specialising in modern biotechnology are located in the UK, France, the Netherlands, Denmark and Germany, and focus primarily on the therapeutic and diagnostic fields of research and production.

Community support

A recognition of the important role of small and medium sized enterprises has led many Member States to encourage the development of the SME sector. Building on this, the White Paper has set out guidelines for an integrated programme, whose focus is on three major themes: improving access to finance and credit facilities, support for cooperation between firms and support for improvements in management quality.

These objectives respond in large measure to the needs of the small and medium sized biotechnology enterprises. Like other SMEs, these firms face difficulties in accessing private sector sources of funds, whether from financial intermediaries, equity market or venture capital. Small and medium sized biotechnology firms have a particular need for industrial and financial partners when starting up.

Other specific characteristics of biotechnology SMEs are the need for and availability of high-tech scientific input and the need to overcome hurdles quickly in bringing inventions and innovations onto the market. In view of this, the Fourth Framework R&D Programme opens up opportunities:

- for facilitating the participation of SMEs, irrespective of their RTD capability, in Community R&D programmes, via the implementation of a special procedure based on the experience of CRAFT activities;

- for encouraging the establishment of industrial platforms. These consist of groups of European companies associated with specific projects under the Community research programmes, with preferential access to their results;

- for demonstrations. The application of the innovative results of research in the life sciences area will be addressed through well targeted and pre-competitive demonstration activities. This will enhance the attractiveness of new biotechnology applications;

- for helping SMEs to find suitable partners to carry forward innovative applications of biotechnology and to establish trans-national networks for technology transfer.

Science parks

The characteristics that biotechnology SMEs share with other science-based SMEs underlie the emergence of science parks at the combined initiative of the SMEs themselves and universities, in collaboration with local and regional authorities. Up to one-third of biotechnology SMEs in the Community are located in science parks. With the steady entry of new biotechnology firms, some 59 of the 250 science parks in the Community now contain an important biotechnology component.

Science parks facilitate the process of technology innovation and diffusion and offer a number of advantages for SMEs. For example, they provide easy and close access to science facilities, which enables the SME to have a "window on the technology" and to be informed on the most up-to-date developments. The costs involved in seeking venture or investment capital partners are considerably reduced for firms and investors alike; sourcing of intermediates and laboratory materials is facilitated; and labour mobility can be encouraged between academic work and research applications.
This evident trend of growth, in the Community, of science parks with a biotechnology component, mirrors a development already witnessed in the USA in the past decade, where, by 1992, there were 81 dedicated biotechnology centres, with some 730 firms, specialising primarily in applied research.

Under the Programme for Innovation and Technology Transfer, SPRINT 1989/93 (Council decision 89/286/EEC), modest Community funding was envisaged to support feasibility studies and expert assistance in creating science parks that serve a market need and that are able to attract firms. Presently the Commission is, following the recommendations of the Communication on Cohesion and RTD Policy , undertaking a study to evaluate the need to create networks, the type of network most conducive to the optimal functioning of science parks and collaboration between Technology Parks within the European Union. This would allow a fuller exploitation of opportunities for increased cooperation between firms operating on the internal market, and hence would contribute to realising the objectives of the integrated programme for SMEs.

THE INVESTMENT CLIMATE

The importance of the investment climate to the transfer of applied research and product development to the commercialisation stage is fully recognised. In general, the allocative mechanism in market economies is efficient in shifting investment flows and factors towards sectors experiencing, or likely to experience, high growth, as with certain areas of application of biotechnology.

While, in a number of products derived from modern biotechnology, market-driven growth is evident, there are others of major long-term potential such as bioremediation products and new ranges of biosensors, where growth is variable or modest. The result is that medicinal products of biotechnology is the target domain of over 60% of the current modern biotechnology firms, while bioremediation product development occupies less than 5% of the existing firms. Investment incentives in particular by Member States, within the existing Community framework, to improve the investment climate in these areas are recommended. This would cover support for R&D activities, or the start-up or expansion of business activities, together with the establishment of sound technological clusters and a business-friendly tax climate. In doing so, Member States would strengthen Europe's competitiveness in high-value added future growth markets. For its part, the Community will, through the implementation of a newly-proposed specific programme on the diffusion and exploitation of R&D results (involving expenditure of 293 MECUs), help to overcome barriers preventing the conversion of scientific achievements into commercial successes.

PUBLIC UNDERSTANDING

The introduction of any new technology, whether in the past or at present, has raised critical reactions from the general public. This is especially true of biotechnology, as it raises value-laden issues. Surveys indicate that understanding of biotechnology varies widely within the Community, as does the perception of the risks and benefits of different applications.
The Commission has helped to bring about a number of initiatives to raise public awareness, although it recognises that other public and private bodies have primary responsibility in this area. The focus for the Community's activities has been the Life Sciences and Technologies Research Programmes. The following actions will be reinforced:

- analytical work concerning public attitudes, including the Eurobarometer surveys. This is necessary in order to understand the scale of the problem and the factors which lie behind it. Such work will guide future awareness activities to be undertaken by the Commission, Member State governments and other interested parties from the public and private sectors.

- raising awareness among the main players. Building upon the experience of analytical work, increased information will be provided in a balanced and impartial way to raise awareness in industries where the commercial potential of the emerging technology may not be well understood; in the public sector, including government institutions, where policies and strategies are developed; among the media communicating biotechnology to the public; among scientists increasing public understanding of science; and public interest groups and educators.

- raising awareness and providing information to the general public. A European Initiative in Biotechnology Education has been launched and will be reinforced to provide teaching materials and expertise to school teachers throughout the European Union. Other specialised materials will be prepared and workshops, conferences and meetings will be held to encourage dialogue and to aid openness.

The Commission recognises that modern biotechnology comprises many varying applications. In view of this, it is important that all parties concerned develop reliable information on all aspects of these applications, especially as regards their potential benefits and risks. This involves illustrating innovative advantages as well as addressing issues such as safety, ethics and environmental protection. It would, however, like to stress that, ultimately, it is the market place which decides the successful commercialisation of individual biotechnological applications.

ETHICS

General

Developments in biotechnology may raise questions of an ethical nature in certain areas. There is concern about tampering with nature and life, and the White Paper stressed the need to ensure that these questions are addressed and identified properly. In response to this, the Commission has reinforced the profile of the Group of Advisers on the Ethical Implications of Biotechnology, thereby building on the results achieved during the first two year term of the Group.

This group, established in 1991, is concerned with:

- the identification and definition of ethical issues raised by biotechnology;
- the appraisal of the ethical aspects of Community activities in the field of biotechnology, and their potential impact on society and the individual;

- and advising the Commission as regards the ethical aspects of biotechnology, with a view to improving public understanding.

So far, the group has given three opinions on the ethical implications of the use of performance enhancers in agriculture and fisheries, of medical products derived from human blood and plasma, and of legal protection of biotechnological inventions. These opinions have greatly assisted the Commission in formulating its policy in these areas.

The Group's mandate has been renewed recently to increase the number of advisers, and hence to make available a broader range of advice. It consists of independent leading experts from several different branches of science. It is the Group's intention to step up its contacts with the general public and international organisations. At the same time, it has also intensified its work programme and its Secretariat has been reinforced. At present, opinions are under preparation on the ethical aspects related to transgenic animals, gene-therapy and pre-natal diagnosis, all of which will be finalised before the end of this year. Because of its terms of reference, the Group has a unique place in the European Union. It is closely involved, in a consultative capacity, in the elaboration of relevant Community policy, but is completely independent. It is also able, at its own initiative, to examine any topic touching on biotechnology.

Several activities such as workshops and seminars on legal and ethical aspects related to biotechnological and biomedical research including their application in the agricultural sector are proposed under the Fourth Framework Programme. These activities are related to more general issues concerning biotechnology (patents, biodiversity, animal models) and the application of classical rules of medical ethics (informed consent, confidentiality, ethical review of research protocols) to new fields of biomedecine like brain research, gene therapy and neurotransplantation.

Biomedical ethics

In the past, the Commission has taken a number of initiatives to clarify ethical issues in relation to biomedical and health research. For example, the human embryo and research (HER) working group has monitored the legal and practical aspects of research on human embryos in the Member States and identified sectors where a consensus could be reached. Two reports, on embryos before and after implantation, have been published, and the state of legislation on embryo research was reviewed. Protection of embryos and specific issues like pre-implantation diagnosis will be the next tasks of this working group.

Moreover, the ESLA (Ethical, Social and Legal Aspects) working group under the human genome analysis research programme, has encouraged public discussion and made recommendations to the Commission on the legal or other initiatives to be taken in this field.

Research in all areas of biomedical ethics has been initiated under the first Biomedical and Health research programme, and the Commission has proposed to continue this under the new second specific Biomedical and Health research programme. To this end, it intends to organise working groups to prepare reports and surveys for the European Parliament and Council of Ministers on relevant biomedical ethical issues. Targeted workshops are to be held to identify and debate issues requiring clarification and debate at an international level.

International

An increasing number of international organisations have undertaken initiatives to clarify the ethical issues related to the different kind of applications of biotechnology. In this respect the Commission attaches importance to the work of the Council of Europe towards the preparation of a Convention on Bioethics. The Commission is preparing a Communication to the Council on its participation in this Convention.

CONCLUSIONS

The Commission considers that the application of modern biotechnology will have a major impact on the development of a wide range of sectors. Whilst naturally committed to guaranteeing maximum standards of safety for man and the environment, it is of the opinion that, by taking a number of specific steps, as a follow-up to the White Paper's recommendations, it will encourage the competitiveness of Europe's bioindustries. It counts upon the other Institutions, Member States and interest groups to give force to these measures. The Commission recognises the important interest of the European Parliament in developments in biotechnology and is ready to establish the necessary dialogue on biotechnological issues, in particular with the Parliament. It will also seek, as in the past, to organise round-table discussions.

Taking account of the considerations outlined above, it has decided upon the following:

- to implement a two-track approach as regards the future development of the biotechnological regulatory framework i.e. to exploit fully, where they exist, the inherent possibilities to adapt to technical progress (via regulatory Committee procedure). At the same time, it will bring forward amendments in order to incorporate changes which cannot be achieved by technical adaptation while leaving the basic structure of the framework intact. In line with this approach it will, as regards :

  . directive 90/219/EEC on the contained use of GMMs, continue to review Annexes II to V and conduct the necessary broad consultations with operators, users, Member State authorities and interest groups, in order to propose amendments in the indicated areas before the European Council at Essen so that the wide ranging available knowledge and experience is incorporated in that directive. By doing so, its functioning will be improved without jeopardising existing safety standards.

  . directive 90/220/EEC on the deliberate release of GMOs, make full use of the possibilities to adapt to progress and in particular to simplify procedures. On the basis of ongoing

experience and scientific and technological developments, in the first half of 1995 an evaluation will take place following the objectives set out, whereby an assessment will be made of the need for bringing forward amendments.

. other parts of the regulatory framework, continue to press for a rapid adoption of the intellectual property protection legislation as well as of product legislation containing an environmental risk assessment similar to that of directive 90/220/EEC. It will ensure adequate implementation of such legislation by preparing guidelines drawing upon already available expertise. The Commission, for its part, will, as a matter of urgency, make a proposal for an amendment to Council Directive 91/414/EEC, in order to complete the environmental risk assessment of plant protection products derived from or consisting of genetically modified microorganisms. A fast track procedure for certain low risk plant protection products, including biological plant protection products, whether derived from GMMs or not, will be proposed.

The rapid transposition of the workers' protection legislation by the Member States is a matter of urgency.

. An ongoing review of the biotechnological regulatory framework shall be carried out as new scientific knowledge and the emerging regulatory practice of major international competitors indicates that this is necessary or desirable.

- to identify and remedy the needs for strengthening scientific advice at its disposal.

- to enhance the rapid adoption of, in particular, the proposed specific programmes for biotechnology, biomedecine, health and agriculture and fisheries within the Life Sciences and Technologies area. The concentrated financial support for areas offering the highest potential returns on R&D and the establishment of networks to build upon Member States' research programmes are guarantees of further developing Europe's inherent strength in the area;

- to facilitate the development of small biotechnology firms, given their inherent advantages for developing new ideas and products. The Fourth Framework R&D Programme opens up opportunities for facilitating the participation of SMEs and for helping them to carry forward innovative applications of biotechnology, both within and outside science parks. Currently, the Commission is evaluating the need to create networks, and the type of networks most conducive to the optimal functioning of science parks. The continued development of a favourable investment climate, following existing Community guidelines, is also essential;

- to facilitate public understanding of biotechnology through the reinforcement of a number of outlined initiatives;

- to reinforce the profile of the Group of Advisers on the Ethical Implications of Biotechnology in order to clarify further value-laden issues related to biotechnology. Biomedical ethical issues will be similarly identified and debated.

STATE OF PLAY OF THE BIOTECHNOLOGICAL REGULATORY FRAMEWORK

The Community's regulatory framework is composed of both "horizontal" and product legislation (medicinal products, additives used in animal nutrition, plant protection products, novel foods, seeds). Legislation on intellectual property protection also forms part of this framework, which is founded upon the following underlying principles:

- Necessity: the Commission will propose legislation in this area only if it is shown to be necessary by a thorough examination, on a case-by-case basis, of the characteristics inherent in specific biotechnological applications.

- Efficient interaction: biotechnologically-derived products will be subject to only one authorisation and assessment procedure before being placed on the market.

- Evaluation criteria: product evaluation will take place in accordance with the three established criteria of safety, quality and efficacy. The Commission will normally follow scientific advice. In exceptional cases, however, it reserves the right to take a different view in the light of its general obligation to take into account other Community policies and objectives.

- Adaptation to progress: the regulatory framework will be kept up to date with scientific and technical progress. This is of particular importance in a rapidly developing field such as biotechnology.

- Standards: the development and existence of standards may be used to complement legislation, particularly on technical details of good practice and safety procedures.

- International obligations: the Commission will ensure that all decisions in the field of biotechnology will be in conformity with international obligations, in particular with the provisions resulting from the Uruguay Round negotiations.

The state of play regarding relevant legislation is as follows:

A. LEGISLATION ALREADY ADOPTED

- "Horizontal" legislation

Council Directive 90/219/EEC of 23 April 1990[2] which covers any contained use of genetically-modified microorganisms (GMMs), both for research and commercial purposes;

Council Directive 90/220/EEC of 23 April 1990[3] on experimental and marketing-related aspects of genetically-modified organisms (GMOs),

2) OJ No L 117, 8.5.1990, p. 1
3) OJ No L 117, 8.5.1990, p. 15

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which covers any R&D release of these organisms into the environment and contains a specific environmental risk assessment for the placing of any product containing or consisting of such organisms onto the market;

Council Directives 90/679/EEC of 31 December 1990[4] and 93/88/EEC of 29 October 1993[5], which provide a minimum requirement designed to guarantee a better standard of safety and health as regards the protection of workers from the risks of exposure to biological agents.

Member States have transposed or are at the final stages of transposing Directives 90/219/EEC and 90/220/EEC, and competent authorities have been appointed in all Member States. Legislation has yet to be adopted in Greece and Luxembourg, and has nearly been completed in Spain. In Ireland, the specific regulations putting into effect the framework enabling legislation have still to be adopted. Over 250 research and development releases have been notified under Directive 90/220/EEC to the Commission and have taken place, the vast majority of which concerned plants. These releases were in Belgium (60), Denmark (11), Germany (10), Spain (8), France (78), Italy (18), the Netherlands (32), Portugal (4) and the United Kingdom (35).

Three products have so far been cleared under the 90/220/EEC system.

As regards Directives 90/679/EEC and 93/88/EEC, the transposition has yet to be widely realised.

- Product legislation

In respect of the other main part of the regulatory framework, namely, specific product legislation, the situation is as follows:

Council Directive 93/114/EC, amending Directive 70/524/EEC on additives in feeding stuffs. This amendment introduced new categories of additives, including, among others, additives containing or consisting of GMOs into the existing legislation: the amendment will enter into effect as of 1 October 1994[6];

Council Directive 93/41/EEC, repealing Directive 87/22/EEC on the the approximation of national measures relating to the placing on the market of high-technology medicinal products, particularly those derived from biotechnology: the legislation will enter into effect as of 1 January 1995[7]. Under the 1987 procedure about 50 medicinal products of biotechnology have been approved ;

Proposal for a Directive to amend Directive 91/414/EEC[8] on the placing on the market of plant protection products: this Directive provides for a specific procedure for evaluating the environmental risk of GMM plant protection products to be included in the Directive. The Commission is preparing a Proposal to that end.
The Commission has proposed to the Council to extend, for the lifetime of the milk quotas, the present moratorium on the placing on the market

4) OJ No L 374, 31.12.1990, p. 1
5) OJ No L 268, 29.10.1993, p. 71
6) OJ No L 334, 31.12.1993, p. 24
7) OJ No L 214, 24.8.1993, p. 40
8) OJ No L 230, 19.8.1991, p. 1

and administration of bovine somatotropin (BST). The Council has adopted a Decision extending the moratorium for one year, to allow time for a detailed examination of all of the available information on BST[9].

B. PROPOSALS NOT YET ADOPTED

Proposal for a Council Regulation concerning novel foods and novel foods ingredients[10];

Proposal to modify existing seed marketing directives, and in particular Directives 70/457/EEC and 70/458/EEC on the acceptance of varieties[11];

Draft Council Directive on Legal Protection of Biotechnological Inventions[12];

Draft Council Regulation on Community Plant Variety Rights[13].

9) OJ No L 332, 31.12.93, p. 72
10) COM (92) 295 and COM (93) 631 Final
11) COM (93) 598
12) OJ No C 10, 13.1.1989, p.3 and COM(92) 589 final
13) COM(90) 347 and COM(93) 104

4. Commission Communication on Competitivity for Industry in Biotechnology - Extracts

EUROPEAN COMMISSION

Secretariat General
SG/C/1

COMMISSION COMMUNICATION "PROMOTING THE COMPETITIVE ENVIRONMENT FOR THE INDUSTRIAL ACTIVITIES BASED ON BIOTECHNOLOGY WITHIN THE COMMUNITY"

SEC (91) 629 final

D. ETHICS AND OTHER ISSUES

Biotechnology, through its wide ranging implications for food, health and the environment, and through the new knowledge and technologies it offers, will have considerable positive impacts on our way of life. It also offers specific new possibilities for information and interventions affecting human life, and raising or reinforcing basic ethical issues. For both these general and ethical reasons, it attracts considerable public interest and debate, some of it confused. This is important for industry as such confusion can adversely influence the whole climate for industrial development of biotechnology.

The questions arising in public debate belong to distinct categories and debate will continue to be ill-defined (and for public policy purposes, ineffectual) so long as a clear differentiation is not made between these issues:

(i) **ethical considerations** relating to human life and identity, which may arise (for example) in medical practice and counselling, or in research on human embryos and the human genome;

(ii) **other value-laden issues** which may be raised by biotechnology, including:

- **animal welfare issues** concerning, inter alia, novel methods to enhance the productivity of agricultural animals and the development of new animals by biotechnological methods for medical research, agricultural or other purposes;

- issues relating to the **limits of intellectual property rights** (patents, plant breeders' rights) and concerning a mixture of economic and ethical aspects - eg. patenting human beings might be universally rejected, patenting of modified microorganisms widely accepted.

(iii) **environmental** issues about the potential impacts of release of living genetically modified organisms into the environment. There is a Community framework for the protection of the environment and it is important that this is implemented. Issues relating to protection of health, safety and the environment are to be satisfied.

(iv) **health and safety** related issues, either concerning worker safety vis-a-vis biological agents, or consumer and public safety issues such as are addressed by applying the usual criteria of quality, safety and efficacy to products of biotechnology;

(v) issues related to transparency and information to allow for well-informed **consumer choice**.

(vi) issues relating to the **socio-economic impact** (eg. on production and employment) of new biotechnology-aided methods of production in agriculture.

It is essential that a clear distinction be made between ethical questions, related mainly to the first and partly to the second of the above categories and other issues raised by the applications of biotechnology. All of these concerns are important and both national and Community policy makers must ensure that legislative and other measures (agricultural, environmental, consumer protection, research, product safety, protection of human rights) respond to the concerns expressed. The Commission is aware that its responsibilities in this area extend beyond the borders of the Community.

On bio-ethical issues, the Community has been seriously involved in the succession of international conferences, from the first at Hakone, Japan, in 1985 to that held in Rome in 1988 (on ethical issues in human genome sequencing) and that hosted by the Commission in 1989 on environmental ethics. Reference has been made to ethical elements of research programmes in biotechnology and human genome analysis (and to the latter's working group on ethical, social and legal aspects); similarly the future programme of environmental research will include ethical aspects of environmental policy and management.

The Commission organised in 1988, in conjunction with the German Ministry of Research and Technology, the first "European Bioethics Conference" on human embryos in modern medical and biological research. During the conference, the scientific and technical aspects relating to this issue were presented and discussed by biologists, physicians, sociologists, philosophers and theologians, as well as legal experts and legislative authorities. A common position was reached on basic considerations: rejection of commercial exploitation; protection of genetic information; and establishment of multidisciplinary ethical committees.

Following a meeting of Ministers of Research at Kronberg in March 19990, the Commission has now established a working group on human embryos and research, which held its first meeting in Brussels in March 1991. In this field it is seen as particularly important to maintain close contact with the substantial and continuing work of the Council of Europe (as it has already done, for example, in the field of animal welfare conventions).

Regarding the other, less directly ethical, issues listed above, the Commission has been and remains actively involved. Some are treated elsewhere at appropriate points in this communication.

The Commission will continue to carry out social, economic and technological assessment studies to accompany its policy initiatives and research programmes in biotechnology, as it has done for many years through programmes such as FAST (Forecasting and Assessment in Science and Technology), and through the work of the European Foundation for the improvement of Living and Working Conditions (who have accorded to biotechnology the highest priority in their work on social assessment of technology).

Through these and other initiatives, in conjunction with the concertation action of the BRIDGE programme, the Commission is developing an approach to stimulate the formation and growth of small companies in biotechnology.

E. ETHICS

The Commission realizes that it is not possible to find general solutions for ethical issues which can be applied as a universal rule and that ethical issues need to be identified on a case by case basis. Recent debate has focussed on ethical and other aspects of human genome analysis, of human embryo research, of environmental research, of animal welfare, and of intellectual property law.

It is desirable that the Community have an advisory structure on ethics and biotechnology which is capable of dealing with ethical issues where they arise in the course of Community activities. Such a structure should permit dialogue to take place where ethical issues which Member States or other interested parties consider require resolution could be openly discussed. It would also enable recognised experts from relevant groups to participate in guiding the legislative process. The Commission considers that this would be a positive step towards increasing acceptance of biotechnology and towards ensuring the achievement of the single market for its products.

The Commission is profiting from, and collaborating with, the important work of the Council of Europe in this area.

The Commission considers that through addressing explicitly the ethical challenges, it is helping to improve the climate of public understanding and opinion concerning the responsible development of biotechnology; hence facilitating the acceptance of its benefits, and ensuring a single market for its products.

5. European Commission activities

EUROPEAN COMMISSION

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ACTIVITIES OF THE EUROPEAN COMMISSION IN THE FIELD OF BIOETHICS

In recent years the European Commission has taken a number of steps to gauge more accurately the impact of biotechnology on society. The main steps have been to set up groups of experts, reorganize internal structures and introduce the ethical aspect into research programmes financed by the Commission. The European Medicines Evaluation Agency, which will be operational from 1 January 1995, will also base itself on certain ethical principles laid down at European level.

1. Groups of experts

1.1 Group of Advisers on the Ethics of Biotechnology (SG)

The Group of Advisers was set up in November 1991 following the Commission's communication entitled "Promoting the competitive environment for industrial activities based on biotechnology within the Community".

The Group's terms of reference are as follows:

- to identify and define ethical issues raised by biotechnology;
- to appraise the ethical aspects of Community activities in the field of biotechnology and their potential impact on society and the individual;
- to advise the Commission in its legislative role as regards the ethical aspects of biotechnology with a view to improving public understanding and acceptance of it.

The Group of Advisers issued three opinions during its first term (1991-93). The first was on BST (bovine somatotropin), the second on the legal protection of biotechnological inventions and the third on products derived from human blood or human plasma. The Group is currently looking at the ethical implications of gene therapy, the use of transgenic animals and prenatal diagnosis.

1.2 HER Working Party (Human Embryos and Research)

In response to a recommendation made at the meeting of Ministers in Kronberg in March 1990, the Council and the Commission set up the HER Working Party, whose objectives are to:

- monitor, analyse and discuss legislation and current practice relating to research on embryos in the Member States;

- determine common ground and scope for cooperation between national ethical bodies or committees and for the development of a common code.

The HER Working Party has produced two reports:

First Report:	The Embryo before Implantation, 1992
Second Report:	The Embryo after Implantation, 1994.

1.3 The ESLA Working Party (Ethical, Social and Legal Aspect of Human Genome Analysis)

In June 1990 the Council adopted the "Human Genome Analysis Programme" and allocated 7% of the programme's budget for the study of ethical, social and legal implications. The ESLA Working Party was set up within the programme for the purpose of:

- analysing the ethical, social and legal aspects of human genome analysis;

- encouraging public discussion;

- making recommendations to the Commission on the legal or other initiatives to be taken in this field.

The ESLA Working Party's First Report was dated 31 December 1991; the second will be finalized at the end of 1994.

1.4 Advisory Committee on the protection of animals used for experimental and other scientific purposes

This Committee was set up by Commission Decision of 9 February 1990 in connection with the implementation of Directive 86/609/EEC on the approximation of Member States' legislation on the protection of animals used for experimental and other scientific purposes.

Its purpose is to help the Commission organize the exchange of relevant information and to assist it in matters raised by application of the directive.

1.5 Scientific Veterinary Committee (DG VI)

This Committee was set up by Commission Decision of 30 July 1981. It provides the Commission with information on all scientific and technical issues concerning the health and protection of animals and veterinary measures affecting public health.

1.6 Committee for Proprietary Medicinal Products and Committee for Veterinary Medicinal Products

These two committees were set up in 1981 to centralize requests for authorization to market proprietary medicinal products and veterinary medicinal products. They issue an opinion on each application submitted to them. These two committees are incorporated in the European Medicines Evaluation Agency (see Section 4).

2. Internal structures and orgnaization

2.1 The Bioethics Unit, DG XII

In 1992 the Commission set up a unit (XII.E.5) concerned with the legal and ethical aspects of the life sciences, which acts as the interface between research activities undertaken by the EC in this field and all the legal and ethical implications of other Community and national policies. Its brief is to study matters relating to the patentability of living matter, the human genome, the confidentiality of medical data in general and genetic data in particular, with special reference to employers and insurance companies, and all other questions relating to the protection of individual rights in applications of biology and medicine, animal welfare, the ecological implications of biotechnology, biodiversity, food legislation and consumer protection in agro-industrial technology.

Unit E.5 will be organizing workshops, the first covering sperm donations, genetic screening and euthanasia.

2.2 Coordinating Committee on Biotechnology, SG

This interdepartmental committee, set up in February 1991, is made up of high-level officials from Directorates-General concerned with biotechnology. Its role is to coordinate Commission action in this field, its main tasks being to:

- examine measures taken by Commission departments;
- check that new operations are consistent with Community policy;
- resolve the problems of overlapping responsibilities between Commission departments;
- coordinate the Commission position in international forums;
- organize round table discussions with special interest groups and Commission departments;
- evaluate the results of Community policy on biotechnology.

3. Research programmes (DG XII)

The ethics debate raises questions and identifies new situations to which responses cannot be found without specific research into the ethical issues themselves.

The research programmes financed by DG XII which have ethical aspects are listed below. Some of them may be amended under the fourth programme. This programme, which has been proposed by the Commission, is currently being discussed by Parliament.

3.1 Biomedicine and health

Budget: ECU 131.67 million
Ref.: Council Decision: OJ L 267, 24.9.1991

Objectives

The objectives are to improve the effectiveness of medical and health research, in particular by better coordination of Member States' research activities and pooling of resources to achieve better application of results. Research in bioethics is also included in this programme.

Structure

The programme covers four areas:

1. development of coordinated research on prevention, care and health systems;
2. study of major health problems and diseases of great socio-economic impact;
3. human genome analysis;
4. research on biomedical ethics.

The studies selected in this latter field are listed at Annex 2.

NB Under the human genome analysis programme (1990-92) 18 international research projects into the ethical, social and legal aspects of this programme were selected by the ESLA Working Party for Commission support. These are short (one year) projects covering genetic counselling, prenatal screening, patentability of the human genome, etc. (See the full list at Annex 1).

3.2 Biotechnology (1992-94)

Budget: 162.36 million
Ref.: Council Decision: OJ C 174, 16.7.1990

Objective

This programme concerns new priorities to enhance basic biological knowledge for applications in agriculture, industry, health, food and the environment. It has a specific sector devoted to study of the ecological implications of biotechnology.

Structure

The programme is in three parts:

1. molecular approaches;
2. cellular and organism approaches;
3. ecology and population biology.

3.3 Environment

Budget: ECU 261.4 million
Ref.: Council Decision: OJ L 192, 16.7.1991

Objectives

This programme is aimed at developing the scientific knowledge and technical know-how required for the Community environment policy: understanding of fundamental mechanisms, identification of sources of pollution and evaluation of their combined effects on the environment and prevention of natural and technological risks and restoration of the environment.

Structure

There are four research areas:

1. participation in global change programmes;
2. technologies and engineering for the environment;
3. research on economic and social aspects of environmental issues;
4. technological and natural risks.

3.4 Agriculture and agro-industry

Budget: ECU 329.67 million
Ref.: Council Decision: OJ L 265, 21.1.1991

Objective

The purpose of this programme is to improve the quality and diversity of agricultural products, to enhance the competitiveness of the agricultural and agri-foodstuffs sectors and to improve management of the rural and forestry area and to protect the environment.

Structure

The programme is in four parts:

1. primary production in agriculture, horticulture, forestry, fisheries and aquaculture;

2. inputs to agriculture, horticulture, forestry, fisheries and aquaculture;

3. processing of biological raw materials from agriculture, horticulture, forestry, fisheries and aquaculture;

4. end use and products.

3.5 Life sciences and technologies for developing countries

Budget: ECU 109.89 million
Ref.: Council Decision: 0J L 196, 19.7.1991

Objectives

The purpose of the programme is to promote cooperation between European scientists and those in developing countries in the fields of agriculture, medicine, health and food.

Structure

The development programme is in two main parts:

1. improvement of living conditions;

2. improvement in health.

3.6 Training programmes

Education and training are key issues in the field of biotechnology. Training is a priority within various Community research programmes such as COMETT, ERASMUS, FORCE and TEMPUS.

4. European Medicines Evaluation Agency

In June and July 1993 the Council adopted a regulation and three directives concerning the future marketing authorization system and the creation of the European Medicines Evaluation Agency (OJ L 214, 24.8.1993). The Agency is to be based in London. From 1995 onwards, therefore, there should be three registration procedures for medicines in the European Community:

- a centralized Community procedure valid for the twelve Member States and restricted to certain new medicines;
- a decentralized procedure, applying to most medicines, based on mutual recognition of national authorizations;
- a national procedure for certain medicines restricted to the market of a single Member State.

Use of the centralized procedure will be compulsory for biotechnological medicines and optional for other high technology medicines and new active substances. Requests for authorization will be sent direct to the European Medicines Evaluation Agency, made up principally of the Committee for Proprietary Medicinal Products and the Committee for Veterinary Medicinal Products with additional resources, the assistance of a permanent administrative and technical secretariat from the Member States and appropriate logistics. The opinions of these two committees will subsequently become Commission decisions valid for the entire Community.

The objective of the decentralized procedure is to enable a marketing authorization issued by one Member State to be extended to one or more other Member State as a result of the recognition of the initial authorization. In the event of major objections and after exhaustion of all the means of bilateral conciliation, the matter will be put to the European Agency for arbitration.

Upon completion of these procedures, the opinions of the Agency (expressed by one or other of the committees) will be sent to the applicant, the Commission and the Member States. If there are no serious objections, the Commission will adopt a decision making this opinion enforceable. In the event of a major objection the Commission will take a decision in consultation with a regulatory committee and with the possibility of appeal to the Council.

The European Medicines Evaluation Agency will also be responsible for the coordination of national pharmacovigilance activities, laboratory inspection and controls in order to guarantee the safety of medicinal products available in the Community.

The Management Board of the Agency is made up of representatives of the Member States, the European Commission and the European Parliament. The Agency's initial budget of ECU 23 million in 1995 will increase, in line with the new tasks assigned to the Agency, to around ECU 60 million in 1999. It will be financed increasingly by fees paid by pharmaceutical companies.

6. State of play of dossiers related to the biotechnological regulatory framework

EUROPEAN COMMISSION

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STATE OF PLAY OF DOSSIERS RELATED TO THE BIOTECHNOLOGICAL REGULATORY FRAMEWORK

A. Implementation of Legislation

1. Council Directive 90/219/EEC on the Contained Use of Genetically Modified Micro-Organisms / Council Directive 90/220/EEC on the Deliberate Release into the Environment of Genetically Modified Organisms (DG XI)

The date of entry into force of these directives was 23 October 1991. Member States have adopted or are at the final stages of adopting legislation and competent authorities have been appointed in all Member States. A Commission report on implementation will be published shortly.

A summary notification information format for Directive 90/220/EEC (Article 9) was adopted by the Council on 4 November 1991 (O.J. L 322 23.11.1991). A further summary format (Article 12) was adopted by the Commission on 11 February 1992 (O.J. L 60 5.3.1992).

A Commission Decision establishing criteria for simplified procedures concerning experimental releases of genetically modified plants was adopted on 22 October 1993 (O.J. L 279/42, 12.11.93).

A Commission decision adapting to technical progress and simplifying the summary notification format taking into account specifically the requirements for releases of plants is currently in written procedure for Commission adoption.

Equally a Commission Decision adapting to technical progress Annex II (notification requirements for releases and streamlining it for releases of plants) is currently in written procedure for Commission adoption.

In total 250 field test notifications and 4 notifications of products containing GMOs have now been received. Three of the products have been approved.

2. Council Directive 90/679/EEC on the Protection of Workers from the Risks Related to Exposure to Biological Agents at Work (DG V)

Member States are required to bring into force the laws, regulations and administrative provisions necessary to comply with the directive not later than 29 November 1993. So far, transposition has not been realised in any of the Member States.

3. Future system for the free movement of medicinal products in the European Community

The package has been adopted by the Council on 22 July 1993 and most parts enter into force by 1 January 1995 (O.J. L 214 of 24.8.1993, p.1). As regards the authorisation of biotechnology derived medicinal products for human use and veterinary medicinal

products is concerned, one integrated notification and one assessment procedure has been fixed. Work has started on the implementation of the provisions concerned.

B. Discussion at Council Level

1. Draft Council Directive on Legal Protection of Biotechnological Inventions (see also point B.2) (DG XV)

The proposal was put forward to the Council in 1988.

At the EP plenary session of October 1992 the first reading procedure was completed and an opinion was voted. A common position on the proposal has been reached on 7 February 1994 (SEC (94) 275 Final - COD 159). The period of three months in which the EP has to vote its opinion in second reading began February 25th. During its plenary session the European Parliament voted, on 4 May, three amendments with respect to the common position.

2. Draft Council Regulation on Community Plant Variety Rights (COM (90) 347) (DG VI)

The proposal based on Article 43 of the Treaty, was sent to the Council in September 1990. It deals with industrial property protection of plant varieties of all types including those obtained by the use of biotechnology.

The Community protection provided for under this proposal is a system sui generis ((UPOV-type) UPOV = Union pour la Protection des Obtentions Végétales). However, patenting of biotechnology-derived plant material other than plant varieties is dealt with under the proposal on patenting referred to in item B.1. Decisions on the appropriate interface between the two types of protection have still to be taken (cf. relevant recital in the above mentioned proposal).

The EP voted an opinion on the proposal at its plenary meeting of October 1992. An amendment on farmers' privileges was adopted. Work has been pursued at Council level on the basis of an amended proposal (COM(93)104 final). On 11 December 1993 a political agreement on the agricultural part of the proposal was reached.

3. Council Directive on the Placing on the Market of EEC Accepted Plant Protection Products (DG VI)

The Directive 91/414/EEC was adopted by the Council of Ministers of Agriculture of 26 June 1991. A draft proposal on the assessment of GMO derived pesticides is under preparation.

4. Proposal for a Council Regulation Concerning Novel Foods and Novel Food Ingredients (DG III)

The proposal provides for a safety assessment of all novel foods and novel food ingredients including those containing GMOs and those produced from GMOs except if they have not undergone any significant change. It aims to ensure that foodstuffs and food ingredients for human consumption including those derived from biotechnology are safe and wholesome.

The proposal was adopted by the Commission on 7 July 1992 (COM (92) 295) and it accomplished its first reading in October 1993. The Commission has adopted an amended proposal on 1 December 1993 (COM (93) 631 Final).

An orientation debate on the file took place at the latest meeting of the Council of Ministers for the Internal Market.

5. Proposal for a Council Directive on the approximation of the laws of Member States with regard to the transport of dangerous goods by road (DG VII) (COM 93, 548 final)

The proposed framework directive extends the scope of the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), to national traffic in order to harmonise across the Community conditions under which dangerous goods are carried by road. Under this directive the establishment of conditions of safety is possible under which biological agents and GMOs regulated under Directives 90/219/EEC, 90/220/EEC and 90/679/EEC should be transported.

6. Draft Council Directive on Genetically Modified Varieties of Plants

The Commission adopted on November 26 1993 a Draft Directive amending, among others, the Directives 70/457/EEC and 70/458/EEC, which lay down the conditions for inclusions in the Common Catalogue of Varieties of agricultural and vegetable plant species. The legal basis is Article 43 of the Treaty.

This proposal establishes a legal basis to take account of developments in the areas of genetically modified varieties, novel food and novel food ingredients. It integrates in these Directives an environmental risk assessment similar to the one foreseen under Directive 90/220/EEC and a food safety assessment similar to that envisaged under the proposed Novel Food and Novel Food Ingredients Regulation.

7. The Administration of BST (DG VI)

The Council has agreed on a ban for another year as regards the administration of BST in the Union (OJ L 333, 31.12.93, p. 72). The product has been marketed in the US.

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A N N E X

RELEVANT LEGISLATION ADOPTED

- Council Directive 85/374/EEC on product liability;

- Council Regulation 1010/86/EEC laying down general rules for the production refund on certain sugar products used in the chemical industry;

- Council Regulation 1009/86/EEC establishing general rules applying to production refunds in the cereals and rice sector;

- Council Directive 87/21/EEC amending Directive 65/65/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medical products;

- Council Directive 87/22/EEC on the approximation of national measures relating to the placing on the market of high-technology medicinal products, particularly those derived from biotechnology;

- Council Decision 89/45/EEC amended by Decision 90/352/EEC notification of dangerous products presenting a serious and immediate risk with the exception of products notified under other equivalent Community notification procedure : pharmaceuticals (Directives 75/319/EEC and 81/851/EEC); animals (Directive 82/894/EEC); products of animal original as far as they are concerned by Directive 89/662/EEC; the system for radiological emergencies (Decision 87/600/Euratom);

- Council Directive 89/381/EEC extending the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulations or administrative action relating to proprietary medicinal products derived from human blood or human plasma;

- Council Directive 89/342/EEC extending the scope of Directives 65/65/EEC and 75/319/EEC and laying down additional provisions for immunological medicinal products consisting of vaccines, toxins or serums and allergens.

- Council Directive 90/219/EEC on the contained use of genetically modified micro-organisms (O.J. no. L 117 of 8 May 1991, p. 1)

- Council Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms (O.J. no. L 117 of 8 May 1990, p. 15)

- Council Directive 90/679/EEC on the protection of workers from risks related to exposure to biological agents at work (O.J. no. L 374 of 31 December 1990, p.1)

Commission Decision 91/274/EEC concerning a list of Community legislation referred to in Article 10 of Directive 90/220/EEC (O.J. L135 of 30.5.1991)

- Commission Decision 91/448/EEC on guidelines for the classification as laid down in Article 4.3 of Directive 90/219/EEC (O.J. no. L239 of 28.8.1991, page 23)

- Council Decision 91/596/EEC concerning the summary notification information format referred to in Article 9 of Directive 90/220/EEC (L322 of 23.11.1991)

- Council Directive 92/59/EEC on the safety of products (O.J. no. L228 of 11 August, 1992, p. 24)

- Commission Decision 92/146/EEC concerning the summary notification format referred to in Article 12 of Directive 90/220/EEC (11.2.1992) (L60 of 5.3.1992)

- Council Decision 92/218/EEC of 26 March 1992 adopting a specific research and technological development programme in the field of biotechnology.

- Council Regulation (EEC) N° 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products. (O.J. no L214 of 24.8.1993, p. 1)

- Council Directive 93/39/EEC of 14 June 1993 amending Directive 65/65/EEC, 75/318/EEC and 75/319/EEC in respect of medicinal products (O.J. no L214 of 24.8.1993, p. 22)

- Council Directive 93/40/EEC of 14 June 1993 amending Directives 81/851/EEC and 81/852/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products (O.J. no L214 of 24.8.1993, p. 31)

- Council Directive 93/41/EEC of 14 June 1993 repealing Directive 87/22/EEC on the approximation of national measures relating to the placing on the market of high-technology medicinal products, particularly those derived from biotechnology (O.J. no L214 of 24.8.1993, p. 40)

- Commission Decision 93/584/EEC of 22 October 1993 establishing the criteria for simplified procedures concerning the deliberate release into the environment of genetically modified plants pursuant to Article 6(5) of Council Directive 90/220/EEC.

- Council Directive 93/114/EEC of 14 December 1993 amending Directive 70/524/EEC concerning additives in feedingstuffs (O.J. no L 334 of 31/12/12

BIOETHICS AND THE EUROPEAN UNION

7. Extracts from speech by President J. DELORS

EUROPEAN COMMISSION

Secretariat-General
SG/C/1

EXTRACTS FROM SPEECH BY PRESIDENT J. DELORS

"The ethical dimension is once again coming to the fore, and we must step up the debate about these fundamental issues which concern the very essence of human life and society. On the basis of what scientists tell us about the laws of Nature, we must take responsibility and decide, according to a certain idea of life and human beings, what action we want to take. For my part I would like [...] to see the debate conducted in philosophical and ethical terms so that our understanding advances to keep pace with scientific progress".

Jacques Delors, Speech on human rights and the European Community : 1992 and beyond", Strasbourg, 20-21 November 1989.

EUROPEAN COMMISSION

Secretariat-General
SG/C/1

EXTRACTS FROM SPEECH BY PRESIDENT J. DELORS

SIXIEME CONFERENCE DU SOMMET ECONOMIQUE SUR LA BIOETHIQUE

"ETHIQUE DE L'ENVIRONNEMENT"

DISCOURS D'OUVERTURE DU PRESIDENT DELORS(Extraits)

Seul le texte prononcé fait foi
Embargo 10 mai 1989, 9 heures

Bruxelles, le 10 mai 1989

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Mesdames, Messieurs,

L'environnement est aujourd'hui une question posée à l'échelle de la planète, les valeurs qu'elle invite à formuler doivent être des valeurs communes et partagées. En d'autres termes, l'éthique de l'environnement se prête aussi à la réflexion du législateur, de l'économiste, ou bien encore du simple citoyen. Réflexion en forme de questions surtout.

A quels problèmes devons-nous faire face? La plupart sont désormais bien connus du grand public - même si parfois inexactement, ou sous la pression parfois alarmiste des médias. Nous savons tous cependant que le réchauffement de l'atmosphère et les risques d'altération climatique, l'appauvrissement de la diversité biologique, l'épuisement progressif des ressources, pour ne citer que celles-là, sont aujourd'hui des données irréfutables de l'évolution de la planète. Aucun de ces problèmes ne peut d'ailleurs faire l'objet d'une approche séparée : ils se posent à nous de manière globale, et transcendent nos cadres traditionnels de réflexion et d'action, celui des espaces strictement nationaux ou des générations présentes.

Ce que ces problèmes soulignent d'abord, c'est la dépendance mal formulée jusque-là de l'homme à l'égard de son milieu. Ils mettent en valeur la fragilité soudaine de la relation traditionnellement maitrisée, faite d'usage et d'exploitation, qui unissent l'homme et la nature. Ce sont donc, au sens large, les conditions mêmes de notre humanité qu'ils invitent à repenser, à reconstruire, dans la mesure où le maintien des modes traditionnels de notre présence au monde entrainerait un nombre toujours plus grand de dommages, et, à brève échéance, menacerait de nous détruire.

D'ou la validité de l'approche éthique : elle vise en effet les valeurs qui régissent les comportements sociaux. Elle est aussi au fondement du droit ; elle détermine donc les différents codes au nom desquels nous agissons, ces codes consacrés par la tradition, et dont il faut aujourd'hui rétablir les véritables enjeux. La dégradation continuelle du cadre de vie que l'homme a reçu en héritage aura par nécessité conduit l'homme à s'exprimer, à l'égard de cet héritage, en termes de devoirs et de responsabilités.

L'ETHIQUE DE L'ENVIRONNEMENT

(...) Nous en sommes venus aujourd'hui à délaisser les biens collectifs, et à proposer comme carte des comportements la satisfaction des besoins ou des désirs de l'individu, à n'importe quel prix. Nous n'avons cessé d'étendre dans notre société le domaine des droits de l'individu. Ce sont aujoud'hui les biens collectifs, les ressources communes qu'il faut par un mouvement inverse, protéger et préserver. C'est l'ensemble des rapports de l'homme au milieu naturel que nous devons, sinon reconstruire, du moins réorienter.

Il s'agit bien d'éthique : à des valeurs jusqu'alors acceptées par l'ensemble des sociétés industrielles, et qui faisaient du cadre de vie un simple bien marchand, il faut substituer d'autres valeurs, une autre approche de l'environnement.

Cette autre approche, elle passe, par une redéfinition de nos responsabilités et de nos devoirs. Responsabilités à l'égard de la nature mais aussi des générations futures et de nos propres sociétés, développées et en voie de développement.

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(...) Nous devons apprendre à respecter le milieu naturel pour lui-même, et non seulement pour la satisfaction de nos besoins. Il existe une logique de la nature, qui peut différer de la nôtre. Et, serions-nous dans l'impossibilité de définir cette logique, de dire à quelles fins la nature obéit, il demeure que rien ne nous autorise, par exemple, à réduire toujours plus la diversité biologique, en favorisant la disparition de certaines espèces, ou en mettant en danger les possibilités de leur reproduction. La valeur du patrimoine génétique de la nature est proprement incalculable et celui-ci suppose aujourd'hui, pour être conservé, l'exercice de la responsabilité humaine. Et celle-ci passe parfois par une attitude de profonde humilité : dans l'absence d'une connaissance établie des conséquences d'une action humaine sur la nature, il est sage de nous abstenir.

Mais cette responsabilité a également une dimension temporelle : ce que nous mettons en danger par notre comportement à l'égard de notre habitat, c'est aussi l'existence des générations appelées à nous succéder, c'est l'existence de notre postérité. Les anglo-saxons disent justement que nous n'avons pas hérité la terre de nos ancêtres, mais que nous l'avons empruntée à nos enfants. (...)

En d'autres termes, l'usage que nous ferons désormais de la nature, de la biosphère, nous devons considérer que nous en sommes comptables au regard du futur. Les dilapidations sont irréversibles : nous nous y sommes livrés par égoïsme concerté, et en fonction d'intérêts immédiats. L'apprentissage de la responsabilité s'impose aussi par considération du long terme, et, comme tel, il doit être aujourd'hui place au premier rang des préoccupations collectives.

Notre responsabilité doit s'exercer enfin à l'égard de nos sociétés, dans la mesure où il faut assurer à celles-ci le cadre de vie auquel elles aspirent. Il ne s'agit pas de condamner en bloc l'intervention de l'homme dans la nature : la nature est aussi par vocation son lieu d'habitation. D'où la nécessité de prendre en compte l'intérêt commun dans une éthique de l'environnement, et la pluralité souvent discordante des opinions. C'est notre responsabilité envers autrui que nous engageons en effet dès lors que nous recherchons le bien public, qui est la destination même de l'éthique : cette responsabilité est de celle aussi que les problèmes de l'environnement doivent nous aider à réinventer.

Et cela d'autant plus que nos sociétés connaissent aujourd'hui des stades de développement très inégaux, que les richesses sont inéquitablement distribuées. L'environnement est cependant une donnée planétaire, qui ignore les découpes géographiques : il suppose des décisions communes. La responsabilité des pays les plus industrialisés joue ici à l'égard de ceux qui ont à supporter les courts très lourds du développement et des ajustements structurels, et à qui nous ne pouvons pas imputer les maux - ainsi la pollution) dont nous avons été les premiers instigateurs.

(...)

Mais il fallait souligner dès maintenant qu'à l'égard des pays en voie de développement nous avons, dans le domaine de l'environnement, "des obligations particulières d'assistance" (Conférence de La Haye, mars 1989). Des politiques communes d'environnement peuvent aider à instaurer cettte pratique nouvelle de la responsabilité partagée. A problème de dimension mondiale, il convient, faute de gouvernement mondial, de répondre par l'adoption et le respect de règles universellement appliquées.

Tels sont nos responsabilités et nos devoirs : devoir de protéger notre écosystème, devoir de préserver cet écosystème pour les générations futures, devoir d'assurer à l'homme un environnement viable, devoir d'assistance enfin à l'égard des pays en développement. Telles sont aussi les valeurs au nom desquelles nous devons agir. (...)

LE DROIT DE L'ENVIRONNEMENT

(...) L'éthique de l'environnement rend ainsi compte de l'émergence d'un droit de l'environnement, qui pourrait être aussi, au sens large, un droit vivant. Car l'une des fonctions premières de l'éthique est d'éclairer et de faciliter la prise de décision. Elle permet, en d'autres termes, de légiférer. Il faut donc que les responsabilités et les devoirs que j'ai cités trouvent, à bref délai, le cadre juridique dans lequel ils puissent effectivement se transformer en obligations.

(...)

A brève échéance (...), le droit de l'environnement devra se rapprocher d'un droit du vivant. A cet égard, la conférence qui s'ouvre aujourd'hui ne peut pas être séparée de celles qui l'ont précédée et qui toucheraient la question spécifique de la bio-éthique. De l'environnement au vivant, la transition nous est imposée par les faits : l'homme, après s'être approprié la nature comme espace géophysique, est en passe de soumettre à la même exploitation le dynamisme biologique de la nature, et son principe créateur, la reproduction.

L'essor des biotechnologies, dans le domaine médical en particulier, a beau se réclamer de l'impératif thérapeutique, il n'est aujourd'hui compréhensible qu'en fonction de la logique commerciale et industrielle, et donc du droit de propriété. Le vivant peut-il être entièrement appropriable. C'est une des question qu'il faut poser à nouveau et que rendent possible nos interrogations sur l'éthique environnementale. Il n'y sera pas répondu, en tout cas, sans que soient clairement fixées les valeurs dont il faut affecter aujourd'hui la nature et son symbiote, l'homme.

ETHIQUE DE L'ENVIRONNEMENT ET TECHNOLOGIE

(...) La technique n'est pas seulement fauteuse de troubles, elle est aussi un instrument au service des politiques environnementales, et elle peut très certainement agir dans le sens des valeurs éthiques et des devoirs. Il revient au politique d'orienter, de guider les emplois de la technologie, non de renier, par décision de méthode, ces apports spécifiques à la cause qu'il a choisi de défendre. Mais il incombe aussi à tous les responsables politiques et scientifiques d'associer leurs efforts pour rendre chacun sensible à l'impérieuse nécessité de gérer la nature "en bon père de famille". Et je crois pouvoir ajouter, sans trop m'avancer, que cette conception correspond aujourd'hui à l'enseignement des religions occidentales.

LES IMPLICATIONS POLITIQUES ET ECONOMIQUES DE L'ETHIQUE DE L'ENVIRONNEMENT

L'éthique de l'environnement, la reconnaissance de nos responsabilités ne sont pas séparables non plus de leurs implications politiques et économiques. Non seulement parce qu'elles doivent s'accompagner du droit et qu'elles affectent ainsi la vie de la cité, mais aussi parce qu'elles sont susceptibles d'aboutir à la révision des traditionnels modes de faire des sociétés industrielles et de notre culture par trop empreinte de productivisme.

Les implications économiques de ces valeurs surtout sont immédiatement sensibles dans la mesure où la dépense et la protection du milieu naturel constituent un secteur d'acitivités compétitif, et qu'un tel engagement peut avoir des conséquences favorables sur l'emploi. Il y a une économicité véritable de l'environnement, surtout lorsqu'on reconnait la nécessité de priviléier la prévention par rapport à la préparation.

(...)

Les politiques environnementales dans les pays en voie de développement engagent donc aussi notre responsabilité : nous détenons les moyens de les rendre effectives, donnée globale, elle ici synonyme d'interdépendance, phénomène également global. Et c'est donc aussi l'importance et le déséquilibre des liens économiques au sein du dialogue Nord/Sud que la reconnaissance de nos responsabilités à l'égard du patrimoine naturel de toute l'humanité invite en dernière analyse à reconsidérer.

Ainsi, la quête d'une éthique de l'environnement ouvre bien des perspectives dans le champ traditionnel de nos activités, de nos comportements, de nos textes de loi. (...)

Je souhaite que le sommet des pays industrialisés ne se contente pas de prendre acte de ces conclusions, mais qu'il engage une réflexion opérationnelle et digne en effet de l'économie politique, puisque ce concept unit le travail de l'homme et sa relation tant avec la nature qu'avec la société, et qu'il doit être éclairer par la connaissance et par une éthique.

Nul doute que vous ayez l'ambition et la capacité de contribuer à ce qui deviendra un réel progrès de l'homme sur lui-même. Que le savant puisse l'y aider, c'est en tout cas ma conviction profonde.

EUROPEAN COMMISSION's GROUP OF ADVISERS ON ETHICAL IMPLICATIONS OF BIOTECHNOLOGY

EUROPEAN COMMISSION's GROUP OF ADVISERS ON ETHICAL IMPLICATIONS OF BIOTECHNOLOGY

8. State of play of work

EUROPEAN COMMISSION

Secretariat General
SG/C/1

STATE OF PLAY OF WORK OF THE GROUP OF ADVISERS ON ETHICS OF BIOTECHNOLOGY

1. OPINIONS ADOPTED

1.1 Ethical implications of the application of performance enhancers (BST)

Rapporteur : Lady Warnock and Prof. Siniscalco
Ref : Second Commmission report on BST (SEC (91) 2521 final)
Request of Opinion from the Commission, dated 27.02.1992
Diffusion : to the public on request

1.2. Directive concerning medicinal products derived from human blood and plasma

Rapporteur : Mrs Mikkelsen
Ref. : Directive 89/381/EEC, 14 June 1989
Own initiative report, dated 03.1992.
Diffusion : to the public on request

1.3. Legal protection of biotechnological inventions

Rapporteur : Mrs Lenoir
Ref. : Proposed directive (COM (88) 496 final)
Own initiative report, dated 03.1992
Diffusion : European Parliament, Council of the European Union, Council of Europe, World intellectual Property Organization, European Patent Office, public on request.

2. OPINIONS PENDING

2.1. Transgenic animals

Rapporteur : Prof. Schroten
Ref. : Request from the Commission, dated 29.09.1992

2.2. Gene therapy

Rapporteur : Prof. Archer
Ref. : Request from the Commission dated 23.09.1992

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2.3. Prenatal diagnosis

Rapporteur : Prof. Rodota
Ref. : Own initiative report

3. FUTURE THEMES WHICH COULD BE TREATED BY THE GROUP

- Bank of tissues and organs
- Biodiversity and North-South relations
- Risk Management and biotechnology
- Medical data protection
- Ethics, biotechnology and environment
- Ethics and new agriculture
- Biotechnology and Society - Employment

EUROPEAN COMMISSION's GROUP OF ADVISERS ON ETHICAL IMPLICATIONS OF BIOTECHNOLOGY

9. Terms of reference

EUROPEAN COMMISSION

Secretariat-General
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TERMS OF REFERENCE OF THE GROUP OF ADVISERS ON THE ETHICAL IMPLICATIONS OF BIOTECHNOLOGY

The Commission has decided to set up a Group of Advisers on the Ethical Implications of Biotechnology.

Terms of Reference

- Identification and definition of ethical issues raised by biotechnology.

- Appraisal of the ethical aspects of Community activities in the field of biotechnology and their potential impact on society and the individual.

- Advising the Commission in the exercice of its powers as regard the ethical aspects of biotechnology with a view to improving public understanding.

Composition

The Group will consist of not more than 9 members.

Its members will be eminent figures.

It will elect a chairman from amongst its members.

Procedure

In performing its tasks, the Group shall :

- provide the Commission with appraisals of the potential ethical impact of activities based on biotechnology;

- give consideration to the work of Commission working parties dealing with specific problems linked to the ethics of biotechnology such as the working parties on the human genome and the human embryo;

- submit reports to the Commission on its own initiative and deliver opinions on all general matters of an ethical nature.

The Commission may also request the Group for an opinion on a particular issue.

The term of office of each member of the Group shall run for two years. Members remain in office until they are replaced or their term is renewed.

Members shall not be paid for their services. Travel and subsistence expenses in respect of Group meetings shall be covered by the Commission in accordance with the current administrative rules.

The Commission, acting in close collaboration withe the Chairman of the Group, shall be responsible for organizing the work of the Group and its secretariat.

The Group shall meet at least twice a year at the headquarters of the Commission. Meetings shall be convened by the Chairman of the Group.

Any person with particular knowledge of a subject entered on the agenda may be invited by the Group to attend a meeting to give an expert opinion. Experts may only take part in the discussion of those items for which they are invited.

The Secretariat-General or, where appropriate, his representative, shall represent the Commission within the Group and shall take an active part in its discussions.

No vote will be taken following the Group's deliberations. The positions expressed shall be recorded in a report drawn up under the responsibility of the Chairman.

Where the Group is unanimously agreed on its opinion in response to a request, this shall be set out in a joint conclusion.

In seeking the opinion of the Group, the Commission may set a deadline by which the opinion must be delivered.

The group's deliberations shall be confidential. No opinions may be published without the prior approval of the Commission.

EUROPEAN COMMISSION's GROUP OF ADVISERS ON ETHICAL IMPLICATIONS OF BIOTECHNOLOGY

10. Composition

EUROPEAN COMMISSION

Group of Advisers on the Ethical Implications of Biotechnology

COMPOSITION OF THE GROUP OF ADVISERS ON ETHICAL IMPLICATIONS OF BIOTECHNOLOGY

Madame Noëlle LENOIR

Nationalité	Française
Titre	Membre du Conseil Constitutionnel français, présidente du Groupe de conseillers pour l'éthique de la biotechnologie, présidente du Comité International de Bioéthique de l'UNESCO, Maire de Valmondois.
Formation	Diplôme de l'Institut d'Etudes Politiques de Paris, DES de Droit Public.
Expérience	Administrateur au Sénat (1972-77). Administrateur Principal au Sénat (1977-82). Directeur de la Réglementation de la Commission Nationale de l'Informatique et des Libertés (1982-84). Maître des requêtes au Conseil d'Etat (Oct. 1984). Affectée à la Section du Contentieux du Conseil d'Etat et à la section des Travaux publics (1984-88). Directeur du Cabinet du Garde des Sceaux, Ministre de la Justice (Nov. 1988-Oct. 1990). Chargée par le Président de la République et le Premier Ministre d'une mission sur la bioéthique (depuis oct. 1990). Assistante à la Faculté de Droit de Paris (1972-82). Maître de conférences à l'Institut d'Etudes Politiques de Paris (1982-88).
Rapporteur	Protection juridique des Inventions biotechnologiques (Avis adopté en sept. 1993)

Dr Anne Mc LAREN

Nationalité	English
Titre	Reproduction biologist, Foreign Secretary of the Royal Society, Member of the Nuffield Bioethics Committee, London. Member of the Human Fertilization of Embryology Authority, UK.
Formation	Doctor in Biology.
Expérience	Member of scientific staff of Agricultural Research Council's Unit of Animal Genetics in Edinburgh (1959-74). Director of Medical Research Council's at Univ. College London (1974-92). Pioneer Award of International Embryo Transfer Society. Chairman of the European Dvpt. Biology Organisation and the WHO Scientific & Technical Advisory Group on Human Reproduction.

Dr Margareta MIKKELSEN

Nationalité	Danish
Titre	Former Head of the Department of Medical Genetics, John F. Kennedy Institute, Member of the Danish Ethics Council (1988-93).
Formation	Professor in genetics, medical doctor.
Expérience	Teacher at WHO courses in medical genetics for university teachers from developing countries (1962, 64, 66, 68). Member of the Paris Conference (1971), of the EEC workinggroup on Down syndrome, of the EEC Steering Committee on "First trimester prenatal diagnosis", of the EEC Study Group on Ethical, Social and Legal Aspects of the Human Genome Analysis Programme (since 1988). President of the European Society of Human Genetics (1992-93).
Rapporteur	Products derived from human blood or plasma (Opinion adopted in March 1993)

Prof. Luis ARCHER

Nationalité	Portuguese
Titre	Professor of Molecular Genetics and Chairman of the Department Biotechnology, Lisbon. Member of the National Council of Ethic, Lisbon.
Formation	Licenciate in Biology, in Philosophy and Theology. Ph. D. in molecular Biology, Doctor degree in Biology, "Agregado" in Botany.
Expérience	Chairman of the lab. of Molecular Genetics at the Guibenkian Inst. of Science (1971-91), of the OECD "Group of National Experts on Safety in Biotechnology" (1990-92). Member of the CAHBI (Council of Europe) (1983-87). Elected member of several Academies. Member of the EC Study Group on Ethical, Social and Legal Aspects of the Human Genome Analysis Programme (since 1988).
Rapporteur	Gene Therapy

Prof. Gilbert HOTTOIS

Nationalité	Belge
Titre	Professeur en Philosophie contemporaine. Co-directeur du Centre de Recherches Interdisciplinaires en Bioéthique (CRIB) de l'Université de Bruxelles.
Formation	Licence en philologie romane et en philosophie. Doctorat en philosophie. Agrégation de l'Enseignement secondaire.
Expérience	Auteur de 8 livres sur des questions de philosophie du langage, des sciences et de la technique (1976-93). Coordinateur et éditeur scientifique d'une dizaine d'ouvrages collectifs, d'une soixantaine d'articles. Co-directeur d'un ouvrage encyclopédique "Les Mots de la Bioéthique" (1993). Co-directeur de la collection "Sciences - Ethiques - Sociétés". Membre de plusieurs Comités de Revues et de Sociétés scientifiques.

Prof. Dietmar MIETH

Nationalité	German
Titre	Professor of Theology Ethics. Chairman of the Centre of Ethics in the Scientific and Humanities of the University of Tübingen.
Formation	Studies in theology, germanistics and philosophy. Doctorate in theology (1968). Habilitation in the Theological Ethics.
Expérience	Publication of a number of works on social-ethical subjects and editor of a collection on bioethics. Professor of Theological Ethics (1974-81, Fribourg/Ch, since 1981 at Tübingen). Chairman of the Centre of Ethics (now). Member of different societies in ethics. Director of the section "ethics" of the international Journal "Coucilium" (now).
Rapporteur	Biotechnology, Ethics and Environment

M. Octavi QUINTANA TRIAS

Nationalité	Spanish
Titre	Advisor to the Vice-Minister for Public Health, President of the Bioethics Steering Committee (CDBI) of the Council of Europe.
Formation	Graduate on Medicine and Surgery (1976). Specialist in Intensive Medicine (1980). Master on Public Health & Health Administration (1986).
Expérience	Resident M.D. Valencia Regional Hospital (1976-80). Staff M.D. (1980-84) then Medical Director (1986-89) in Malaga Regional Hospital. Deputy General Director of INSALUD (health care institutions) (1989-92). Secretary of the Spanish Society of Quality Assurance (1990).

Prof. Stefano RODOTA

Nationalité	Italien
Titre	Professeur en droit civil, membre du Comité d'éthique du Conseil National de la recherche, Député du Parlement italien.
Formation	Professeur de Droit civil.
Expérience	Membre du Comité d'éthique du Conseil National de la Recherche. Directeur de la recherche "Identité personnelle et normalité génétique". Travaux dans le domaine des effets juridiques et sociaux des innovations scientifiques (1972-92).Travaux majeurs dans le domaine de la bioéthique (1989-1993). Auteur de livres et directeur de plusieurs revues.
Rapporteur	Diagnostic prénatal

Prof. Egbert SCHROTEN

Nationalité	Dutch
Titre	Professor of Christian Ethics at Utrecht University, Director of the University Centre for Bioethics and Health law.
Formation	Studies in Theology and Philosophy. Doctorate in Theology (1970)
Expérience	Lecturer in philosophy of religion and ethics (1969-87), professor in Christian ethics, director of the University Center for Bioethics and Health Law at Utrecht Univ. Chairman of the Provisional Committee for Ethical Assessment of Genetic Modification of Animals. Member of the Netherlands Health Council. Advisor of the general synod of the Netherlands Reformed Church.
Rapporteur	Transgenic Animals

EUROPEAN COMMISSION's GROUP OF ADVISERS ON ETHICAL IMPLICATIONS OF BIOTECHNOLOGY

11. Activity Report (91-93)

EUROPEAN COMMISSION

SECRETARIAT-GENERAL

EUROPEAN COMMISSION'S GROUP OF ADVISERS ON THE ETHICAL IMPLICATIONS OF BIOTECHNOLOGY

ACTIVITY REPORT 1991-93

"The ethical dimension is once again coming to the fore, and we must step up the debate about these fundamental issues which concern the very essence of human life and society. On the basis of what scientists tell us about the laws of Nature, we must take responsibility and decide, according to a certain idea of life and human beings, what action we want to take. For my part I would like [...] to see the debate conducted in philosophical and ethical terms so that our understanding advances to keep pace with scientific progress".

Jacques Delors, Speech on "Human rights and the European Community: 1992 and beyond", Strasbourg, 20-21 November 1989.

"The Union shall respect fundamental rights, as guaranteed by the European Convention for the Protection of Human Rights and Fundamental Freedoms signed in Rome on 4 November 1950 and as they result from the constitutional traditions common to the Member States, as general principles of Community law."

Treaty on European Union, Common Provisions, Article F.2.

SUMMARY

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1. INTRODUCTION

The past few years have seen an explosion in the biological and biomedical sciences, which has triggered an ethical debate both among the general public and at the political level and has led to the emergence of a concept of bioethics. Ethics may be defined as "the collective norms adopted by a group or a society which wishes to preserve a sense of proportion" (Jean Bernard) and bioethics as "a collection of questions with an ethical dimension (i.e. which raise the issue of values and can only be resolved by making choices) prompted by the growing capacity for technical and scientific intervention in living matter" (Gilbert Hottois).

The ethical debate has spawned numerous committees at local, regional, national and even international level with the establishment of the UN's International Bioethics Committee [1] and the Council of Europe's planned standing conference of National Ethics Committees.

The European Union cannot remain isolated from the mainstream, not least because as a member of the international community it must respect the undertakings entered into by its Member States and/or those which it has itself accepted, namely:

1) at universal level : in particular the Universal Declaration of Human Rights (ONU, 1948), the International Covenant on Economic and Social Rights and the International Convenant concerning Civil and Political Rights (ONU, 1966), the Rio Convention on Biodiversity (ONU, 1992);

   at Council of Europe level, the European Convention on Human Rights of 1950 [2]

   at European Union level, the Joint Declaration of April 1977, the Preamble to the Single European Act, paragraph 3 and the Treaty of European Union, common provisions and declaration.

In addition, the Community has already adopted many instruments concerned with bioethics in the areas where it has traditionally exercised powers (agriculture, industry, the environment, etc...), i.e. the directive on the deliberate release of genetically modified micro-organisms into the environment and the directive on the legal protection of biotechnology inventions which will be adopted soon.

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1 This Committee was set up in September 1993 and has 50 members representing various disciplines and coming from 35 countries. Its terms of reference include a study into the possibility of drafting an international instrument on the protection of the human genome, which would base bioethics on universal principles of Human Rights.

2 A Bioethics Convention is in progress, based upon the principles of the European Convention on Human Rights.

Several "ad-hoc" working parties have also been set up within the Commission services:

- the human embryo and research group (HER), whose purpose is to draw up an inventory of legislation in the Member States and develop a code of conduct in the field of human embryo research;

- the ESLA group which investigates the ethical, social and legal aspects of the Community's specific research programme on human genome analysis;

- the Advisory Committee for the protection of animals used for scientific purposes, which insures the fow up of directive 86/609/EEC;

- the bioethics working group which monitors progress in the preparation of the Council of Europe's bioethics convention.

The Commission is also backing research projects in bioethics under the Human Genome Analysis Programme and BIOMED and has created a unit specifically concerned with the legal and ethical aspects of Life Sciences and Technologies.

The growing importance of ethical parameters in biotechnology has led the Commission towards making a new step by creating an original structure. The Group of Advisers on Ethical Implications of Biotechnology is indeed independent, multidisciplinary and cutting across the Commission services. Its area of action is wide. Its procedures are based upon the notion of an indispensable dialogue between the various Community institutions as well as with the relevant external bodies.

This report gives an account of the Group's activities during its first term.

- It describs its role and working methods.
- It presents the results achieved so far.
- It makes proposals for the future which will integrate the Group in the Community process.

2. THE GROUP OF ADVISERS ON THE ETHICAL IMPLICATIONS OF BIOTECHNOLOGY

2.1 Creation and role

In its communication entitled "Promoting the competitive environment for the industrial activities based on biotechnology within the Community" (SEC(91)629 final), the Commission warns that the confusion surrounding the ethical debate could adversely affect the general climate for industrial development of biotechnology. It considers biotechnology to be one of the keys to the industrial development of the Community, an objective which was reaffirmed in its recent White Paper on Growth, Competitiveness and Employment. Besides, progress towards a citizens' Europe depends on informing the public better as to this objective and to the likely effects that the spread of biotechnology applications are likely to bring into play fundamental issues concerning rights.

In the light of these considerations and on the basis of a proposal by the President, Jacques Delors, the Commission set up the Group of Advisers on the Ethical Implications of Biotechnology by a decision of 20 November 1991. Its terms of reference were as follows:

- to identify and define the ethical issues raised by biotechnology,
- to evaluate the ethical aspects of Community activities in the field of biotechnology and their potential impact on society and the individual,
- to advise the Commission in the exercise of its powers as regards the ethical aspects of biotechnology with a view to improving public understanding.

2.2 Composition

In view of the nature of the interests at stake a pluralist and multidisciplinary approach was called for. The members of the Group of Advisers are accordingly drawn from the world of science, law, philosophy and politics. Each member serves a two-year term.

The Group was intended to be a flexible structure which would encourage exchanges. The members during its first term were as follows:

- Lady Warnock, philosopher, Mistress of Girton College, Cambridge;
- Noëlle Lenoir, lawyer, Member of the Constitutional Council in France;
- Margareta Mikkelsen, Head of the Department of Medical Genetics of the J.F. Kennedy Institute, Glostrup;
- Marcelino Oreja, lawyer, Member of Parliament in Spain;
- Professor Marcello Siniscalco, Professor of genetics in Italy, Member of the Imperial Cancer Research Institute, London;
- Professor Hans Zacher, Professor of law, President of the Max Planck Institute, München.

Marcelino Oreja was elected Chairman for the first term.

2.3 Procedure and working methods

The Commission may request an opinion from the Group on a specific topic, but the Group may also present an opinion to the Commission on its own initiative.

One member is appointed rapporteur for each topic selected, depending on his or her expertise and interests. Once the research is completed, the rapporteur drafts a report accompanied by a draft opinion, which is then considered by the Group. Dissenting opinions may also be attached.

The Group meets four or five times a year. In order to facilitate contacts with ethics committees in the Member States, some meetings have been held outside Brussels (e.g. Madrid, March 1993).

The Group's discussions are not public. However, the Commission decides whether to publish the Group's opinions.

The Biotechnology Coordination Committee, chaired by the Commission general Secretary : Mr Williamson, set up to improve internal coordination in the field of biotechnology, provides the link between Directorates-General and the Group. The Committee also puts forward the work programme to be examined by the Group.

2.4 A guarantee of independence

The Group's opinions are purely advisory. They are designed to guide the Commission in biotechnology-related activities to enable it to lay down ethically responsible rules.

Because of its advisory role, the Group of Advisers has to be an independent body. The external, non-partisan outlook of the Group means that its opinions strengthen the Commission's hand in its dealings with the Council, Parliament and the Member States, and with external bodies such as the Council of Europe, UNESCO, OECD and GATT.

The different fields covered by Directorates-General are taken into account in the work of the Group of Advisers: industry, science and research, agriculture, the environment and social affairs. The expertise of Directorates-General is the basis for the Group's deliberations. The composition of the Group reflects the different cultural sensitivities of European society.

The fact that the Group can submit opinions to the Commission on topics of its own choice and the complete freedom enjoyed by the individual Advisers underline the Group's independence.

3. THE WORK OF THE GROUP

3.1 Opinions adopted

3.1.1 Opinion No 1 on the ethical implications of the use of performance-enhancers in agriculture and fisheries (Annex 1)

Rapporteurs: Lady Warnock and Professor Siniscalco
Ref.: Second Commission report on BST (SEC(91)2521 final)
Referral: Commission request for an opinion, 27 February 1992.

Background

Bovine somatotropin (BST) is a hormonal protein produced by the pituitary gland which stimulates not only bone growth and protein anabolism, but also galactopoiesis (increase in milk secretion during lactation in cattle).

Several studies have shown that the use of BST increases the incidence of bovine mastitis, which is treated with antibiotics. The concentration of antibiotics in milk and beef could pose a danger to consumer health. In addition levels of somatic cells in the milk produced using BST could be excessive and hence harmful to consumers.

The risk of bovine mastitis and frequent inflammation as a result of the administration of BST could be harmful to the health and well-being of the animals concerned.

In a decision of 10 February 1992 the Council asked Member States not to authorize the use of BST until 31 December 1993 and asked the Commission to report on the situation by July 1993. The Commission accordingly referred the matter to the Group of Advisers in order to determine the ethical implications of BST.

The Group's opinion

The Group concluded that the use of BST was ethically acceptable provided certain measures were adopted, particularly as regards:

- Consumer health and safety: administration of BST should be stopped if mastitis or other inflammatory reactions occur. Milk produced by animals treated with antibiotics should be withdrawn from sale until all traces of antibiotics have disappeared. The level of somatic cells per millilitre should not exceed that found in milk produced by traditional methods.

- Animal welfare: animals should not suffer extreme pain or discomfort that is disproportionate to the human benefit expected from the use of BST.

- Biological diversity: the use of BST does not adversely affect biodiversity.

- Freedom of choice of the consumer: milk and milk products derived from BST-treated cows should be labelled accordingly once it is possible to distinguish them from other milk and milk products.

The Group appreciated that, in addition to the ethical implications, the distribution of BST also raised important economic and political problems. However, it felt that these issues went beyond its terms of reference.

Subsequent developments

The Commission felt that the measures recommended by the Group would be difficult to implement at the present time. Backed by the Group's recommendations and on the basis of the conclusions of the Committee for Veterinary Medicinal Products, the Commission issued a recommendation to the Council and Parliament, on 13 July 1993, that the sale of BST should be banned within the Community for a period of seven years.

The Commission authorized the distribution of the Group of Advisers' Opinion No 1 to the public upon request.

3.1.2 Opinion No 2 on products derived from human blood or human plasma (Annex 2)

Rapporteur: Margareta Mikkelsen
Ref: Directive 89/381/EEC extending the scope of Directives 65/65/EEC and 75/319/EEC
Referral: Own-initiative opinion (March 1992)

Background

Directive 89/381/EEC entered into force on 1 January 1992. It aims

- to encourage Community self-sufficiency through voluntary unpaid blood and plasma donation;
- to introduce strict criteria guaranteeing the quality and safety of medicinal products derived from human blood or plasma, notably to avoid viral contamination;
- to harmonize conditions for authorizing the manufacture of blood-based products by 1993.

The publication of the French National Ethical Committee's Opinion No 28 of 2 December 1991 triggered a debate and protests in France about the application of the Directive. The Committee took the view that, by treating blood and plasma as "starting material" and blood derivatives as "medicinal products", the Directive appeared to make them tradeable goods, which conflicted with the principle that the human body was not a marketable commodity and offended against human dignity.

This terminological difficulty connected with the use of the term "medicinal product" would no longer appear to be an issue.

The Group also examined the issue with reference to the cases of HIV infection following contaminated blood transfusions, particularly in France, Germany and Spain.

The Group's opinion

In the light of its discussions the Group identified the following ethical considerations:

- respect for the donor, donor anonymity and the principle of voluntary donations;
- health of the recipient, availability and quality of blood supplies;
- the human body is not a marketable commodity: no-one should make additional profits from blood donations.

As regards the Directive, the Group concluded that it was appropriate to use the term "medicinal product" with reference to products derived from blood because it provides a guarantee of quality and security.

In the Group's view, measures relating to blood donations should be the responsibility of organizations under strict public control.

Subsequent developments

The Commission authorized the distribution of the Opinion to the public on request.

3.1.3 Opinion N° 3 on the ethical questions arising from the Commission proposal for a Council Directive on legal protection for biotechnological inventions (Annex 3)

Rapporteur: Noëlle Lenoir
Ref.: Proposal for a Directive (COM(88)496 final) and amended proposal (COM(92)589 final), Common Position of 7 February 1994, 2nd Report of Mr Rothley (EP 156.257)
Referral: Own-initiative, March 1992

Background

The proposal for a Directive, published in October 1988 was one of the measures connected with the establishment of the Single Market. Its purpose was the harmonization of Member States's laws on the patenting of biotechnological inventions.

The adoption process has been held up since 1988, largely because of the ethical debate about the patentability of living matter, but also because of the discussions about farmer's privilege. The compatibility of the Directive with the Rio Convention on Biological Diversity prompted Parliament to ask the Commission to review all the provisions.

The Group's opinion

The Group's verdict was that the patentability of living matter, a long-established principle, did not in itself raise any ethical problems. Concerning the ethical issues related to human body and transgenesis, the Group suggested that the Directive had become too complex and should be simplified to include in its substantive provisions only certain elements essential for the protection of human rights.

It should therefore expressly prohibit the patenting of:

- the human body or parts of the human body per se;
- techniques of human genetic engineering (except those used for therapeutic purposes and then only if they do not undermine human dignity).

It also urged the Community to work towards the conclusion of an international agreement on patentability tests for inventions resulting from genetic research programmes. The discussions about the patentability of genes with no known function had highlighted certain ambiguities in the basic principles of patent law when applied to living matter.

Subsequent developments

On 16 December 1992 the Commission presented an amended proposal for a Directive to the Council, incorporating the ethical dimension. The Council agreed to adopt the Commission's proposals. The Group's opinion served as a catalyst in this process. The Council's common position was adopted on 7 February 1994.

The Group of Advisers achieved its full potential in this particular case:

- because its opinion was perfectly timed to coincide with the preparation of the Directive. Consequently, the rapporteur, Ms Lenoir, was able to meet Parliament's rapporteur and take part in the Council's expert meetings

- it strengthened the Commission's position in relation to the Council and Parliament;

- because the opinion addressed issues of general importance the Commission distributed it widely. It was sent to Parliament, Council, the Council of Europe, the World Intellectual Property Organization and the European Patent Office. It is available to the public on request.

3.2 Work in progress

3.2.1 Transgenic animals

Rapporteur: Lady Warnock and Professor Siniscalco
Referral: Commission request of 29 September 1992

Background

Developments in the field of animal transgenesis raise numerous ethical issues which require clarification. It is also important to decide whether there is a case for Community guidelines in this area, particularly as regards research and technological development programmes funded by the Commission.

Report

The Advisers have studied the effect of animal transgenesis from the point of view of animal welfare, genetic diversity, commercialization and the current state of the technique.

They have left the task of finalizing this report to their successors.

3.2.2 Gene therapy

Referral: Commission request of 23 September 1993

Progress in genetic engineering suggests vast possibilities for applications of gene therapy. While this raises very high hopes it also entails risks which pose certain ethical questions. Germ-line therapy, for example, would transmit the genetic modification to all descendants of the patient. With a view to defining certain criteria and formulating certain ethical principles, the Commission requested an opinion from the Group of Advisers on this issue.

The councellors, at the time of their initial discussion, made a clear distinction between somatic and germ-line therapies. Only the former had been experimented upon. The latter, where experiments were not yet envisaged, already raised ethical issues of unprecedented magnitude.

The Advisers have left the task of formulating an opinion on this issue to their successors.

3.2.3 Ethics and science

In this report, produced by the Group on its own initiative, Professor Zacher examines the fundamental ethical values which have to be preserved in the field of biotechnology. The report is intended to serve as a philosophical basis for the Group of Advisers.

3.3 International conferences

The Group of Advisers was represented at recent major events in the bioethics field by one of its members and/or its secretariat.

These include the following conferences: BioEurope '93 organized by the Senior Advisory Group Biotechnology, Brussels, May 1993; the colloquium on international cooperation for the Human Genome Analysis Programme in Bilbao, May 1993, sponsored by the Banco Bilbao Vizcaya Foundation; the inauguration of UNESCO's International Bioethics Committee in Paris, September 1993; the second Council of Europe Symposium on Bioethics in Strasbourg, November 1993.

4. GROUP WORKING METHODS

Discussions between advisers and the experience they have acquired have enabled the Group to develop guidelines on which to base its future work.

4.1 Approach followed

The Group:

* studies ethical aspects on a case-by-case basis in an attempt to extract general principles or ethical criteria. Its aim is not to halt progress in the field of biotechnology but to control the applications which can raise ethical questions. Any bioethical compromise will continue to depend on the progress of science.

* analyses ethical aspects following a triple approach:

  - a general approach investigating any conflict of values,
  - a subjective approach taking into account the predictable or less predictable reactions of the public,
  - a forward-looking approach aimed at assessing the consequences of the potential use of a product or the possible application of a technique.

* discusses whether or not there is a need for legislation for each topic under consideration.

* monitors work carried out at Community level (European Parliament STOA programme, ESLA and HER working parties at the Commission) and in other bodies such as the Council of Europe and UNESCO. Its aim is to work with these organizations in a spirit of cooperation and coordination to promote the emergence of a common system of values.

4.2 Guiding principles

The Group:

* gives priority in its deliberations to the concerns of European citizen and emphasizes the need to promote public information, education and training in this field. The idea is to increase awareness of risk, in order to avoid any unjustified hostile reaction. In all its debates it takes into account the aspirations of the public and the need to set ethical markers;

* sees its role, in its relationship with the Commission, as a watchdog, alerting it to the risks accompanying advances in biotechnology. It uses its right of initiative when it considers that such a risk is virtual or, on the contrary, is overstated because of erroneous data;

* is aware of the scale of the economic and industrial challenge of biotechnology, maintaining that ethical considerations are an integral part of the development strategies concerned and are at the very heart of the political debate. However, it makes a clear distinction between ethical and other considerations relating to the development of biotechnology (e.g. the BST issue);

* applies a proportionality criterion to ensure that the benefits of biotechnological progress come before the possible drawbacks or the risks that may be involved;

* takes as its basis the principle of freedom of research. Ethical control should not compromise this principle, even though today it demands that thought be given to the purpose of the research.

* stressed the priority given to safeguarding human rights ahead of promoting economic and social development, ideas which are at the foundation of European construction.

5. CONCLUSION

Throughout the Twelve bioethics is at the heart of the debate on the choices of society, a society which now, more than ever before, is debating its future.

What is more, bioethics involves a sector - biotechnology - which, in economic terms, represents a major proportion of what are among the most strategic activities for the development of the Community.

Finally bioethics affects the relations and hence the understanding which must exist between the citizens of Europe and the decision-makers at both national and Community level.

For these reasons the Commission must be able not only to take part in the discussions on bioethics but also to take clear options. In each instance observance of individual rights must be reconciled with the demands of economic and social development.

To do this the Commission must anticipate. It must make a choice between what is foreseeable and what is desirable.

This is the reason for enhancing the role of the Group of Advisers.

The Group will operate in the following way:

* To begin with, it will listen, so that its opinions are based on comprehensive, accurate and up-to-date information.

* It will be pragmatic, taking each case individually and without any prejudices.

* It will be open and dynamic, bearing in mind that progress is part of the adventure of mankind and stopping progress would be to lose hope.

For any further information on the Group of Advisers, would you please contact in the European Commission : Mrs I. Arnal and Mr. A. St Rémy, Secretariat-General, BREY. 7/232, 200 rue de la Loi, 1049 Brussels, Tel. 322-296.21.19.

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ANNEX 1

OPINION OF THE GROUP OF ADVISERS ON ETHICAL ASPECTS OF BIOTECHNOLOGY OF THE THE COMMISSION OF THE EUROPEAN COMMUNITIES

N° 1 Date: 12.03.93

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THE ETHICAL IMPLICATIONS OF THE USE OF PERFORMANCE-ENHANCERS IN AGRICULTURE AND FISHERIES

Reference: Commission request for an opinion dated 27 February 1992.
Rapporteurs: Lady Warnock and Mr Siniscalco

* *

1. Presentation of the problem

1.1 DEFINITION

Performance-enhancers manufactured using biotechnology are administered to animals and fish in their feed or by techniques such as injection or implantation, on a regular basis or over a period, to stimulate their productivity and/or improve the ratio of meat to fat.

Bovine somatotropine (BST) or bovine growth hormone is one of these performance-enhancers. This involves a hormonal protein produced by the pituitary gland which stimulates not only bone growth and protein anabolism, but also galactopoesis (increase in milk secretion during lactation shown in cattle). BST can currently be produced by genetic engineering on an industrial scale.

In the second Commission Report on bovine somatotropine of 21 January 1992[1], the Commission outlines current data on BST assessment and invites the Advisory Group on biotechnology ethics to form an opinion on the ethical consequences which may result from the administration of growth promoters in agriculture and fisheries.

1 SEC(91) 2521 final

1.2 CURRENT GENERAL SITUATION

Currently, four American pharmaceutical companies (American Cyanamid, Eli Lilly, Monsanto, UpJohn) are in a position to market BST and have applied to the American and European authorities for authorization.

Some countries have authorized its use (Mexico, the former USSR, Czechoslovakia, Bulgaria, South Africa, Namibia and Zimbabwe). However, no authorization has been given to date in the Member States, the United States, Canada, New Zealand, Austria, Switzerland or the Scandinavian countries.

1.3 REGULATORY SITUATION AT THE COMMUNITY LEVEL

Under Directive 87/22/EEC, applications for authorization to place veterinary medicinal products on the market manufactured using biotechnology must be submitted for opinion to the Committee on Veterinary Medicinal Products (CMVP), before a final decision can be adopted at national level on the authorization of the product in question. These opinions are delivered on the basis of objective scientific criteria of quality, safety and the efficacy of the product, and not any economic or other consideration[1].

So far the CMVP has delivered an opinion on two applications: in March 1991 on the application submitted by Monsanto for "Somatech"; in December 1991, the Committee delivered a public opinion in the form of a statement on the application submitted by Eli Lilly for "Optiflex 640". From the point of view of safety, quality and efficacy both products are apparently considered to be satisfactory. However, some Member States think no satisfactory answer has been given to questions concerning the possibility of an increased incidence of mastitis and inflammatory reactions at the site of injection among dairy cows treated with BST[2].

At present the CMVP consultation procedure has been suspended as the Council has intervened to prohibit the use of BST in the Community until 31 December 1993 pending the results of the current studies on the effects and consequences of this product - in particular from the point of view of health and animal welfare[3].

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1 Second Commission Report on bovine somatotropine - ibid p.7
2 Second Commission Report on bovine somatotropine - ibid p.7
3 Time limit extended successively by Council Decisions 90/218 of 25 April 1990, 91/61 of 4 February 1991 and 92/98 of 10 February 1992.

2. Identification of the aspects to be taken into account by the Group

2.1 GENERAL ASPECTS

The Group is aware of the fact that among the various aspects to be taken into consideration in deciding for or against the use of BST, economic and political arguments play a major role, such as the advisability or not of an increase in milk production in Europe and the possible exploitation of the European market by American pharmaceutical firms.

The Group is also aware of the fact that European needs cannot be seen in isolation from the needs of the rest of the world and yet that the european market must be considered in a realistic light.

However, the Group considered that such problems go beyond its terms of reference, since they are not ethical problems in a narrow sense.

2.2 ETHICAL ASPECTS

The ethical considerations relevant to the use of BST fell into four categories:

2.2.1 Human health and safety

Two kinds of fears have been expressed:

- The US General Accounting Office finds that the use of BST is associated with the frequency of bovine mastitis, against which antibiotics are administered. The antibiotic concentration in milk and in beef or veal could be a risk factor (indeterminate) for consumer's health.
- Somatic cells in the milk produced using BST could be excessive and damaging to consumers.

2.2.2 Animal welfare

The use of BST or medication subsequently administered on animals could lead to pain or discomfort for these animals which is disproportionate to the human good expected from the use of the product.

2.2.3 Freedom of choice of the consumer

Concern has been expressed about the freedom of consumers to choose between BST treated milk and other milk.

2.2.4 Biological diversity

The fear has been expressed that the use of BST on selected subgroups of animals could be harmful to the biodiversity of the species involved.

3. Opinion

The following opinion was expressed with respect to the above listed Ethical Aspects:

3.1 HUMAN HEALTH AND SAFETY

- Mastitis and other inflammatory reactions are caused not peculiarly by BST but by high yield of lactation wether brought about by BST or by selective breeding. Milk derived from animals treated with antibiotics for mastitis and other inflammatory reactions should be banned from human consumption for as long as required for the drug to be totally absent. Such a requirement would favor the practice- which is by itself sufficient to solve the problem- of controlling animal infections through the mere observance of drug free hygienic measures. In addition, it has to be pointed out that a high-yield lactation can be stopped at will by removal of the drug in BST-treated animals, but it is irreversible in animals which are the result of selective breeding.

- The problem about a possible, yet unproven, unhealthy effect of an excessive number of somatic cells in milk produced by high-yield lactation animals (again regardless of the technique applied for their production, i.e. BST treatment or selective breeding) can be easily settled by fixing a threshold level of somatic cells acceptable per millilitre of milk such as the one already observed for the milk of high-yield lactation cows obtained through selective breeding.

3.2 ANIMAL WELFARE

The Group considers that though it is ethically acceptable for humans to use animals for good human ends, they must not treat them with indifference, and thus any drug or procedure likely to induce severe or enduring pain should not be authorized.

3.3 FREEDOM OF CHOICE OF THE CONSUMER

The Group thinks that the freedom of choice of the consumer will be guaranteed once it is possible to detect BST traces in milk and it is labeled as BST-treated milk.

3.4 BIOLOGICAL DIVERSITY

The Group concludes that the procedure of inducing high-yield lactation through drug-induced treatment is expected to safeguard the preservation of Biological Diversity if applied judiciously i.e. to improve the performance of all domesticated breeds of animals. On the contrary, the persistent application of intensive selective breeding in favor of the phenotypical trait in question with or without BST, could not only lead to general loss of genetic heterogeneity, but -in the long run- also to the deterioration of the desired phenotypical feature itself, as a result of the well known irreversible accumulation of homozygosity brought about by protracted inbreeding. Thus the Group considers that on the basis of the data available the use of BST as such will not threaten Biological Diversity.

4. Recommendation

The Group concludes that the use of BST to increase lactation in cows is ethically unobjectionable, and safe for both human and animals, provided that the following measures are adopted:

4.1- assurance should be provided that BST-treated animals do not suffer extreme pain or even discomfort that is disproportionate to the human good expected from the use of the product;

4.2- treatment should be stopped when increased lactation of milk is associated with mastitis or other inflammatory reactions;

4.3- these reactions should be controlled through the application of simple hygienic measures or -if cured with antibiotics- the milk produced by the animals so treated should be banned from human consumption until the antibiotics are totally eliminated;

4.4- the level of somatic cells per millilitre of milk should not be higher than the concentration found in the milk thus far produced by high-yield lactation cows obtained through selective breeding;

4.5- if it becomes possible to distinguish milk derived from BST-treated cows from other milk, then the vendors should be required to label it and its derivatives to allow free choice to the buyers.

Besides these ethical aspects, the question of marketing or non-marketing BST in the European Community is mainly a political issue which should be discussed as such. In this context, the effects of BST on evolution of agricultural structures, as well as consumers' reactions should be taken into account in the appropriate forum when the relevant data is available.

In accordance with its terms of reference, the Group of Advisers on Ethical Aspects of Biotechnology submits this Recommendation to the Commission.

The Chairman

Signatures of the members of the Group of Advisers:

OPINION OF THE GROUP OF ADVISERS ON THE ETHICS OF BIOTECHNOLOGY
OF THE COMMISSION OF THE EUROPEAN COMMUNITIES

N° 2 Date: 12.03.1993

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PRODUCTS DERIVED FROM HUMAN BLOOD OR HUMAN PLASMA

Reference: Own-initiative report proposed by President Delors
Rapporteur: Mrs Mikkelsen

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1. General introduction

1.1 MEDICAL ASPECTS

Blood is an integral component of the human organism and can, as such, be donated to patients. Its unique feature is that the same donor can give blood repeatedly over a consiserable number of years. Blood carries cellular and non-cellular components throughout the vascular system. It consists of red and white cells, platelets and plasma. The major proteins are albumin, immunoglobulins and coagulating factors which, in conjunction with platelets, repair lesions to the vascular walls. Blood cells and a variety of plasma proteins are extensively used in modern medical therapy and prophylaxis.

1.2 LEGAL ASPECTS

Directive 89/381/EEC extends the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products and lays down special provisions for medicinal products derived from human blood or human plasma. It entered into force on 1 January 1992; six Member States (Denmark, Greece, Ireland, Italy, Portugal and the United Kingdom) have notified national measures transposing it.

The Directive pursues the following objectives:

* to encourage the self-sufficiency of the Community through voluntary unpaid blood and plasma donation;
* to introduce strict criteria guaranteeing the quality, safety and efficacy of medicinal products derived from human blood or plasma, notably to avoid viral contamination;
* to harmonize conditions for authorizing the manufacture of blood-based products.

The Directive does not apply to whole blood, plasma or blood cells of human origin, or to blood donation and transfusion activities, except where aspects of the production of medicinal products from blood are concerned.

It should be noted that blood donation is now considered an old fashioned methodology and significant ameliorations are expected in the future. Production of factor 8 by genetic engineering is already available and should be encouraged further. Other developments will make products from human blood less necessary.

1.3 THE NATIONAL ETHICAL COMMITTEE'S REACTION TO THE DIRECTIVE

Opinion N° 28 (blood transfusion), issued on 2 December 1991 by the French National Ethical Committee, considers that the Directive treats blood and plasma as a "starting material" ("matière première" in French corresponds more closely to "raw material" in English) and blood derivatives as medicinal products, thus making them seem to be tradeable goods, contrary to the principle that the human body is not marketable and contrary to human dignity.

The Commission does not accept this. Since 1965 the Community definition of medicinal products given in Article 1 of Directive 65/65/EEC has applied to blood products. It reads: "any substance or combination of substances presented for treating or preventing disease in human beings ...".

The problem is thus purely terminological.

1.4 THE CONTAMINATED BLOOD AFFAIR

When the human immunodeficiency virus (HIV) was detected among blood donors in 1980 or thereabouts, hemophiliacs were faced with the new fatal risk of AIDS. The finding of a link between seropositive hemophiliacs and blood plasma donations was first shown in 1983. At the end of 1985 most fractionation laboratories had introduced a system of deactivating HIV by heat treatment. By then a large number of hemophiliacs had been infected. Unluckily there was a brief period around 1985 when hemophiliacs were still being infected as business interests dictated the further use of old techniques.

2. Identification of ethical considerations

2.1 PROTECTION OF THE DONOR

Blood is an organ of the human body and should be treated as such. This should include the concept of human dignity. The donor should be protected against to him or her unfavourable results of blood or plasma donation. This can be more easily achieved when blood donation is volontary and unpaid.

Those who give blood for money may not be motivated by wholly idealistic considerations; poverty may play a role, for one thing. Excessively frequent plasmapheresis can render the subject vulnerable to infection and even provoke a state of malnutrition.

2.2 PROTECTION OF THE DONEE

There are pathogenic risks in human blood. Several diseases can be transmitted by blood: AIDS, hepatitis, syphilis, malaria and toxoplasmosis are among them. On the safety front, Directive 89/381/EEC lays down stringent rules to guarantee the quality, safety and efficacy of products derived from blood, through the proper validation of manufacturing and purification processes and examination of donors. The Directive makes the measures adopted by the Council of Europe and the World Health Organization on the selection and testing of donors mandatory in the Community.

2.3 THE MARKETING OF BLOOD

Respect for the individual (right to life, to physical integrity and to human dignity), whether as donor or as donee, is at the foundation of the ethical principle that the human body in general and human blood in particular are not marketable.

Two points flow from this:

* blood donations should be voluntary, unpaid and anonymous;
* nobody should be allowed to make a profit from a donor's blood. If blood is used for the manufacture of derivatives, neither the supplier nor the manufacturer should be allowed to charge more than the actual costs incurred.

2.4 AVAILABILITY OF SUPPLIES AND SELF-SUFFICIENCY

In general terms, a shortage of blood supplies is ethically unacceptable. Blood should be used more economically in order to arrive to a level of self-sufficiency as fast as possible.

National and Community self-sufficiency helps to reduce the risk of spreading non-endemic diseases such as malaria in the Member States and makes quality controls easier. Article 3 of the Directive requires the Member States to take the necessary measures to promote Community self-sufficiency. In cases of blood importation from third countries, the authorization process should include requirements for the blood importation for products derived from human blood.

3. Opinion

The Group has scrutinized Directive 89/381/EEC on products derived from human blood and human plasma. It has concluded that it is sound.

It has also discussed recent developments in the field, and in particular the Opinion given by the French National Ethical Committee on the Directive and on the contaminated blood affair.

Following its discussion, and having regard to the suggestions made by the French Committee, the Group of Advisers on the Ethics of Biotechnology is of the opinion that:

3.1 The following ethical principles should be stressed in the Directive:

- the donee's health (availability and quality of blood supplies);
- the donor's human dignity (anonymity, voluntary donations);
- non-marketability of the human body (donations to be unpaid).

Apart from the obvious payments that are acceptable for administrative purposes and industrial developments, no one should have additional profits from blood donations that contradict the principle of non-marketability of human body.

3.2 The expression "medicinal products" as applied to products derived from blood, should not be rejected as these products are used as therapeuticals, and this term gives a guarantee of quality to the products through the authorization process related to medical products.

3.3 All the guarantees as to the safety, quality and efficacy of medicinal products should be applied in relation to products derived from blood.

3.4 All the proceedings related to blood donation should rest with organizations submitted to public control which are able to ensure a maximum guarantee with respect to the quality of the products.

The group intends to deal separately with the problem of an adequate compensation to the victims of medicinal products derived from human blood.

In accordance with its terms of reference, the Group of Advisers on the Ethics of Biotechnology hereby presents this Opinion to the Commission.

Signatures: The members

The Chairman

ANNEX 3

OPINION OF THE GROUP OF ADVISERS ON ETHICAL ASPECTS OF BIOTECHNOLOGY OF THE THE COMMISSION OF THE EUROPEAN COMMUNITIES

N° 3 **Date:(30.09.1993)**

* *

OPINION ON ETHICAL QUESTIONS ARISING FROM THE COMMISSION PROPOSAL FOR A COUNCIL DIRECTIVE ON LEGAL PROTECTION FOR BIOTECHNOLOGICAL INVENTIONS

Reference: Own initiative of 12 March 1992.
Rapporteur: Mrs Noëlle Lenoir

* *

I. BACKGROUND

1.1 Scope of the Directive

The purpose of the proposed Directive, the first version of which was presented by the Commission on 21 October 1988, is to harmonize patent law relating to living matter throughout the Community.

As a single market measure, it seeks to ensure the free movement of goods and prevent abuses of dominant positions.
Since protecting innovation through patent law is an important part of promoting research and economic growth, the Directive is also intended to help European companies compete with their American and Japanese counterparts in the very promising biotechnology industry.

The Directive would appear to be the first international text to deal specifically with biotechnological inventions.

1.2 History of patent law as a way of protecting inventions

The beginnings of patent law can be traced back to the Age of Enlightenment. Originally, patents were seen as a form of social contract between the inventor and society: society protected the inventor, by ensuring that he was rewarded for the disclosure of his invention and, in return, the inventor agreed to make his invention freely available.

Through the patent, the inventor shared the knowledge of his invention with the rest of society (see the report to the French National Assembly for the debate on the Act of 7 January 1791, one of the first to establish patent protection of inventions).

The first three to pass laws on patents were after Venice. (Statute of Inventors, 1474), England (Statute of Monopolies, 1623), the United States (in 1790) and France in 1791.

Since then, all of the industrialized countries and many developing countries have enacted patent legislation.

1.3 The situation today

Patent law today is complex in the extreme.

First, in addition to all the domestic legislation, there is a myriad of international conventions, covering many different fields and geographical areas.

The basic agreement is the 1883 Paris Convention for the Protection of Industrial Property. It established such corner stones for the international protection of intellectual property rights as the principle of national treatment, the right of priority and other minimum rights. It also led to the setting up of an International Bureau in Berne. This has since developed into the World Intellectual Property Organization (WIPO), with its headquarters in Geneva. The Convention has been ratified by over 100 countries.

Patent law, whether domestic or international, generally applies across the board to inert and living matter alike. The Budapest Treaty (1977), ratified by some thirty countries, would appear to be the only treaty to deal exclusively with patents on living matter, albeit only with the procedure for filing patents. It does no more than require international recognition of the deposits of microorganisms with the relevant institutes and offices by contracting States.

However, in countries which are member states of the International Union for the Protection of new Varieties of Plants an obligation for legislation has been established to distinguish between inventions relating to plant varieties on the one hand and to other living matter (microorganisms, for instance) on the other hand. Due to the originally established ban on double protection under the so-called UPOV Convention, member states were obliged not to protect plant varieties belonging to the same botanical species or genera by utility patents and plant variety certificates along the lines of the UPOV Convention. This ban on double protection, however, has been removed from the UPOV Convention through the new UPOV Act adopted in March 1991.

1.4 European regulations

While there is not as yet Community patent law as such, there are many European conventions covering more than just the twelve Community Member States.

The first of these to be concluded was the Strasbourg Convention on the Unification of Certain Points of Substantive Law on Patents of Invention, signed by the Member States of the Council of Europe in 1963. The Strasbourg Convention has established an obligation of contracting parties to protect microbiological processes and the resulting products, but left open to the contracting states to protect plant or animals and essentialy biological processes for the protection of plants or animals. This Convention laid down the criteria for the patentability of inventions. It also specified the circumstances under which an invention was not patentable.

However, the main convention at European level is the European Patent Convention (EPC), which was concluded in Munich in 1973 and entered into force in 1978. It was signed by seventeen states, all the Community Member States, Austria, Sweden, Switzerland, Lichtenstein and Monaco.

The EPC also included specific provisions on biotechnology. Although it essentially followed the basic lines of the Strasbourg Convention, it introduced an essential change in so far as plant or animal varieties and essential biological processes for the production of plants or animals have been declared unpatentable. It also laid the foundation for the setting up of the European Patents Office (EPO), which is known for the very important part it has played in developing European patent law.

The European Community is about to adopt its own rules in two areas.

First, the Directive under consideration here lays down rules concerning biotechnology in general.

The second set of rules is concerned, in particular, with the protection of new varieties of plants. Special protection for new varieties of plants, as distinct from general patent protection, is already afforded by the "UPOV" Convention, a major international convention adopted in Paris in 1961. The new Community legislation would take the form of a Regulation (currently at the drafting stage) establishing a Community system for the protection of new plant varieties.

A comparison of European legislation (existing and draft) with US laws reveals that:

(a) as regards the tests of patentability - apart from novelty, a universal condition, US law requires also "non-obviousness" which equals our prerequisite of an inventive step. US requires that the invention be useful, whereas, under European law, it must be capable of industrial application ("if it can be made or used in any kind of industry, including agriculture", art. 57 EPC);

(b) US law makes no provision for the many exceptions to be found in European law (particularly the EPC) which make certain products and processes involving living matter unpatentable. Those exclusion clauses (art. 53 b EPC) have been the main obstacles for EPO's work.

The Directive under consideration in this Opinion does not set out to revise these exceptions. Its stated aim is merely to harmonize the interpretation of existing international conventions throughout the Community. The Directive even includes certain provisions taken over verbatim from existing European conventions (in particular the EPC).

The Group notes that, in spite of this, the drafting process has taken longer than expected, mainly as a result of the ethical objections raised by Parliament.

Several new provisions, mostly on ethical questions relating to the patentability of living matter, were added to the Directive at the committee stage in Parliament (particularly in the Committee on Legal Affairs and Citizens' Rights, acting on the Rothley Report).

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Most recently, Parliament adopted a resolution at the beginning of 1993 condemning the production of transgenic animals outright and calling for a moratorium.

This shows that, in the discussions on the Directive, ethical considerations now outweigh the purely legal and economic concerns.

II. ISSUES TO BE TAKEN INTO CONSIDERATION

2.1 General questions

The Group is aware how important it is for Europe to step up biotechnological research and develop the industry as a whole. It feels, therefore, that the Community should have its own legislation on the legal protection of biotechnological innovation.

The Group welcomes the fact that, during discussion on the Directive in question, the Community institutions, particularly Parliament, have had the opportunity to express their concern about the ethics of advances in biology and genetics. Lastly, the Group sees it as a democratic imperative that the public be provided with clear up-to-date information on the science and the related ethical issues.

2.2 Ethical questions

2.2.1 Patentability of living matter

Since its birth in the 1970s, genetic engineering has given man tremendous power - power to manipulate living matter. The apprehension about this is reflected in the debate on the Directive.

Some people are so concerned as to question the legitimacy of patenting living matter. "You cannot invent nature", was how one French lawyer put it in a highly critical commentary on the judgment given by the Supreme Court of the United States on 16 June 1980 in Diamond v Chakrabarty, which upheld the patentability of a microorganism per se (Ananda M. Chakrabarty, a researcher of general Electric, had discovered plasmids which, when incorporated into bacteria, were capable of breaking down the components of petroleum, and had patented their invention as a useful anti-pollution agent).

The Group is of course unable to subscribe to such a utopian and simplistic view of nature, described as being never modified by humankind.

Its view on this is set out in greater detail below.

1. The practice of granting patents on living matter goes back a long way. It certainly predates the emergence of genetic engineering and was explicitly endorsed in the early 1960s, first by the UPOV Convention (1961) and subsequently by the Strasbourg Convention (1963).

   One should but note that the first known patent of a living organism was granted in Finland in 1843 and Louis Pasteur received a patent from US Patent Office for a yeast free from organic germs of desease as early as in 1873.

of course, the opening up of so many new possibilities for altering living organisms does justify changing patent law, which is what the Directive rightly sets out to do.

2. The Group sees no ethical grounds for opposing the patentability of inventions relating to living matter in principle, even though there are certain types of genetic manipulation which should, in its view, be strictly prohibited.

This should be mainly a matter to be dealt with under the competent branches of public law dealing with the use and commercialization of research results in respect to public safety, health, environment and animal welfare. Nevertheless if patent law cannot substitute laws in the respective fields, it is useful to mention in the directive the ethical concerns raised by genetic engineering.

The Group is mindful of the reservations some people have had for some time now about biological inventions. But it is also worth considering that, originally, chemical and pharmaceutical inventions were also denied all protection under patent law. The value of biotechnology for industry, agriculture, the environment and medicine cannot be denied. The Group is of the opinion that, in order not to hinder its development, the principle of the patentability of inventions relating to living matter must be upheld wherever ethically possible.

2.2.2 Non-patentability of inventions whose publication or exploitation would offend against public policy or morality

The Directive reproduces Article 53(a) of the EPC prohibiting the patenting of any invention the publication or application of which would be contrary to public policy or morality.

When the Directive was going through the Parliamentary committees, provisions were added prohibiting the granting of patents for certain products and processes involving humans and animals.

The group shares the ethical considerations behind the provisions added as reaction to the debate in the european Parliament. Yet, it is wondering wether the amendments are to be considered as part of the directive's body.

The appropriate place to address and resolve some of those considerations seems to be the recitals of the directive. Moreover, attention is drawn to the fact that a patent does not confer on the patent owner the right to make use of the patented invention but only to prohibit its use by others. There is no positive right to make use linked with a patent.

2.2.3 Protection of human dignity

The concept of human dignity appears for the first time in Community law in Article 2(3)(b) of the amended proposal for a Directive, which states that "processes for modifying the genetic identity of the human body for a non-therapeutic purpose which is contrary to the dignity of man" are unpatentable (implicit reference to cloning and chimera-production, etc.)

Human dignity was already expressly protected by a variety of international conventions (e.g. the European Convention on Human Rights) and certain domestic legal instruments (e.g. the Basic Law of the Federal Republic of Germany, adopted in 1949) but not, it would appear, by Community law. Hitherto, the concept has figured only in the two following declarations of principle:

(i) the Parliament resolution of 16 March 1989 on the ethical and legal problems of genetic engineering; and

(ii) Council Decision 90/395/EEC of 29 June 1990 adopting a specific research and technological development programme in the field of health: human genome analysis.

While it may seem strange that the first-ever reference to the principle of respect for human dignity should be made in a directive on patents, it is an indication of the concern aroused by certain developments in the fields of human genetics and medicine. That is not to say that the attention given to ethical considerations in the Directive does not constitute a new departure in patent law.

(a) Article 2(3)(a) prohibiting the patenting of the human body or parts of the human body per se.

It is necessary that the question of the patentability of human genes and partial gene sequences should be dealt with in the recitals to the Directive. The controversy over this issue started with the American National Research Institutes' decision to file patent applications with the US Patent Office. It must be made clear that identifying genes or partial gene sequences without discovering their function does not constitute an "inventive step" and is not patentable. Any ambiguity on this point must be cleared up in order to uphold the freedom of research and the freedom of researchers to exchange information.

Furthermore, the acknowledgement at a community level of the principle that parts and products of the human body may notbe commercially exploited (e.g. in the case of organ transplants) should be studied.

(b) Article 2(3)(b) on human genetic engineering

The Group acknowledges the need to reaffirm the ban on genetic engineering for non-therapeutic purposes, contrary to the dignity of man, but feels that the Directive is not the right place to deal with the very complex issue of the legitimacy of germinal therapy.

On a different note, it is questionable whether Article 2(3)(b), which seemingly endorses the patenting of genetic therapy techniques, is compatible with the other provisions of the Directive prohibiting the granting of patents for surgical and therapeutic methods of treatment and diagnostic methods practised on the human (or animal) body.

The same methods are also unpatentable under Article 52(4) of the EPC, the original purpose of which was to protect medical practitioners from prosecution for infringement in the exercise of their profession. Today, however, the medical profession would appear to be adequately protected by the laws on the use of inventions for private purposes.

Nevertheless, the remaining restrictive provisions concerning human medicine should be removed from the Directive in the interests of consistency.

2.2.4 Transgenic animals

By making it possible to mix genetic material from separate species, genetic engineering has given man the power to produce an endless range of plant and animal varieties, all tailor-made to suit his own needs.

In recent years, a number of transgenic animals have been created by micro-injection and embryo-fusion (in the United States, four patents have been issued for Onco-mice, including the Harvard mouse, and in May 1992 the EPC agreed to grant a patent to the mouse's inventor). Transgenic animals open up a number of possibilities:

(i) they can be used in medical research to study human disease patterns;
(ii) they can be used to synthesize chemical substances needed for human medicines, which can easily be obtained from their physiological fluids;
(iii) in agriculture, there is scope for rearing fast-growing, high-weight animals yielding predetermined nutritional values or with in-built resistance to disease.

Despite the fact that animals have always been used by man as a resource (at one time, they constituted his main source of food), the production of transgenic animals arouses strong feelings among the public.

Parliament's resolution calling for a moratorium, adopted at the beginning of 1993, relayed the feelings expressed by various groupings (e.g. associations opposing animal experimentation).

The Group cannot ignore this reaction or the people expressing it.

At the same time, it does not feel it would be advisable to ban transgenesis on animals as this would bring medical progress to a standstill or, worse still, result in experiments being carried out on humans before essential preliminary tests had proved them safe.

Thus, there is a strong case for making transgenic animals patentable (the animals rather than just the process of transgenesis because of the need to protect the inventor for successive generations).

The Group does, however, feel that the legal and ethical questions surrounding transgenic animals do require some clarification.

1. The Directive should make clear that it is possible to patent the production of a transgenic animal if it is at the end, useful to man, particularly in the field of scientific research, medicine and agriculture.

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2. A more detailed study should be carried out at Community level into the uses of transgenic animals, with reference to the objectives pursued in the various areas in question.

3. Effective inspection arrangements should be devised to ensure that animals are not subjected to unnecessary or excessive suffering in laboratories.

4. It is essential to address the question what constitutes an animal species, a stock or a "breed" and what exactly should remain non-patentable.

It is to this end that the Commission has just officially requested an opinion from the Group.

2.2.5 Biological diversity

Biodiversity has come to be seen as ethically desirable. Some people fear that it is threatened by advances in biology and genetic engineering. As the Group sees it, however, there is no direct link between patent law and biodiversity.

III OPINION

The Group's opinion is set out below.

After examination of the ethical questions relating to:

the legitimacy of patenting living matter;
the need to protect human dignity;
the production of transgenic animals; and
the preservation of biodiversity,

the Group of Advisers on the Ethics of Biotechnology:

- is of the opinion that there are no ethical objections to the patenting of biotechnological inventions per se; and that, furthermore, in pursuit of its economic and social objectives, it is essential for the Community to harmonize patent law relating to biotechnology;

- acknowledges the ethical questions raised by biological and genetic research and the applications thereof, and considers it right that, at the initiative of Parliament, in touch with people's concerns, these questions should be addressed mostly in the recitals of the Directive;

- considers that, since these issues have never previously arisen in the field of patent law, some clarifications are urgently needed on certain concepts and on the scope of certain provisions in the Directive.

Human genetics

Genes and partial gene sequences whose functions are unknown should be made expressly unpatentable to end the international debate on the matter. In due course, the Community should try to arrange an international agreement on the patentability tests for inventions resulting from genetic research programmes.

Furthermore, the Community should take a stand against the commercial exploitation of the human body.

Transgenic animals

There is no need to impose a complete ban on the production of transgenic animals. Extreme care must be taken to ensure that they are used for adequate purposes, not suffer inadequate pain or cause damage for the general public.

Biodiversity

The Directive itself poses no threat to biodiversity. However, with ratification of the UN Convention on Biological Diversity, the Community would be well advised to start considering the matter with view to clarifying what it understands the concept to mean in practical terms.

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None of the other themes dealt with in the Directive (e.g. farmer's privilege) raises ethical questions which fall within the Group's remit.

The Group wishes to draw the Commission's attention to the need for measures to familiarize the public not only with the scientific and economic side of biotechnology but also with the social, legal and ethical implications. This is a democratic imperative.

In accordance with its remit, the Group submits this opinion to the Commission.

One member of the group is of the opinion that the demands worded in Section II, par. 2.2.4., points n° 2 and 3 should be addressed to general public law, not to patent law.

Concerning Section III, 3rd par., second dash, one member of the group emphasizes that respective provisions must, as a matter of principle, be made in general public law, not, however, in patent law.

[signed]
Chairman

[Signatures of the members of the Group of Advisers]

Opinions adopted - Repercussions - State of play

12. BST

EUROPEAN COMMISSION

Secretariat-General
SG/C/1

BST - OPINIONS ADOPTED AND REPERCUSSIONS

Opinion No 1 on the ethical implications of the use of performance-enhancers in agriculture and fisheries.

Rapporteurs: Lady Warnock and Professor Siniscalco
Ref.: Second Commission report on BST (SEC(91)2521 final)
Referral: Commission request for an opinion, 27 February 1992.

Background

Bovine somatotropin (BST) is a hormonal protein produced by the pituitary gland which stimulates not only bone growth and protein anabolism, but also galactopoiesis (increase in milk secretion during lactation in cattle).

Several studies have shown that the use of BST increases the incidence of bovine mastitis, which is treated with antibiotics. The concentration of antibiotics in milk and beef could pose a danger to consumer health. In addition levels of somatic cells in the milk produced using BST could be excessive and hence harmful to consumers.

The risk of bovine mastitis and frequent inflammation as a result of the administration of BST could be harmful to the health and well-being of the animals concerned.

In a decision of 10 February 1992 the Council asked Member States not to authorize the use of BST until 31 December 1993 and asked the Commission to report on the situation by July 1993. The Commission accordingly referred the matter to the Group of Advisers in order to determine the ethical implications of BST.

The Group's opinion

The Group concluded that the use of BST was ethically acceptable provided certain measures were adopted, particularly as regards:

- Consumer health and safety: administration of BST should be stopped if mastitis or other inflammatory reactions occur. Milk produced by animals treated with antibiotics should be withdrawn from sale until all traces of antibiotics have disappeared. The level of somatic cells per millilitre should not exceed that found in milk produced by traditional methods.

- Animal welfare: animals should not suffer extreme pain or discomfort that is disproportionate to the human benefit expected from the use of BST.

- Biological diversity: the use of BST does not adversely affect biodiversity.

- Freedom of choice of the consumer: milk and milk products derived from BST-treated cows should be labelled accordingly once it is possible to distinguish them from other milk and milk products.

The Group appreciated that, in addition to the ethical implications, the distribution of BST also raised important economic and political problems. However, it felt that these issues went beyond its terms of reference.

Subsequent developments

The Commission felt that the measures recommended by the Group would be difficult to implement at the present time. Backed by the Group's recommendations and on the basis of the conclusions of the Committee for Veterinary Medicinal Products, the Commission issued a recommendation to the Council and Parliament, on 13 July 1993, that the sale of BST should be banned within the Community for a period of seven years.

The Commission authorized the distribution of the Group of Advisers' Opinion No 1 to the public upon request.

EUROPEAN COMMISSION

SECRETARIAT GENERAL
SG/C/1

BOVINE SOMATOTROPIN (BST)
STATE OF PLAY

Bovine somatotropin (BST) is a biotechnological product which stimulates lactation in cows. The state of play as regards the marketing and administration of BST in the Community and in the United States is as follows.

European Community

In December 1993 the Council decided to extend the moratorium on BST until 31 December 1994. Discussions in the Council can therefore be expected to resume in the autumn.

The Commission had initially proposed a ban on BST until the year 2000 when the milk quota system is due to expire, since the effects of the substance conflict with the aims of the common agricultural policy.

The Commission's Group of Advisers on the Ethics of Biotechnology has recommended specific safeguards (a veterinary certificate in each case) for the administration of BST.

United States

Marketing and administration of BST had been allowed in the United States since 15 February 1994.

Consumer groups are now campaigning for the introduction of a labelling system to identify milk from cows treated with BST.

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13. Products derived from human blood or plasma

EUROPEAN COMMISSION

Secretariat General
SG/C/1

PRODUCTS DERIVED FROM HUMAN BLOOD OR PLASMA
OPINIONS ADOPTED AND REPERCUSSIONS

Opinion No 2 on products derived from human blood or human plasma.

Rapporteur: Margareta Mikkelsen
Ref: Directive 89/381/EEC extending the scope of Directives 65/65/EEC and 75/319/EEC
Referral: Own-initiative opinion (March 1992)

Background

Directive 89/381/EEC entered into force on 1 January 1992. It aims

- to encourage Community self-sufficiency through voluntary unpaid blood and plasma donation;
- to introduce strict criteria guaranteeing the quality and safety of medicinal products derived from human blood or plasma, notably to avoid viral contamination;
- to harmonize conditions for authorizing the manufacture of blood-based products by 1993.

The publication of the French National Ethical Committee's Opinion No 28 of 2 December 1991 triggered a debate and protests in France about the application of the Directive. The Committee took the view that, by treating blood and plasma as "starting material" and blood derivatives as "medicinal products", the Directive appeared to make them tradeable goods, which conflicted with the principle that the human body was not a marketable commodity and offended against human dignity.

This terminological difficulty connected with the use of the term "medicinal product" would no longer appear to be an issue.

The Group also examined the issue with reference to the cases of HIV infection following contaminated blood transfusions, particularly in France, Germany and Spain.

The Group's opinion

In the light of its discussions the Group identified the following ethical considerations:

- respect for the donor, donor anonymity and the principle of voluntary donations;
- health of the recipient, availability and quality of blood supplies;
- the human body is not a marketable commodity: no-one should make additional profits from blood donations.

As regards the Directive, the Group concluded that it was appropriate to use the term "medicinal product" with reference to products derived from blood because it provides a guarantee of quality and security.

In the Group's view, measures relating to blood donations should be the responsibility of organizations under strict public control.

Subsequent developments

The Commission authorized the distribution of the Opinion to the public on request.

EUROPEAN COMMISSION

SECRETARIAT GENERAL
SG/C/1

PRODUCTS DERIVED FROM HUMAN BLOOD OR PLASMA
STATE OF PLAY

Directive 89/381/EEC on medicinal products derived from human blood or human plasma

Purpose of the Directive

The purpose of the Directive is to protect human health by extending Community rules designed to guarantee the quality, safety and efficacy of medicinal products to products derived from human blood or human plasma (manufacturing authorization, marketing authorization). Application of these rules also guarantees free movement of these products.

The Directive also addresses the ethical aspects and advocates the promotion of voluntary unpaid donations to achieve self-sufficiency in the supply of blood and blood products.

Implementation of the directive

1. Technical provisions

Eleven Member States have transposed Directive 89/381/EEC and the twelfth (the Netherlands) is in the process of doing so. National legislation is now being checked by Commission departments for conformity with the Directive.

2. Voluntary unpaid donations

When the directive was adopted in 1989 the Council left it to the Member States to determine, in the light of their own situation, the best way of achieving the goal of Community self-sufficiency by means of voluntary unpaid donations without depriving patients of essential treatment.

The Council of Europe, which is referred to in the Directive, has produced a definition of voluntary unpaid donations. This specifies that donations of blood, plasma and cellular components must be freely made and that no benefits in cash or kind should be offered to the donor. Gestures such as refreshments and reimbursement of travel expenses are consistent with the notion of voluntary unpaid donations.

The Council of Europe, which is referred to in the Directive, has produced a definition of voluntary unpaid donations. This specifies that donations of blood, plasma and cellular components must be freely made and that no benefits in cash or kind should be offered to the donor. Gestures such as refreshments and reimbursement of travel expenses are consistent with the notion of voluntary unpaid donations.

Three Member States (France, Belgium and the Netherlands) have opted to promote voluntary unpaid donations by confining authorization to blood and plasma products derived from this source. Their degree of self-sufficiency made this option possible. Other Member States are not in a position to do the same without depriving patients of essential treatment. As a general rule[1], they do not allow payment for blood donations on their national territory but they do import plasma or products derived from paid donations, notably from the United States, to make good the shortfall in supplies.

In any event, provided they satisfy the requirements of Community legislation, products manufactured in any Member State must be given access to the territory of the other Member States on the same terms as products manufactured locally.

Follow-up to the Directive

Directive 89/381/EEC was challenged, notably in France, by blood donor associations on the grounds that it classified blood derivatives as "medicinal products".

The matter was referred to the Group of Advisers on the Ethics of Biotechnology, which endorsed the Directive and its public health objectives in March 1993.

In December 1993 the Council confirmed the importance of achieving self-sufficiency in blood and blood derivatives by means of voluntary unpaid donations, promoting blood donations with Community support, guaranteeing the quality and safety of blood collection and ensuring optimum use of blood and blood products.

The Commission will update its studies on blood donations and the utilization of blood and blood products at regular intervals and decide whether any action is needed.

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1 With the exception of Germany, which does allow a fixed payment for travel expenses and loss of earnings occasioned by absence from work.

Opinions adopted - Repercussions - State of play

14. Legal Protection of Biotechnological Inventions

EUROPEAN COMMISSION

Secretariat General
SG/C/1

LEGAL PROTECTION OF BIOTECHNOLOGY INVENTIONS
OPINIONS ADOPTED AND REPERCUSSIONS

Opinion N° 3 on the ethical questions arising from the Commission proposal for a Council Directive on legal protection for biotechnological inventions.

Rapporteur: Noëlle Lenoir
Ref.: Proposal for a Directive (COM(88)496 final) and amended proposal (COM(92)589 final), Common Position of 7 February 1994, 2nd Report of Mr Rothley (EP 156.257)
Referral: Own-initiative, March 1992

Background

The proposal for a Directive, published in October 1988 was one of the measures connected with the establishment of the Single Market. Its purpose was the harmonization of Member States's laws on the patenting of biotechnological inventions.

The adoption process has been held up since 1988, largely because of the ethical debate about the patentability of living matter, but also because of the discussions about farmer's privilege. The compatibility of the Directive with the Rio Convention on Biological Diversity prompted Parliament to ask the Commission to review all the provisions.

The Group's opinion

The Group's verdict was that the patentability of living matter, a long-established principle, did not in itself raise any ethical problems. Concerning the ethical issues related to human body and transgenesis, the Group suggested that the Directive had become too complex and should be simplified to include in its substantive provisions only certain elements essential for the protection of human rights.

It should therefore expressly prohibit the patenting of:

- the human body or parts of the human body per se;
- techniques of human genetic engineering (except those used for therapeutic purposes and then only if they do not undermine human dignity).

It also urged the Community to work towards the conclusion of an international agreement on patentability tests for inventions resulting from genetic research programmes. The discussions about the patentability of genes with no known function had highlighted certain ambiguities in the basic principles of patent law when applied to living matter.

Subsequent developments

On 16 December 1992 the Commission presented an amended proposal for a Directive to the Council, incorporating the ethical dimension. The Council agreed to adopt the Commission's proposals. The Group's opinion served as a catalyst in this process. The Council's common position was adopted on 7 February 1994.

The Group of Advisers achieved its full potential in this particular case:

- because its opinion was perfectly timed to coincide with the preparation of the Directive. Consequently, the rapporteur, Ms Lenoir, was able to meet Parliament's rapporteur and take part in the Council's expert meetings

- it strengthened the Commission's position in relation to the Council and Parliament;

- because the opinion addressed issues of general importance the Commission distributed it widely. It was sent to Parliament, Council, the Council of Europe, the World Intellectual Property Organization and the European Patent Office. It is available to the public on request.

EUROPEAN COMMISSION

SECRETARIAT GENERAL
SG/C/1

LEGAL PROTECTION OF BIOTECHNOLOGICAL INVENTIONS
STATE OF PLAY ON THE CO-DECISION PROCEDURE

PURPOSE OF THE PROPOSAL

The purpose of the proposal is to offer biotechnological inventions the same level of legal protection in all Member States, to require national patent offices to follow a uniform patenting procedure and generate a uniform body of case law in national courts, and to define the scope of patent protection. This extension of patent law has been made necessary by the growing market in biotechnological products.

BACKGROUND

1. The Commission published its proposal for a directive on 20 October 1988.
2. On 29 October 1992 Parliament delivered a favourable opinion on first reading incorporating 46 amendments.
3. On 16 December 1992 the Commission adopted an amended proposal taking over 27 of Parliament's amendments in whole or in part. These related in essence to the ethical dimension and incorporation into patent law of what is known as "farmer's privilege".
4. The Council adopted its common position on 7 February 1994. On the ethical dimension of biotechnological inventions, hotly debated at Council level, the opinion of the Group of Advisers on the Ethics of Biotechnology (Opinion No 3, 30 September 1993) did much to clarify the issues.
5. The Commission accepted the Council's common position on 17 February 1994.
6. On 4 May 1994 Parliament voted three amendments to the common position on second reading.

OUTLOOK

It must be said that Parliament's second reading did not go as planned. It could only vote three amendments because of a quorum problem. Nevertheless, the co-decision procedure provided for in Article 189b of the Treaty will continue to apply when these three amendments are officially notified to the Council and the Commission. The Conciliation Committee will meet if necessary. In line with the conclusions of the White Paper on growth, competitiveness and employment, the Commission will do everything in its power to facilitate agreement between the Council and Parliament on a joint text creating a legislative environment for the protection of biotechnological inventions and will contribute in an appropriate manner to the necessary political compromise. A final Council decision can be expected before the end of the year.

Relations with the European Parliament and Council of Europe

15. Relations with the European Parliament

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RELATIONS WITH THE EUROPEAN PARLIAMENT

The Group of Advisers would like to increase its exchanges with the other European Union Institutions and in particular with the European Parliament. In this context it is foccusing its attention on dossiers presently submitted to the European Parliament, namely:

- The Proposed Directive on Legal Protection of Biotechnological Inventions, examined in second reading (rapporteur : Mr Rothley);

- The Parliament report undertaken at its own initiative on competitivity which follows the 1991 Commission Communication with respect to the promotion of the competitivity of bioindustries in the Community (rapporteur : Ms Breyer);

- The new specific research programe in biotechnology in the fourth framework programe which has been debated at the level of the Energy Commission (CERT)

- The draft report on prenatal diagnosis, elaborated by Mr Pompidou.

Finally, the report "*Bioethics in Europe*", edited in September 1992 in the context of STOA programe (Scientific and Technological Options Assessment) of the European Parliament, which presents analogies and differences between Member States' ethical approaches, is used a great deal by the Group in its work.

Relations with the European Parliament and Council of Europe

16. Draft Convention and Texts of Council of Europe in respect of Bioethics

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THE EUROPEAN COMMISSION AND THE COUNCIL OF EUROPE'S DRAFT BIOETHICS CONVENTION

The draft bioethics convention was produced by the Council of Europe's Steering Committee on Bioethics (CDBI).

It sets out to protect human dignity and to guarantee to every individual, without discrimination, that the applications of biology and medicine respect his identity and his rights and fundamental freedoms.

Protocols on organ transplantation, on medical research and the human foetus, and on genetic engineering will be annexed to the Convention.

The pace of work on the draft convention has slowed down because of the difficulty of reaching a consensus. It now looks as if the convention will not be finalized as expected in July 1994.

The draft convention is being monitored by Commission departments through the working party on bioethics.

This was set up to promote interdepartmental coordination and ensure that departments adopt a coherent position on bioethical issues.

The working party is therefore taking a keen interest in work on the draft convention and is preparing a request for negotiating directives.

The Legal Services of the Commission and the Council of Europe are due to begin talks on the matter.

The draft convention is also being monitored by the Group of Advisers on the Ethics of Biotechnology, which includes Mr Quintana-Trias, chairman of the Council of Europe's Steering Committee on Bioethics (CDBI).

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TEXTS OF THE COUNCIL OF EUROPE ON BIOETHICAL MATTERS

CDBI/INF (93) 2

TEXTS OF THE COUNCIL OF EUROPE ON BIOETHICAL MATTERS

Directorate of Legal Affairs

Strasbourg 1993

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A. Parliamentary Assembly of the Council of Europe

Resolution 613 (1976)	on the rights of the sick and dying
Recommendation 779 (1976)	on the rights of the sick and dying
Recommendation 818 (1977)	on the situation of the mentally ill
Recommendation 934 (1982)	on genetic engineering
Recommendation 1046 (1986)	on the use of human embryos and foetuses for diagnostic, therapeutic, scientific, industrial and commercial purposes
Recommendation 1100 (1989)	on the use of human embryos and foetuses in scientific research
Recommendation 1159 (1991)	on the harmonisation of autopsy rules
Recommendation 1160 (1991)	on the preparation of a convention on bioethics
Recommendation 1213 (1993)	on developments in biotechnology and the consequences for agriculture

B. Committee of Ministers of the Council of Europe

Resolution (78) 29	on harmonisation of legislation of member States relating to removal, grafting and transplantation of human substances
Recommendations R (79) 5	of the Committee of Ministers to member States concerning international exchange and transportation of human substances
Recommendation R (83) 2	of the Committee of Ministers to member States concerning the legal protection of persons suffering from mental disorder placed as involuntary patients
Recommendation R (84) 16	of the Committee of Ministers to member States concerning notification of work involving recombinant deoxyribonucleic acid (DNA)
Recommendation R (90) 3	of the Committee of Ministers to member States concerning medical research on human beings
Recommendation (90) 13	of the Committee of Ministers to member States on prenatal genetic screening, prenatal genetic diagnosis and associated genetic counselling
Recommendation F (92) 1	of the Committee of Ministers to member States on the use of analysis of deoxyribonucleic acid (DNA) within the framework of the criminal justice system
Recommendation R (92) 3	of the Committee of Ministers to member States on genetic testing and screening for health care purposes

C. Ministerial Conference

European Ministerial Conference on Human Rights (Vienna, 19 -20 March 1985):

- Resolution No. 3 on human rights and scientific progress in the fields of biology, medicine and biochemistry

17th Conference of European Ministers of Justice (Istanbul, 5 - 7 June 1990):

- Resolution No. 3 on bioethics

D. Report on human artificial procreation

Principles set out in the report of the ad hoc Committee of experts on progress in the biomedical sciences (CAHBI, published in 1989)

EUROPEAN COMMISSION

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SG/C/1

PRODUCTS DERIVED FROM HUMAN BLOOD OR PLASMA
STATE OF PLAY

Directive 89/381/EEC on medicinal products derived from human blood or human plasma

Purpose of the Directive

The purpose of the Directive is to protect human health by extending Community rules designed to guarantee the quality, safety and efficacy of medicinal products to products derived from human blood or human plasma (manufacturing authorization, marketing authorization). Application of these rules also guarantees free movement of these products.

The Directive also addresses the ethical aspects and advocates the promotion of voluntary unpaid donations to achieve self-sufficiency in the supply of blood and blood products.

Implementation of the directive

1. Technical provisions

Eleven Member States have transposed Directive 89/381/EEC and the twelfth (the Netherlands) is in the process of doing so. National legislation is now being checked by Commission departments for conformity with the Directive.

2. Voluntary unpaid donations

When the directive was adopted in 1989 the Council left it to the Member States to determine, in the light of their own situation, the best way of achieving the goal of Community self-sufficiency by means of voluntary unpaid donations without depriving patients of essential treatment.

The Council of Europe, which is referred to in the Directive, has produced a definition of voluntary unpaid donations. This specifies that donations of blood, plasma and cellular components must be freely made and that no benefits in cash or kind should be offered to the donor. Gestures such as refreshments and reimbursement of travel expenses are consistent with the notion of voluntary unpaid donations.

The Council of Europe, which is referred to in the Directive, has produced a definition of voluntary unpaid donations. This specifies that donations of blood, plasma and cellular components must be freely made and that no benefits in cash or kind should be offered to the donor. Gestures such as refreshments and reimbursement of travel expenses are consistent with the notion of voluntary unpaid donations.

Three Member States (France, Belgium and the Netherlands) have opted to promote voluntary unpaid donations by confining authorization to blood and plasma products derived from this source. Their degree of self-sufficiency made this option possible. Other Member States are not in a position to do the same without depriving patients of essential treatment. As a general rule[1], they do not allow payment for blood donations on their national territory but they do import plasma or products derived from paid donations, notably from the United States, to make good the shortfall in supplies.

In any event, provided they satisfy the requirements of Community legislation, products manufactured in any Member State must be given access to the territory of the other Member States on the same terms as products manufactured locally.

Follow-up to the Directive

Directive 89/381/EEC was challenged, notably in France, by blood donor associations on the grounds that it classified blood derivatives as "medicinal products".

The matter was referred to the Group of Advisers on the Ethics of Biotechnology, which endorsed the Directive and its public health objectives in March 1993.

In December 1993 the Council confirmed the importance of achieving self-sufficiency in blood and blood derivatives by means of voluntary unpaid donations, promoting blood donations with Community support, guaranteeing the quality and safety of blood collection and ensuring optimum use of blood and blood products.

The Commission will update its studies on blood donations and the utilization of blood and blood products at regular intervals and decide whether any action is needed.

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1 With the exception of Germany, which does allow a fixed payment for travel expenses and loss of earnings occasioned by absence from work.

14. Legal Protection of Biotechnological Inventions