EBIS

EUROPEAN BIOTECHNOLOGY INFORMATION SERVICE

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Editorial: On Bio-Ethics

The ethical implications of the life sciences and their applications, their uses and abuses, the right to know and the right not to know – our BIODOC files are fast expanding in this sector. Mindful of the report on biotechnology from the World Council of Churches, we recall the words of the Bible: "He that increaseth knowledge increaseth sorrow" (Ecclesiastes i. 18); but remember also Alexander Pope, the poet: "A little learning is a dangerous thing".

Eurobarometer measures the ignorance and the attitudes

To bring some scientific quantification to bear on this unhappy dilemma, between the dangers of ignorance and the sorrows of knowledge, the Commission has through Eurobarometer sought to measure the sorrow and the knowledge, the ignorance and the attitudes; first results reported inside.

People may have an uneasy sense that to take genes from one living creature and put them into another is to take an irrevocable step

But ethical matters are deep topics, and people are uneasy about the sorcerer's "scientific" apprentices tampering with "nature" and "life". People with little or no formal religion may have an uneasy sense that to take genes from one living creature and put them into another, especially into a human, is to take an irrevocable step towards assuming responsibilities traditionally attributed to a designing deity, or at least to the blind forces of evolution.

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Other pages

Is it ethical to delay a biotechnology development, for continued discussion motivated more by public concern than public interest?

On the other hand, most EBIS readers will be aware of the hopes and expectations (increasingly well-founded) that biotechnology can be the basis – the essential basis – for addressing both the central long-term bio-problems (food, health, environment, population), and many shorter-term problems for health care, industry and agriculture. Given the safe track record of biotechnology ancient and modern (particularly the more precise modern techniques, and the advances they offer in vaccines and food hygiene), is it ethical to delay or defer their accelerated diffusion and application, for continued discussion motivated more by public concern than public interest?

Helping to improve the climate of public understanding and opinion concerning the responsible development of biotechnology

But fear is there and it will not easily diminish as the ethical and regulatory debate intensifies. It is in response in part to such public concern that the Commission, as foreseen in its recent communication SEC(91) 629 (see EBIS 3) is now establishing an appropriate advisory structure, "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 ... 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".

Recent debate in the Commission and in various Member States has focussed on ethical and other aspects of human genome analysis, human embryo research, environmental matters, animal welfare and of intellectual property law.

The following table gives a summary, and further articles inside indicate national activities; as always, we seek to give sources for fuller details. But we recall, in bio-ethics as elsewhere, the James Thurber story of the response of a little girl required by her teacher to read, and write about, a set text:

> "This book told me more about this subject than I ever wanted to know".

Obviously a spiritual descendant of the writer of Ecclesiastes; but unlikely to discourage scientists from extending the book of knowledge. And as the Belgian teachers recently expressed it, "If you think knowledge is expensive, try ignorance".

OVERSIGHT GROUP OR ACTIVITY	MANDATE	ORIGIN
Human Embryos and Research Working Group	Monitor, exchange views, explore consensus, examine options (common code?), report annually to Commission and Research Council	Commission established group at request of Research Ministers, March 1990; first met 20.3.91
Working Group on Ethical, Social and Legal Aspects ("ESLA") of Human Genome Analysis	Advise Commission on HGA-ESLA; and on Commission annual report to EP, Council, ESC and public; recommend future initiatives, including legislative	• Request of Research Ministers, March 1990 • Council Decision of 29.6.90 on HGA Research Programme • First meeting 26.4.91
Future CAN* for Biomed and Health Research in FP 3	Area 4: Research on Biomedical Ethics: ethical aspects of the other 3 areas (including HGA) + inventory of existing information and legislation in Europe	Commission proposal, following EP amendment, accepted and included in Council common position, 24.4.91
Future CANs for Environment and Biotechnology Research in FP3	"...ethical ...aspects of environmental policy and management"; "ethical implications of (biotechnology) research"	Council Decision, 23.4.90, on FP3
CAN-BRIDGE, and concertation group	Increase public knowledge of nature, potential and risks of biotechnology	Council Decision of 27.9.89 on BRIDGE programme

*CAN: Committee of an Advisory Nature (Member State representatives)

I. Community activities (Commission, Parliament, Council)

I.1. Commission News

Biotechnology Coordination Committee meetings: bio-ethics and Round Table

BCC: routine, high level discussion on biotech

The BCC, following its formal adoption in March and the general policy communication (SEC (91)629) in April (see EBIS 3), continues to meet routinely on matters requiring inter-service coordination, under the chairmanship of Commission Secretary-General David Williamson. Each meeting reviews the "state of play" on all current dossiers in biotechnology, facilitating inter-service awareness, and providing a high-level opportunity for comments and questions between the Directors-General. On 30th May, a principal topic was "bio-ethics".

Following the April 1991 communication, a "Bio-Ethics" advisory group is prepared

In line with the intention signalled in the April communication, the Committee considered the mandate and constitution, of a small group of persons of high moral standing which could advise the Commission on specific ethical and moral issues related to biotechnology.

First BCC Round Table with industry and others

Preparations were also discussed for the meeting of the BCC with a "Round Table" on 11 July, which will be reported in EBIS (5). The idea of a Round Table is to have an open forum of variable composition depending on the subjects to be discussed and where participants are invited on a personal basis. The first Round Table will provide an occasion to discuss the future of biotechnology in Europe. The point of departure for this discussion is the Commission's communication "on promoting the competitive environment for the industrial activities based on biotechnology within the community". SEC(91)629.

Bio-Industry dialogue with the Commission changes gear: an obituary for EBCG?

Dialogue between bio-industry and the Commission should improve as a result of recent changes. In addition to specific channels such as IRDAC (for industrial R & D advice) and CEN (on standards), the articulation of bio-industrial opinion has for the last six years been formally expressed through the European Biotechnology Coordination Group.

EBCG: a voice for bio-industry in Europe, 1985-91

EBCG was created in June 1985, following a meeting (12 December 1984) between (then) Commission Vice-President Etienne Davignon (Industrial Affairs and R& D) and seventeen bio-industry leaders. The consensus at that time was against a new association. EBCG would be supported logistically by CEFIC (chemicals), and would meet in rotation in the premises of this and 4 other interested sectoral (or "trade") associations: EFPIA (pharmaceuticals), GIFAP (agrichemicals), CIAA (food and drink), and AMFEP (microbial food enzymes).

EFPIA would handle regulatory matters (and produce papers in response to Commission consultation); on patents, the activity

was merged with a UNICE group on bio-patents; CEFIC would handle "anything else".

More sectoral members and NBAs: representative but ineffective

By early 1989, EBCG had acquired more members (FEDESA for animal health, COMASSO for plant breeding, GIBiP for seeds); national biotech associations ("NBAs") led by France's Organibio, were coming in increasing numbers to the meetings; but it still lacked a plan, budget, officers, or an operational base. It was increasingly criticised as long on representativeness, but short on effectiveness – particularly in delivering clear messages to public, politicians and Commission in the growing Community debate on bio-regulation.

Indefinite postponement

The NBAs started meeting separately; big companies (and, more recently, others) have joined the effective and articulate SAGB (see below). The next EBCG meeting should have taken place at GIFAP in June; but when Technical Director Ron Gardiner checked with other participants, there was no opposition to a postponement "sine die".

(For a more extended history, and details of all the acronyms, see Biofutur November 1989, special edition on Europe, article by Dr. Gérard Nominé, life president of Organibio. We have some copies at CUBE).

In the U.S., IBA and ABC; in Europe, SAGB and NBAs

In retrospect, the 1984/85 decision (by industry) was probably mistaken. In the US, although there was fragmentation between the Industrial Biotechnology Association (some 30 major firms) and the Association of Biotechnology Companies (a wide membership of small firms, affordable subscriptions), the two coordinate their approaches to Congress, and provide a competent and visible focus for bio-industry representation and public communication. In Europe, a vacuum developed which EBCG did not fill. The most effective European industry voice is now coming from the SAGB (created July 1989); and (quieter, but gradually growing) in the Member States, from the NBAs. This has been recognised in the invitations to the 11 July BCC Round Table meeting – see earlier article this issue.

Seminar on public attitudes to genetic engineering 29–31 May 1991, Madrid

Various elements determining public attitudes to biotechnology discussed

The European Foundation for the Improvement of Living and Working Conditions (EFILWC), Dublin, invited experts in the field (sociologists, PR scientists, journalists) as well as representatives from research, industry, public authorities and public interest groups to discuss the various elements determining public attitudes to biotechnology in order to identify future strategies to improve the public-science-industry interaction. It was generally understood that scientific and technological knowledge is not sufficient to define public responses. This was confirmed by provisional data from the recent Eurobarometer survey on biotechnology (see feature article this issue) presented by the Commission. It was emphasised that the social basis of trust and credibility is a crucial (yet largely neglected) question affecting public reception of new developments in biological sciences. The need for further information therefore, is not only for the public but also for political and industrial players in biotechnology who often have questionable ideas on how information is processed in society. Particular emphasis was placed on the inter-cultural aspects

which are important for both the comparative analyses of phenomena and the evaluation of Community strategies in the field. The various contributions will be issued as part of a general analysis paper on further research possibilities.

Details: O. Diettrich, CUBE team. Tel. (32) 2 2355033.

I.2 Research and related

Pre-normative research and standards: CEN meeting, IRDAC opinion

Pre-normative research: the S&T base for regulations and standards

Pre-normative research can be defined as "research to supply the scientific and technological base for the establishment, improvement and implementation of regulations and standards".

CEN biotech group meets, CEC prepares mandate

In its April 1991 communication on promoting the competitive environment for biotechnology in Europe (SEC(91)629), the Commission confimed its intention to draft a mandate for biotechnology work by CEN, the European standardisation committee. This draft mandate is nearing completion (requests for copies will be met as soon as it is released). CEN's Technical Committee on Biotechnology (TC 233) met again on 13th June in Brussels, agreeing outline mandates for its working groups in the presence of national and industry standards specialists, and observers from the Commission and OECD. These presences underline growing international recognition of the need for coherence between regulations, standards, OECD safety work (see Section III, this issue), the work of CEN, and pre-normative research; Community and other. Pre-normative research is also an interest of the EC-US Task Force for Biotechnology Research (see EBIS (1)). The new wave of Community pre-normative (safety-related) BRIDGE projects was summarised in EBIS (3).

IRDAC = Industrial R+D Advisory Committee of the Commission of the European Communities

In its formal opinion on the "First Report on the State of Science and Technology in Europe" (issued in April 1989), IRDAC stated:

> Without harmonised standards, regulations and product approval procedures, it will not be possible to achieve a unified market in 1992. It is recognised that much is happening at the European level to strengthen standards making activities but IRDAC feels that there is still room for extra effort. In particular, attention will need to be given to the important area of pre-normative research in order to provide the conditions in which applied research and investment can go ahead on a European scale.

Following various workshops and meetings on the subject and considerable discussion in its Plenary Session IRDAC has now given its opinion to the Commission (April 1991) on pre-normative research, which is aimed at influencing future Community R+D programmes.

Pre-normative research is an important means of realising the European internal market, promoting the international competitiveness of European industry and protecting the consumer and the environment. However, there exists a widespread lack of awareness on this concept both in industry

Pre-normative research is an important means of realising the European internal market, promoting the international competitiveness of European industry, and protecting the consumer and the environment

and the Commission of the European Communities. For this purpose IRDAC is in favour of an awareness exercise which should consist of training and information activities. Although IRDAC recognises that there exist different needs for pre-normative research in the different industrial sectors, it believes that the Commission should develop, upon consultation with industry, a coherent policy on pre-normative research. The establishment of a clearing house where industry can obtain information on its pre-normative research questions could be a part of such a policy.

Details: R. Smits. IRDAC Secretariat. Fax. (32) 2 236 20 07.

The VALUE programme can assist you in patenting and "valorizing" your CEC research results

VALUE has been designed to support the useful exploitation, or "valorization", of Community research results, through assistance in patenting issues, support for exploitation projects and dissemination of non-confidential research results

Most researchers are familiar with publications in scientific journals, presentations given at conferences etc. as common dissemination procedures for their results. However, few are familiar with patenting issues. For EC research contractors, VALUE can provide support and advice on patenting and publishing. Whenever potentially valuable results arise, consideration should be given to patenting before publishing; bearing in mind that, with good coordination, the two can be carried out almost in parallel. It is most important to be aware that once any public disclosure has been made, e.g. posters or public presentations, abstracts, publications etc., results are no longer eligible for patenting in Europe, because they have fallen into the public domain. Therefore, should patenting be desirable, an application should be submitted as first priority; publication can follow. Moreover, the patent literature is an important part of the recognised technical and scientific literature.

EC research contractors can find help and support for patent issues

VALUE can help with:

- valuation of the patentability of results, including library searches;
- preparation of the patent application in collaboration with specialist European patent lawyers in all scientific domains (eg. biotechnology), throughout Europe;
- the patent application and follow-up.

Additional opportunities in patent matters have to be discussed on a case by case basis.

In parallel to assistance in patenting results, VALUE can provide advice and support for their commercial exploitation, or "valorization". Major activities in this area are providing expert help in finding an industrial partner, assistance in assessing the exploitation potential of the invention, help in analysing the target market, assistance in finding venture capital for the project etc. VALUE may also support prototype projects, scale-up, tests and trials under pre-industrial conditions etc.

If you are interested, do not hesitate to contact us for fuller information (address below).

Focus on biotechnology

VALUE devotes special attention to biotechnology. This reflects

not only its importance for the future of European industry, but the uncertainties about patentability. In order to overcome this difficulty, VALUE plans to make a particular effort in this area.

Typical examples of VALUE activities in modern biotechnology include the following:

Examples of VALUE supported projects

- Pharmaceuticals:
  1. chemical synthesis by enzymatic systems;
  2. protein engineering (modified human growth hormone);
  3. novel drug administration routes (incorporation of various drugs into human erythrocytes);
- Agro-food:
  1. genetic engineering (various applications of gene cloning
  2. vectors (including "food-grade" vectors);
  3. bio-molecules (astaxanthine production);
  4. pest control (PCR based Erwinia test kit, etc.).

Community bio-research participants and interested firms should make contact

Participants in Community research Programmes concerning biological resources (BEP, BAP, BRIDGE, FLAIR, ECLAIR, Agricultural Research etc.), and companies interested in cooperation with academics involved in these programmes can obtain further information, concerning the VALUE programme from:

Dr Constant Gitzinger, Tel. (352) 4301 3887/3519; Fax. (352) 4301 4129.

Patent issues from:

Dr Edwin De Pauw, Tel. (352) 4301 2642; Fax. (352) 4301 2073.

Commission of the European Communities Directorate-General XIII/C/2 and XIII/C/1 VALUE Programme Jean Monnet Building L-2920 Luxembourg

Research in the fisheries sector: the FAR programme

Some aspects of this programme may be of interest to biotechnologists and a full description will be given in a future EBIS.

A call for proposals has recently been issued with a deadline of August 1, 1991.

Interested persons should make contact with:

W. J. Brugge, Commission of the European Communities, DGXIV/C/2. Fax. (32) 2 2365952.

II. Member States

Belgium

The BBA opens its Tokyo office to European Bioindustries

BBA = Belgian Bioindustries Association

The Belgian Bioindustries Association (BBA) was founded in 1986, for industrial and university members. BBA has 2 divisions: Industrial and Scientific Affairs. The Industrial Affairs Division includes 2 departments: BBA-Japan and BBA-International. BBA-Japan is located in Tokyo and is directed by Mr. T. Yoshida, who is particularly well-informed about Japanese biotechnology industries and university departments.

BBA-Japan services offer:

- personalized work for each member on a confidential basis;
- overall cost of the office shared between the members;
- preparation of travel and meeting arrangements for members visiting Japan, local guidance and translation;
- access, on a regular basis, to Japanese scientific and commercial information sources.

Tokyo office of BBA-Japan offers services to European Bioindustries

If interested in penetrating the Japanese Market and in having your own representative in Tokyo at shared cost, please contact:

Dr. P. Crooy, Chairman BBA, Fax: (32) 2 656 81 49.

France

Wide ranging report on biomedical ethics submitted to the President

President François Mitterand and Prime Minister Edith Cresson received in June from Mme Noëlle Lenoir the wide-ranging report on biomedical ethics which the latter has been preparing over recent months, in accordance with a request from Elysée and Matignon; entitled "Aux frontières de la vie: pour une démarche en matière d'Éthique biomédicale". The document does not present simple options for legislation, and follows a 5 year history of reports, debates and deferments – on "PMA" (medically assisted procreation), prenatal diagnosis, human experimentation, surrogate motherhood, or the use of human embryos in research. Parliamentarions are drafting laws (particularly on PMA); the Lenoir report advocates rather a "framework law", allowing flexibility to adapt rules within it to rapid scientific and technical progress.

Three principles would be incorporated in the framework law:

i respect for the human body and its "non-commercial" character;

ii free and informed consent prior to medical intervention in the human body;

iii an affirmation of the principle of protecting the human genetic inheritance (DNA-fingerprinting to require authorisation by a magistrate; individual genetic data to be accessible for epidemiological research).

Germany

Forschungszentrum Biotechnologie und Recht

Biotechnology and Law Centre seeks international collaborators

A research centre for biotechnology and law has been established at the Universities of Lüneburg and Hannover. The centre has a databank covering German biotechnology laws (recommendations, decisions, comments, literature). They are now seeking partners in Universities, firms or other organisations in the EC Member States who would be interested in establishing an international data bank. The objective is to provide a Europe- wide on-line source of information for consultation, communication and research that might aid in standardizing the law throughout the Member States.

Details: Prof. Dr. J. Simon Forschungszentrum Biotechnologie und Recht an den Universitäten Hannover und Lüneburg, Hanomagstrasse 8 D-3000 Hannover 91 Tel. (49)511 449 81 67; Fax. (49)511 83 03 37; ECHO EUROMAIL NOMOS R 457 22 19 32 02.

UK

New life for Industry – NEDO Biotechnology report

NEDO = National Economic Development Office – bringing together government and industry

The National Economic Development Council brings together government and industry, trade unions and other interests to assess economic performance in the UK and opportunities for improving it. Its Biotechnology Working Party under the chairmanship of David Barnes (ICI) has now reported on the impact of biotechnology on industry and the community in the 1990's and beyond.

The report examines current developments in different sectors of biotechnology application such as healthcare, agriculture, food, chemicals and environment and the public policy issues which influence them, such as manpower, finance, intellectual property rights, public perception, regulatory controls and technology transfer.

Of particular novelty in the report are the results of a 1990 census of the biotechnology activities of British industry in terms of sales, growth over previous year and share of market, R&D expenditure and number of employees.

The 1990's will see the rapid exploitation of biotechnology and the fulfillment of its earlier promise

The report concludes that the 1990's will see the rapid exploitation of biotechnology and the realisation of the promise seen in its early days. Now is not the time to slow down any of the activities aimed at rapid commercialisation of the range of possibilities being discovered in biological and related fields. Various recommendations are made for future action.

Details: National Economic Development Office Millbank Tower Millbank London SWIP 4QX. Tel. (44) 71 217 40 41.

BioIndustry Association stands at Biotech USA 91 and IBEX 91

Continuing its active international representative role (Japan in May, Biolatina, Brazil in July), BIA offers two "windows" in North America

Biotech USA 91 – Philadelphia, 25–27 September 1991 features an extensive multi-disciplinary conference programme developed by Bio/Technology magazine, repeating last year's successful four-part structure: PharmBiotech, AgBiotech, BioBusiness and BioLab. Over 100 exhibitors and 3,000 visitors have already registered.

IBEX 91 – San Francisco, 6-8 October 1991, the largest biotechnology conference and exhibition in the US has already attracted more than 350 exhibitors and 8,000 people have registered.

The BIA will have a stand at both events and now invites companies/individuals wishing to exhibit materials to make contact before the end of July.

Details: Dr. Daphne Christie. BIA Office Tel. (44) 71 222 2809; Fax. (44) 71 222 2876.

HFEA – proposes Code of Practice for infertility treatment and embryo research

HFEA = Human Fertilisation and Embryology Authority

The HFEA came into existence on 7 November 1990 following Royal Assent of the "Human Fertilisation and Embryology Act".

Under the chairmanship of Professor Colin Campbell it has issued a draft code of Practice covering a range of topics, amongst them:

> embryo research, including the types of research which will or will not be granted a licence, and the scrutiny of research projects.

The Code of Practice will apply to all centres carrying out activities to be licensed under the Act. Licensed activities are: any infertility treatments involving the use of donated gametes or the creation of human embryos outside the body, research on human embryos, or storage of gametes or embryos. The consultation document addresses ethical and social aspects as well as clinical and scientific.

Details: HFEA, Room 502, Clements House, 14-18 Gresham Street, London EC2V 7JE. Tel. (44) 716003272; Fax. 6003270.

III. International Developments

OECD: Group of National Experts ("GNE") on Safety in Biotechnology

GNE plenary: GILSP, GDP, LSR and Food Safety

The next EBIS issue will report on the plenary meeting of the above group of experts, Paris, 26-28 June.

On the agenda are:

- follow-up work on "GILSP" (good industrial large scale practice), (Chairman of GILSP working group, W.G. II, M. Kuenzi of Ciba-Geigy, Basel);
- following de-restriction of the "GDP" report on "good developmental principles for the conduct of small scale field trials", a new activity on large scale release ("LSR") is proposed. A first outline working document by E. Malewski, of U.S. Environmental Protection Agency.

Safety principles for food biotechnology

- Progress of the working group on "food safety in biotechnology", launched following the October 1990 GNE plenary, under the chairmanship of F. Young of U.S. Public Health Service (former FDA Commissioner). A progress meeting in Bethesda, February 1991, considered principles of food safety, such as the concept of "substantial equivalence" (to traditional food), and the paper by J. Linde mann, "Biotechnologies and Food: A summary of Major Issues regarding Safety Assurance" (Regulatory Toxicology and Pharmacology 12, 96-104(1990)). This paper summarises the International Food Biotechnology Council's report, "Biotechnology and Food: Assuring the Safety of Foods Produced by Genetic Modification". The food safety working party meets 24-25 June in Paris, preceding the plenary GNE meeting.

workshop report: monitoring GMO releases

- A report on the Copenhagen workshop on monitoring GMO releases in the environment (3-7 December 1990) is likely to be debated; a further, ambitious document on the monitoring of introductions (GM and other) will be considered.

UN and East European links

- Other points of interest include relations with other international bodies (particularly UN agencies and CEN), and the expressed wish of some Eastern European countries to attend as observers. These points, and the ever-growing scale of the delegations being sent to the OECD meeting, underline the perceived value of the OECD forums as part of the international "learning process" for the safe management of biotechnology.

OECD/GNE papers are in principle restricted, but for relevant experts can usually be provided on a personal basis for comment.

Details: Ms. B. Teso, OECD, 2, rue André Pascal 75016 Paris.