July, 1992

EBIS

EUROPEAN BIOTECHNOLOGY INFORMATION SERVICE

Vol.2 no. 3

NEWSLETTER

Editorial: "You can't invest in a technology"

"You don't invest in trends or technologies; you have to invest in companies"

At the Montreal "Bio-Recognition" conference in June, the "Bio-Business" sessions sought to digest the lessons of the US investment bonanza which in 1991 poured some $ 3.6 billion into biotechology, including $ 1.2 billion for initial public offerings (IPOs). Lots of governments round the world seek to "stimulate biotechnology"; but as Mary Tanner of Lehman Brothers said, "you don't invest in trends or in technologies; you have to invest in companies".

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Other pages:

EUROPEAN BIOTECHNOLOGY INFORMATION SERVICE

Commission of the European Communities

Other speakers explained the mysteries of "mezzanine" financing on the way to the IPO, how to get your company started if your friends won't lend you $ 25 m, and why the rich friends want to see an "exit route" before they put their money in.

More vigorous development of European SMEs is essential

In Europe, more of the biotech investment occurs within the big companies; but in industry and government there is consensus that a more vigorous development of "SMEs" (small and medium enterprises) in the bio-industry sector is essential. The recommendations of a Commission-sponsored report from Eurotechnology Associates on SME needs are summarized on p. 17, and its recommendations for actions at Community level are now under study.

UNCED Biodiversity Convention seen as inimical to intellectual property interests of US biotechnology

The role of public and private finance in biotechnology for development was highlighted at Rio in June, at the UN Conference on Environment and Development. 154 countries signed the conventions on Climate Change and on Bio-diversity negotiated by the UN Environment Programme. The latter was thought to be contentious, President Bush seeing some clauses as inimical to intellectual property interests of US biotechnology. In the European Parliament, the proposed directive on the protection of biotechnological inventions was referred back to the Legal Affairs Committee to check its consistency with the Bio-diversity Convention. However, there are important examples of how to reconcile such conflicts e.g. the model agreements pioneered by Commission-supported initiatives in the 1980s which are now ensuring the supply of plant germplasm samples for screening in the laboratories of the developed world, on a basis equitable for the source country, while offering exclusivity to the companies.

Agenda 21 document including "sustainable agriculture and rural development" and "biotechnology" signed by all parties at Rio

Less contentiously, the Agenda 21 document was signed by all parties at Rio. Amongst its 40 chapters are "Sustainable Agriculture and Rural Development", and "Biotechnology": the latter focussing on increasing the availability of food, feed and renewable raw materials, and the related measures.

But to return to our theme — if biotechnology is to become something more than mere intellectual curiosity (and the subject of numerous public sector reports and Newsletters), it will require investment; and we must offer companies the possibility of creating innovative intellectual property in order to stimulate that investment.

I. Community Activities (Commission, Parliament, Council)

I.1. Commission News

BCC continues Work

BCC continues routine, high level discussion on biotechnology Progress on the April 1991 communication to be reviewed

The Commission's Biotechnology Coordination Committee (BCC) met for the 10th time in Brussels on 21 May 1992 under the chairmanship of the Secretary-General, David Williamson. The progress of the many Commission activities relating to biotechnology was considered. DGIII (Internal Market and Industrial Affairs) was charged with preparing a progress report on the implementation of the recommendations contained in the Commission communication of April 1991 (see EBIS 3, p. 3) on competitiveness in biotechnology.

Commission view on patenting cDNA sequences agreed

On patenting of partial cDNA sequences (see following article) it was agreed that the Commission representative in Washington should speak at the US government organized public hearing on genome patenting.

2nd Round Table planned

The results of the meeting on a "Citizen's Audit of Biotechnology" were reviewed (see following article) and it was agreed to hold a second Round Table on biotechnology later in the year (see EBIS 5, p. 3 for report on 1st Round Table). Forthcoming international meetings in biotechnology were discussed. It was agreed to return to the topics of biotechnology SMEs in the Community, and the EC/US/Japan technology linkages and relative competitive positions.

Citizen's Audit of EC Policy on Biotechnology, Brussels 19-20 May 1992

ECAS = Euro Citizen Action Service

Several Commission officials participated in this meeting organized by Euro Citizen Action Service (ECAS). The conclusions of the Audit may be summarized as follows:

Public concerns must be taken into account at the earliest possible opportunity

— public concerns on ethics, health, safety, environment and information must be taken into account at the earliest possible stage of the Commission's development of biotechnology policy;
— a Round Table on biotechnology should be called by the Commission with major participation from associations representing the public interest;

The opinions of the group of bioethics advisers should be made public

— the opinions of the Group of Advisers on the Ethical Implications of Biotechnology should be made public. There should be a notification procedure so that interested parties can make known their views on subjects under review.
— Biotechnology healthcare products must be introduced as early as possible for the benefit of patients.

Call for greater transparency in Commission's processes and procedures

— There is a need for greater transparency in the Commission's development of biotechnology policy.

To obtain a report of the meeting prepared by ECAS, use the Response Form.

Patenting of partial cDNA Sequences? US public Meeting, Commission and Member States Views

EC Research Ministers (F, UK, I) criticize NIH patent action

Over the past 12 months, worldwide debate has followed the applications by the US National Institutes of Health for patents on partial complementary DNA ("cDNA") sequences (expressed sequence tags ESTs) of unknown utility or function. Critical letters have appeared in Science from three Research Ministers in EC Member States (Mr. Curien of France, 20 December; MM. Howarth of UK and Ruberti of Italy, 3 April), arguing that such patents (if ever granted) would dilute the "utility" criteria for patenting, and unhelpfully inhibit international scientific collaboration.

Scientists (HUGO and ASHG) and industrialists (IBA, PMA) also opposed

Similar criticisms have been voiced by HUGO (Human Genome Organisation), ICSU (the International Council of Scientific Unions), and the American Society of Human Genetics; and more recently, by the (US-based) Industrial Biotechnology Association and Pharma-

ceutical Manufacturers' Association. These criticisms do not question the validity of patents on a genuinely useful invention involving a known human gene. The smaller ABC (Association of Biotechnology Companies) has endorsed the NIH action.

Public meeting, 21 May, hears European arguments and CAN-HUG Resolution

The US organized on 21 May a public meeting chaired by Dr. Mary Clutter of US National Science Foundation, also Chair of the panel on Genome Patents (reporting to Office of S&T Policy). At the meeting, Commission science attaché Gilbert Fayl indicated European concerns and the need for pursuing an international agreement. He quoted in his statement a resolution unanimously adopted on 15 May by the Member State representatives CAN-HUG (Committee of an Advisory Nature on the EC Human Genome Analysis programme), which states:

"Don't patent basic scientific results"

"This committee, mindful of its responsibility to advise the Commission on the management of the Human Genome Analysis programme, expresses to the Commission its unanimous opinion and concern that the submission of patent applications for fragmentary complementary DNA (cDNA) sequences of unknown utility or function is contrary to the interest of international scientific collaboration; and calls upon the Commission to seek international agreement to the effect that such applications should not be pursued.

The concerns of the committee are amplified by the reflection that the present case may be a paradigm for future attempts to patent basic scientific information.

Further to this point, the committee considers that the dilution of patentability criteria by applications which demonstrate little genuine utility diverts resources and attention from the pursuit of genuine innovation".

Strong criticisms were voiced also by France's representatives, Dr. Axel Kahn of INSERM (National Institute for Medical Research), chairman of the Biomolecular Engineering Commission and Dr. Jacques Damagnez of the Foreign Office. Dr. David Owen of UK Medical Research Council indicated the reluctance with which they have been forced into a similar step by the US action, and emphasized the desirability of an international agreement.

Dossier available

A dossier of relevant materials, including those referred to, is available from CUBE. (use Response Form).

I.2. Research and Related

Concertation in BRIDGE, 1991-1992

Report on concertation tasks: information and promotion for biotech

In a 20-page report to the Biotechnology Coordination Committee and the Advisory Committee for the BRIDGE programme (1990-93) now cleared for publication, the CUBE team summarize the concertation action over the past year and a half.

The action has four tasks:
(i) monitoring, and assessing developments in biotechnology, and informing public authorities (hence EBIS);

(ii) identifying how to promote biotechnology in Europe, via Member State and Community programmes and policies;
(iii) public information, to increase awareness and understanding;
(iv) promoting the biotechnology small firm sector.

Future expansion: Ethical, socio-economic and risk assessment

Beyond the various actions itemized, the report looks ahead to the expansion of BRIDGE objectives via "horizontal activities" under BIOTECH (1992- 94), on ethical, social and economic consequences of biotechnology, and in the fourth Framework Programme.

To obtain the report, use the Response Form.

Cooperation in Science and Technology with Central and Eastern European Countries

55 MECU 1992 programme with closing date of 7 August 1992

The call for proposals for this 55 MECU programme has been issued with a closing date of 17:00 hrs. 7 August 1992.

Several actions of relevance to biotechnologists

The actions proposed of relevance to biotechnologists are as follows:
1. Scientific and technical mobility (research fellowships; go East and go West) — 15 MECU for 1992.
2. Networks, Conferences, Workshops and Seminars — 5 MECU for 1992.
3. Joint Research Projects in priority areas including quality of life (environmental protection, biomedicine and health) and industrial technologies (agro-industry and food) — 20 MECU for 1992.
4. Participation in EC RTD programmes including Environment, Non-nuclear energy, Biomedical and Health Research and Human Capital and Mobility — 10 MECU for 1992.
5. Participation in COST projects — 5 MECU for 1992 (see article on COST and biotechnology in this issue).

Details: M.P. Venet. Tel.: (32) 22355936; M.L. Durieux. Tel.: (32) 22350718.

Advanced Workshops in Biotechnology

60% of time devoted to practical work

In the framework of the Biotechnology R&D programme BRIDGE, the Commission of the European Communities is organizing a series of 9 Advanced Workshops in Biotechnology at which at least 60 % of the time will be devoted to practical work.

Some grants for travel and accommodation expenses available

Attendees are expected to have a fluent knowledge of English; their number will be limited to +/- 15 per workshop. A few grants covering travel expenses and accommodation will be available.

The relevant information can be obtained from the local organizer; the selection of participants will be made by the services of the Commission on the basis of the scientific curriculum vitae.

All requests, together with a recent copy of the C.V. should be mailed at least two months before the start of the workshop to:

Applications to arrive 2 months before workshop

A. Léonard, Commission of the European Communities, DG XII/F-2, rue de la Loi, 200, 1049 Brussels.

Advanced Workshops in biotechnology. Applications for travel and accomodation grants must arrive at the Commission two months before workshop

1. Biotechnological process engineering
Bellaterra (Barcelona), Spain
7-18 September 1992
Local organizer: Prof. Carles Sola, Departement de Quimica, Unitat d'Enginyeria Quimica, Edifici C, 08193 Bellaterra (Barcelona), Spain. Tel.: (34) 35811018; Fax: (34) 35812013.

2. Production of antibodies & immunological methods to detect and compare plant pathogens
Moncada-Valencia, Spain
26 October-6th November 1992
Local organizer: Dr. M. Cambra, Instituto Valenciano de Invest.Agrarias, Apartado Oficial, Carretera Moncada-Naquera, Km 4,5. Tel.: (34) 61391000; Fax: (34) 61390240.

3. Biocatalysis in non-conventional media
Athens, Greece
19-30 October 1992
Local organizer: Prof. B.J. Macris, Dr. F.N. Kolisis/Dr. D. Kekos, Department of Chemical Engineering, National Technical Univ. of Athens, 5 Iroon Polytechniou Str., Zogafru Campus, 15700 Athens, Greece. Tel.: (30) 17757737; Fax: (30) 17700989.

4. Sexual plant reproduction
Siena, Italy
15-29 January 1993
Local organizer: Prof. M. Cresti. Dipartimento di Biologia Ambientale, Università Degli Studi di Siena, Via P.A. Mattioli 4. 53100 Siena, Italy. Tel.: (39) 577298920; Fax: (39) 577298860.

5. Fish genes & regulation of their expression
Würzburg, Germany
October 1992 (one week)
Local organizer: Prof. M. Schartl, Theodor-Boveri-Inst. für Biowissenschaften, Physiologische Chemie I, Am Hunbland, 8700 Würzburg, Germany. Tel.: (49) 9318884198; Fax: (49)9318884150.

6. Membrane proteins
Lisbon, Portugal
28 September-9 October
Local organizer: Prof. J.M. Novais, Instituto Superior Tecnico, Departamento de Engenharia Quimica, Av. Rovisco Pais, 1096 Lisboa, Portugal. Tel.: (351) 1802045 Ext. 1233; Fax: (351) 18480072.

7. Molecular ecology of rhizosphere bacteria
Cork, Ireland
22 March - 2 April 1993
Local organizer: Prof. F. O'Gara, Department of Food Microbiology, University College Cork, Ireland. Tel.: (353) 21276871; Fax: (353) 21275934.

8. Introduction of genetically modified organisms into the environment — Biosafety aspects
Wageningen, The Netherlands
10-18 December 1992
Local organizer: Dr. N. CH. Wevers, EERO, P.O. Box 182, 6700 AD Wageningen, The Netherlands. Tel.: (31) 837084924; Fax: (31) 837084941.

9. Applications of advanced immunological techniques
Porto, Portugal
2-8 October 1992
Local organizer: Prof. M. de Sousa, Instituto de Ciencias Biomedicas de Abel Salazar, Largo Prof. Abel Salazar 2, 4000 Porto, Portugal. Tel.: (351) 2323818; Fax: (351) 22001918

Biosensor Technology in Europe

Final report on EC sponsored study

The final report on this study led by Prof. Marco Mascini of Florence and Dr. Tony Turner of Cranfield (UK) and supported by the Concertation Action of the BRIDGE programme is now available (see EBIS 1, p. 5 for a description of the study).

Considerable differences between EC, US and Japan. A marked lack of European industrial interest

The report finds considerable differences both between EC Member States and between the EC, US and Japan. Although there is a comparable level of research activity in the EC, Japan has the highest number of patents and the USA is the most important single market. The EC is lacking in industrial interest compared with the US and Japan. EC Member States have varying policies towards biosensors and the amount of research varies considerably between them. No attempt appears to have been made to coordinate Member State policies.

Academic/industrial collaboration is recommended — A common strategy for biosensor research

The report recommends that the Commission should do more to encourage industrial interest in the sector through the support of collaboration between industry and academia. It suggests how public policy might be developed both at national and Community level to formulate a common strategy for biosensor research which will ensure that Europe does not lag behind in the commercialization of this important technology.

To obtain the report, use the Response Form.

Protein Design/Bioinformatics — Catalogue of BAP Achievements

Final reports of BAP contractors available

The detailed final reports of BAP contractors for the period 1989-1990 in the areas of Protein design and bioinformatics have now been published in a report edited by B. Nieuwenhuis. To obtain the report (limited numbers), use the Response Form.

Report EUR 14089 available from Office for Official Publications of the European Communities. L-2985 Luxembourg.

BRIDGE T-(Targetted) Project. Biotechnology of Lactic Acid Bacteria (LAB)

34 laboratories collaborating in a coordinated research programme

An illustrated brochure has been produced describing the activities of this coordinated project (see EBIS 2.1., p. 9) which involves 34 laboratories in 11 Member States and Norway.

LABIP = Lactic Acid Biotechnology Industrial Platform, to establish a dialogue with researchers

An industry platform (LABIP) comprising some 40 firms and industrial associations has been established in view of technology transfer and commercialization of the results.

To obtain the brochure, use the Response Form.

Lipase T-Project Meets

Annual meeting of Lipase T-project, Capri, Italy

The Annual Meeting of the Lipase T-project in the BRIDGE programme will take place in Capri (Italy) from 1 to 3 October 1992 and is organized by Prof. E. Cernia, of the Consorzio per il Trasferimento delle Biotecnologie (CTB). The meeting is entitled "Lipase: Structure, Mechanism and Genetic Engineering" and will have four main sections: molecular cloning and expression, purification, structure and mechanism.

Details: E. Cernia. Tel.: (39) 6485451; Fax: (39) 64885614.

The Yeast Industry Platform (YIP)

Industrial platforms in association with BRIDGE "T" Projects

Industrial platforms have been set up by industry in association with most of the BRIDGE programme "T" = targeted projects (see EBIS 2, pages 8&9 for articles on the Lipase Industrial Platform and the Animal Cell Technology Industrial Platform (ACTIP). They are seen as efficient channels for dialogue between European industry and academic researchers, technology transfer and ultimately commercialization of EC sponsored research.

YIP member companies: Total annual sales 180 billion ECUS, total workforce 600,000 employees

YIP members are looking for possible applications of Yeast Genome knowledge

YIP (Yeast Industry Platform) represents a group of European companies who all produce yeast or yeast-based products and use yeast in the biochemical, agro-food and pharmaceutical sectors. The purpose of the platform is to organize the exchange of information concerning EC research programmes, particularly the BRIDGE project involved with sequencing the yeast genome. YIP members are looking for possible applications of the sequencing knowledge to their own research and development projects. YIP also seeks to contribute to regulatory, educational and communication issues, in order to achieve a balanced public image of the biotechnology industry.

Descriptive booklet available

A 12 page illustrated booklet describing YIP, "From tradition to High-Tech; the yeast, products, processes, prospects, impacts" is available from Tech-know, 2 Avenue de l'Observatoire, 1180 Brussels, or use the Response Form.

COST and Biotechnology

23 European States cooperating in science and technology

Cooperation in Science and Technology (COST) is an association of 23 States (the 12 EC Member States and 6 EFTA Member States plus Czechoslovakia, Hungary, Poland, Turkey and Yugoslavia). The aim of COST is to develop cooperation in specific projects of science and technology research and development, in particular by coordinating the work of national research agencies.

The methods used to reach these objectives are as follows:

— organization of regular meetings
— exchange of reference materials and methods
— exchange of scientists for short term training
— exchange of results
— formation of small working parties on specific topics.

Booklet describing COST and Biotechnology available

A number of COST projects are in the field of biotechnology and these have been described in a booklet "COST Cooperation in biotechnology". To obtain, use the Response Form.

I.3. Regulatory Activities

Implementation of Directives 90/219/EEC on Contained Use of GMMs and Directive 90/220/EEC on Deliberate Release of GMOs

Group of national experts on biotechnology became the Committees of Competent Authorities

Since the adoption of both Directives in April 1990, experts on biotechnology from the twelve Member States have met regularly, at first as the Group of National Experts on Biotechnology and then as the Committees of Competent Authorities, to discuss details of implementing the Directives (see EBIS 6, p. 7). The objective has been to reach agreement by consensus on a uniform and clear interpretation of the text, and also to prepare a number of documents referred to in the Directives. Handbooks for both Directives have now been published by DGXI, which bring together the results so far achieved.

Handbooks provide guidance for the implementation of the directives

The handbooks provide guidance for the implementation of the Directives and are intended to assist the Competent Authorities in their work, to guide those intending to work with GMMs or release GMOs and generally to inform interested groups and the public at large.

To obtain the handbooks, use the Response Form.

NGOs on GMOs: Exchange of Views

"Information Seminar" for NGOs = Non-Governmental Organizations

On 21st-22nd May, DGXI.A.2 organised an "Information Seminar" on the Implementation of EC Directives 90/219/EEC and 90/220/EEC on the contained use and deliberate release of Genetically Modified Organisms (GMOs).

Representatives from the European Parliament and the Economic and Social Committee participated

Over 100 participants from all the EC Member States and EFTA countries attended the Meeting, over half of them NGOs, in order to be informed about progress in implementation and to express their own views on the legislation. Representatives from the European Parliament and the Economic and Social Committee also participated. Six months after the 23rd October 1991 deadline for implementing the two Directives, significant progress in implementation was seen, although the meeting revealed certain differences between Member States. However, there was political commitment in all Member States and it was expected that most, if not all, would be implementing the legislation fully in the next few months.

In addition to the Commission and the Competent Authorities of all the EC Member States reporting on their respective activities, experts

Five EFTA countries gave presentations

from five EFTA countries gave presentations of their own States activities concerning biotechnology regulation. The Commission in general, and DGXI in particular, are responsible for the full and correct implementation of these Directives, and such meetings help both to provide information widely, and provide a basis for comparison between Member State activities. NGOs were critical of the lack of progress made in some countries and they raised the question as to how a single unified system of regulatory oversight for environmental protection and a single market could operate in the absence of some Member States' implementation of the legislation.

NGOs critical of the lack of progress made in some Member States

NGOs indicated they are seeking a more active role in the implementation process, and offered their technical expertise to the Commission. Issues of particular interest to participants were the way that the environmental risk assessment was being undertaken, as well as the question of public information and consultation in the context of the Directives.

Environmental risk assessment, public information and consultation

All participants welcomed the fact that such a meeting was held and expressed appreciation at the openness and genuinely informative role of the meeting. DGXI/A.2 are planning a further information seminar in the autumn, this time targetted more specifically at industry.

Further information seminar planned for the Autumn targetted at industry

II. Member States

European Federation of Biotechnology

"Biotechnology in Public" Answers some of the Key Questions

Conference organized by EFB Task Group on Public Perceptions of Biotechnology

This report entitled "Biotechnology in Public: A review of recent research" is based on a conference organized by the EFB Task Group in November 1991. Research on public awareness, understanding and attitudes with related studies of risk communication and media coverage of biotechnology are included.

Questions of safety, risk and regulation are very real concerns for the public

As John Durant, the editor points out in his introduction, questions of safety, risk and regulation of biotechnology are very real concerns for the European public. "It is vital that biotechnologists take these concerns seriously; for in mutual understanding lies the best prospect for the creation of a healthy relationship between the biotechnological industries and the wider European public".

"Mutual understanding will lead to healthy relationships between industry and the public"

Scientists, industrialists, policy-makers and educationalists will find the report helpful in creating greater public awareness and balanced understanding of the key issues that have been raised.

Report available from:
Dillons at the Science Museum, Exhibition Road, London SW7 2DD. Fax: (44) 71 9388118 or DECHEMA, Theodor-Heuss-Allee 25, D-6000 Frankfurt am Main 15. Fax: (49) 697564201.

A limited number are available from CUBE — use the Response Form.

Dieter Behrens: a founder of EFB, and European internationalist

EBIS notes with regret the recent death of Professor Dieter Behrens, head of DECHEMA (German Chemical Equipment Manufacturers' Association), and one of the founders of the European Federation of Biotechnology (Interlaken, 1978). The support for EFB by Dieter Behrens, and through him by DECHEMA, was a crucial factor in building it to its present strength of over 60 learned societies; his gentle discipline, determination, and European/internationalist spirit, were an inspiration to those who had the pleasure of working with him. Under his leadership, DECHEMA initiated German (and Research Ministry, BMFT) interest in biotechnology in the early 70s. Through collaboration with the Community's first FAST programme (Forecasting and Assessment in Science and Technology), the EFB produced in 1982 the first "Community Strategy for Biotechnology in Europe". Dieter Behrens was also a great innovator at DECHEMA in the development of its renowned databases for chemical engineering.

Denmark

Risk Evaluation of Genetically Modified Microorganisms in Relation to Human Health. Workshop, Copenhagen, 10-13 November 1992

A scientific basis for human health risk assessment of microorganisms

This workshop organized by the National Food Agency of Denmark and supported by the EC's FLAIR programme will discuss the possibility of using scientifically sound test systems (both *in vivo* and *in vitro*) for evaluating the risk to human health of GMMs or microorganisms in general. It will aim to develop common risk assessment procedures which could be internationally accepted.

Details: BB Jacobsen, National Food Agency of Denmark, Institute of Toxicology. Tel.: (45) 39696600; Fax: (45) 39660100.

Germany

Information Centre for European Culture Collections (ICECC)

ICECC supported by EC BRIDGE Programme

A major resource for biologists and biotechnologists has been set up with EC support at Braunschweig, Germany. The Information Centre for European Culture Collections (ICECC) is hosted by the DSM-Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH.

Focal point and information service for European scientists

The ICECC provides a permanent secretariat for Community culture collections and a focal point for European scientists to seek advice and information on cultures and culture collections generally. It will coordinate the exchange of information between culture collections and provide an information service to users throughout the world.

Further information from:
Katja Fröhlich, Information Centre for European Culture Collections, Mascheroder Weg, 1b, D-3300 Braunschweig. Tel.: (49) 531 618715; Fax: (49) 531 618718.

Italy

BIORAMA '92 — October 15-18 1992

Exhibition: products and processes; Round-Tables: Food, environment, energy, bioethics.

An exhibition and conference on innovative biotechnology will be held at Bari, Italy, 15-18 October 1992. The exhibition will relate particularly to biotechnology products, machinery and processes. A series of conferences and round-tables will take place at the same time on a number of topics including: the food sector, environmental and energy problems, bioethical issues, training and patent protection.

Details: Madex srl, via Montevideo 12, I-1200198 Rome. Tel.: (39) 68419700; Fax: (39) 66744070.

United Kingdom

Guidelines on the use of animals in research

Guidelines on genetic modification of animals

The Agricultural and Food Research Council (AFRC) has published a useful set of guidelines on this subject covering topics such as current legislation, genetic modifications, planning and design of experiments, education and training and conditions for funding research.

ACGM = Advisory Committee on Genetic Manipulation
ACNFP = Advisory Committee on Novel Foods and Processes

The chapter on genetic modification draws largely on the Advisory Committee on Genetic Manipulation (ACGM) Guidelines on work with transgenic animals (1989). Genetically modified animals or their products must not enter the food chain unless evaluated by the Advisory Committee on Novel Foods and Processes (ACNFP).

Details: Agricultural and Food Research Council, Central Office, Polaris House, North Star Avenue, Swindon SN2 1UH.

III. International Developments

OECD

Safety Considerations for Biotechnology 1992

A 2nd Blue Book on biotechnology safety

This report has been published as a follow-up to the 1986 publication "Recombinant DNA Safety Considerations" which set out the first international safety guidelines for biotechnology applications in industry, agriculture and the environment. This second "blue book" prepared by the Group of National Experts on Safety in Biotechnology, (see following article), considers the further development of biotechnology into industrial production and field experimentation.

Defines GDP = Good Developmental Principles, for the design of safe small-scale field research

The 1986 report defined "Good Industrial Large Scale Practice" (GILSP) for fermentation-derived biotechnology products. This report defines "Good Developmental Principles" (GDP) for the design of safe small-scale field research using plants and microorganisms with newly introduced traits.

Details: OECD, Publication Service, 2, rue André Pascal, F-75775 Paris Cédex 16.

OECD Safety Group

Swiss Chair OECD Safety Group of 100 experts

The Paris-based Organization for Economic Cooperation and Development held on 17-18 June the sixth Plenary Session of its Group of National Experts on Safety in Biotechnology (GNE), preceded (15-16 June) by a meeting of its Working Group III on Safety. Dr. Martin Kuenzi of Switzerland was elected Chairman of the GNE. Over 100 delegates were present. This was the final meeting for retiring GNE Secretary Bruna Teso, head of the Biotechnology Unit within the Directorate for Science, Technology and Industry.

Food safety by land and sea

Many projects are in progress; nearest to publication is a report on the safety for human consumption of foods produced by biotechnology, describing the concept of "substantial equivalence". A symposium on "Aquatic Biotechnology and Food Safety" was held in Bergen, 10-12 June, and following positive reactions the Norwegian government (with UK collaboration) will organize next year a workshop on environmental safety aspects of aquatic biotechnology.

Safety principles for scale-up of plants, microorganisms

Work in progress includes reports on safety principles for scaling up trials of transgenic crop plants (US leadership), micro- organisms (a group under Canadian-UK chairmanship is starting first on biofertilisers and biovaccines). A "Preamble" document prepared under Dutch leadership may be combined with one or more of the preceding activities in a future report, but debate on a common language to embrace somewhat different national views was extensive.

Monitoring

A monograph from the Environment Directorate on methods of monitoring GMOs in the environment has already been produced, and further work is continuing, including a workshop on monitoring in Ottawa in September (14-17).

EC research

Dr. Ioannis Economidis presented the EC programmes on bio-safety research and their conclusions.

Public information

A discussion of "new activities" for the GNE (whose current mandate ends in August 1993) focussed particularly on public information/ public education and on a preliminary survey of national activities in this area.
An enlarged mandate for the GNE is planned for discussion at the OECD Committee for Science and Technology Policy (CSTP) in October 92.

USA

FDA First past the Post in Implementing White House Policy Guidelines

Clarification of regulations on foods from new plant varieties

On Friday 29 May 1992 the US Food and Drug Administration (FDA) issued a 21-page policy statement in the Federal Register which clarifies the FDA's interpretation of the Federal Food Drug and Cosmetic Act (FFDCA) on foods from new plant varieties. This is the first of

four documents being prepared by US agencies following the publication on 27 February 1992 by the White House Office of Science and Technology Policy (OSTP) of a policy on the exercise of federal oversight on the planned introductions of biotechnology products into the environment. The February statement laid down a coordinated framework for biotechnology regulation, called on agencies to adopt a risk based approach and required them to exercise discretion within the scope of their statutory authority.

A food is considered to be "adulterated" if it bears or contains deleterious substances

The producers of new foods are held to be primarily responsible for their safety in the USA, as in Europe, and foods are not subject to premarket authorization as a general rule. However the FDA retains reserve powers in respect of the safety of foods and under section 402 of FFDCA a food can be considered to be "adulterated" if it bears or contains deleterious substances. A substance not normally present in food can be regarded as an "adulterant" unless it is demonstrated otherwise.

The FDA has reserve powers to deal with the marketing of "adulterated" foods

If such a substance, which has been added to a food, complies with the provisions in the FFDCA for a food additive, a colour additive, a pesticide chemical or a new animal drug and the substance has been authorized it is not considered to be an "adulterant". The FDA has reserve powers to deal in various ways with the marketing of "adulterated" foods which include prosecution of the offender. These would be applied in cases where the FDA judges that a food placed on the market should have been submitted to them for review or is considered to contain a "dangerous substance" or its equivalent.

New policy applies to food derived from plants developed both by traditional and new biotechnological techniques

The new policy statement applies to foods derived from new plant varieties developed both by traditional and new biotechnological techniques. It does not cover foods produced by fermentation containing microorganisms, food ingredients produced by fermentation including flavours and additives, or colours derived from plants, or foods derived from animals which may be covered in future notices.

OECD principle of "substantial equivalence" retained

Much of the document is devoted to giving guidance on how to address safety of foods from biotechnology. In brief, the introduction of genetic material into a food plant from the pool of food genes with a safe history of consumption does not automatically trigger a requirement for examination of the safety assessment by the FDA. The fundamental principle is that retained by the OECD of "substantial equivalence".

Examples where FDA oversight is required

The concept of "adulteration" is clarified in respect of foods from new plant varieties and FDA oversight is required only where there is reason to suspect that toxicants may have been raised to unsafe levels, nutritional value significantly reduced, an allergen transferred or a new "non- food" substance introduced. Also, if parts of food plants which have been modified to produce non-food substances (pharmaceuticals, chemicals) are to be offered as food, then the matter has to be referred to the FDA, even though the food part of the plant may not contain a dangerous substance.

Labelling only if common or usual name would no longer apply

As regards labelling, a genetically modified food should bear a new name if its characteristics are so changed that the common or usual name would no longer apply. Consumers should also be informed if a potential allergen has been transferred into a food in which it did not normally exist.

The requirements for pre-market assessment

The FDA has produced 6 charts to help those marketing foods to decide when no pre-market assessment is required by the FDA and FDA officials anticipate that this will be a very large proportion of foods from "novel" plants placed on the market. A specific case is cited of an antisense modified tomato which is currently under assessment under old rules but which the FDA concludes would be unlikely to require referral to the FDA had it been considered after the issuing of the statement. The regulation of pesticide residues, e.g. BT toxin, introduced by biotechnology would continue to be subject to EPA. There is also close cooperation with USDA which is responsible for meat and poultry.

Policy statement represents a considerable clarification of the rules for the marketing of food from biotechnology. Other documents expected soon

Although there is a 3 month period for comment the publication of this policy means that manufacturers can immediately apply it and companies correctly following the criteria set out therein for a product would have a satisfactory defence against allegations of selling "adulterated" foods. The policy represents a considerable clarification of the rules governing the marketing of food from biotechnology which is put on an equivalent status with other food production technologies. Three further documents on plant field testing, microbials and microbial pesticides and animals are expected in the autumn.

Biotechnology for the 21st Century: A report by the FCCSET Committee on Life Sciences and Health.

This report by the Federal Coordinating Council for Science, Engineering and Technology (FCCSET) of the Office of Science and Technology Policy (OSTP) describes the Presidential Initiative in Biotechnology Research.

$ 4.03 billion to sustain and extend US leadership in biotechnology research

The strategic framework outlined in the report is a coordinated, interagency effort intended to develop and implement a national Biotechnology Research Programme. The biotechnology activities of 12 Federal Agencies are included with a FY 93 budget of $ 4.03 billion, by far the largest of the "Presidential Initiatives". The stated goal of the Initiatives is to "sustain and extend US leadership in biotechnology research for the 21st century to enhance the quality of life for Americans and the growth of the US economy".

Report available from:

Committee on Life Sciences and Health, C/O Office of Energy Research ER-70, US Department of Energy, Washington DC.

To obtain report (limited numbers), use the Response Form.

US-Japan Linkages in Biotechnology

Scope, significance and trends in US-Japan technology linkages

The Committee on Japan under the National Research Council has published a report "US-Japan linkages in biotechnology". The report discusses the scope, significance and trends for such linkages against the background of the main question for the US: whether it can maintain its position as world leader in biotechnology through the 1990's. The report concludes that unless concrete steps are taken, the

US biotechnology industry could lose its competitive edge by the end of the decade.

Call for two-way exchange of technology between US and Japan

It proposes that government, industry and universities should ensure a two-way exchange of technology between the US and other countries — particularly Japan.

Details:

National Academy Press, 2101 Constitution Avenue, NW, Washington DC 20148. Tel.: (1) 202 3343313; Fax: (1) 800 6246242.

DNA Technology in Forensic Science

National Research Council confirms general reliability of DNA typing

The National Research Council has published a report which confirms the general reliability of using DNA typing evidence in criminal cases, a practice that has been challenged in some legal and scientific circles. However, a number of recommendations are made to resolve deficiencies in the system, including federal control of laboratory standards.

Details: National Academy Press, 2101 Constitution Avenue, NW, Washington DC 20148. Tel.: (1) 202 334 3313; Fax: (1) 800 624 6242.

Corresponding issues in Europe. EDNAP = European DNA Programme, an informal group of forensic scientific experts

Corresponding issues in Europe are being addressed by EDNAP, the European DNA Programme of forensic scientists, who held (with Commission support) a Symposium in London in May 1991 on PCR (polymerase chain reaction) and other matters. The meeting was also informed about the Council of Europe Recommendations on DNA analysis in the criminal justice system.

Details:

TJ Rothwell, Forensic Science Service, Hinchingbrooke Park, Huntingdon, Cambridgeshire PE18 8NP, UK.

Details of EDNAP:

VJ Emerson, The Forensic Science Service, Aldermaston, Reading, Berks RG7 4PN. Tel.: (44) 734814100; Fax. (44) 734815490.

Australia

Genetic Manipulation: The Threat or the Glory? Report by the House of Representatives. Standing Committee on Industry, Science and Technology, February 1992.

Government enquiry into development, use and release of GMOs

The report is the result of the Committee's enquiry into the development, use and release into the environment of genetically modified organisms. It considers many of the fundamental philosophical and ethical questions that have been raised by the "new genetic manipulation techniques" as well as possible environmental impacts,

effects on human health, and legal issues such as patent rights, compensation for injury or property damage, and clearance and registration procedures for the sale and import of a wide range of products.

Regulatory structure to be established

Chapter 8 in this 353-page report concerns the Committee's recommendations for the kind of regulatory structure under which it believes the use of genetic manipulation techniques should be allowed to proceed. Among the report's 48 recommendations, it is proposed to retain the Genetic Manipulations Advisory Committee (GMAC) (see EBIS 2.1., p. 24) for contained work and as a specialist advisory body and to create a new GMO Release Authority for the authorization of all releases of GMOs and for setting minimum standards and procedures.

Proposed new GMO Release Authority

Details:

The Manager, Commonwealth Information Services, Australian Government Publishing Service, GPO Box 84, CANBERRA ACT 2601.

IV. Reports/Books Received

"Ecological Effects of Genetically Modified Organisms" edited by Jaap Weverling (of Mondiaal Alternatief) and Piet Schenkelaars (European Coordination, Friends of the Earth). 110 pages. Netherlands Ecological Society, Drenthesingel 11, 6835 HG Arnhem, NL. Price D.fl. 27,50.

Netherlands Ecological Society in cooperation with the Provisional Committee on Genetic Modification

This report presents nine papers by qualified specialists writing for a general audience, the proceedings of a national symposium organized by The Netherlands Ecological Society in cooperation with the Provisional Committee on Genetic Modification, Amsterdam, September 1991.

The papers range from scientific topics (the ecology of invasions, horizontal plasmid transfer), mainly covering micro-organisms, plants and insects, via risk assessment to risk management and regulatory policy for field release. Finally a list of knowledge gaps or research requirements is provided.

Regulation and Discussion on Genetic Modification of Animals

The situation in the European Community, The Netherlands, the United Kingdom, Germany, Denmark, France and the United States by René Custers and Lydi Stemenberg.

Public attitudes and legislative position is compared

The Netherlands Organization for Technology Assessment (NOTA) has produced a most useful review of attitudes towards, and legislation controlling the genetic engineering of animals and their use in the EC

and the US. The report reveals that there are clear differences of opinion in the different countries on the perception of risks, economic significance, animal welfare and ethical considerations. The issue of animal patenting is fuelling much of the discussion in the European Parliament on the desirability of transgenic animals.

Production of vital medicines more acceptable than more or better food

The genetic modification of animals to produce more or better food appears generally to be less acceptable than their modification for the production of vital medicines.

The report in English may be ordered from:

Distributiecentrum Overheidspublicaties (D.O.P), P.O. Box 20014, 2500 EA The Hague, The Netherlands. Price Dfl 25 quoting ISBN 9034628116.

Advances in Biochemical engineering/Biotechnology. Edited by A. Fiechter. Vol. 46. Springer-Verlag.

Neural networks; protein production; filamentous fungi; immobilized cells; and EC programmes

A number of exciting new developments in Biochemical Engineering Science are covered including topics such as artificial neural networks in bioprocess control, protein production from animal cells, modelling the growth of filamentous fungi and use and engineering aspects of immobilized cells in biotechnology.

A comprehensive overview is given of the biotechnology research activities in the EC programmes, written by I. Economidis.

To obtain a reprint of this article, use the Response Form.

An Investigation into Ways of Promoting Greater Activity in the Biotechnology Small-Firm Sector in the Community

Context for SME development and EC supportive measures

Prepared for the Commission, this report explores the context in which smaller firms and start-ups have to operate within the EC at present, and examines the various supportive measures at EC or other levels.

It envisages possible improvements, including:

- formulation of realistic business plans by entrepreneurial scientists
- better, more informed project assessments by financial backers
- easier availability of suitable premises, and necessary equipment, for start-up companies
- more generous fiscal treatment of stock options for staff of newer companies
- better 'exit routes' in the EC for potential equity investors

— realizing an internal market for new biotechnology-based products, without national discrimination on grounds irrelevant to health and safety

— encouraging use of new technologies in established industry sectors

— disseminating more effectively information about EC programmes and policies

— improving the cost/benefit potential for participants in EC programmes

Specific recommendations at EC and national level for possible improvements

Specific recommendations are made at EC and national levels, touching on business training, venture capital, easier stock market access for smaller, younger companies (providing a foreseeable exit route for investors encourages their entry). Other recommendations envisage the reinforcement in, or extension to, biotechnolgy of existing Community initiatives such as feasibility awards for SMEs in R&D programmes, SPRINT Technology Performance Financing, CORDIS and other database information, improved statistics on biotechnology industries and products.

The report is on the agenda of the Commission's Biotechnology Coordination Committee, so energetic follow-up can be expected.

To obtain the report, use the Response Form.

Response form

To order articles/reports mentioned in the text, please tick and return form to editors.

- Report of ECAS Citizen's Audit ❑
- Dossier on cDNA patenting ❑
- Concertation in BRIDGE 91-92 Report ❑
- Biosensor technology in Europe ❑
- Lactic Acid bacteria brochure ❑
- Yeast Industry Platform booklet ❑
- Protein design/Bioinformatics BAP final reports ❑
- COST cooperation in biotechnology ❑
- 90/219/EEC and 90/220/EEC handbooks ❑
- Biotechnology for the 21st century ❑
- Reprint on EC biotech research ❑
- Promoting SMEs in Europe - report ❑

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European Biotechnology Information Service

Volume 2, issue 3
July 1992

Published for the Commission of the European Communities by ASFRA BV, Voorhaven 33, 1135 BL EDAM, The Netherlands.

Editors:

M.F. Cantley and M. Lex
Commission of the European Communities, CUBE, DGXII/F-1
rue de la Loi, 200, B-1049 Brussels, Belgium.
Tel.: (32) 2 2365619/2356736; Fax: (32) 2 2355365.

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