May, 1993

EBIS

EUROPEAN BIOTECHNOLOGY INFORMATION SERVICE

Vol.3 no. 2

NEWSLETTER

Editorial: Towards the Greening of Industry

BRIDGE meeting considers the potential of biotransformations

The use of enzymes, the natural catalysts found in all living things, to carry out specific biotransformations, is proving of great potential to a number of different industries. A recent BRIDGE meeting on "Biotransformations" was held at Braunschweig, Germany, to report on progress in this area.

Unlike fossil fuels enzymes are renewable and potentially inexhaustible

Over many millions of years enzymes have evolved to provide a natural resource as real and ancient as coal or oil. But unlike fossil fuels, enzymes are renewable, potentially inexhaustible and easily carry out complex chemical reactions at room temperatures and at atmospheric pressure. Furthermore, they can be improved by protein engineering and through genetic engineering are available comparatively cheaply.

Continued on page 2

Other pages

EUROPEAN BIOTECHNOLOGY INFORMATION SERVICE

Commission of the European Communities

Provided any allergenic effects can be overcome enzymes offer to many industries the possibility of developing safer, cleaner and, because they need no extra heat or pressure, cheaper, and more environmentally-friendly ways of making products.

Enzymes with great versatility and potential in industry

Other enzyme attributes lie in their ability to make chemicals in such a way that all their molecules are either left-handed or right-handed. Such chirality is very important in therapeutic molecules as right or left-handedness (or mixtures of both) may result in drastic consequences, as in the thalidomide disaster. Further, although enzymes usually function in the user-friendly environment of the living cell they can be made to work in non-aqueous systems such as organic solvents. In novel chemical environments it is possible to enlarge the range of reactions they can catalyse and thus the range of tasks they can carry out in industry.

An industrial association but no industrial platform to exploit the results

The industries that may benefit from enzyme technology in terms of increased economic profitability and reduced environmental impact include detergents, textiles, pulp and paper, leather, baking, brewing and many other food industries as well as pharmaceuticals. Not surprisingly, "Enzyme biotransformations" is an appropriate topic for consideration by the precompetitive research of the BRIDGE programme. All that is lacking is an industrial platform of companies with potential to exploit the results. Perhaps, the Association of Microbial Food Enzyme Producers (AMFEP) (see page 26) will take notice.

I. Community Activities (Commission, Parliament, Council)

I.1. Research and Related

New Commissioner Ruberti Takes New Approach to FP4

An update on 1st working document

A second Commission Working Document COM(93)158 has been published on the Fourth Framework Programme (FP4). It updates the first working document of October 1992 COM(92)406 (see EBIS 2.4. page 5) to take account of the conclusions reached at the Edinburgh Summit; developments in the world context; and the comments and opinions received on the first working document.

Some major policy changes are evident:

Greater selectivity and better integration of national and Community research programmes

- Greater selectivity with regard to Community RTD activities in order to increase their economic impact (while retaining their focus on generic technologies). The number of areas proposed originally has been reduced from 54 to 28.

- Greater integration of national, Community and European activities (Article 130 H of the EC Treaty — an important existing article which the Maastricht Treaty will further strengthen).

- Development of a research/training synergy.

- Increased flexibility of Community activities in order to respond rapidly to new scientific and technological challenges.

Revised financial perspective

- Bringing the financial requirements of FP4 into line with the new Community financial perspective for 1993 to 1999.

To obtain the document use the Response Form (Item 1).

DGXII Reorganisation

DGXII's new "Life Sciences and Technologies" Directorate (see EBIS 2.4 page 4) is taking shape with the appointment of Mr. Bruno Hansen (from Denmark) as its Director. It currently comprises the following:

Director:	B. Hansen
Adviser:	A. Dickens
E-1 (Biotechnology):	E. Magnien
E-2 (Agro-Industrial Research):	F. Rexen
E-3 (Agro-Industrial Demonstration Projects):	A. Herrero
E-4 (Medical Research):	A. Baert
E-5 (Legal and Ethical Aspects):	J. Elizalde

Any further developments will be reported in future EBIS issues.

Biotechnology Makes Second Call

Deadline 31 August 1993

The Biotechnology programme (1992–1994) has published its Second Call for proposals (OJ C114 p. 18–24.4.93) with a deadline of 31 August 1993.

This call does not cover all the topics included in the Biotechnology "Work programme".

Only 5 topics considered

Proposals will be considered which fall under any of the following five topics:

1.1.4. Production of novel biocatalysts

1.2.1. Sequencing of the genomes of Saccharomyces cerevisiae and Bacillus subtilis.

2.2.1. Transgenic animal models for the protection of human health.

2.2.7. Mechanisms of gene regulation for the expression of economically important products from microorganisms.

3.1.4. Genetically engineered fish, insects and nematodes.

Numbering corresponds to the "Work programme" document.

Info pack available

To obtain the 2nd call Information Pack, state language required and use the Response Form (Item 2).

FLAIR-Flow Europe (F-FE) 1-page Documents 1992

Budget of 25 million ECU for 33 transnational projects

FLAIR is an on-going research and development programme of the European Community on food quality, food safety and nutrition/wholesomeness. It has a budget of 25 million ECU and 33 transnational research projects. F-FE is one of the 33 projects in the programme, and helps to disseminate information from the other 32 to the food industry, health professionals and consumer groups. The information is tailored in layman's language as 1-page technical documents (in all 37). Each document contains a number, key-words, a title, text, and a contact name/address for more in-depth information on the topic in question.

If you would like to be on the mailing list for future documents please contact:

L. Breslin, Commission of the European Communities, DGXII/E-2, 200, rue de la Loi, B-1049 Brussels. Tel. (32)2-2950477; Fax (32)2-2964322.

To obtain report, use the Response Form (Item 3).

Methods of Communicating Biotechnology with the Public — EC/US Task Force on Biotechnology Research

EC/US biotech policy forum

The EC/US Task Force on Biotechnology Research was established in 1990 as a policy-level forum to increase mutual understanding and exchange information on scientific aspects of biotechnology (see EBIS 0 page 3). Effective communication being recognised as critical to the acceptable development of biotechnology, the U.S. Department of Agriculture (assisted by other federal agencies) and the Commission of the European Communities (under the BRIDGE concertation action) co-sponsored a workshop in Dublin in March 1992 on the above topic. The workshop was organised locally by Bioresearch Ireland.

Workshop on communication with the public hosted by Bioresearch Ireland

49 Experts, 5 panels, 6 questions

49 Invited experts, from US and EC, heard case study presentations (Frost-Ban, bovine somatotropin, the Danish Teacher's group), then were assigned to five panels, according to background, each considering their "Role": Media; Scientists; Public and Public Interest Groups; Government Institutions; Educators.

The panellists, selected to represent a diversity of opinion, all addressed the same six basic questions:

a. What determines public perceptions?
b. What tools do we have to identify and analyse public attitudes towards biotechnology?
c. What are the key differences in public perceptions between European countries and the United States?
d. What are the obstacles to effective communication practices (educational, social, cultural, economic, psychological, legal, financial, political), and what are the solutions to overcome such obstacles?
e. How do we measure and evaluate the effectiveness of communication projects ?
f. What actions can be taken, by public authorities and others in the field to improve understanding, trust, and credibility ?

Action recommendations, but not consensus

The panels were not intended to be consensus-building, but explored issues and solutions; each panel provided a report, with recommendations for action.

To obtain the report, use the Response Form (Item 4).

Or in America, apply to: Office of Agricultural Biotechnology, US Dept. of Agriculture, Room 101, RPE, 14th & Independence Ave., S.W., Washington, DC 20250–2200, USA. Tel. (703)2354419; Fax (703)2354429.

Global Perspective 2010: The Case of Biotechnology

The application of biotechnology to important future global problems

The final report prepared for the EC-FAST programme (with co-sponsorship from the concertation action of the BRIDGE programme) by the Science Policy Research Unit of the University of Sussex, UK, aims to identify the factors which will promote the application of biotechnology to important global problems confronting the world in 20 years time. The 77-page report contains the following chapters:

- present and future trends in the applications of biotechnology;
- the role of the private and public sectors in the development of biotechnology;
- regulations;
- intellectual property rights (IPR);
- regional development of biotechnology.

Recommendations for developing countries and IPR

The report recommends that the developing countries adopt IPR for biotechnology products and processes to encourage the licensing of foreign technology, foreign investment and diffusion of knowledge. The report also suggests that international organisations contract industry in the First World to apply biotechnology to resolve specific developing country problems. Finally, it recommends that national governments in the First World commit funding to support R&D on biotechnology for the environment.

To obtain the report, use the Response Form (Item 5).

I.2. Manpower and Training

Skills Shortages in Europe — IRDAC Opinion

IRDAC = Industrial Research and Development Advisory Committee

IRDAC, the Industrial Research and Development Advisory Committee of the European Community, established in 1989 a Working Party (WP 11) on education and training issues relevant to industry. The Working Party created in 1990 two specific sub-groups, one on the school-industry interface and one on skills shortages. The 55-page report on the above topic has been prepared by the latter sub-group. In this report, the skills shortage issue is considered from a European and macro-economic point of view and suggestions are made for remedial actions.

Skill shortages identified and suggestions made for remedial actions

After an analysis of the skills shortages, the report concludes that if sufficient attention is not given to the skills shortage problem, in particular in areas of technological advance, Europe's competitive position will be

threatened. The report makes a series of recommendations which can be summarized as follows:

- An overall approach by all actors (administrations at Community, national, regional and local levels; enterprises; the education sector and individuals).
- A massive investment in upgrading of the existing workforce.

Calls for a massive investment in education and training

Supply of highly skilled people in Europe must be maintained and even increased.

- Improving productivity of education and training.
- Understanding skill requirements.
- Investment in education and manpower requirements.

To obtain the report, use the Response Form (Item 6).

I.3. Bioinformatics

Sequence-related Databases in Europe: Two Initiatives

Concerns about future EMBL Data Library: CEFIC report recommends ENSC = European Nucleotide Sequence Centre

For more than a decade, the European Molecular Biology Laboratory (EMBL) Data Library has provided for Europe a central, unified source of DNA sequence information. As the size of the database has grown, so have concerns about its future, in particular its accommodation and long-term funding. In November 1990, the European Chemical Industry Federation (CEFIC) published a report (see EBIS 1 page 20 and EBIS 5 page 11) which drew attention to the importance of high quality bio-informatics support for research and industry and also made some specific recommendations to the Commission of the European Communities. Among the latter was the "urgent need to stabilise the European nucleotide sequence effort"; the development of plans for a European Nucleotide Sequence Centre (ENSC) was suggested.

PA report provides plan for an ENSC while EMBL proposes EBI — European Bio-Informatics Institute

From this report, two related but separate initiatives ensued. Under the concertation action of the Community's "BRIDGE" programme (Biotechnology Research, Innovation and Development for Growth in Europe), the PA Consulting Group was funded to provide, in detailed form, an organisational blueprint and implementation plan for an ENSC. Meanwhile, the Director-General of EMBL conceived the idea of a European Bio-Informatics Institute (EBI) and began to develop plans for the establishment of such a body under the aegis of EMBL.

Future activities of ENSC proposed

The PA report was delivered to the Commission at the end of 1992. It acknowledges the importance to Europe of the DNA sequence database and concludes that national, or EC, funding is essential because "an unsubsidised ENSC could not long survive. Users will prefer to access the free (subsidised) USA data library rather than pay for essentially the same service in Europe".

The report defines the future activities of the ENSC as:

- a core DNA library.— an essential building block which includes annotation (i.e. basic reference information) of the data;

- a network management service activity;

- an information transfer, training and development component.

It also describes the conditions under which a "lower cost, flexible, efficient and effective service" could be provided, noting that the research environment at EMBL is not suited to the successful delivery of a service, though its legal structure could be appropriate.

It is suggested that the ENSC be an administratively distinct entity within the EMBL structure i.e. an outstation, along the lines of the existing ones at Hamburg and Grenoble. The importance of a defined, user-orientated mandate is emphasised, as is the recommendation that EC funding be contingent on this.

EMBL plans for EBI at Cambridge

The report further specifies core staffing and funding levels; the latter is estimated to be 5 MECU per annum, increasing by no more than 4 % p.a. over the first 5 years.

As mentioned above, EMBL proceeded to draw up its own plans for an EBI, which are rather more ambitious in scale and included a research component as well as housing the Data Library. However, they too came to the conclusion that the best way forward was the creation of a new EMBL Outstation. The EMBL plan was accepted by EMBL Council in December 1992 and a Call for Tenders for the EBI was launched. Following reactions from Sweden, Germany and the UK, EMBL has recently announced that the Outstation will be located on the Genome Campus at Hinxton Park, Cambridge, UK, which also houses the Sanger Centre directed by Dr. John Sulston. The Welcome Trust and the UK Government are providing the infrastructure needs but EMBL will need to find additional financial support for the day-to-day running of the outstation.

Hitherto the Commission has helped support both the EMBL Data Library and the EMBnet project which allows national and specialist laboratories all over Europe to obtain information from both the data centre and each other. The possibilities of future support — and the convergence of the two institute initiatives described above — are yet to be explored.

Future for ENSC and other bioinformatics needs unclear

Some interesting questions remain. The EMBL case for the EBI rested strongly on sequence-related informatics and, not surprisingly, EMBL has shown some enthusiasm for incorporating the ENSC within the EBI. However, details are lacking about the extent to which the Data Library's current tasks would be expanded to cover the activities foreseen by PA for the ENSC. And the uneasy relationship between service-oriented efforts and a research mission needs further consideration. Also, biologists in Europe have considerable informatics needs which are not sequence-linked. These cover the whole gamut of collection, storage, retrieval and manipulation of a variety of biological data and range from molecular modelling software to bibliographic databases. As the EBI will take care of only part of these, how is Europe to take care of the rest?

To obtain the PA Report, use the Response Form (Item 7).

Details of EBI from Graham Cameron, EMBL Data Library, Meyerhofstrasse 1, Postfach 102209, D-6900 Heidelberg, Germany.

Documentation Centre set up at Joint Research Centre

Documentation centre on Biotechnology Safety and Regulation

BIOSAFE will be publishing a bulletin

A documentation centre, BIOSAFE, has been set up at the Community's Joint Research Centre, Ispra (Italy) to serve the Competent Authorities for the implementation of EC Directives 90/219 and 90/220. This will collect documents relating to biotechnology safety and regulations. The Centre will produce a regular bulletin containing, among other things, a list of the collected documents. The first issue was published in November 1992. Copies of documents which are not subject to copyright may be ordered. There is no charge to the Competent Authorities for this service but a charge of 10 ECU for each 50 pages copied will be made for all other interested parties.

Details: G. Van den Eede, BIOSAFE T.P. 634, Joint Research Centre, Institute for Systems Engineering and Informatics, I-21020 Ispra (VA). Tel. (39)332-785239; Fax (39)332-785483

I.4. The Regulatory Framework

Scientific cooperation in the food sector to start on 1 June 1993

Scientific Committee for Food consulted on a wide range of questions

The completion and smooth operation of the internal market for foodstuff requires a community procedure for the examination and evaluation of scientific questions relating to food. To assist with this task, the Commission set up a scientific Committee for Food by Decision 74/234/EEC (OJ N L136, 20.5.1974, page 1). This committee is consulted for questions relating to human nutrition and public health, incidents involving food contamination and new rules concerning foodstuffs which affect human health.

Information and scientific support from the Member States under new Directive

In order to carry out these tasks the Commission must have access to the information and scientific support in the Member States. The Council on 25 February 1993, therefore, adopted Directive 93/5/EEC (OJ N L52 4.3.1993, page 18) on assistance to the Commission and cooperation by the Member States on the scientific examination of questions relating to food.

The main objective of the new Directive is to ensure that the Member States take all the necessary measures including financial measures, within the limits of their resources, to enable their competent authorities and bodies to cooperate with the Commission and lend it the assistance it needs in the scientific examination of questions of public interest relating to food. Provisions for third countries to participate in this cooperation were made.

The Member States are requested to implement this Directive by 1 June 1993. For the scientific cooperation it is foreseen that the Commission will be assisted by the Standing Committee on Food set up by Decision 69/414/EEC.

Principal tasks of institutes participating in the new cooperation

Article 3 of Council Decision 93/5/EEC indicates that the principal tasks to be carried out by the institutes participating in the cooperation shall include those listed in Annex, i.e.:

- drawing up protocols for the assessment of risks related to food components and elaborating methods and nutritional evaluation;
- assessing the nutritional adequacy of the diet;

- examining test data submitted to the community rule and the production of a monograph for assessment by the Scientific Committee for Food;
- carrying out food intake surveys, particularly those necessary for the determination or evaluation of the conditions of use of food additives or the laying down of limit values for other substances in food;
- conducting investigations relating to components of diets in the Member States or of biological or chemical food contaminants;
- helping the Commission honour the Community's International commitments by providing expertise on food safety questions.

It also requires the establishment of rules for the administrative management of scientific cooperation which the Commission services have drafted. At present they are planning the written procedure foreseen for the creation of Commission Decisions.

Details: O. Rohte, DGIII. Tel. (32)2-2953141; Fax (32)2-2951735.

I.5. Innovation and Investment

EUROTECH CAPITAL and EUROTECH INNVEST: A simple route to finance

EUROTECH INNVEST provides the liaison between firms seeking capital and the network of investors

Small and medium-sized enterprises (SMEs) may find it difficult to secure private capital investment for their activities in the field of high technology. In order to encourage capital investment in such high technology developments on a pan-European basis, the EUROTECH CAPITAL initiative has been established by DGXVIII of the Commission of the European Communities.

Network of European financial institutions

A network of European financial institutions have agreed to invest approximately 150 million ECU primarily in SMEs involved in high technology. The SMEs should be registered in a member country of the EC and should have a product or process which is aimed at a Transnational Market. Enterprises are required to provide information concerning the management team as well as financial details of the firm. This information is treated in the strictest confidence by the EUROTECH INNVEST management team, who screen, select and process the data before presenting it to the investors by means of a confidential database.

For further information please contact: Longman Cartermill Ltd., Technology Centre, St. Andrews, Fife KY16 9EA Scotland, United Kingdom. Tel. (44)334-77660; Fax (44)334-77180, or: J. Berger, EEC–DGXVIII. Tel. (352)4301-36246, Fax (352)4301-6322.

II. Member States

BioEurope '93. 1–6 June 1993

International Conference and Exhibition in Brussels

An International Conference and Exhibition will be organised in Brussels by the Senior Advisory Group on Biotechnology with the International Bio-Industry Forum.

Bio Europe 1993 aims to:
- provide a unique opportunity to shape future European and global prosperity through the responsible application of new technologies.
- identify how Europe can improve its comparative advantages in embracing new technologies.

The conference will take place 1–2 June 1993 and the exhibition from 1–6 June 1993 at the Brussels Congress Centre.

Details: Bio-Europe '93, C/O Challenger Communication, rue J-B Decock 5, B-1080 Brussels. Tel. (32)2-4100350, Fax (32)2-4101994.

AMFEP — Association of Microbial Food Enzyme Producers

The members of AMFEP produce and sell enzymes

The AMFEP is a European Industry association founded in 1977. The members of AMFEP produce and sell enzymes for, among other things, food processing. The main objectives of AMFEP are :
- to provide a common basis for representing the interests of its members in negotiations with the Commission of the EC;
- to ensure a free flow of information between members about developments related to the regulatory status of food enzymes in Europe.

Microbial enzymes and their uses

AMFEP has published a report about the production of enzymes and their use in a variety of industries,particularly the food industry. Other short publications are also available from AMFEP :
- regulatory aspects of microbial food enzymes;
- regulatory aspects of food enzymes produced by recombinant microorganisms;
- classification and labelling of microbial enzyme preparations.

Details: AMFEP Secretariat, Avenue de Cortenberg 172, B-1040 Brussels. Tel. (32)2-73558170, Fax (32)2-736.81.75.

Germany

Amendment of the German Genetic Engineering Law (GenTG)

Industry and academia agree "insurmountable bureaucratic burdens have to be overcome"

The German Genetic Engineering Law, which came into force on 1 July, 1990, has been under review for several months. Industry and scientists argue that the "insurmountable bureaucratic burdens have to be overcome" for the development of a competitive German biotechnology industry. They are also very concerned that the law has been interpreted in different ways in the different Länder. Furthermore, the European Commission has requested the German Government to make the necessary changes to correctly implement the EC Directives 90/219/EEC and 90/220/EEC on the contained use and deliberate release of GMOs. As a consequence, the Ministry of Health has issued on 17 March 1993, a draft proposal for a revision of the law. The initial Bundestag resolution called for much wider amendments (including the corresponding EC Directives) but the present draft appears to be in line with the existing EC-Directives. A first discussion with different interest groups was organised in the middle of April. Both the Bundestag and the Bundesrat will probably debate the new law for the first time before the summer break.

Main amendments proposed

The main proposed amendments include:

1. Production plants for work with group 1 (no risk) organisms will require to be notified only. The time-limit of 90 days will be dropped.
2. Time-limits for research work with micro-organisms in group 1 (no risk) and group 2 (low risk) will be shortened by 30 days. The obligatory participation of ZKBS will be dropped in certain cases.
3. Further continuing work with organisms in higher safety classes (groups 2, 3 and 4) will require notification (the time-limit of 90 days will be dropped).
4. Public hearings for the authorization of a production plant in lower safety classes (groups 1 and 2) will be dropped, and construction of the plant can be started before the permit is received.
5. The possibility of introducing simplified procedures as foreseen in the EC-Directive 90/220 will be included. A public hearing in those cases will not be necessary.

Consumer and environmental organisations lay down their demands

Recently, several consumer and environmental organisations such as the Deutsche Naturschutz Ring (German Environmental Society) and the BUND (Friends of the Earth) have agreed on a common position on the revision of the Gene Law. Their main demands are:

1. The purpose of the law should be limited to the protection of human health and the environment and should not include the promotion of genetic engineering.
2. Inactivation of all GMOs and the DNA in all industrial plants and laboratories.
3. Public participation must take place for all commercial plants at every safety level.
4. The authorisation procedure must be kept transparent.
5. Products placed on the market containing or consisting of GMOs should be labelled.
6. A general product liability for the producer should be established.

Italy

Italian Activities to Promote R&D Programmes and Services in the Bioinformatics Field

Bioinformatics centre set up in Bari

The need to set up research centres and to provide biotechnology-relevant information in less developed regions, such as the Italian Mezzogiorno, has spurred TECNOPOLIS CSATA to start a feasibility study on setting up a Bioinformatics Centre within TECNOPOLIS Scientific Park in Bari. This study has been carried out in cooperation with the Centro Nazionale delle Ricerche (CNR = national research council - Bari area). The main implications of the study concern the opportunity of offering services in "molecular" form both to Research Centres and to the firms involved in the biotechnology and bioinformatics markets.

Research, development and training opportunities made available to industry

Three major objectives have been formulated:

- provision of information on research and development (in close cooperation with other national and foreign research centres);
- services to industry (information, quality of production, technology and computer science);
- specialized training.

Details: TECNOPOLIS, Anna Maria Annicchiarico, P.O. Box 775, I-70010 Valenzano/Bari. Tel. (39)80-8770321; Fax (39)80-651868

The Netherlands

Biotechnology in the Netherlands — The Network Approach

Who's who of Dutch biotech

The Dutch Ministry of Economic Affairs Project Team Biotechnology and the Netherlands Society for Biotechnology have produced a comprehensive Directory of biotechnology in The Netherlands.

It includes detailed information on Government and semi-government organisations, Research and Development Institutions, Professional and Social organisations, Public Interest groups, etc. Information Sources and International Organisations. Companies are not included but a useful "directory of directories" of companies is provided.

The loose-leaf report (in English) is available at price Dfl. 65 from: Ministry of Economic Affairs, Project Team Biotechnology, 2500 EC The Hague. Tel. (31)703798911; Fax (31)703474081.

United Kingdom

Biotechnology Friend or Foe? — Report

Social, Ethical, Political, Religious and Economic Impacts

The report of the 1st Annual Meeting of the BioIndustry Association (BIA) held on 18 November 1992 has been published. The report is entitled "Biotechnology — Friend or Foe ? The Social, Ethical, Political, Religious and Economic Impacts."

The meeting was organised by the BIA Working Party on Public Awareness and Information.

Details: BioIndustry Association, 1, Queen Anne's Gate, UK-London SW1H 9BT. Tel. (44)71-9574600; Fax (44)71-9574644.

III. International Developments

OECD

Safety Evaluation of Foods derived by Modern Biotechnology: Concepts and Principles

Report coincides with GMO foods

This latest OECD report is timely in view of the food products now coming to market, including those containing or comprising genetically modified organisms. It is the product of work undertaken by the Group of National Experts on Safety in Biotechnology, and has been prepared by the OECD Environment Directorate, in collaboration with the Directorate for Science, Technology and Industry.

Scientific principles and "substantial equivalence"

The book elaborates scientific principles to be considered in making evaluations of new foods or food components based on comparison with foods that have a history of safe use. It advocates the concept of "substantial equivalence". The use of this concept is illustrated by case studies

Case studies: Micro-organisms, plants and animals

comprising: lactic acid bacteria; low erucic acid rapeseed oil; myco-protein; genetically modified baker's yeast; tomato; potato; rice; animals from transgenesis experiments; and swine transgenic for porcine somatotropin.
A list of further reading is included. The book is also published in French. It can be ordered through national OECD Distributors who will fix prices in local currency, or directly through OECD Paris, price FF 80; shipping is free of charge. If you wish air mail service, contact OECD for the additional charges. OECD publications, 2 rue André Pascal, 75775 Paris cédex 16.

Council of Europe

Long-term Ecological Impacts on GMOS Examined

Group of specialists on the ecological impacts of gene technology

The Council of Europe, based in Strasbourg, has a Steering Committee for the Conservation and Management of the Environment and Natural Habitats (CDPE). This Committee set up a group of specialists on the Ecological Impacts of Gene Technology. The group was responsible for a report on the "potential ecological impacts of the contained use and deliberate release of genetically modified organisms".

Pan-European Conference on potential long-term ecological impacts

They now plan to hold a Pan-European Conference on potential long-term ecological impacts of the release of genetically modified organisms, from 24–26 November 1993 in Strasbourg. The conference will be co-funded by the EC Commission.
Details: Piet Schenkelaars, P.O. Box 38, NL-2250 AA Voorschoten.
Tel. (31)71-611298; Fax (31)71-617791.

Biotechnological implications for agriculture

Economic and social impacts

The hazards of biotech and need for work on ethical considerations

Also in the Council of Europe on 22 February 1993, the Spanish Socialist Gonzalez Laxe presented a report on developments in biotechnology and the consequences for agriculture. The objective of the 16-page report is to identify the most recent developments and to assess some of the major economic and social impacts likely to follow. Particular attention is given to the use of biotechnology in plant and animal breeding and food and non-food production. The report warns against the hazards of biotechnological inventions and urges the Council to extend its work on bioethics to include genetic engineering of animals and other living organisms.

To obtain the report (in English) use the Response Form (Item 8).

Canada

National Research Council (NRC) Canada, Strategic Assessment of the NRC Biotechnology Program

Canada's $60 M commitment assessed

This English/French (2 x 60 page) publication is the final report of the review committee set up in 1990 to assess Canada's $ 60m commitment to biotechnology. The authors note that "biotechnology has not grown as quickly as expected", but remain confident that the potential remains for influence on many industrial sectors.

250 firms; 27% in health care

Of Canada's 250 biotech-involved firms, only 27% operate in health care (contrasting with the US); a substantial number related to agriculture, forestry and aquaculture.

Problems: Capital, regulations, competition

Critical issues mentioned by the report are a lack of investment capital, the regulatory environment, and intense competition. It notes concerns about "fragmentation of public sector efforts... inadequate linkages with industry to identify commercial priorities and opportunities", advocating better coordination and focussed efforts.

10 recommendations

Lighten regulatory burden

The report makes a series of 10 recommendations, culminating in the need to develop a 5-year strategic plan. The authors emphasise level funding and better focussing; a review of options for the Biotechnology Pilot Plant at Montreal; and "research projects which can contribute to decreasing the negative impact of regulations on the competitiveness of Canadian biotechnology".

For copies of the report, contact Dr. Alain Albagli,Head of International Affairs, at NRC, Ottawa, Canada K 1A OR6; Tel. (1)613-993.7362; Fax (1)613-952.9907.

USA

1500 attend ABC final at RTP

ABC + IBA = BIO

The Association of Biotechnology Companies (ABC) held its 7th annual meeting in Research Triangle Park, North Carolina, on 13–16 April, 1993. The registered attendance of 1500 doubled the previous best; but this was the final meeting prior to the merger with IBA, the Industrial Biotechnology Association, to form BIO, the "Biotechnology Industry Organisation", with effect from 1st July.

From biopharmaceuticals to flavr savr

Biopharmaceutical interests were predominant, in the exhibition as well as in the programme, which had up to six parallel sessions. But there were Agriculture/Environment sessions, and considerable interest in public perception and communication issues, including those relating to FDA policy on genetically modified foods. (Re-stated by Commissioner David Kessler at a Congressional hearing on food biotechnology, 20th April).

Venter on genome progress, Simon on policy

Plenary addresses included a sparkling presentation on genome sequencing progress by Craig Venter of TIGR (The Institute for Genome Research), and a humorous, upbeat and encouraging speech by Greg Simon, Domestic Policy Adviser to Vice-President Al Gore. Simon's speech was consistent with the pro-biotechnology stance in the Clinton-Gore Technology paper of 22nd February. He emphasised the investment tax-credit for stock held 5 years.

New administration favours broad approach to biotech regulation with public dialogue

On regulation, he emphasised avoiding regulating the marketing of biotechnology "on the basis of single, controversial products", favouring a "broad approach", and "open dialogue about how we are going to regulate and market biotechnology products". Referring to the recently finalised USDA rule, Simon said it "embodies our belief that there exist classes of product that can move through the pipeline faster".

As the new administration settles down in Washington, key posts influencing biotech policy are being filled. President Clinton's "Earth Day" speech announced his intention to sign the Convention on Biological Diversity, but referred to its "flaws".
The US may look to other developed countries to support its interpretive statements (on the control mechanism for money and project selection, and on intellectual property/access to germplasm) before the Senate ratifies the signature.

IV. Reports Received

Europe Culture Collections: Microbial Diversity in Safe Hands

1-ECCO: European Culture Collections' Organisation

This 48-page booklet has been produced by the European Culture Collections' Organisation, ECCO, a 10-year-old body bringing together the major service collections.

Biotechnology demands more services

The advance of biotechnology imposes new pressures on the collections to provide additional services (rapid identification, patents, deposits, databases and computer searches, industrial contracts), and ECCO facilitates collaboration and the exchange of ideas and information.

ICECC: For information on the collections

Mine: For "Who's got what"

MSDN: World-wide information network

The booklet gives details of the Information Centre for European Culture Collections, ICECC, which has received co-finance from successive Community biotechnology R&D programmes. Also described here (and also EC co-financed) are the Microbial Information Network Europe, MINE, which is creating a centralized and integrated database on bacteria, fungi and yeasts; and MSDN, the Microbial Strain Data Network, an international information and communications network for microbiologists and biotechnologists.

Details of these and other matters, including descriptions of the holdings and services of all the member collections are also provided, with full addresses and numbers.

This valuable reference work is available free from ICECC, Mascheroder Weg, 1b, D-3300 Braunschweig, Germany. Tel. (49)531-618.715; Fax (49)531-618.718; teletex 531.104; E-mail Telecom Gold/Dialcom 10075: DB10274.

Ecological Risks of Releasing Genetically Modified Organisms into the natural environment

Possible risks and potential impacts reviewed

At the request of the Norwegian Directorate for Nature Management a committee of experts was established to identify the relationship between modern biotechnology and the environment. In this 57-page report the emphasis is placed on the possible outcome of deliberately or unintentionally releasing genetically modified organisms. Possible risks and potential ecological impacts of undertaking such releases are assessed. The report also recommends the research and development required before proper environmental risk assessments can be adequately provided. The committee concludes that risk assessments should follow the internationally established practice where each case is assessed individually (case by case) using a stepwise procedure (step by step) based on the worst possible scenario. The report appears to ignore the large amount of research relating to risk assessment of GMOs and to the 1000 or so release experiments that have been safely carried out to date, world-wide.

More research is needed!

More than 1000 release experiments world-wide

Details: J. Husby, Executive Officer, Directorate for Nature Management, Tuerg. 2, N-7005 Trondheim. Tel. (47)7-580500; Fax (47)7-915433

Biochemical Engineering Science Proposals for Research under Framework Programme IV

Multidisciplinary research underpining integrated bioprocesses

This document presents proposals for a programme of integrated research on Biochemical Engineering Science which might be included under the Fourth Framework Programme, to investigate fundamental aspects of bioprocessing. A meeting, attended by participants from nine countries, was held in Amsterdam on 9–10 November 1992, at which the contents of this document were defined. The 13-page report makes the following recommendations:

Generic research needed at a pan-European level

- The programme should support coherent multi-disciplinary research concentrating on the biochemical engineering science underpining the development and operation of integrated bioprocesses.

- Biochemical Engineering Science should be given greater priority to ensure that adequate resources are allocated to this important development of generic technologies at a pan-European level.

To obtain report, use the Response Form (Item 9).

Response form

To order items mentioned in the text, please tick and return to M. Lex, DGXII/E-1 at address below.

1. FP4 working document ❑
2. Biotechnology second call for proposals (State language required) ❑
3. FLAIR- Flow Europe ❑
4. Methods of communicating biotechnology with the public ❑
5. Global Perspective 2010: the case of biotechnology ❑
6. Skills shortages in Europe ❑
7. PA report on European Nucleotide Sequence Centre ❑
8. Council of Europe report ❑
9. Biochemical Engineering Science ❑

European Biotechnology Information Service

Volume 3, issue 2
May 1993

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

Your name and address (please print clearly)

Name _____

Address _____

_____

_____

Produced by DGXII/E-1
Commission of the European Communities
rue de la Loi, 200
B-1049 Brussels, Belgium
Tel.: (32) 2 2965619
Fax: (32) 2 2955365, or (32) 2 2964322

EBIS is distributed without charge. Please write to ASFRA if you wish to receive it on a regular basis. It is not a statement of Commission policy. While every effort is made to ensure accuracy, no liability can be accepted by the Commission or its servants for the consequences of errors.