



# EBIS

EUROPEAN BIOTECHNOLOGY INFORMATION SERVICE

OCTOBER 1991

ISSUE FIVE

## Editorial: Biotechnology regulation – a Societal Learning System

**Demands for info about biotech regulations: many and various**

Requests for information about "biotechnology regulations" are frequently made to the Commission, and often they are difficult to answer. Some requests are specific, needing simply a copy of the official text of a Community Directive. Currently demanded are 90/219 (contained use of genetically modified micro-organisms), and 90/220 (environmental release of genetically modified organisms), which were adopted 23rd April 1990, and should be implemented via Member State legislation by 23 October 1991. Other demands are more general, requesting copies of "all Community regulations affecting biotechnology", or forecasts of future Commission intentions, or a summary overview; these are sometimes harder to answer.

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**What is meant by  
"biotechnology", "horizontal  
legislation"?**

What is biotechnology? – there are of course, many definitions that may be given ; in what sectors is it applied? – in more and more. The Community has over 300 directives/regulations in the food and agricultural products sector alone – on a broad definition, all at least potentially "biotechnology-relevant". What is "horizontal" legislation, and how does it relate to "vertical", "sectoral", or "product" legislation? "Horizontal" is a convenient shorthand for laws which are not specific to sectors and may be applied to several – e.g. on worker safety, animal welfare, or focussing on the conduct of research and the safety of specific techniques.

**How does it relate to product  
regulation?**

The relationship between horizontal and vertical was discussed in the April 1991 Commission communication, (see EBIS 3, p. 3) a general policy statement outlining Commission intentions and interpretations in specific cases, such as the new pesticides directive (see p. 8), or the future Community system for pharmaceutical and veterinary medicinal products (see EBIS 1, p. 7).

**Worldwide and multi-level:  
UN  
OECD  
EC  
Member State  
Regions  
Institutions**

Debate on biotechnology regulation (or guidelines, codes of practice, standards, etc) for obvious reasons – internationalism of science, trade, markets and competition – and in conjunction with risk/safety concerns, attracts the attention of a growing number of UN agencies. The 1992 UN Conference on Environment and Development (Rio de Janeiro, June 1992) will be a high profile focus for debate, including on its agenda "bio-diversity" and "the environmentally sound management of biotechnology". Within the developed world, the OECD expert groups continue to play a valued role in the safety debate, influencing legislation in regional groupings such as the Community, and at national level within Europe and elsewhere –the US and Japanese positions always major considerations. Within the Community Member States, several have federal structures delegating legislative and/or executive powers to regional authorities, and to add a further level to this complex picture, there are institutional bio-safety committees.

**Dynamic – a Societal  
Learning System**

The complexities of "multi-level" and "worldwide" are compounded by a "dynamic" situation. Biotechnology regulations are rapidly evolving, either science-and-technology-driven (technical adaptation), or demand-pulled by social and competitive pressures for better and safer products and processes. The whole complex of safety research, practical experience, public communication, legislation, its implementation and adaptation may be considered as a societal learning system.

**EBIS offers - transparency**

To contribute constructively to this process in a democratic society, EBIS will continue to offer transparency and awareness and to present the facts as they become known.

# I. Community activities (Commission, Parliament, Council)

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## I.1. Commission News

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### BCC holds first round table on biotechnology

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#### **A first Round Table for an exchange of views on the future of biotechnology in the Community**

On 11 July 1991, the Commission's internal Biotechnology Coordination Committee (BCC) held the first Round Table on biotechnology under the chairmanship of Mr. D.F. Williamson, Secretary-General. The aim of a Round Table is to provide an open forum for a free exchange of views and ideas between the Commission and the community it serves. Participants, who are invited in an individual capacity will vary according to the subject under discussion.

#### **Participants from large and small industry, environment and consumer protection groups**

The first Round Table was devoted to a presentation by the Commission of its Communication of April 1991 on promoting the competitive environment for the industrial activities based on biotechnology within the Community, followed by a wide-ranging discussion. Participants (some 50 in number) were drawn from various industrial sector associations, the national biotechnology associations (mostly representing the small company sector), environmental and consumer protection groups.

The main points of the discussion were as follows:

#### **Call to speed up adoption of research programmes**

1. BCC and consultation procedures. In general, participants welcomed the commission's establishment of the BCC as a high level internal mechanism for policy coordination. The importance of transparency and consultation in the development and implementation of policies was stressed.
2. Research. The need for more research and development to support the growth of the industry and to maintain a balanced policy towards biotechnology was recognized. Procedures for the adoption of research programmes must be speeded-up if industrial competitiveness is to be maintained.
3. Public acceptability. The Eurobarometer Spring Survey had revealed considerable confusion among the public about the risks and benefits of biotechnology. Efforts should be made to increase the general understanding of biotechnology and a sector by sector approach might be most successful.
4. The legislative framework. There was general agreement that products should be assessed on the basis of the risks they presented to human health and the environment before being placed on the market. The approach to be taken, the criteria of risk assessment and the scope of the regulations needed further debate. Legal clarity was necessary to provide the confidence for industry to invest.

**"Horizontal" legislation  
needs to be implemented by  
Member States to provide  
immediate protection for  
human health and the  
environment**

5. It was recognised that horizontal legislation had been necessary to provide immediate protection for human health and the environment during the pre-marketing stages of a product. This should be implemented in Member States legislation as a matter of urgency. However, it was now essential that vertical legislation relating to product sectors should be introduced or adapted to ensure that a single integrated assessment and notification procedure will apply to all products placed on the market.

**A single integrated risk  
assessment and notification  
procedure**

This principle will apply to all existing and future legislation. The horizontal legislation will continue to safeguard situations not covered by sectoral product legislation. Risk assessment would continue to be based on the three scientific criteria of safety, quality and efficacy. Only in exceptional cases where a conflicting impact on other Community policies was expected would the need for additional criteria be considered. In response to concern over longer-term risks (e.g. to a natural ecosystem exposed to an environmental release) it was pointed out that these were poorly understood at present and hence the subject of longer-term research programmes. The benefits of a new product should be taken into account as well as the risks.

**Separation of ethical and  
scientific considerations?  
Ethical limits to biotech  
research and patenting?**

6. Bioethical considerations. There was general support for the Commission's proposal to set up an independent bioethics advisory body. Some participants considered that ethical issues should be clearly separated from scientific and technical considerations. Others raised the need for setting specific ethical limits to biotechnological research and patenting.
7. Intellectual property. With some dissension there was general agreement that a strong system of intellectual property protection was necessary to encourage and safeguard investment. Community legislation currently under discussion should be urgently adopted.
8. Standards. It was important that the work of CEN (European Standards Committee) should complement existing and planned EC legislation and the drawing up of a mandate for CEN by the Commission was welcomed.

## **I.2. Research and related**

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### **3rd framework progress**

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Agreement has been reached by the Council of Ministers on several new specific programmes, of relevance to biotechnologists, within the Third Framework Programme. The Commission is launching Calls for Proposals in the following areas:

PROGRAMME	COMMISSION OFFICER RESPONSIBLE
Marine Science and Technology	J. Boissonas (DG-XII)
Environment	H. Ott (DG-XII)
Life Science and Technologies for Developing Countries	J. Santàna Calazans (DG-XII)
Agriculture and agro-industry, including fisheries	D. Dessylas (DG-VI), F. Rexen (DG-XII), and W. Brugge (DG-XIV)

On the Biotechnology Programme, Parliament's Committee on Energy, Research and Technology adopted on 17 September its draft "opinion", which should be considered and voted in plenary session during October to complete the first reading. The Commission will then, in the light of Parliament's opinion and amendments, present its revised proposal to Council, and seek to ensure the adoption by Council of a "common position".

Once specific programmes are finally adopted, the Commission issues quickly the calls for proposals. The need is nonetheless expressed by many scientists (at least in biotechnology - see earlier article on BCC Round Table, point 2) to reduce the multi-year lag, from drafting the Technical Annex of the Commission's first proposal for a Framework Programme, to start of the corresponding research work. This need is being addressed within the ongoing discussions of the Community institutions on future procedures.

**Biosensors included in environmental research programme**

It is worthwhile for biotechnologists to screen the topics covered by all these life science programmes. For example, the new Environmental Research Programme includes as one of its objectives "the development of biosensors and/or improvement of their performance for the assessment of environmental quality and monitoring". For the details of this programme: J. Büsing, SDME 3/51, Tel. (32) 22355625.

**EC-US task force on biotechnology research meets for a second time: July 1991**

**EC-US task force meeting to exchange information and encourage cooperation**

The EC-US Task Force on Biotechnology Research was set up in September 1990 (reported in EBIS O November 1990) to encourage the exchange of information and to provide opportunities for collaboration. Its second meeting, in July 1991, was chaired by P. Fasella, Director General DGXII, on behalf of the EC, and C. Hess, Assistant Secretary Science and Education, US Dept. of Agriculture, on behalf of the US.

The following topics were included:

- Public understanding, attitudes and information concerning biotechnology
- Biosafety research
- Studies of the socio-economic impacts of biotechnology
- Genome analysis
- Training in biotechnology
- Application of biotechnology to toxicological testing
- Data banks and collections
- Assessment and conservation of genetic diversity
- Development of non-medical bio-materials

**Public Understanding of Biotechnology and field release meetings planned.**

Among the conclusions of the meeting it was agreed to hold a joint workshop on public understanding of biotechnology in Dublin in March 1992, and a follow-up symposium to the Kiawah Island International Symposium (EBIS 1, p. 17 and EBIS 4 p. 14) on Field Tests of Genetically Modified Plants and Microorganisms. This meeting will be held in Goslar, Germany in May 1992. The next meeting of the Task Force is planned for July 1992.

## **Conservation and effective use of genetic resources**

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**New Research Area on "conservation of genetic resources"**

A new priority area for the Biotechnology Programme under the Third Framework will be "conservation of genetic resources". A workshop on this topic recently held in Brussels made the following recommendations for future Community research:

**Techniques concerning the generation, handling and application of molecular probes**

1. Rapid molecular genetic screening methods (plants and animals)

The object of this kind of research is to develop efficient routine procedures to obtain genetic data on large numbers of samples in order to estimate genetic distances or to identify specimens bearing genetic traits associated with commercially interesting properties. While conventional approaches provide insufficient characterisation, modern technologies are as yet too slow and too expensive for large scale application. Techniques concerning the generation, handling and application of molecular probes (e.g. chromosome-specific probes, non-radioactive hybridisation techniques, hard- and software for data entry and data processing) must therefore be further developed.

A specific goal should be the interdisciplinary cooperation between collections, breeding companies, population geneticists and molecular biologists. Structural developments should lead to joint centres, or networks, for genetic screening in order to overcome bottlenecks in the

application of modern identification methods due to existing limitations in scale.

**Development of plant taxonomy information systems to include commercially interesting plant metabolites**

2. Plant taxonomy information systems

Research in this field should contribute towards the development of internationally accepted plant taxonomy information systems with specific emphasis on the integration of molecular genetic data and the inclusion of information on commercially interesting plant metabolites. Ultimately, this should lead to the increased exploitation by industry, particularly pharmaceutical industry, of new phytochemical resources. Corresponding information networks, databanks or interfaces between databanks have to be developed in order to link resource data for science, breeding and industry to taxonomy reference systems.

**Animal conservation using modern technologies to be evaluated**

3. Animal germplasm conservation strategy

The lack of appropriate *ex situ* conservation techniques as alternatives to the expensive maintenance of herds is the most critical bottleneck in animal germplasm conservation. Various approaches to storing genetic diversity at different levels (organisms, organs, tissues, cells, genes, DNA) using modern technologies have to be evaluated. Based on the nature of the genetic material, and techniques applicable, a conservation strategy has to be developed which combines the different approaches to supplement or substitute the maintenance of herds in a most efficient and beneficial way. These studies might be complemented by research into cryopreservation methodology.

**Novel approaches to the study of extreme environments**

4. Exploitation of as yet hidden microbial communities

Lack of knowledge of microbial diversity is a major obstacle to the preservation and exploitation of this important resource for the biotechnology industry. Extreme environments, in particular, often contain unknown, micro-organisms with potential for commercial exploitation. Novel approaches are needed to the isolation, cultivation, conservation and taxonomic characterization of these organisms.

**Inter-service group on genetic diversity**

This new research activity is being conducted with consultations via a new inter-service group on genetic diversity, reflecting the numerous service interests in this topic.

Details:

Dr. Kay Beese, DGXII/F-2; Tel. (32) 223554484/50361; Fax (32) 22355365; Email TELECOM GOLD 75:dbi0577; Telex COMEU B 21877

## Risk assessment final report

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**BAP (Biotechnology Action Programme) 1985-1990 final report makes important contribution to understanding biotechnology risks**

This final report on BAP projects funded 1985-1990 in two parts includes two important reviews:

"The release of genetically modified microorganisms in the environment", by J. Davies, and "The release of transgenic plants into the environment", by W. De Greef. The results of BAP projects on risk assessment are described in the areas of: microbial containment, depollution bacteria, plant interacting microorganisms, transgenic plants and genetically engineered viruses.

The report (in English) is available on request from Dr. I. Economidis, DGXII. Fax (32) 22355365.

## News from SAST

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**Contract study on "innovation in agrobiotechnology"**

SAST (Strategic Analysis in Science and Technology), a part of the MONITOR programme, is announcing the following two recent developments with respect to its project "Innovation in Agro-Biotechnology" (see EBIS 3, p. 7-8).

\*First, a new investigation – the seventh one – has been added to the project. It concerns the potential of biotechnology for the characterization and measurement of quality in agro-industrial production.

This new investigation has the same general strategic objectives as the first six ones (EBIS, *ibid*). It will consider the whole range of concerns and interests of agri-business in terms of characterization and measurement of quality attributes along the chain, from inputs through production to final manufactured products, distribution and consumption. The extent to which the characterization and measurement methods can assist in the development of legislative and regulatory initiatives will also be considered.

There will be an initial overview, followed by quick additional analyses sector by sector to identify the key areas for more detailed investigation. While detailed appraisal of these key areas will take place, the preliminary conclusions drawn from the overview will be extended by circulation of a suitable questionnaire to appropriate bodies in the various Member States.

**Consultation workshop to be held**

\*Second, it is the intention of SAST to discuss the draft final reports of all investigations within this project with a number of key representatives of European agencies and other interested persons at a "consultation" workshop, which is to take place in early 1992 (exact dates and other details to be announced later). This workshop will help the SAST contractors, having carried out these investigations, to finalize their reports and refine their recommendations to the Commission.

For further enquiries:

Bruno Schmitz, DGXII/H-2 (MONITOR-SAST) – MO 75;  
Tel. (32)22350514; Fax (32)22356995.



## VALUE to cooperate with FLAIR in the FLAIR-FLOW EUROPE Project\_\_\_\_\_

The project is exploring existing and new national routes and procedures in EC and in some non EC states for the dissemination of food related information stemming mainly from the ongoing FLAIR Programme (33 major projects) to SMEs, consumers and policymakers. An analysis and assessment of the effectiveness of alternative ways of checking the efficiency of the dissemination process is also being made as is feedback from SMEs and consumers on the usefulness of the disseminated information.

**European network to disseminate FLAIR-results in the form of "tailored information" to SMEs and consumers**

The project is organised via national networks who disseminate the 'tailored' information on an ongoing basis. The project is managed by a project leader together with a 5-person team. Each participating country has a national network and a network leader. The national network leaders together with the project management team and occasional co-opted experts comprise an international network which meets twice annually.

**National network leaders are the key personnel to make FLAIR-FLOW EUROPE a success**

National network leaders are the key personnel in relation to a successful outcome of the project. The functions of a national network leader include: establishing a viable national network; holding two meetings of the national network annually and assessing 'the pulse' of network reaction to information suitability; assessing information flow methods; pushing edited FLAIR information through the network system and assessing feedback; reporting progress at meetings of the international network; entering FLAIR information on in-house databases; profiling SME and consumer information needs/interests.

Some of the anticipated results and benefits from the project include:

1. Deep penetration of accurate and useful information from the FLAIR programme to SMEs and consumers in each of the participating states; this should in turn enhance a two-way flow of information thereby bringing SME and/or consumer organisations into direct contact with the workers in particular FLAIR projects.
2. The identification of new methods and routes for information flow and also ways of assessing the quality, accuracy, usefulness and penetration of the dissemination information.
3. The setting up of key dissemination networks in each state for the dissemination of information flow and feedback will be worked into a dissemination blueprint which could be used as a model for other EC programmes.

**The cooperation between VALUE and FLAIR may become the model for results dissemination for other EC programmes**

An evaluation of the pilot phase of FLAIR-FLOW EUROPE will take place at the end of 1991.

For further information contact:

Dr. Constant Gitzinger, CEC DG XII/C2-VALUE Programme, Jean Monnet Building, L-2920 LUXEMBOURG. Tel. (352) 43013887; Fax (352) 43014129.

or:

Mr. Liam Breslin, CEC DG XII/F3-FLAIR Programme, rue de la Loi 200, B-1049 BRUSSELS. Tel. (32) 22350477; Fax (32) 22355365.

### I.3. Regulatory Activities

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#### Plant protection products directive

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The Council Directive of 15 July 1991 (91/414/EEC) has been published in O.J. Vol. 34. 19 August 1991 Number 1.230/1-32. Of interest to biotechnologists the Directive states in Article 1 point 3:

"This Directive applies to the authorization to place on the market plant protection products containing or composed of genetically modified organisms, provided that authorization to release them into the environment has been granted after the risk to the environment has been assessed in accordance with the provisions of Parts A, B and D and the relevant provisions of part C of Directive 90/220/EEC. (Environmental release Directive).

**An amendment within 2 years to include a specific procedure for evaluating the risk to the environment**

The Commission shall submit to the Council, in sufficient time for the latter to be able to act not later than two years after the date of notification of this Directive, a proposal for an amendment with a view to including in this Directive a specific procedure for evaluating the risk to the environment analogous to that provided for in Directive 90/220/EEC ...".

This is consistent with the Commission's commitment in its April 1991 communication that all recombinant products will be subject to a single notification and authorization procedure i.e. the "one-door, one-key" principle. Member States are required to implement this Directive within two years of its notification.

#### **Community system for the rapid exchange of information on dangers arising from the use of consumer products**

(Decision 89/45/EEC amended by Decision 90/352/EEC)

The Rapid Exchange system was established by Decision 84/133/EEC although for the food sector it had existed informally since 1978. Under this system Member States have to inform the Commission when they take urgent measures to prevent or restrict the sale of a product because of the grave and immediate danger it presents to the health and safety of the consumer. Member States appoint contact points within their administrations for both the food and non-food sectors, who are responsible for transmitting and receiving notifications. Within the Commission itself the food network is managed by DG III and the non-food network by the Consumer Policy Service. The system, which will be integrated into the General Product Safety Directive, covers all consumer products, except where equivalent procedures exist under other community legislation (e.g. for pharmaceuticals, animals and products of animal origin and the system for radiological emergencies).

Details : Consumer Policy Service : Mr. R. Gielisse,  
Tel. (32)2 2359649.

## I.4. Bioinformatics

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### Progress with CEFIC recommendations on bioinformatics

The European Chemical Industry Federation (CEFIC) recently published the outcome of a study, co-financed by the Commission of the European Communities, in which strong recommendations for a European biotechnology information infrastructure strategy were made (EBIS 1, p 20). In May of this year the Commission, through its high level Biotechnology Coordination Committee (BCC), endorsed the recommendations in general and an ad-hoc interservice group discussed the various ways and means of implementing these. Several important recommendations will be implemented under the Community's R&D Framework programmes.

#### Management study for the possible establishment of a European Nucleotide Sequence Centre (ENSC)

Probably the most crucial one is the Management Study for the possible establishment of a European Nucleotide Sequence Centre (ENSC). This centre should guarantee a future for the European nucleotide sequence database, currently based at the European Molecular Biology laboratory (the EMBL Data Library), as well as its international collaboration. An organisational blueprint and implementation plan for the establishment of an ENSC is needed and a Management Study is expected to start before the end of the year. The results of the study will make an input to the discussions on the next Community R&D Framework programme.

#### "Bioinformatics in the 90's" – 20–22 November 1991, Maastricht

At the same time, the forthcoming conference "Bioinformatics in the 90's" (20-22 November 1991, Maastricht, The Netherlands) will take place just one year after the CEFIC report has been published and will be an excellent occasion to discuss the future strategy for bioinformatics in Europe.

Details:

B. Nieuwenhuis; Tel. (32) 223558549; Fax (32) 22355365; E-mail Telecom Gold 75:DBI0004.

## II. Member States

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### France

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#### French protein engineering

French protein engineering is compared with the International competition in the 12th report from CADAS (Comité des Applications de l'Académie des Sciences), June 1991. The report provides a useful overview of several recent research initiatives in France such as the "Proteins 2000" project (Commissariat de l'Energie Atomique (CEA)) and the IMABIO project launched by the CNRS. Among its important recommendations the report calls for improved bio-informatics networks in Europe (see above CEFIC article).

Report available from CADAS, 23 Quai de Conti, 75006 Paris. Tel. (33) 140517725.

## Italy

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### **"European biotechnology today" – The impact of basic science on diagnosis and therapy**

This Congress will be held at the Congress Centre of Florence on 8-10 October 1991 and aims to present "State-of-the-Art" reports on basic science topics as well as their application in diagnosis and therapy.

The main topics are:

- Gene cloning in relation to new diagnostics and drugs ;
- Bioprobes: from monoclonal antibodies to nucleic acid probes;
- Recombinant cytokines and growth factors as therapeutic and diagnostic tools;
- Gene therapy.

Details:

Clas International

Via Pace, 8

25122 Brescia

Tel. (39) 30480006/43007/45126; Fax (39) 30293282

## The Netherlands

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### **"European Biotechnology Directory 1991", StiPT, the (Netherlands) Executive Agency for Technology Policy**

**Basic information about companies undertaking biotechnology R&D in Europe**

The Netherlands occupied the presidency of EUREKA from mid-1990 to mid-1991, and currently are President of the European Council of Ministers (second half of 1991). It was therefore an appropriate gesture for StiPT to develop (with Commission co-finance) a directory providing basic information about companies undertaking biotechnology R&D. The information given is name, address and contact details, size, sector, technologies, short descriptions of the R&D efforts, and the kinds of collaboration in which the company is interested.

Such a directory depends on questionnaire responses and the interests of companies in seeking collaborators, and the coverage is correspondingly uneven. Of the 415 companies described, 107 are Dutch; 81 British; 41 German; 38 French; 26 Belgian; 19 Spanish; 19 each Finnish and Swedish; 17 Norwegian; 14 Irish; 13 Swiss; 8 Italian; 7 Danish; 5 Austrian. There are weaknesses (e.g. subsidiary/parent status and relations are poorly completed) and many significant omissions (e.g. Plant Genetic Systems, Novo-Nordisk) ; but a lot of useful information has been collected particularly for The Netherlands – and as is carefully pointed out in preface (lest you had any misunderstandings about Dutch generosity, or the meaning of a "Dutch treat") it is free of charge. If successive presidencies or a further effort by StiPT could bring other sections up to the

standard of the Dutch, the directory would more nearly live up to its ambitious title.

Available on request from: Philip van Lelyveld, StiPT, Executive Agency for Technology Policy, P.O. Box 30732, 2500 GS The Hague; Tel. (31) 703610341; Fax (31) 703614430.

## United Kingdom

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### **Biotechnology – A strategy for industrial strength**

#### **Commercial exploitation of the biotechnology research base**

The UK's Biotechnology Joint Advisory Board (BJAB) which advises the Department of Trade and Industry (DTI) and the Research Councils (AFRC, NERC and SERC) has published a strategy document for biotechnology in the UK. The report makes recommendations on how the science base can better respond to the broad innovation requirements of industry through specific areas of future research, technology transfer, training, public perception and balanced regulations.

Details: DTI Biotechnology Unit: Laboratory of the Government Chemist, Queens Road, Teddington, Middlesex TW11 0LY; Tel. (44) 819437381.

### **GENHAZ report published by Royal Commission on Environmental Pollution**

#### **Release of genetically modified organisms into the environment**

GENHAZ – a system for the critical appraisal of proposals to release genetically modified organisms into the environment has been devised by a small Working Party set up by the Royal Commission. The report recommends the UK government to consider whether to integrate GENHAZ into the procedures for risk assessment of GMO releases.

Details:  
Royal Commission on Environmental Pollution, Church House, Great Smith Street, London SW1 P3BL; Tel. (44) 712762080; Fax (44) 712762098.

### **Nuffield Council on Bioethics**

#### **Ethical issues of increasing importance**

The Nuffield Foundation has announced the 14 eminent members of the Nuffield Council on Bioethics which will be chaired by Sir Patrick Nairne. The Foundation's initiative in establishing a Council in Bioethics is in response to recent developments in biological and medical science which present ethical issues considered to be of great potential difficulty and increasing importance.

The terms of reference of the Council are:

1. To identify and define ethical questions raised by recent advances in biological and medical research in order to respond to, and to anticipate, public concern.
2. To make arrangements for examining and reporting on such questions with a view to promoting public understanding and discussion; this may lead, where needed, to the formulation of new guidelines by the appropriate regulatory or other body.

3. In the light of the outcome of its work, to publish reports; and to make representations, as the Council may judge appropriate.

Details:

David Shapiro, Nuffield Foundation 28, Bedford Square, London WC1B 3EG; Tel. (44) 71 631 0566; Fax (44) 71 323 4877.

### III. International developments

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#### United Nations Environment Programme (UNEP)

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##### Release of organisms into the environment

###### IRRO = Information Resource on the Release of Organisms into the environment

The proceedings have been received of a UNEP/MSDN workshop organised by MSDN at the request of UNEP with co-finance from UNEP, USEPA, USDA, Environment Canada and the Commission of the European Communities (BRIDGE concertation action), held in Vienna, Austria and Rockville, MD, USA on 11-15 March 1991 (see EBIS 2, p. 17). The workshop on the needs and specifications for an Information Resource for the Release of Organisms into the environment (IRRO) made several recommendations, some of which have been followed up in a meeting at the University of Nottingham, UK, of the IRRO steering group established in Vienna. This second meeting was held adjacent to "REGEM 2", the second meeting on the release in the environment of genetically engineered micro-organisms.

###### Electronic network to provide access to information on environmental releases in different regions of the world

It has been agreed to form an electronic network providing access to information on environmental releases, including release events, organisms, scientific, technical and regulatory information. The network will provide centralised access to existing data sources in different regions of the world for all those studying the release of organisms into the environment.

Details of report and network:

IRRO Secretariat, 307, Huntingdon Road, Cambridge CB3 0JX; Tel. (44)223277628.

#### OECD

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##### OECD looks at biotechnology for a clean environment

###### Biotechnology for the prevention, detection and remediation of environmental damage

The OECD Committee for Scientific and Technological Policy has created a group of national experts to examine scientific and technical aspects of environmental applications of biotechnology and to draft a report on the subject. The group met for the first time on 11 & 12 July 1991 and selected as Chairman Dr. Michael Griffiths from the UK. A grant towards the work of the group has been made by the Commission, under the concertation action of the BRIDGE programme.

The group is interested in gathering the views of industry (amongst others) on aspects of biotechnology covering the topics of prevention, detection and remediation of

environmental damage. Interested firms/individuals should contact the OECD secretariat Dr. S. Wald, OECD, 2 rue André Pascal, 75016 Paris, Fax (33)145249767 or Dr. I. Economidis, Commission of the European Communities DGXII; Fax (32) 22355365.

## Japan

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### The strength and weaknesses of the Japanese innovation system in biotechnology

**JETS=Institute for Japanese-European Technology Studies**

JETS Paper Number 3 by Martin Fransman, of the Institute for Japanese-European Technology Studies, University of Edinburgh and Shoko Tanaka, Cornell University pays particular attention to the three high-profile cooperative Japanese research programmes:

- i the "NEXT Generation Base Technologies" Programme
- ii the Protein Engineering Research Institute (PERI)
- iii the Exploratory Research for Advanced Technology (ERATO) programme

The distinctiveness of Japanese Government industry relations in biotechnology is highlighted.

The 37 pages paper is available from University of Edinburgh at UK£ 4.50 plus UK£ 1.50 postage on Fax (44) 31 668 3094.

### JTEC takes measure of Japanese biotechnology

**JTEC = US Japanese Technology and Evaluation Centre**

For those following biotechnology developments in Japan another study has been made showing that the Japanese are getting better at exploiting biotechnology and turning it into products. The study team headed by Daniel Wang of MIT's Chemical Engineering department pays particular attention to Japanese R&D programmes and their dependence on foreign scientists.

Report available from JTEC's director, Paul Herer, National Science Foundation, 1800 J Street S.W., Washington, DC 20550; Tel. (1)2023579774.

## USA

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### ABC opens European chapter/information office

**ABC European office for better lines of communication**

The Association of Biotechnology Companies (ABC) has announced its first European chapter and information office in Hannover. The stated objective of this office is to provide ABC members in Europe and North America with better lines of communication on availability of capital, technology transfer, policy development and strategic alliances etc.

Details: Tom Wiggans, Vice President of European Affairs for ABC, Serono Laboratories Ltd., 99, Bridge Road East, Welwyn Garden City, Herts, UK AL71BG. Tel. (44) 707331972.

# Response form

This page is used to invite responses, contributions and comments from EBIS readers or to offer details for ordering articles etc. mentioned in the text.

Items mentioned in the text:

- Final reports of the BAP Risk Assessment projects
- Proceedings of the UNEP/MSDN Workshop on IRRO
- BJAB report "A Strategy for Strength"

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**European Biotechnology  
Information Service**

Issue Five  
October 1991

## Editors:

M.F. Cantley and M. Lex  
Commission of the European Communities, CUBE, DGXII,  
rue de la Loi, 200, B-1049 Brussels, Belgium.  
Tel. +32(2)2358 145; Fax +32(2)2355365.

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