

# E B I S

EUROPEAN BIOTECHNOLOGY INFORMATION SERVICE

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## Editorial: Intellectual Property and the Competitive Environment for Biotechnology

**"Europe's future will be built not upon its cows, but upon its brains"**

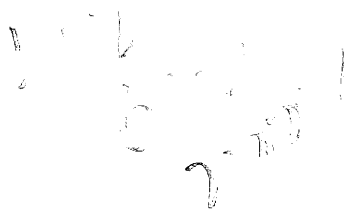
**The competitive environment for biotechnology in Europe - new Commission communication**

Aggressively but memorably, former Commissioner Ivor Richard remarked (in a speech to Commission scientific staff, January 1985) that "Europe's future will be built not upon its cows, but upon its brains". Resisting (almost) the temptation to make a tasteless joke about BSE, we would use the remark quoted to underline the importance, for societies that respect intellectual achievement and expect increasingly to earn their living by it, of developing an effective and equitable system for intellectual property: for its definition, its defence and its diffusion.

Concern for the creation of intellectual property, its protection and exploitation, features prominently in the Commission's new communication to the Council of Ministers and the European Parliament entitled "Promoting the competitive environment for the industrial activities based on biotechnology within the Community" - see p. 3 in this issue. This communication, 15 months in gestation, clarifies the Commission's positive view of biotechnology and sets the tone for the foreseeable future.

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**The shift from physical to intellectual assets as the basis for economic activity is essential**

In the Community's first "FAST" programme (Forecasting and Assessment in Science & Technology), many long-term trends were summarised in three words: informatisation, dematerialisation, globalisation (they sound better in French). These terms apply particularly to biotechnology, given the fundamental role of DNA as an information storage and transmission system whose messages we can now read (slowly) and write (with difficulty). The shift from physical to intellectual assets as the basis for economic activity is of course essential, and to be welcomed as the salvation of our planet: how else will we feed 10 billion and improve their health, within the constraints of current cultivated areas and quality of administration? But this shift raises particular problems in the life sciences and biotechnology.

CUBE has a natural bias towards 3 dimensions, and the ongoing intellectual property arguments are no exception. Firstly, there are differences of legal tradition and system between the US and Europe (e.g. the "grace period", first to invent v. first to file, access to deposited strains, burden of proof of infringement, exclusion of double protection – indeed, the OECD report<sup>1</sup> stated that "In no other field of technology, old or new, do national laws vary on so many points and diverge so widely as they do in biotechnology.") Secondly, there are differences between the traditions and methods of the patent system used typically by academic and industrial inventors, and the system of plant breeders' rights, developed in a different context, under different constraints. Thirdly, there is the "North-South" dimension: obvious differences exist between the abilities of sophisticated companies and countries in the developed world to defend their intellectual property, and those of less developed countries and their economic actors.

**Bio-ethical advisory structure to be established**

Other value-laden issues abound – e.g. in relation to the patentability of living organisms in general (especially higher), and the commercialisation of trade in cells and tissues. The ethical aspects of biotechnology, and their treatment in the Community context, are matters for another issue (the new Commission communication announces the intention to develop a bio-ethical advisory structure, and makes important distinctions). The completion of the UPOV negotiations in March, and the continuing negotiations at GATT on "TRIPs" (trade related intellectual property issues), justify special emphasis at present on this topic, which will certainly figure prominently in EBIS over the coming months.

<sup>1</sup>Belser, F.K., Crespi, R-S. & Straus, J. "Biotechnology and Patent Protection: An International Review", OECD, Paris, 1985.

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

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## I.1. Commission news

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**Biotechnology is recognised as an increasingly important element in many areas of Community activity**

### **Commission reinforces internal coordination in biotechnology**

A formal announcement has been made of the new arrangements for the coordination of the Commission's services in biotechnology. This reflects the increasing importance attached by the European Commission to biotechnology for Europe's future. It is intended to convey a clear message to interested parties of the Commission's intentions in this field.

Biotechnology is an increasingly important element in, or influence on, many areas of Community activity, requiring reinforcement of interdepartmental cooperation. Key areas for biotechnological applications are the chemical, pharmaceutical and food industries.

The use of biotechnology has a bearing on the environment, ethical issues, health and safety of human beings and the protection of consumers' interests, and agricultural policy, production and structures.

**New high-level interservice group established to develop a well-balanced Community policy in biotechnology**

The Commission therefore has created a new high-level interservice group to develop a coherent Community policy in biotechnology. The Biotechnology Coordination Committee (BCC) is chaired by the Commission's Secretary-General, Mr. David Williamson.

**BCC = Biotechnology Coordination Committee**

The BCC covers all sectors and activities of the Commission in the field of biotechnology, with the participation of all relevant services. Its main tasks are three-fold. First, it is to examine new initiatives made by the Commission's services and to prepare the Commission's decisions. Second, it may create, as necessary, a system of Round Tables involving the Commission, industry and other interested parties. Third, it will evaluate existing Community policy on biotechnology.

CUBE will continue the concertation activities as defined by the BRIDGE programme, providing information and other services to all sectors and Commission activities involved under the Biotechnology Coordination Committee, and in conjunction with Member States. As part of that service, a new Inter-Service Editorial Board will be set up for EBIS.

### **Commission emphasises positive policy for industrial biotechnology in Europe**

**The document has been the object of intense inter-service work and debate over the past 15 months**

The Commission on 17th April adopted a communication to the Council of Ministers and the European Parliament entitled "Promoting the competitive environment for the industrial activities based on biotechnology within the Community".

The document has been the object of considerable inter-service work and debate over the past 15 months; under the leadership of DG III (internal market and industrial affairs); but with considerable inputs from services responsible for

agriculture, environment and research.

Amongst the "measures to enhance competitiveness and public acceptability", the Commission proposes to give priority to these seven:

1. Research: to be reinforced, in the next review of the R&D Framework Programme;
2. Infrastructure: through research programmes, information market policy, and international collaboration, contribute to the development of biotechnology information infrastructure within the Community and worldwide (databanks, software, electronic networks and services);
3. Standards: in order that work in the field of standards may fully complement the Community's legislative work, a clear and precise mandate shall be prepared in consultation with CEN, the European Standardisation Committee;
4. Intellectual Property: legislation currently under discussion should be adopted, and that already adopted should be transposed into Member State legislation, as a matter of urgency, in order that the Community will have a coordinated approach, strengthening its position in international negotiations;
5. Statistics: specific to biotechnology to be compiled, to allow monitoring of developments in the industrial application of biotechnology;
6. Bilateral and multilateral international contacts to be further strengthened; in addition, via international bilateral working groups, GATT, OECD, EFTA and other international bodies, environmental and health objectives to be established, and integrated into economic and other policy decisions;
7. Ethical issues: an appropriate advisory structure to be established at Community level.

**The regulatory assessment of new biotechnology products will continue to be based on the three criteria of safety, quality and efficacy**

**Biotechnology's strategic significance is stressed in dealing with some of the major challenges facing the developed and developing world**

The document emphasises that regulatory assessment of new biotechnology products will continue to be based on the three criteria of safety, quality and efficacy, ensuring a coherent regulatory approach and an efficient and simplified interaction between sectoral and horizontal legislation, without over-regulation. It emphasises the Community's determination to ensure that testing and authorisation procedures are streamlined, and that one assessment and notification procedure covers all that is required for product authorisation.

Biotechnology's importance is stressed, not only for industrial competitiveness, but for its "strategic significance in dealing with some of the major challenges facing the developed and developing world, i.e. food, health, environment and population growth ... higher standards of health, safety and environmental protection do not act as limiting factors but as major opportunities for industry to develop through biotechnology more precise, effective and non-polluting products and services". "Socio-economic aspects need to be

considered in a different way" from the 3 traditional criteria, and the document is emphatic on avoiding another systematic assessment. "The Commission will normally follow scientific advice. (It) reserves the right however to take a different view in the light of its general obligation to take into account other Community policies and objectives. This might, in exceptional cases, lead to requirements for further information. It might equally, in exceptional cases, lead the Commission to propose that other policies be modified in the light of biotechnological developments".

EBIS understands that the recently-established Biotechnology Coordination Committee (see earlier article) would be likely to play a significant role in identifying or discussing such exceptional cases, and preparing the ground for Commission decisions.

The document was discussed on 29th April by Industry Ministers, and received a strongly favourable reaction.

Copies of the document, reference SEC (91) 629, are available, in all nine official languages, from Mr. Paul Gray, Adviser on Industrial aspects of biotechnology, DG III (Internal Market and Industrial Affairs), fax (32) 2 235 17 35; or from CUBE.

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

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### **3rd Framework Progress**

Amid the gloom surrounding the Third Framework programme and the organisational complications between the Commission, the Parliament and the Council – a ray of light. Political agreement was reached by the Research Ministers on 24th April, on the Agriculture and Agro-Industrial Research Programme, and a common position was formally adopted in May. Subject to Parliamentary procedure at second reading, a final decision may be achieved before or just after the Summer break; publication of a call for proposals in the Official Journal is expected within a month thereafter.

### **BRIDGE Programme – progress with Biosafety proposals**

The final call for proposals within the BRIDGE programme (deadline September, 1990) attracted 41 transnational proposals, for projects on biosafety involving 185 research laboratories.

The proposals were evaluated independently by scientific experts and were selected on the basis of their relevance to the specific areas of the programme as laid down in the Council decision and information package of 1990.

Based on the above procedure and with the advice of representatives of the Member States, 16 projects have been proposed for financing; involving 78 research groups, total value more than 8 MECU.

The projects address issues of biosafety relating to the release of transgenic plants, genetically modified microbes and viruses, and the development of automated methods for microbial

**16 projects selected  
involving 78 research groups  
valued at more than 8 MECU**

identification. The last of these is the object of a large, so-called "targetted" T-project, involving 16 laboratories (10 on cost-sharing contracts, 6 under "concerted action").

Details of these projects will be disclosed after the signature of the contracts with the Commission. Details: I. Economidis.  
Fax: (32) 2 235 53 65.

### **BRIDGE Programme: The "Immunoclone Database" project**

#### **From "mabs" to "IMMUNOCLONES"**

The medical, industrial and other applications of monoclonal antibodies ("mabs") are amongst the largest current and future applications of modern biotechnology; Kohler and Milstein received the Nobel Prize for demonstrating how the pure mabs could be produced by "hybridomas", cells created by fusion of lymphocytes (producing antibodies) and tumour cells ("immortal" in culture).

The Commission has co-financed the launching of an international "Hybridoma Data Bank" by supporting, 1987-1989, its European node, from which developed CERDIC. More general than "hybridoma", the term "IMMUNOCLONE" is defined as any permanent cell line (obtained by hybridisation, virus transfection, DNA transfer, etc.) producing (secretion, cell surface expression, etc.) homogeneous substances of immunological interest (monoclonal antibodies, T-cell receptors, interleukins, macrophage factors, etc.).

#### **ICDB = Immunoclone Database**

The new "ICDB" project launched under the BRIDGE programme coordinates the activities of seven leading European centres and aims at building up the complete database of all immunoclones and their related products.

It is expected that 2,000 new records per month will be collected, via:

- computerised screening of the scientific literature (covering more than 1,500 journals);
- patent applications at the European Patent Office;
- industrial and commercial catalogues of biotechnology firms;
- descriptions sent by public or private research laboratories. The procedures used will allow most sources to be included within 3 months of publication date. More than 25,000 descriptions are currently included.

#### **Coordination of the activities of seven European centres**

#### **CERDIC = Centre Européen de Recherches Documentaires sur les Immunoclones**

The network of laboratories will enable rapid utilisation of European immunoclone resources, which will serve as a model for the management of similar products in the face of strong international competition.

Details: CERDIC (Centre Européen de Recherches Documentaires sur les Immunoclones) Centre International de Communication Avancée, 2229 route des Crêtes, Sophia-Antipolis, F-06560 Valbonne / France.  
Tel: (33) 9294 22 88  
Fax: (33) 9365 30 58.

**SAST: Strategic Analysis in  
Science and Technology**

**Innovation strategies in agro-biotechnology**

SAST – Strategic Analysis in Science and Technology – is part of the Monitor Programme which aims to identify new directions and priorities for Community research and technological development (RTD) policy and help show more clearly the relationship between RTD and other Community policies.

One of SAST's projects, in the 1991 workplan, concerns innovation strategies in agro-biotechnology.

The project, with a total budget of around 450,000 ECUs, involves six problem/goal-oriented investigations:

- lowering the levels of fertilisers and pesticides in agricultural crop production;
- development of non-food uses of European agricultural production;
- efficiency improvements in animal production;
- speed, precision and better commercial targetting in the selection and breeding of agricultural and forestry crops;
- use of trout recombinant growth hormone in trout and salmon farming;
- agricultural and forestry developments in Portugal.

**A contribution to the  
definition of the Community's  
research programmes and  
other policies**

Such analyses are of particular interest to the European Commission as a contribution of its own agricultural, agro-industrial and biotechnology RTD programmes, and with respect to its other related areas of competence, e.g. concertation activities for biotechnology in Europe, reform of the common agricultural policy (CAP), rural development, GATT negotiations, education and training programmes.

For each of the study areas, the objectives will be:

- an identification of the benefits that could be gained from the application of modern biotechnology;
- an appraisal of biotechnology-based "solutions" as compared to other technological or practical options (e.g. change in management practices);
- a characterisation of the major factors – of a social, economic, regulatory and institutional nature – which would act as constraints on innovation and on the effective exploitation of biotechnology in the area under consideration;
- a synthesis of the analysis carried out, together with recommendations on the strategic orientations to be taken within the context of the RTD policy and other policy concerns of the Community.

**Serial, economic, regulatory  
and institutional constraints  
on innovation**

The terms of reference of each individual investigation have been set out taking particular account of the relevant

**Each individual investigation is carried out by a core team of experts**

Community policies and initiatives and of the international context in which they ought to be placed. Account has also been taken of the numerous and recent existing studies on the subject and there are coordination procedures to achieve synergy between studies.

Each individual investigation is carried out by a multidisciplinary core team of experts, supervised by a Study Leader and complemented, as necessary, by other specialists from university and industry. Policy advisors in key agencies will be interviewed by the contractors and, at key points, more formal consultation and review by interested parties, within and outside the Commission, will take place. The project as a whole is being supervised by SAST in conjunction with a Steering Group composed of the Commission services with direct interest in the subject. The timing for the project is February 1991 - February 1992.

Details: Bruno Schmitz DG XII-H-2 (MONITOR-SAST) - MO 75  
Tel: (32) 2 235 05 14  
Fax: (32) 2 235 69 95

### **Scientific-Technical backgrounds for biotechnology regulations—JRC Course**

**JRC=Joint Research Centre  
Training course for  
biotechnologists**

The Community's Joint Research Centre at Ispra is running a training course for biotechnologists engaged in research; agronomics; industrial production or management; representatives of the public; biosafety officers and regulators. The course will run from 4-7 June 1991 and will cover three main areas: Research and experimental work; Industrial production; and uses in agriculture and environment. Invited lecturers include: Mr. Comer, Boehringer Mannheim GmbH, Mannheim (D), P. Dale, John Innes Institute, Norwich (UK), J. Davies, Pasteur Institute, Paris (F), W. de Greef, Plant Genetic Systems, Gent (B), J. Thorley, Eli Lilly, Int. Corp. Liverpool (UK), and L. Mahler, Novo Nordisk A/S, Bagsvaerd (DK).

Details: Course Coordinator: F. Campagnari Joint Research Centre.  
Tel: (39) 332 789819/789308  
Fax: (39) 332 789839.

## **I.3. Regulatory activities**

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### **Calls for expressions of interest in carrying out studies for DG XI**

**Studies and/or expert assessments relating to biotechnology**

In a recent O.J., DG XI (Environment, Nuclear Safety and Civil Protection) has called for expressions of interest in carrying out studies and/or expert assessments in a number of subject areas including biotechnology.

Of specific relevance to biotechnology are:

- Situation in the Member States as regards the implementation of the Directives on biotechnology.
- Assessment of the risks to the environment arising from the use of biotechnology.



Other topics mentioned may have some relevance to biotechnology including:

- Protection of animals used for experimental purposes;
- Development of alternative methods;
- Administration of the Directive on the protection of laboratory animals;
- Waste Management;
- Clean technologies;
- Water quality; treatment processes;
- Bioaccumulation;
- Agriculture and the environment;
- Ways to reduce the use of chemical products;
- Protection of rainforest-biodiversity.

Applicants are requested to express their interest in one or more subjects by registered letter, addressed to: Commission of the European Communities Directorate-General XI,C, "Environment, Nuclear Safety and Civil Protection", For the attention of Mr. P. Bonnet, Rue de la Loi, 200 Office Breydel 7/293 B-1049 Brussels before 30th May, 1991.

Details: Official Journal of the European Communities, No C105/14- 20.4.91.

### **Draft Directive on the marketing of EEC-accepted plant protection products: a case study in biotech regulatory principles**

The Commission in 1976 tabled a proposal for a Council Directive concerning the placing of EEC-accepted plant protection products on the market (OJ C212, 9.9.-1976, p.3). Various political difficulties prevented its adoption, but in February 1989, the Commission put forward an amended proposal (COM (89)34, OJ C89, 10.4.1989, p.22). This seeks to update and strengthen the technical provisions, in particular those relating to environmental protection, and to reinforce the envisaged Community regulatory arrangements so that they correspond more closely to the objectives of the White Paper on completing the internal market. Following adoption of the European Parliament's opinion and amendments (OJ C324, 24.12.1990, p.351), the Commission put forward on 25.3.1991 a second amended proposal (COM (91)87, OJ C93, 11.4.1991, p.7).

The Commission's March '91 proposal accepts many of the European Parliament's amendments, including those relating to the placing on the market of genetically modified organisms used as plant protection products; but faces opposition at Council from some Member States.

The debate in Council has been about whether the

### **Community legislation on pesticides: a 15-year debate**

### **The Commission's March '91 compromise proposal**

**The relation between  
"horizontal" and "vertical"  
legislation**

environmental risk assessment for such recombinant biopesticides should be handled under the horizontal "field release" Directive 90/220 (whose importance is emphasised in a resolution adopted 29.4.91 by the Environment Committee of the European Parliament), via a "co-implementation" procedure; or (at least ultimately - e.g. after some years) under the sector-specific ("vertical") procedures to be established in implementation of the pesticide Directive - thus ensuring, as envisaged by the new Commission communication SEC(91)629 (reported elsewhere in this issue) that "one assessment and notification procedure covers all that is required for product authorisation".

**Towards a "one door"  
approach**

As EBIS goes to press, compromise appears attainable, on the basis envisaged in 90/220, Part C (Placing on the market of products containing GMOs): the authorisation procedures there indicated "shall not apply to any products covered by Community legislation which provides for a specific environmental risk assessment similar to that laid down in the Directive". The question is one of timing for including in Community pesticide legislation the required "specific environmental risk assessment", to complete for this sector the "one door" approach.

**Proposal for a directive concerning the General  
Safety of Products (COM (89) 162, COM (90) 259 SYN  
192)**

This draft directive, prepared by the Consumer Policy Service, constitutes a key element in the Commission efforts to establish a global policy for product safety, as a necessary corollary to the establishment of the internal market. Given the Commission's general commitment to the principle of simplification, it is aimed at complementing existing regulations which require the safety of specific product categories. On the one hand, it concerns the regulation of sectors and products not covered by specific rules and on the other hand, complements arrangements foreseen by the horizontal instruments, for aspects not already covered.

In this context, the proposal comprises the following elements:

- a general obligation incumbent on suppliers to place only safe products on the market, of "acceptable risk";
- specific obligations to provide information to the consumer of residual risks;
- harmonisation of the powers and mechanisms available to the Member States to enforce the general safety obligation;
- development of procedures for the rapid exchange of information;
- establishment of a Community-wide intervention procedure.

Details: M. Jimenez Beltran.  
Tel: (32) 2 235.39.84.

## II. Member States

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### Denmark

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#### Parliament votes against patenting of animals

On January 24 there was a debate in the Danish parliament on patenting of life forms in relation to the Commission's proposed Community directive on the protection of biotechnological inventions. The debate was initiated by 3 parties outside the government, the Socialist People's Party, the Social Democracy and the Christian People's party. These parties made a resolution stating that the Danish conditions to agree to the directive would be:

- that the ban against patenting of human beings should be implemented in the text of the directive,
- that it should not be possible to apply for product patents on animals,
- that the rules on intellectual property protection for plants should be developed so that the principle of the farmer's privilege is not limited in any way. Furthermore, breeders would always be able to breed on a genetically modified plant by paying a license to the owner of the patent,
- that the directive should not be contrary to the efforts of the UN to conserve biological diversity, and
- that third world interests should be considered.

The debate in the parliament divided the parties into 3 groups: one group, the 3 parties plus the Liberal party shared the point of view, that the question of patenting of life forms raises ethical principles. Therefore, they argued, it is reasonable to tell industry beforehand so as not to raise any false hopes. The other group, consisting of the government plus another non-socialist party, was against this position and wanted to "wait and see". Only one party, the Progress party, was in total favour of patenting.

The resolution was adopted by a majority in the parliament (group 1). Group 2, including the parties from the government, abstained. Only the Progress party voted against the resolution.

Details: Jesper Toff, NOAH, Denmark.  
Tel: (45) 46 757711.

### France

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#### Directory of biotechnology in France

The new edition of the French biotechnology directory (ADEBIO) has been published. It contains 2,400 references covering many different aspects of biotechnology: health, agro-food, agriculture, chemistry, energy, environment and pollution, instrumentation and finance. More than 1,100 industrial organisations are mentioned and 3,800 biotechnology

specialists. References are classified in 4 areas:

- industrial by areas of application;
- major research centres;
- professional organisations in public and private sectors;
- financial organisations.

ADEBIO's directory is available from Elsevier, Editions Scientifiques, Rue Buffon 29, F-75005 Paris / France.

## Germany

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### Molecular phytopathology programme

The German Research Society (*Deutsche Forschungsgemeinschaft*, DFG) recently established a programme focussing on research on interaction between plants and pathogenic fungi and bacteria.

The DFG is interested in exploring the basic understanding of the molecular mechanisms of plant-pathogen-interactions, especially the molecular recognition between the plant and its pathogen, the plant defence reaction and cell-to-cell communication. Work will focus on systems with phytopathogenic fungi and bacteria. Symbiotic associations will also be considered but not virus systems.

The following goals are aimed at:

- characterisation of genes and gene products responsible for pathogenicity, virulence and avirulence;
- analysis of molecular signals following the plant-pathogen/symbiont interaction (elicitors, suppressors, receptors, signal transduction);
- characterisation of plant resistance genes;
- biochemical and cytological analysis of pathogens and resistance mechanisms together with an analysis of mechanisms responsible for the differentiated activation/deactivation of the related genes.

Details: Ms. R. Kahmann, IGF, Ihnesstr. 63, 1000 Berlin 33 / FRG.

Tel: (49) 30 83000765.

Ms. R. Schönwitz, DFG, Kennedyallee 40, 5300 Bonn 2 / FRG.

Tel: (49) 228 8852362.

## The Netherlands

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### NIABA – profiles of Members

**NIABA = Netherlands  
Industrial and Agricultural  
Biotechnology Association**

The Netherlands Industrial and Agricultural Biotechnology Association (NIABA) has published the 3rd edition of the book "Profiles of Members". NIABA's membership includes the majority of Dutch biotechnology companies representing five groups:

- industrial enterprises;
- agricultural companies;
- new biotechnology firms (NBFs);
- trade organisations;
- suppliers of processes or equipment.

As indicated in its introduction, the publication is intended to help you find your way around Dutch commercial activities in biotechnology, and as such it is a very useful document. Each profile describes the company and its interests in biotechnology: its field of activities, as well as its products, number of employees, etc.

Details: J.H.L. van Lissa, Director NIABA, PO Box 185, NL-2260 AD Leidschendam  
Tel: (31) 70 32704 64  
Fax: (31) 70 32036 71.

### Ethics and biotechnology in Animals

This report in English was prepared by the Dutch Advisory Committee, Ethics and Biotechnology in Animals. The Committee considered the various problems raised by genetic engineering of animals particularly in the light of the public debate concerning this matter. It proposed an evaluation framework for such projects and made various recommendations for further government action.

Details Drs. H. Wierenga, Ministerie van Landbouw, Natuurbeheer en Visserij Bezuidenhoutseweg 73, Postbus 20401, NL-2500 EK 's-Gravenhage  
Tel: (31) 70 3793911  
Fax: (31) 70 3793547.

## Spain

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### New NBA established

**NBA = National  
Biotechnology Association**

The *Asociacion de Bioindustrias* has recently been established as the new NBA organisation for the coordination of Spanish biotechnology companies. It has been formed initially from 12 companies working in many different areas of biotechnology but membership is available to all companies in this field in Spain.

Its aim is to provide relevant information on issues important to

the successful development of biotechnology in Spain, such as public policy issues, regulations, research and training programmes and business opportunities and to develop collaborations between Spanish and other European institutions and associations.

Details: Mr. Joan Guixer, Asociacion de Bioindustrias, C/Bruc, no 72-74, 6a Planta E-08009 Barcelona  
Tel: (93) 318 33 83  
Fax: (93) 302 35 68.

## UK

**Initiative to broaden the understanding of environmental issues in the development of biotechnology and genetic engineering**

### **New Initiative to address environmental issues within scientific research**

The BioIndustry Association (BIA), the trade body which represents the UK biotechnology industry, has announced an initiative to broaden the understanding of environmental issues in the development of biotechnology and genetic engineering and to encourage commercial applications that contribute to an improvement of the environment.

To this end, the BIA has set up a new working committee entitled "Environment Protection and Sustainable Development" chaired by John Elkington, Director of Sustainability Ltd., Editor of Biotechnology Bulletin since 1982, and co-author of the Green Consumer Guide.

The Committee will advise the BIA council on ways of coordinating effective strategies as well as liaising with government regulators, and relevant campaigning organisations. It will also consider ways of enhancing the public understanding of these issues.

Details: Louis Da Gama, BioIndustry Association, Queen Anne's Gate 1, London, SW1 H9BT  
Tel: (44) 71 222 2809  
Fax: (44) 71 222 8876.

## III. International Developments

### **EUREKA & Biotechnology: National Project Coordinators and E.C. Liaison**

**National Project Coordinators = NPCs studying in depth EUREKA sector "Medical and Biotechnology"**

**64 projects involving 232 organisations, 143 of them industrial**

The EUREKA project portfolio on medical and biotechnology projects was updated in April 1991 by Olaf Meyer, head of the EUREKA Brussels-based secretariat. This was one of several informative documents tabled at the meeting in Amsterdam on 9-10 April of the National Project Coordinators (NPC's), who were holding one of their "X-ray sessions", studying in depth the sector "Medical and Biotechnology".

The 64 projects, 17 % of the total, form less than 7 % by value, because their average value is only 8 MECU, as against 20 MECU for EUREKA in general. 232 organisations are involved, 143 of them industrial, including 48 SMEs, 53 research institutions, 33 universities and 3 government bodies.

The first impact of biotechnology has been in the area of human health. The EUREKA project portfolio reflects this reality. Of the total of 64 projects in this area, 29 are directly linked to medical or pharmaceutical technology.

There is, however, a great deal more to biotechnology than the health care sector. As a set of technologies it also offers benefits to a number of other industrial sectors and areas of research which are also reflected in the EUREKA project portfolio: agrobiotechnology and genetic engineering of plants (14 projects), biotechnological production processes (14 projects) and animal breeding (7 projects).

Seven projects can also be classified as "bio-informatics" projects, a very important field of research for the future (see EBIS (1)).

For details of EUREKA activities, interested companies (or other organisations) should in the first instance contact the National Project Coordinator in their country; if you don't know who is your NPC, contact O. Meyer, Director of the EUREKA central secretariat in Brussels (tel: (32) 2 217 00 30, fax: (32) 2 218 79 06, address: Avenue des Arts, 19H, Box 3 / 1040 Brussels)

The meeting of NPCs emphasised the need for greater EC liaison, and the importance for industrial projects in biotechnology of "supportive measures", such as the general legal framework, and specific aspects such as intellectual property law (see elsewhere in this issue). It is the intention of Commission staff in programmes such as VALUE and VENTURE CONSORT to collaborate with EUREKA, and the Commission has appointed a "EUREKA Coordinator", Mr. N.K. Newman (tel: (32) 2 235 59 76, fax (32) 2 236 33 08), who covers all EUREKA technological domains apart from telecommunications and information technology, which are covered by Mr. G.C. Grata.

**Need for greater EC liaison identified, specifically with programmes such as VALUE and VENTURE CONSORT**

## USA

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International Marine Biotechnology Conference 91, Oct. 13-16 1991. Stouffer Harborplace Hotel, Baltimore, Maryland, USA. Organised by the Society for Industrial Microbiology the conference will serve all these interested in this rapidly developing field: from academic scientists to technologists to policy makers.

Details: IMBE'91, Society for Industrial Microbiology, PO Box 12534, Arlington VA 22209-8534 Tel: (1) 703 941 5373 Fax: (1) 703 941 8790.

## Singapore

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Bio-Industry 91. Joint EC-Singapore Convention for industrial biotechnology. 1-3 Oct, 1991, Marina Mandarin Hotel - Singapore.

This 3 day Convention will look at the contribution made by the biotechnology industry to the spectacular growth of the Asia Pacific region. It is organised jointly by the European Commission and the Economic Development Board of Singapore.

Details: BioIndustry 91, Professional Conference Support Group.

Westcott House, 43 Derwent Drive, Purley, Surrey CR81ER / UK.  
Tel: (44) 81 660 7290  
Fax: (44) 81 660 7290.

## China

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Seventh International Congress for Culture Collections. ICCC - VII Theme: Biodiversity and the role of culture collections. Oct 12-16, 1992. Beijing, China.

Details: Secretariat ICCC - VII Local Organising Committee, c/o Institute of Microbiology, Chinese Academy of Sciences, Beijing 100080 / P.R. China.

## Nordic Research

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### Long range Nordic biotechnology research

The Nordic Fund for Technology and Industrial Development has produced Information booklet NR9/1990, in English, relating to biotechnology in five Nordic countries: Denmark, Norway, Sweden, Finland and Iceland.

The report covers the following areas of biotechnology:

- protein engineering;
- bioprocess engineering;
- plant cell research;
- thermophilic and psychrophilic microorganisms;
- biotechnology for the food industries; and
- biotechnology and the environment.

The report estimates that more than 2,300 researchers are involved with biotechnology in the Nordic region, which has more than 150 biotechnology companies, employing an additional 2,800 researchers. The benefits of networking and collaborative projects aimed at strengthening the position and competitiveness of the Nordic industry are emphasised in the report.

Details: Nordic Fund for Technology and Industrial Development, Nedre Vollgate 8, N-0158 Oslo 1 / Norway.  
Tel: (47) 2416480  
Fax: (47) 2412225.

New Scandinavian Technology no 1, 1991 - covers medicine and biotechnology in English.

Details: New Scandinavian Technology, Box 5173, S-10244 Stockholm / Sweden.



## IV. Feature Article

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### Are consumers prepared to accept genetically engineered foodstuffs? Results of a Dutch consumer study.

**The consumer's opinion will strongly influence market possibilities for new products.**

**The important question is: will genetically engineered food products be acceptable to consumers?**

Developments in new biotechnology are taking place very quickly. For researchers, it is already hard to keep up with developments; for consumers it is nearly impossible to get a comprehensible, up-to-date and coherent picture of what is taking place. But it is the consumer who will find the products of new food biotechnology on the dining table. The consumer's opinion will strongly influence market possibilities for new products. The important question is: will genetically engineered food products be acceptable to consumers?

In 1988, SWOKA, the Institute for Consumer Research in the Netherlands, carried out a study on consumer knowledge and formation of opinion about new biotechnology. The results showed that knowledge of biotechnology was rather low. Furthermore, consumer arguments to assess new biotechnology and its applications were examined. In 1990, this study was followed by a study, co-financed by the Netherlands Ministry of Agriculture, the Ministry of Economics Affairs, and the Commission of the EC (under the concertation action in biotechnology), on consumer acceptance of genetic engineering in food production. Below we briefly review the latter.

In the spring of 1990, 870 adult consumers answered an extensive questionnaire about genetic engineering in food production. The central part of this questionnaire was formed by a set of nine examples of food products, manufactured with the help of genetic engineering. All product examples had consumer advantages, for example longer shelf-life, better for health, less pesticides used, etc. Respondents indicated to what extent they found introduction of each new product onto the market acceptable and to what extent they would be prepared to try the new product themselves.

**Group A assessed the products as manufactured with traditional methods; group B received information about the genetic engineering production method; group C additionally received some information about possible adverse effects of the production method**

To see the effect of information about the introduction of the example products, three versions of these introductions were made, thus creating three experimental groups: group A assessed the products as manufactured with traditional methods; group B received information about the genetic engineering production method and group C additionally received some information about possible adverse effects of the production method. The effect of information in the question was large. Group A, the control group, thought all product examples fairly acceptable, group B clearly had doubts about the production method and gave a slightly negative to slightly positive assessment of the nine products; group C clearly rejected product examples. One of the questions at the start of this study, was whether different product characteristics would influence the acceptance of the various products. A significant difference in assessment of example products was found, but the differences were small and the correlation between the acceptance of the different products was strong. Consumers who accepted some genetically engineered food products, accepted other genetically engineered food products as well, and vice versa.

**Apart from the assessment of the specific products, more general questions were asked about various aspects of genetic engineering in food production**

Apart from the assessment of the specific products, more general questions were asked about various aspects of genetic engineering in food production. Consumers appeared to be not very enthusiastic about genetic engineering in food production. On a 38-point scale, their acceptance of genetic engineering for food production purposes was only 5.6 on average. To use genetic engineering for decreasing the use of pesticides in food crops was more acceptable (7.8) than for longer shelf life (6.3) or better tasting food (5.7). Genetic engineering of micro-organisms and plants seemed more acceptable (6.3 - 6.4) than of animals (4.3). The use of human genetic material to improve food production was strongly rejected: only 2.5 on the 38-point scale, ranging from 1 (totally unacceptable) to 38 (totally acceptable). The assessments of the various aspects were strongly correlated, indicating an underlying general attitude towards the application of genetic engineering in foodstuffs.

After this negative assessment one might expect a strong concern about risks or adverse effects of genetic engineering. This is not the case. The expressed concern about adverse effects of application of genetic engineering in food production in general was only 6.5 on the 38-point scale (a higher point indicates more concern); this was about the same for adverse effects on the environment (6.2), on human health (6.9) and on animal welfare (7.2). In combination, the replies on these aspects form an underlying factor of concern about possible adverse effects of genetic engineering in foodstuffs.

In summary, in this study three factors are identified that influence the acceptance of genetically engineered food products. These are:

1. a general attitude towards application of genetic engineering techniques for food production purposes;
2. a feeling of concern about possible adverse effects when genetic engineering techniques are applied to the production of foodstuffs;
3. product characteristics.

The effect of the factor of product characteristics has not been quantified in this study; this will have to be elaborated in the next phase of the project. The other factors were quantified in a first explorative "acceptance model". Although the level of consumer concern about adverse effects was low, it had a strongly diminishing effect on the level of acceptance of the product examples. The general attitude factor appeared to have good predictive value for the acceptance of genetically engineered products, but only if no adverse effects were mentioned.

As was seen in the 1988 study, public knowledge of biotechnology is rather low. Opinions will develop as more information reaches the public. It is important to realise that consumer opinions, measured at this moment, are not an absolute fact, but give an indication of the public opinion at a certain stage of the acceptance process.

It is not yet possible to indicate the direction of the

**Reliable, trustworthy information to consumers is indispensable to support the development of a balanced view**

development of consumer opinion about genetically engineered foodstuffs. Reliable, trustworthy information to consumers is indispensable to support the development of a balanced view. This might help to prevent rejection of beneficial applications of new biotechnology for unjust reasons. However, not all information will lead to a greater acceptance.

**Consumer acceptance of new biotechnology may increase if attention is given to applications with general accepted aims and clear benefits**

To gain public confidence and approval, industry and governments will have to respect the serious objections of consumers to applications such as genetic engineering of animals and the use of human hereditary materials for food production purposes. Information campaigns are not very likely to overcome this type of moral-based aversion. Consumer acceptance of new biotechnology, however, may increase if special attention is given to the development of applications which serve generally accepted aims and have – in the eyes of consumers or society as a whole – clear benefits, compared to traditional alternatives.

Details: A.M. Hamstra, Biotechnology in Foodstuffs, towards a model of consumer acceptance, SWOKA research reports nr. 105, The Hague, The Netherlands, 1991.

This report will be published this spring and can be ordered from SWOKA, Institute for Consumer Research, Koningin Emmakade 192-195, 2518 JP's-Gravenhage, fax 070-3603963.

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