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NEWSLETTER

EDITORIAL

BIOTECHNOLOGY AND JOBS

Commission presents White Paper on employment

The EU's White Paper on growth, competitiveness and employment presented by the Commission to the December 1993 European Summit in Brussels, has been widely discussed and reported. Biotechnologists will be interested to know of the attention it gives to their subject. Biotechnology is compared with Information and Communication technologies in terms of its potential to create jobs and increase productivity in highly competitive areas of industry and agriculture as well as the health sector.

A major section of chapter 5 of the White Paper entitled "The changing society — the new technologies" is devoted to biotechnology and the role it might play in dragging Europe out of its recession.

For a copy of this section, use Response Form (Item 1).

CONTENTS

EUROPEAN BIOTECHNOLOGY INFORMATION SERVICE

Commission of the European Communities

Biotechnology will improve productivity and create highly skilled labour demand

The EU is highly competitive in industrial sectors such as chemicals, pharmaceuticals, health care, agriculture and agricultural processing, bulk and specialized plant protection products as well as decontamination, waste treatment and disposal. These are the very sectors where biotechnology is having the greatest potential impact not only in maintaining employment by improved efficiency and stimulated productivity but also by the creation of innovative new products resulting in highly skilled labor demand.

Global indicators of growth are very positive

The White paper notes that in the US, growth rates for the biotechnology industry of 28% with employment growing at 13% are being experienced. An estimated world market of 100 billion ECU for the industry by the year 2000 suggests that the scope for European growth and the generation of new jobs in this sector is considerable.

Key factors that may jeopardize growth

Particular attention is paid to the key factors that may jeopardize a significant expansion of biotechnology in the EU. It notices that public research and development expenditure lags behind the major competitors of the US and Japan (see EU/US comparison report, page 2 of this issue but see also the Commission proposals for biotechnology under FP4). Regrettably, European privately financed research and development has not compensated for the shortfall in public funding and several available indicators continue to point to an investment outflow. The regulatory approach is also unfavourably perceived by scientists and industry and technology hostility, social inertia and risk perception continue to plague widespread diffusion (see EBIS 3.4, page 51 for the Eurobarometer survey)

The solutions

What to do about it? The White Paper comes up with several solutions:

1. The regulatory framework should be open to review to ensure that advances in scientific knowledge are constantly taken into account and that regulatory control is based on potential risks.
2. Maximum use should be made in the present regulatory framework of flexibility and simplification of procedures as well as for technical adaptation (see page 10 in this issue). Scientific support for regulations should be reinforced and greater collaboration should be encouraged between experts in the Member States.
3. There must be greater focussing on the most vigorous biotechnology research and development areas and on increased coordination between the Member States.
4. More should be done to encourage and support the small and medium-sized enterprises (SME's).
5. Member States should provide greater incentives to improve the investment climate for biotechnology and facilitate technology transfer.
6. Specific measures should be taken to enhance public understanding mostly through the availability of objective information and dialogue with interest groups.
7. Ethical issues should be further clarified in relation to some applications of biotechnology.

Capital investment is the life-blood of development

The Ernst and Young's Eighth Annual Report on the US Biotechnology Industry, Biotech 1994, quotes figures of 1,272 companies with 97,000 employees. The potential for job creation is also here in Europe, provided the climate for capital investment is right, which after all, is the life-blood of all new developments.

Due to a printing error pages 55 and 66 or 56 and 65 were missing from some copies of EBIS 3.4 (December 1993). If you wish to receive the missing pages please write to the editor.

I. European Union Activities (Commission, Parliament, Council)

I.1. Biotechnology Coordination Committee (BCC) News

EC/US Comparison: Regulations and Research

New sections on contained use and protection of biotechnology inventions

The Commission's Biotechnology Coordination Committee (BCC) has prepared the final version of a report entitled "A comparison of the regulatory framework and research policy efforts on modern biotechnology in the EU and the USA". An interim report on this subject was distributed for comment in 1992. In the light of the comments received including those from the US authorities and of the developments which have occurred since then, the final report has been prepared.

Two new sections on contained use and protection of biotechnology inventions have been added and other sections have been reviewed and updated.

The interplay of many factors determines the climate for investment

The report recognizes that while the regulatory frameworks and research activities are among the major issues determining competitiveness, a number of other factors, such as availability of finance, structure of the industry, dynamics of market demand, etc., also have great influence. It is the interplay of all these factors that is responsible for the investment climate that leads to commercialisation and diffusion of the technology.

Scope, procedures, public information and flexibility

In comparing the regulatory frameworks attention is paid to the different institutional arrangements; the main elements of the legislative acts; the scopes and procedures; flexibility in scopes and procedures; requirements for informing the public; and user-friendliness.

In both EU and US regulations are based on the precautionary principle but conditions that trigger applications are different

The report finds that there are distinct differences in the regulatory approach, which is to be expected, but also many similarities. Regulations both in the EU and the US are based on the precautionary principle. The conditions that trigger the application of regulations differ. In the EU the genetic modification per se triggers the legislation. In the US the situation varies depending on the nature of the product.

Differences in the legislative structure and approach

There are differences in the legislative structure. In the EU, placing a product on the market requires consent under Directive 90/220/EEC but in future an environmental risk assessment will be integrated into specific product legislation as part of a single notification and authorization procedure. In the US, product legislation is in place which contains provisions for industrial contained use, deliberate release and product authorization. However, contained use of GMOs for R&D purposes is dealt with in most cases by NIH guidelines, which are binding for federally funded research and widely applied in other areas of research.

In the US greater flexibility in amending the scope of the regulations but more public consultation

The US system appears to offer greater flexibility to amend the scope of the oversight and the NIH guidelines for R&D contained use provide a flexible approach combined with oversight at the institutional level. Public consultation procedures are generally more structured, formalized and extensive than in Europe.

Differences in patent rules

Comparing the legislation on patenting it is found to be largely similar in approach but the EU excludes from patentability "plant and animal varieties or essentially biological processes for the production of plants or animals" whereas the US does not.

R&D expenditure much greater in US. Focussed networks in the EU

Expenditure on biotechnology R&D in the US is far greater than in all the E U Member States combined and the US Federal agencies appear to be well coordinated. The European approach of networking between laboratories of different Member States is leading to some distinct achievements but more needs to be done in coordinating activities and focussing objectives.

To obtain the report, use the Response Form (Item 2).

Commission Reinforces its Group of Advisers on the Ethical Implications of Biotechnology

Three opinions adopted and work continues on other topics

The Commission's Group of Advisers on the ethical implications of biotechnology set up following the Commission's April 1991 communication (see EBIS 2.1, page 3) has now been expanded and given a new mandate. To date the Group has adopted opinions on the following topics:

1. The ethical implications of the use of performance-enhancers in agriculture and fisheries.
2. Products derived from human blood or human plasma.
3. On the ethical questions arising from the Commission's proposal for a Council Directive on the legal protection of biotechnological inventions.

Work is in progress on the topics of transgenic animals and gene therapy.

Group expanded from six to nine

Following a recommendation of the White Paper (see Editorial) to expand the Group and further clarify several applications of biotechnology, its membership is now as follows:

- Mme Noëlle LENOIR (Chairman of Group) — (F) Member of the French Conseil Constitutionnel, Chairman of UNESCO International Committee of Bioethics.
- Dr. Anne Mc LAREN (GB) — Researcher in Reproductive Biology, Foreign Affairs Secretary of the Royal Society, Member of the Nuffield Council of Bioethics, London.
- Dr. Margareta MIKKELSEN (DK) — Chairman of Department of Medical Genetics, John F. Kennedy Institute, Member of the Danish Council of Ethics, Member of Ethical, Social and Legal Aspects of Human Genome Group (ESLA) of DGXII
- Prof. Luis Jorge Peixeto ARCHER (P) — Professor of Molecular Genetics, Lisbon, Member of the National Council for the Ethics of Science and Life, Lisbon.
- Prof. Gilbert HOTTOIS (B) — Professor of Philosophy, Co-Director of the Centre For Interdisciplinary Research in Bioethics of the University of Brussels.
- Prof. Dietmar MIETH (D) — Professor of Theology and Ethics and Chairman of the Centre for Ethics and Humanity of the University of Tübingen.

- M. Octavi QUINTANA TRIAS (ES) — Adviser to the Vice-Minister for Public Health President of the Comité pour la Bioéthique (CDBI) Council of Europe, Member of the Group of Ethical, Social and Legal Aspects of Human Genome Analysis (ESLA)
- Prof. Stefano RODOTA (I) — Professor of Civil law, Member of the Ethical Committee of the National Research Council, Deputy of the Italian Parliament.
- Prof. Egbert SCHROTEN (NL) — Professor of Ethics and the Philosophy of Religions, Director of the Centre for Bioethics and Health Law, University of Utrecht, Chairman of the Ethical Committee for the Evaluation of genetic modifications to animals.

The activity report (1991-1993) of the Group is available on request.

Use the Response Form (Item 3).

I.2. RESEARCH AND RELATED

EU/US ADMINISTRATIONS CONTINUE RESEARCH DIALOGUE

Exchange of information and opportunities for collaboration and joint activities

The EU/US Task Force on Biotechnology Research has met again in Washington 18-19 October 1993 under the joint chairmanship of Dr. Mary Clutter of the National Science Foundation and of Professor Paolo Fasella, Director General of DGXII of the Commission. The varied agenda items included the US National Biological Survey, genome database, bioinformatics, databases for field experiments, brain research, plans for the Third International Symposium on Biosafety results, environmental biotechnology, methods of communicating biotechnology to the public, mapping and sequencing non-human model genomes and bioprocess engineering.

Genome databases, field release databases, brain structure and functions and environmental biotechnology.

A number of actions are expected to follow including setting up a EU/US working group on informatics systems for brain structures and functions, collaboration in the analysis of databases for field experiments and public perception activities. The Task Force is also organizing the Third International Symposium on Biosafety Results. A second publication has been produced on Biotechnology and Genetic Resources which results from a workshop held in the US in October 1992 to examine the interrelationships between biological diversity - especially at the genetic and organismal levels — and biotechnology. The focus is on four topics:

(i) screening of organisms for useful properties and the concomitant development of biotechnological tools for evaluating biodiversity,
(ii) databases for genetic resources,
(iii) biotechnology for conservation and use of animal genetic resources, and
(iv) microbial diversity.

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

BRIDGE BIOSAFETY RESULTS

62 E.U. and E.F.T.A. Laboratories

The assessment of possible risks associated with the release of GMOs in the environment is one of the scientific topics covered by BRIDGE (1990-1994). 62 laboratories from the E.U. and E.F.T.A. countries have collaborated in 14 transnational projects.

The final meeting of BRIDGE biosafety contractors took place in Granada, Spain on 24-27 October 1993. The proceedings of the meeting have now been published.

Topics focus on major potential biosafety issues

Topics covered include: analysis of gene transfer between microorganisms and plants; fate of genetically engineered microorganisms and plants; fate of genetically engineered microorganisms in environmental hot spots; safety assessment of the deliberate release of two model transgenic crops: stability of fungi used as biocontrol agents; safety of genetically engineered retroviruses; and assessment of environmental impact from use of live recombinant virus vaccines.

Useful general conclusions section separates science fact from fiction

The proceedings also include a useful general conclusions section which while not going so far as to say GMOs are safe, does conclude that the results to date have shown that no specific risks can be attributed to rDNA techniques. According to the results obtained in the field, gene transfer between introduced and native organisms occurs, if at all, below the limit of detection by available methods.

To obtain a copy of the proceedings, use the Response Form (Item 5).

WORKSHOP ON HUMAN SOMATIC GENE THERAPY

Exchange of views on current techniques and their regulation

An EU sponsored workshop on this topic was held on 23 and 24 September 1993 at the National Institute for Biological Standards and Control, UK, with the following aims:

(i) to exchange views on current techniques used in human somatic gene therapy;

(ii) to encourage discussion among representatives of academia, the pharmaceutical industry and the regulatory authorities;

(iii) to catalyze debate on the various problematic issues such as ethical considerations that have been raised.

Proposal for an E.U. guideline on quality, efficacy and safety of vectors used in human somatic gene therapy

It was anticipated that the workshop would prepare the ground for the drafting of a E.U. guideline paper on the quality, efficacy and safety of vectors used in human somatic gene therapy. Gene therapy products (rather than the process or practice itself) will probably fall under the E.U. definition of a medicinal product under the 87/22/EEC "high technology" Directive.

A report of the meeting is available:

National Institute for Biological Standards and Control,
Blanche Lane,
South Mimms,
Potters Bar,
Herts EN6 3QG, U.K.
Tel: (44) 707 65 47 53
Fax: (44) 707 64 68 54

Parliament Discusses E.C.V.A.M.

E.C.V.A.M. — European Centre for the Validation of Alternatives to animal testing Methods

The establishment at Ispra (Italy) of an European Centre for Validation of Alternative Methods (ECVAM) has been the subject of a recent debate in the CERT (Committee on Energy Research and Technology) of the European Parliament. ECVAM was set up by the Commission (see EBIS 2.2, page 4) to coordinate the validation of alternatives to animal testing among other tasks.
Professor Michael Balls, formerly of the UK research charity FRAME (Fund for the Replacement of Animals in Medical Experiments) has been appointed as its head.

Rapporteurs draft report and amendments available

The Parliament has a long-standing interest in the welfare of animals used for experimental and other scientific purposes within the EU. A report on ECVAM has been produced by the CERT rapporteur, Mr. M. Seligman (UK, Cons.) and is available on request.

Use the Response Form (Item 6).

ACTIP Raises its Profile

28 European companies in association with BRIDGE 'T' project

The Animal Cell Technology Industrial Platform (ACTIP) is a grouping of 28 European Companies established alongside the BRIDGE 'T'-project on animal cell biotechnology (see EBIS 2, page 9). All its member companies have a strong commitment to research in animal cell technology, which they use in vaccine production or the development of novel therapeutic products. A descriptive booklet is available.

Details:

ACTIP secretariat,
C/O Scientific Writing and Consultancy,
PO Box 23161
NL-3001 KD Rotterdam
Tel: (31) 104 36 37 25
Fax: (31) 104 36 10 04

The Intellectual Property Unit in DGXIII — Focus on Biotechnology Patents Resulting from Community Research.

Intellectual property unit working alongside VALUE and SPRINT

DGXIII-D, located in Luxembourg, organizes the dissemination and exploitation of EU-funded RTD results, fosters technology transfer and stimulates innovation in the Member States by a variety of strategies and actions. The corresponding programmes, VALUE II and SPRINT, are well known in the scientific community.
Another service in this unit may be less well known, i.e., the protection of intellectual property by DGXIII D-1, the patents division, headed by Henning Bank.

All E.U. research considered, special attention to SMEs.

For more than 25 years, this unit has secured intellectual property from research out of the Commission's Joint Research Centres. More than 2300 files have been handled to date, mostly patent applications in the Member States. More recently, this service has been opened to results from EU contract research. Small and Medium-sized Enterprises (SMEs) will be given special consideration.

Advice on intellectual property protection

What is on offer? First of all, advice on the necessity for intellectual property protection for every contractor; on the procedure of filing patents; and on the prospects for future granting of a patent. If research results are deemed suitable for protection, publication or other communication to colleagues as well as the public, should be halted until a first patent application has been filed. Following a primary examination of the research results by in-house patent experts, the division charged with the exploitation of research results, DGXIII D-3 is notified of a potential licensing case and starts, in close collaboration with the inventors, to develop strategies for commercialisation of the invention.

Finance available

Secondly, financing for a primary filing is available to SMEs. If the contractor wishes to be holder of the patent, support by DGXIII D-1 stops after this first filing. If the European Community holds the patent, all secondary filings and the yearly fees will be paid by the Commission.

Thirdly, and most importantly, the patents division will hire competent patent lawyers and keep track of the rather complex and intricate patenting procedure.

Much interest in biotechnology sector

It has been recognized by the patents division that one of the most promising sectors for high-value patents today is biotechnology. DGXIII-D is thus raising awareness among researchers in this field to take advantage of the service offered. Through close collaboration with units

DGXII E-1 to E-5, up-to-date information on the various research programmes and on regulatory issues is secured. However, there is a need for technology push, i.e. the contract researchers need to bring their potentially patentable results to the attention of the patent experts in Luxembourg. It is virtually impossible to screen all research funded by the RTD programmes for results needing or deserving protection.

Details:

Intellectual Property Unit
CEC — DG XIII D-1
Jean Monnet Building
L-2920 Luxembourg
Tel: (352) 4 301 33 353
Fax: (352) 4 301 33 389

I.3. Regulatory Framework

Commission's Decision Paves the Way for Simplifying Procedures For Field Tests Of Certain Genetically Modified Plants

Considerable knowledge and experience of many releases at numerous sites have been obtained

In 1990 when Directive 90/220/EEC on deliberate release of Genetically Modified Organisms into the environment was adopted, very few experimental releases had taken place anywhere in the world. However, an element of flexibility was incorporated into the Directive, so that when more releases of certain GMOs had taken place and as a consequence, knowledge and experience related to safety had been acquired and evidence on safety was available, simplified procedures for releases of certain GMOs could be adopted. The situation now is very different (see OECD report on page 11 of this issue) and considerable knowledge and experience of many releases at numerous different sites have been obtained. Evidence on safety to human health and the environment has been accumulated and to date, no experiment, as far as is known , has been stopped for safety reasons. The stage has been reached therefore which allows the adoption of simplified procedures for experimental releases of certain genetically modified plants

The technical criteria and how they may be used

Against this background the Commission has recently published a Decision (93/584/EEC *) establishing criteria for simplified procedures for releases of certain genetically modified plants. The Commission Decision covers two aspects: firstly the actual technical criteria and secondly, indications as to how they may be used to enable simplified procedures to be introduced with the greatest possible applicability. The criteria are based on the knowledge obtained so far from releases of genetically modified plants which has identified the requirements which have to be satisfied for a release to be without hazard for human health and the environment. Once a Competent Authority requests a certain type of simplified procedure other Competent Authorities may join in the request within a period of 45 days.

* OJ L 279, 12.11.93.

Details:

Dr. J. Kioussi
DGXI/A-2
Tel.: (32) 2 29 90 428
Fax: (32) 2 29 90 313

Herbicide-Resistant Plants — Are They Safe?

Safety considerations for herbicide-resistant plants

On the 26 January 1994, the Belgian Competent Authorities for Directive 90/220/EEC organized a workshop in Brussels with the support of the European Commission to discuss safety considerations for the commercialization of herbicide-resistant plants. The workshop was attended by Competent Authorities of most Member States, EFTA countries and Industry experts, some of whom serve as members of National Advisory Committees. Presentations were made by C. Gliddon (UK), M. Aigle (F), H. Bergmans (NL), G. Howins (B) and K. Madsen (DK).

Impact on the environment of resistance gene transfers

A number of issues were discussed, including the inevitability of herbicide resistance genes being transferred to weedy relatives and the ecological impact of such transfer. It was noted that herbicide resistance in weeds is quite a common natural phenomenon which has not proved disastrous for agricultural environments to date. A secondary impact of using herbicide resistant plants, not necessarily associated with safety, may be increased overall use of herbicides

Details:

W. Moens
Institute of Hygiene and Epidemiology
Rue Juliette Wytsmans, 14
1050 Brussels
Fax: (32) 2 640.52.92

Competent Authorities Propose Simplified Procedures for Release of Plants

Competent authorities for 90/219 and 90/220 Directives meeting in Brussels

From time to time EBIS has reported on progress of implementation in the Member States of Directives 90/219/EEC on Contained Use and 90/220/EEC on Deliberate Release of Genetically Modified Organisms (see EBIS 2.4, page 7).

The competent authorities for the implementation of these Directives met most

recently in Brussels immediately following the Workshop mentioned above.

Two proposals for simplified procedures from France and United Kingdom

Among the topics discussed were two proposals, one from France and the other from the UK, for introducing simplified procedures for the release of genetically modified plants. These proposals will be the subject of a Commission proposal to the Article 21 Committee of the 90/220 Directive, to assess against the criteria already the subject of a Commission Decision (see page 6 of this issue).

Novel Foods Take Shape

Commission adopts amended proposal for a Council Regulation

After the first reading in Parliament in October 1993, the Commission adopted an amended proposal for a European Parliament and Council Regulation on novel foods and novel food ingredients (see EBIS 2.4, p. 9).

The Commission has accepted a number of the amendments voted by Parliament, regarding in particular the scope of the regulation, the procedure (deletion of the role of individual experts, integration of the evaluation criteria in the text) as well as provisions on control measures and confidentiality.

Consumer has to be informed about any significant differences in the characteristics of the novel food

As regards the labelling, the general rules set out in the labelling Directive 79/112/EEC will apply, but in the decision authorizing the placing on the market of a novel food or novel food ingredient additional labelling requirements can be decided upon. In any case, the consumer has to be informed about any significant differences in the characteristics of the novel food or novel food ingredient in comparison with the equivalent conventional food or food ingredient.

Discussions continue in the Council working group and it is hoped that a common position on the proposal can be reached under the Greek presidency. The amended proposal COM(93)631 final of 1 December 1993 is available on request.

Use the Response Form (Item 7)

BST — Commission Proposes: Council Disposes

Seven year moratorium reduced to 12 months

As reported in EBIS 3.4, page 58, the Commission had proposed to the Council that the marketing of BST or its administration to dairy cows in the Community be prohibited for the duration of the application of milk quotas which would involve an extension of the moratorium for another seven years.

A compromise position in the absence of a qualified majority in favour of the commission proposal

The Council has decided otherwise. In the absence of a qualified majority in favour of the Commission proposal it decided on 22 December 1993 on a 12 month extension of the moratorium to allow more time for examining the various implications of the decision to be taken, including the consequences with regard to international trade and the newly-created situation in the U S following USFDA approval. The European Parliament had supported the Commission proposal for a seven year ban.

"Common Position" in Council on Biotechnology Patents Directive

Qualified majority in favour of Directive

The long saga of the Directive on the legal protection of biotechnological inventions (see EBIS 3.1, page 6) appears to be coming to a conclusion. On 7 February 1994 the General Affairs Council has definitively adopted by qualified majority (Denmark, Spain and Luxembourg voted against) its "common position" on this Directive which the Commission first proposed in 1988.

Aims to clarify and harmonize E.U. patent law

Its main aims are to clarify and harmonize throughout the Union the patent law as applied to biotechnology and to ensure consistency with the European Patent Convention.
Member States have until the end of 1996 to transpose the Directive into national laws.

To obtain the text of the "Common Position", use Response Form (Item 8).

II. Member States

EFB Publication on "Ecological Bioprocessing"

Ecological bioprocessing and the contribution of biotechnology to sustainable development

The European Federation of Biotechnology (EFB) Working Party on "Ecological Bioprocessing" has recently published a book on fundamental principles and applications of ecological bioprocessing as a result of an international workshop held at Potsdam.

The book covers general problems, basic ecological principles and requirements of sustainability, bioprocess examples in the field of closed-cycle processes and renewable resources utilization.

Available at price DM 68 (including postage) from:

Gesellschaft für ökologische Technologie
und Systemanalyse
Scientific Centre
C/O
Dr. Konrad Soyez,
Orianienburger Strasse, 22
D-10178 Berlin
Tel: (49) 302 81 04 25

Belgium

New B.B.A. Office In Beijing

Belgium industry well-placed to exploit Chinese biotechnology

The Belgian Bioindustries Association (BBA) has opened a new office in Beijing similar to those it already has in other world capitals.

The BBA Beijing Office, which became functional on 1 January 1994, is hosted by the Institute of Scientific and Technical Information of China and no doubt is well-placed to enable the Belgian biotechnology industry to take full advantage of the booming Chinese developments in biotechnology.

Details:

B.B.A.
Rue de Crayer, 10
1050 Brussels
Tel: (32) 2 646 05 64
Fax: (32) 2 643 24 32

Denmark

Ethical Issues Raised by the New Biomedicine

Copenhagen conference from 11-14 April 1994

The Danish Council of Ethics will hold an international conference entitled 'The Ethical Debate — Public Participation" in Copenhagen from 11-14 April 1994. The aim of the conference is to clarify how the interaction between scientists, politicians and the public can be managed in view of the important ethical questions raised by the dramatic developments in biomedicine.
Details:
The Danish Council of Ethics
2-4, Ravnsborggade,
DK-2200 Copenhagen N.
Tel: (45) 35 37 58 33
Fax: (45) 35 37 57 55

France

Les Techniques de Transgenese en Agriculture: Applications aux Animaux et aux Vegetaux

Comité des Applications (CADAS) de l'Académie des Sciences, Rapport Commun no. 2, Oct. 1993; pub. Lavoisier, Paris, 156 pages.

French scientists address national and international readership

A distinguished group of more than 30 French scientific experts, academic and industrial advisers to government and/or responsible for public research institutes, has contributed to this timely and informative report. It is addressed to the general (French-reading) layman; the Conclusions and Recommendations are also given in English, to facilitate a wider international readership, and the report throughout reflects an awareness of the international perspective.

Techniques, application and impacts

The report starts with short explanations of the techniques, aims and applications, in animals and in plants. The impact assessment chapter emphasizes the rapid growth in the number and variety of experimental trials, and discusses the strategic as well as socio-economic impacts. On the protection of intellectual property, the presentation is up-to-date and balanced, distinguishing the similarities and differences between the animal and plant domains.

Bio-diversity, public perception, ethics

Short chapters discuss bio-diversity (and the Convention): opposition movements and public perceptions; and ethical considerations.

Regulations — need for balance

The discussion of regulatory issues includes national, European and global debates, in developed and developing countries. The report stresses the need for balance between safety considerations in the use of GMOs, and the concern not to hamper research and applications in genetic engineering which are seen overall as positive for society.

Recommendations include more work on patentability issues

Recommendations cover basic research; regulations (need for an evolutionary approach); public acceptability (emphasis an information and transparency); agricultural policy and Third World impacts. On regulations, the authors advocate a more active role by France in EU and OECD contexts; and further work by

the Academy and CADAS on issues concerning the patentability of living systems.

Glossary and informative annexes

Informative notes and a glossary of technical terms enhance the value of the report, as do seven Annexes of supplementary information on laboratories and companies active in the field, good practices and the French law on GMOs.

The report can be ordered from:

Technique & Documentation
Lavoisier
11, rue Lavoisier
F-75384 Paris Cedex 08
Tel: (33) 1 435 41 296
Fax: (33) 1 405 17 725

GERMANY

AMENDED GENETIC ENGINEERING LAW IN FORCE SINCE DECEMBER

Three major reasons given for changing the 1990 gene law

The first amendment of the Genetic Engineering Law (GenTG) came into force in December 1993.

Three major reasons were given for changing the first law, which came into force in July 1990:

(i) The arguments of industry and scientists were taken into account. The "insurmountable bureaucratic burdens" on the development of a competitive German biotechnology industry had to be overcome.

(ii) The various different interpretations and executions of the law needed to be harmonized between the Länder.

(iii) The concerns of the European Commission about not implementing completely the EU Directive on the contained use of genetically modified microorganisms (90/219/EEC) as well as on the deliberate release of genetically modified organisms into the environment (90/220/EEC) had to be met.

A list of proposed changes for the EU directives agreed

A draft proposal for a revision of the law, which was issued in March 1993 (see EBIS 3.2, page 26) by the responsible Federal Ministry of Health, was put forward for parliamentary discussion by the cabinet in May. At the same time, a list of proposed changes for the EU Directives was agreed. After several debates within the Bundestag and the Bundesrat a final agreement was reached in November on the following changes:

Procedures speeded up and administrative arrangements reduced

(i) time periods are reduced for notifications and approvals of installations as well as operations using no- or low-risk organisms of class 1 and 2; the obligatory participation of the national scientific advisory board (ZKBS) is reduced to an appropriate level (paragraphs 8 to 12).
(ii) the administrative requirements for deliberate releases of genetically modified organisms are reduced (paragraphs 14(4) and 18(2)).
(iii) the requirement of a public hearing for installations, where Type B operations with safe organisms of class 1 are performed, is deleted as well as for class 2, if not required by paragraph 10 of the federal emission-control law (paragraph 18(1)).
(iv) for the notification of an installation performing operations with class 1 organisms the administrative requirements are streamlined following the one-door-one-key-principle for other administrative requirements if necessary (paragraph 22(2)new).

Humans excluded from scope of the law and exchanges between research organisations allowed

(v) it is made clear that the direct application of GMOs to humans does not come under the scope of this law (paragraph 2(2) new).
(vi) the term "placing on the market" is newly defined to specify that it does not apply to the national and international exchange of GMOs between research organisations (paragraph 3(8).

A bureaucratic burden without gaining safety is not justified

The responsible Minister of Health, Mr. Seehofer has commented: "A bureaucratic burden without gaining safety is not justified. Therefore there was an urgent need to adapt the requirements of this law of 1990 to the present knowledge as far as possible within the existing framework of the EU Directives. The politicians involved have demonstrated their willingness and ability to promote the key-technology of genetic engineering. Now, it is up to science and industry to make use of this positive legal framework: successful basic research must be used faster and be turned more directly into marketing of products."

No compromise with safety

The amended law improves the conditions for the application of biotechnology in research and industry but the safety issues concerning human health and the environment are not affected. Furthermore, the public's participation and information rights are adequately taken care of. The German authorities are now keeping up the pressure for modifying the existing EU Directives. This process is already underway (see editorial).

THE NETHERLANDS

TITLE: STRATEGIES FOR FOOD SAFETY ASSESSMENT OF GENETICALLY MODIFIED AGRICULTURAL PRODUCTS

Dutch government finances project on risk assessment for novel foods

"RIKILT-DLO" is the State Institute for Quality Control of Agricultural Products of the Netherlands.

They are conducting a project on "risk analysis on novel foods for the consumer", as part of the programme on "ecological, social and ethical aspects of biotechnology" financed by the Department of Science and Technology of the Ministry of Agriculture, Nature Conservation and Fisheries.

Report summarizes genetic engineering applications, reviews international and national guidelines

A 56-page report in English, by Ir. E.J. Kok of RIKILT-DLO, has been published, entitled: "Evaluation of strategies for food safety assessment of genetically modified agricultural products". The report gives a brief overview of the main applications of genetic engineering to food plants; then reviews and compares the approaches to food safety assessment of such plants as advocated or practiced by the following international and national bodies:

- International Food Biotechnology Council (IFBC)
- Scandinavian Advisory Committee on Food Problems
- United Kingdom Advisory Committee on Novel Foods and Processes
- Food and Agriculture Organisation/ World Health Organisation
- The Netherlands Health Council and Food Council
- Commission of the European Communities — DG III Industry
- Organisation for Economic Cooperation and Development (OECD)
- US Food and Drug Administration (FDA)

Conclusions: common approaches, case-by-case, possibility of simplified procedures

The report offers conclusions and recommendations, noting the similarity of the guidelines offered by the various bodies, with differences only on minor aspects. It proposes to start with evaluating products according to the guidelines of the Dutch Health Council, OECD and FDA, using a case-by-case approach, but recognising that, given sufficient experience, categories of products can be indicated for evaluation by simple procedures.

Consumer and labelling issues

Consumer communication is emphasised, labelling issues are discussed.

Details:

RIKILT-DLO, PO Box 230
6700 AE Wageningen
Tel: (31) 83 70 75 400
Fax: (31) 83 70 17 717

United Kingdom

Fast Track Procedures for Certain G.M.O. Releases

Certain types of genetically modified organisms present low risk to U.K. environment

The UK's Department of the Environment has published a Guidance Note which sets out new procedures for handling applications for releases which are considered to be low hazard, low risk or repeat releases. Application for releases of certain types of genetically manipulated organisms (GMOs) for research and development purposes will be handled within 30 days in a fast track procedure.

Plants and modifications listed together with criteria for classification

The guidance note lists several plants such as maize, tomato, bean and sunflower together with a number of genetic modifications such as herbicide tolerance and pest resistance, which are considered to be low hazard, i.e. they do not possess inherent characteristics that pose a risk of damage to the UK environment and therefore there is no requirement to take special control measures.

30 day handling time equivalent to U.S. placing on the market remains at 150 days

The 30-day handling period appears to be equivalent to the current US Department of Agriculture handling time (see EBIS 3.3, page 38). It remains to be seen whether other Member States will consider that these plants and modifications pose low risk or hazard to their environments. For commercial releases or placing a product on the market the Community approval procedure remains which lasts a maximum of 150 days (90 days for the main assessment and 60 days for clearance from other Member States).

Details:

D.O.E. Biotechnology
Unit
Room B353, Romney House,
43, Marsham Street,
London SWIP 3PY
Tel: (44) 71 276 81 87
Fax: (44) 71 276 83 33

Genetic Screening — Ethical Issues

115-page report; popular version follows

The UK-based Nuffield Council on Bioethics has produced in December 1993 a 115-page report on the above topic, and intends to publish in 1994 a shorter, popular version.

Science, issues and recommendations — e.g. on confidentiality

The report outlines the scientific basis; the principles of genetic screening and current programmes in the UK; the provision of information, informed consent, and the need for consulting, disclosure of results, confidentiality, and the difficult issues which in some cases may lead to departures (e.g. in the interest of a family) from the normal principle of confidentiality to the individual. Here as in each chapter, conclusions and recommendations are formulated.

Screening in employment and insurance

Further chapters deal with genetic screening in employment; in insurance (a succinct statement of the issues from the various prospectives); the issues for public policy, and genetic screening programmes. On the last, the Council's recommendation is:

Genetic screening programmes

"That the Department of Health in consultation with the appropriate professional bodies formulate detailed criteria for introducing genetic screening programmes, and establish a central coordinating body to review genetic screening programmes and monitor their implementation and outcome".

Here as elsewhere, the tone is one of robust common sense and practicality; dealing with issues that are real and current or imminent, and leaving aside more speculative issues.

The focus is only on screening for serious diseases.

The report is available for £ 6.00 sterling (postage included) from:

Nuffield Foundation,
28, Bedford Square,
London WCIB 3EG,
Tel: (44) 71 631 05 66;
Fax: (44) 71 323 48 77

III. INTERNATIONAL DEVELOPMENTS

WORLD HEALTH ORGANIZATION

HEALTH ASPECTS OF MARKER GENES IN GENETICALLY MODIFIED PLANTS — REPORT OF A W.H.O. WORKSHOP

A workshop on the above topic, under the aegis of the World Health Organization and with support from the National Food Agency of Denmark and the Nordic Council of Ministers, was held in Copenhagen on 21-24 September 1993.

Dr. F. Küferstein, head of Food Safety in W.H.O., set the workshop in the context of the work started in 1990 with a Joint FAO/WHO consultation on assessing the safety of foods produced by biotechnology (see EBIS 4, July 1991, page 13).

Conclusions and recommendations

The Conclusions and Recommendations of the report include the following points:

Many genetically modified plants approaching commercialization

1. Many genetically modified varieties of food plants are approaching commercialization , so consideration of the health aspects of marker genes used in plant biotechnology is timely.

Marker genes: needed for identification and selection, impractical to remove

2. There is a need for marker genes in plant biotechnology to facilitate identification and selection of modified varieties following a genetic modification process even though these genes may have no function in the product. It is impractical at present to remove marker genes from modified plants after they have fulfilled their function.

Two antibiotic resistance markers, a few herbicide tolerance markers

3. Although a number of different marker techniques have been investigated, the number of marker genes in varieties approaching commercialization is restricted to two antibiotic resistance markers and to a few herbicide tolerance markers.
This is because of the ease of availability of these marker systems and the level of understanding of their mode of action.

Genes per se not a safety concern; for expressed proteins focus on function

4. The presence of market genes per se in food does not constitute a safety concern. In assessing the safety of the proteins expressed by marker genes used in plant biotechnology, the focus of the assessment should be on the function of the expressed protein rather than its structure.

Allergenicity? Check source

5. There is no reason to suppose that marker gene proteins pose a particular allergenic concern. However, if the genes are obtained from a source known to cause food allergy, the allergenicity of the gene product will need to be investigated.

Nothing to suggest secondary effects

6. There are no characteristics of marker genes or their products that suggest that their site of insertion into the plant genome will give rise to additional secondary and/or pleiotropic effects. The general safety assessment strategies elaborated by FAO/WHO and OECD should be applied to the safety assessment of plant varieties containing marker genes.

Specific strategies for different genes

7. Specific strategies would need to be applied to different categories of marker genes, such as antibiotic resistance marker genes, herbicide tolerance marker genes, and metabolic marker genes.

Towards a "positive list" of plant marker genes"?

8. At present, it is not possible to develop a positive list of plant marker genes which did not cause food safety concerns. Nevertheless, such a list would be valuable and, once the data become available to enable such a list to be constructed, this should be done under the auspices of an international health agency like W.H.O.

The report (32 pages) is available on request from:

Distribution and Sales,
World Health Organization,
Avenue Appia,
1211 Geneva 27
Switzerland
Tel: (41) 22 791 07 46
Fax: (41) 22 791 21 11

OECD

SCIENTIFIC ASSESSMENT OF GENETICALLY MODIFIED PLANTS

OECD: risk assessment in the GNE

The Organisation for Economic Cooperation and Development (OECD) has for several years provided a forum for 24 developed countries to discuss, among other things, common scientific principles and concepts for risk/safety assessment and management in biotechnology. The deliberations of the OECD Group of National Experts on Safety in Biotechnology (GNE) are occasionally enriched by a volunteer country offering to host a

workshop, generally on a topic of particular interest to the host country.

France hosts workshop on assessing genetically modified plants

As the world's number 2 agricultural exporter (after the US) and having a world class agricultural research establishment, France has special interest in promoting the application of modern biotechnology in this sector. With this background, France hosted in April 1992 at Jouy-en-Josas a two-day seminar on "Scientific Approaches for the Assessment of Research Trials with Genetically Modified Plants".

Potato, rapeseed and maize: 3 favourite targets

The papers presented have now been published by the OECD. The Workshop focused in depth on just three crop plants, widely the target of attempts at improvement by genetic engineering:

- Potato
- Rapeseed
- Maize

Towards harmonisation of approaches

The purpose was to share and compare experiences with field tests in various countries, to identify areas of disagreement and consensus, and to encourage harmonisation of approaches. The second day addressed more general issues, particularly questions concerning the molecular characterisation of transformed plants and the use of antibiotic and herbicide resistance genes as selectable markers. Three consensus statements emerged from this discussion:

Consensus points:

- *"sufficient description?"*
- *kanamycin OK*
- *the herbicide, not the gene*

1. There is a general consensus that the evaluation of the potential risk associated with field tests of transgenic plants requires a sufficient description of the genetic modifications of the plant. However, there are different views as to what constitutes a sufficient description of the genetic modifications.
2. The presentations made and the ensuing discussions indicated that there is no experimental evidence supporting a deleterious effect from the use of Kanamycin resistance genes in transgenic plants.
3. Issues and controversies regarding herbicide resistance genes centre on the use and management of herbicides, rather than on the gene modifications themselves.

New project on commercialisation aspects of agricultural crop plants

The OECD has recently initiated a project on the commercialisation aspects of agricultural crop plants derived through modern biotechnology.

The focus of the project is on the national policies of Member countries with respect to oversight/regulation which will affect the movement of these products into the marketplace in order to harmonize international approaches.

This project is timely as agricultural biotechnology emerges as one of the significant technologies of the decade and the promise of products becomes a reality.

Details:

OECD,
2. rue André Pascal,
75775 Paris Cedex 16
Tel: (33) 1 45 24 82 00
Fax: (33) 1 45 24 97 67

AUSTRALIA

1. "GENE TECHNOLOGY: ISSUES FOR AUSTRALIA"

Australian Science and Technology Council (ASTEC), Occasional Paper n 27, August 1993, 151 pages.

2. "GENE TECHNOLOGY"

A paper prepared by an independent working group convened by ASTEC for consideration by the Prime Minister's Science and Engineering Council at its ninth meeting, 29 November 1993, 33 pages.

Positive response to biotechnology

These two publications illustrate the vigorous and positive response of the Australian authorities to the opportunities and challenges which biotechnology presents to their country. The first is aimed at a broad readership. It gives a well-written overview of the subject and the background to the evolution of ASTEC's interest and activities since 1982.

Lists, guide and glossary

Useful appendices include address lists, a guide to genetic engineering, a glossary of terms and a list of research centres.

Four key issues: regulation, partnership, wealth, research

Four key issues are presented:

1. Regulation ("..... efficient, effective and open and which commands the confidence of both industry and of the public").
2. Science, business and community partnership ("....both formal and informal channels for dialogue should be developed...").
3. Wealth creation ("... ensure that Australia shares fully in the international development of genetic engineering as well as generating new products and processes from Australian ideas... may be special opportunities for Australia... catalyze the reshaping of our agricultural production industries... market opportunities in the .... growth centres of Asia.... strategic alliances ....").
4. Research focus and interaction with industry ("... Structures to facilitate cooperation .... Adequate protection of intellectual property...").

Action recommendation for policy-makers

More succinct, and written for the top policy-makers, the second report recommends a programme of action involving:

* communication and public acceptance
* a clear and efficient regulatory system
* effective linkage between research and industry

Personal commitment by Ministers

On communication, relevant Ministers are urged to give strong and personal support, and emphasis is placed on school curricula, transparency, and a research programme on social and ethical issues.

Regulation to focus on products, not processes

On regulation, Ministers responsible for product regulatory agencies are urged to review existing regulations and procedures to ensure that there is a clear, timely and simple path for commercialisation; that foods produced with involvement of gene technology be regulated in terms of the properties of the food products themselves, and not of the processes used in their production,

Guide gene therapy within existing frameworks

and a regulatory environment and guidelines within existing frameworks to provide guidance for clinical trials and marketing of gene therapy products and procedures.

Details:

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

USA

Biomedical Ethics in US Public Policy

OTA on bioethics

The US Congressional Office of Technology Assessment (OTA) has published in October 1993 a 92-page report on the above topic. The terms "Biomedical Ethics" and "Bioethics" are used interchangeably.

International (30 + countries), US federal and state experience

The report covers international and national experience from over 30 countries, as well as US State initiatives;

Focus on 4 federal initiatives

and focuses particularly on the history of 4 Federal bioethics initiatives:

- the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research;
- the Ethics Advisory Board;
- the President's Commission for the Study of Ethical problems in Medicine and Biomedical and Behavioral Research;
- the Biomedical Ethics Advisory Committee.

Lessons from the past; relevant to growing need

It emphasises the relevance of these "lessons from the past", arguing that as the frontiers of biomedical research and technology continue to advance, it will become increasingly important for policy-makers and the public to understand the ethical implications of such innovation.

6 elements for success or failure

The report finds from its review of past history, six specific elements contributing to success or failure, and therefore relevant to future strategies:

"....the budget is important, but mandate, appointing process, bureaucratic location, targeted client, and reporting and response requirements are also key".

The report is sold by

Superintendent of Documents,
PO BOX 371954
PITTSBURGH
PA 15250-7954
USA
Tel: (1) 202 783 32 38
Fax: (1) 202 512 22 50

$ 6.00 plus 25% for non-US customers. Quote Order Processing Code *7080; if ordering by credit card (Visa or Mastercard), include number and expiry date as well as signature.

IV. Books/Reports Received

"Dublin Foundation" projects on implications of biotech for living and working conditions

"Public Attitudes to Genetic Engineering: Some European Perspectives"

By Louis Lemkow. European Foundation for the Improvement of Living and Working Conditions, Dublin, 44 pp., 6 ECU.

4-country studies financed by DG XI

This report draws together results from two studies in the UK, France, Germany and Spain, financed by the European Commission's Dublin Foundation and DGXI, the Directorate-General for Environment.

The studies were based upon small "focus groups" with members of the "informed public", to discuss their attitudes to various applications of Biotechnology. The second project used a workshop format to establish priorities and consensus among specific interest groups.

Opinion polls superficial; "qualitative" methods needed

The author argues that while opinion polls play a significant role in improving our understanding of public perceptions of biotechnology, they can at best provide only a superficial impression of the state of opinion on scientific applications in such areas as genetic engineering.

Resource methods should include "qualitative" methods and should take account of social and cultural diversity. Lemkow suggests that the agenda for future analysis could include:

Suggestions for future analysis

- Documentation of preferences and not only attitudes among different groups of the "public".
- Clarification of the relationship between the so-called "underlying" attitudes to science in general and perceptions of biotechnology.
- The need to distinguish more clearly attitudes to different applications of biotechnology: food, therapeutics, agriculture, environment or industry.
- Analysis of the (in)stability of public perception of biotechnology over time.
- The need to take into account specific concerns: ethical, safety and health questions.

Public fora, ways to involve the public in policy

The studies conducted in the four countries stressed that public attitudes to genetic engineering are ambiguous and complex.

The author advocates public fora to bring together the plurality and diversity of views and interests, and urges consideration of mechanisms which would "put the public back into policy".

The book can be ordered from the Foundation at:

Loughlinstown House,
Shankill,
Co-Dublin,
Ireland
Tel: (353).1.282.68 88
Fax: (353) 1 282 64 56

Or from the:
Office for Official Publications of the European Communities, Luxembourg and its national sales offices.

Biotechnology Related to Human Beings

Readable report for Parliament; legislation in 1994

This 90-page document, attractively illustrated and well laid out for ease of reading, is an English-language summary of a report presented to the Norwegian Parliament by the Government in March 1993 and debated in June that year.

The Ministry of Health and Social Affairs is now preparing legislation to implement the Government's proposals (which were almost all accepted), and these will be presented to Parliament in Spring 1994.

Balance between restraint and new possibilities

The report emphasizes balance, the need to practice restraint being weighed against the possibilities created by development. The government's main objective is to use modern medical expertise and technology in the best interests of mankind, within ethical boundaries laid down by society. Distinctions have to be drawn between that which is ethically defensible and that which must be abandoned as questionable and undesirable. Such distinctions may have to be reviewed as research will continually lead to change.

Range of ethical topics — gene testing, therapy, etc.

The usual range of ethical and value-laden topics is reviewed — genetic testing, prenatal diagnosis, gene therapy — including consideration of matters such as the use/abuse of genetic information and the scope or limitation of patents. Explanations are short but clear, in each case leading to statement of government's current view and intentions.

Government intentions; international experience

There is extensive reference to international practice and ongoing discussions and legislative developments in the Nordic Council, the European Union and the Council of Europe.

Copies of the document can be obtained on request (while stocks last) from:

Ministry of Health and Social Affairs,
P.O.Box 8011 DEP,
N-0030 OSLO, Norway
Fax: + 47 22 34 95 75

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