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EBIS

EUROPEAN BIOTECHNOLOGY INFORMATION SERVICE

Vol. 5 no. 2

NEWSLETTER

Editorial: Global Biotechnology Regulation?

Second COP considers need for biosafety protocol

This EBIS reports on the preparations for the second Conference of the Parties (COP) to the Convention on Biological Diversity (see EBIS 3.1, page 10). Among other things, this will consider "the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organisms resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity".

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Other pages

EUROPEAN BIOTECHNOLOGY INFORMATION SERVICE

Commision of the European Communities

Opposing view-points passionately expressed

As with so many biotechnology issues, opposing points of view are being passionately promoted by the different protagonists. Environmental groups, such as the Friends of the Earth and Genetic Resources Action International (GRAIN), have called unequivocally for a binding regulatory mechanism to rule the testing, release and trade of GMOs. Several developing and developed countries share this point of view. They fear the unscrupulous operator unable to obtain permission to release in Europe or the US using the developing world as testing grounds for uncontrolled and risky experiments. On the other hand, the International Bio-Industry Forum (representing the major biotechnology industries worldwide) have issued a statement of principle indicating their support for the development of biosafety principles and guidelines at the national level. Where such national guidelines are not in place they promise to adhere to generally accepted scientific standards of care as observed in their own countries.

Technology specific or a risk-based sectoral approach?

Others have argued that a legally binding protocol might take considerable time to be agreed and enter into force between so many parties. In the meantime, the possible role of scientifically based technical guidelines might be seriously considered. These could be drawn up quickly and easily on the basis of worldwide experience to date. An appropriate biosafety instrument, whether legally binding or not, should be risk-based and should not lead to unnecessary stigmatisation of a technology with potentially great benefits. Furthermore, it must not provide possibilities for a technical barrier to trade just at the time when the GATT and other agreements are working towards freer trade.

The biosafety results of field tests of Genetically Modified Plants and Micro-organisms persuades US regulators

These debates take place at the same time that the US regulatory authorities are rapidly giving consent for the marketing of transgenic crops (some 15 agronomically improved crops will be planted widely in the USA next year). Presumably, these regulators believe that the risks to be addressed and the means to manage them in these new and improved crops do not differ significantly from those developed by more traditional means. The knowledge and experience gained from biosafety research (see page 14) is leading to increased confidence. This suggests that consideration should be given to whether existing sectoral provisions including quarantine controls for seeds, plants, vaccines, foods, pesticides etc. are not the most appropriate response to ensure the safety of biotechnology. This is the approach being taken in the European Union for medicinal products, additives in feeding stuffs, plant protection products, novel foods and seeds (see EBIS 4.2, page 11).

I. News from Brussels (Commission, Parliament, Council)

1.1. News from the Biotechnology Coordination Committee (BCC)

BCC Continues its Work

High level inter-service discussion

The Commission's Biotechnology Coordination Committee (BCC), consisting of high-level officials from the Commission services, met on 20 July 1995 to discuss the following points:

90/219/EEC proposed amendment

1) The proposal for amendment of the Directive 90/219/EEC was further discussed.

Report on functioning of 90/220/EEC

2) Concern was expressed at the unacceptably long delays experienced in getting products approved under the 90/220/EEC Directive. The Commission will be preparing a report on the functioning of the Directive.

New Patents Directive discussed

3) The progress made in drawing up a new proposal for a Directive on Legal Protection of Biotechnological Inventions was discussed.

Conference for Commission, Parliament and Council

4) Plans were discussed for the Conference on biotechnology to be held between the Commission, Parliament and Council before the end of the year. The aim is to generally improve the dialogue on biotechnology issues.

5) The Group of Advisers on the Ethical Implications of Biotechnology is planning further contacts with the European Parliament.

Biodiversity Convention mandate proposed

6) On the Biodiversity Convention: Protocol on biosafety, the Commission is expected to propose a mandate for a Community position to the Council (Environment).

7) In relation to the Council of Europe: Bioethics Convention the BCC discussed procedural aspects relating to the possibility of the Community's participation.

8) Discussions with the USA and Japan were noted.

Details: L. Mitek, Secretariat General.
Fax: 32-2-295.76.37

I.2. Research and Related

Call for Proposals Published

New call published

On 15.09.1995 a new call for proposals for the specific programme of research and technological development, including demonstration, in the field of biotechnology (1994–1998) was published in the Official Journal of the European Communities (N C 240/9).

8 Areas included but different means of support

This includes:

Objectives requiring concentrated means in
Area 1: Cell factories.
Area 2: Genome analysis.
Area 3: Plant and animal biotechnology.
Area 4: Cell communication in neurosciences.

Objectives addressed by concertation in
Area 5: Immunology and transdisease vaccinology.
Area 6: Structural biology.
Area 7: Prenormative research, biodiversity and social acceptance.
Area 8: Infrastructures.

Objectives treated by means of horizontal activities
- demonstration activities (RTD projects related to the 8 above-mentioned areas, see article below).
- biotechnology and society, ethical, social and legal aspects.
- socio-economic impacts.

Closing date 10.01.1996 Preparatory Awards for SMEs until 31.12.1996

The deadline for receipt of proposals is 10.01.1996. Proposals for shared-cost preparatory awards in view of the participation of SMEs in RTD projects can be submitted continually until 31.12.1996.
An Information Package is available.

Details: DG XII E-1
Tel.: (32) 2-296.22.29
Fax: (32) 2-299.18.60

Demonstration Projects in the Biotechnology Programme of the European Union (1994–1998)

6% of budget allocated for Demonstration Projects

The new Biotechnology programme includes for the first time, support for demonstration projects. Up to 6% of the total programme budget is earmarked for this activity. The intention is to provide an additional mechanism for the exploitation and dissemination of the technology. Indeed, since "seeing is believing", undertaking a demonstration project seems particularly appropriate when the uncertainties and risks associated with innovation might discourage potential users from adopting a newly developed technology. Such uncertainties might appear, for instance, when new biotechnologies have to substitute well-proven existing practices; when there is a need to show compliance with regulatory requirements and market standards; or when the negative public perception of biotechnologies is a deterrent for their application by users.

"To prove the technical viability of a new technology"

A general definition of demonstration states that its objective is "to prove the technical viability of a new technology, together with, as appropriate, its economic advantage". Thus a demonstration project is to verify, on a scale of operations representing reality the different aspects of the new technology which might affect its implementation, in the real world. Thus, proving the "technical viability" of a new technology might involve proving its superiority with respect to current practices, its ability to comply with regulations, its validity with respect to standards, its public acceptance, etc. In the context of the Biotechnology programme, the second objective of a demonstration project, "proving the economic advantages of a new technology", firstly applies to increased profits for industry, but can also be taken in a wider sense to include economic advantages in enhanced efficiency of Public Services who use the new technologies (e.g., Food, Health, Environment, etc.) or even in a direct contribution of a particular project to improving the public perception of new biotechnologies.

Characteristics of Demonstration Projects

The following characteristics must be evident in a demonstration project:

1) It must be precompetitive in nature.
2) It must show novelty in technological innovation.
3) It must be on the basis of established knowledge without a research component.
4) The partnerships established must include technology producers and users.
5) Proposals should indicate project deliverables and their exploitation, dissemination etc.
6) Extended audiences of demonstration projects may include industrial platforms, consumer organisations, public authorities, etc.

Details: A. Herrero, DG XII E-3
Tel.: (32) 2 295.46.83
Fax: (32) 2 295.53.65

BRIDGE in the Context of European Research

Need to overcome weakness in cross-European co-operation for R&D

How the BRIDGE programme, (Biotechnology Research for Innovation, Development and Growth in Europe), which is intended to build links between European research groups in biotechnology, fits in to the total pattern of biotechnology research in Europe is the subject of a booklet "Building Bridges in Biotechnology".

Research budgets estimated for Europe and USA

It is no surprise that research and development spending on biotechnology both by companies and by public bodies in the Member States of the European Union far outstrips the Ecu 100 million in the BRIDGE budget. However, the largeness of general research budgets makes any co-ordination all the more laudable. As to the size of total budgets, it was estimated, by accountants Ernst & Young, in 1992, that the EU nations spent over Ecu 0.92 billion per year on biotechnology-related research and development. For comparison, the United States government spent around Ecu 3.1 billion in the sphere during that year. Company research activity was also high. In 1993, biotechnology companies around the world (1500 or so mostly small and medium-sized enterprises) between them spent over Ecu 5.5 billion on R&D.

To obtain the report, use the Response Form (Item 1).

Protein Engineering a Suitable Field for Coordinated RTD in the European Community

An imperative requirement for a radical improvement in coordination of research

Protein engineering might be a typical area in the field of Research and Technological Development in the European Union that could, following review at national and Community levels, be subject to achieving a good level of co-ordination across the EU. Its suitability for cross-border research is because the technology is relatively new, and consists of the combination of several disciplines and techniques.

Generally, there is an imperative requirement for a radical improvement to the co-ordination of RTD of all kinds across the European Union. The problem is well expressed in the European Commission White Paper entitled "Growth, Competitiveness, Employment, the challenges and ways forward into the 21st century"

It states: "A second weakness is the lack of co-ordination at various levels of the research and technological development activities, programmes, and strategies in Europe. First, there is a lack of co-ordination between the national research policies. The Community's research budget accounts for only 4 per cent of research spending by the 12 Member States. Even adding the resources allocated to joint European RTD activities in other frameworks ..., the budget amounts to only 10 per cent or so of the total.

National policies still developed largely without reference to one another

"Despite the co-ordination called for by the existence of these activities and the need for the Member States to take them into account when defining their own policies, the national policies are still developed largely without reference to one another."

As a step in the direction of meeting the challenge to improve co-ordinated RTD, the European Commission has published a report on "Protein Engineering RTD Programmes in Europe".

In this notably practical document, a three step approach has been taken: 1, to collect information on the national protein engineering programmes; 2, to share and analyse this information and find a common presentation "format"; and, 3, to list topics for further action on the basis of a rigorous analysis of the available data (gaps, duplications of effort, possible synergies, etc. ...).

A start made to coordinate Protein Engineering through collaboration

For instance, the report lists a "Contact Group", with the address and other co-ordinates, of relevant bodies in each country. Notes on national programmes are given. Budget details are included where available. Mention is made of newsletters. There is a list of protein engineering scientists, with their contact details. Furthermore, there is a section devoted to other countries – USA, Japan and Canada.

To obtain the printed report without charge, use the Response Form (Item 2). Is is also available on the World Wide Web: http://www.cryst.bbk.ac.uk/CEC/eupage.html

Animal Cell Technology Explained

Avoiding the risk of Creutzfeldt-Jakob disease and other pathogens

Human growth hormone, which is used for the treatment of dwarfism, used to be extracted from the pituitary glands of deceased humans. To produce the amount of growth hormone necessary to treat one patient, tens to hundreds of human pituitaries had to be processed. The quantity available was sufficient to treat only some, but not all, patients. In addition, this production method involved a risk of transferring an infectious agent, causing Creutzfeldt-Jakob disease and other unknown pathogens.

Animal cells propagated *in vitro*, in bioreactors

Now, a vastly improved system is in operation. The current production method uses genetically modified animal cells, which enables the treatment to be offered to all patients. In addition, it is claimed to be a much safer product. A recombinant human growth hormone produced in a genetically engineered bacterium is also available.

Book for well-educated, non-specialist reader

This use of animal cell technology is one example cited to explain the technique that has been written up in a colour booklet published by ACTIP, the Animal Cell Technology Industrial Platform, which has its office centre at Rotterdam. The booklet, which is intended for the well-educated, non-specialist reader, describes how animal cell technology is playing a substantial role in the fields of biotechnology.

The booklet defines the technology as "the use of animal cells propagated *in vitro*, that is, outside the animal, and usually in so called bioreactors, for the manufacture of bioproducts and as vehicles in the discovery and/or testing of medicines." This technology is now widespread in modern pharmaceutical research.

Details: Animal Cell Technology Industrial Platform.
Scientific Writing and Consultancy
P.O. Box 23
NI-3001 KD Rotterdam
Tel.: (31) 10-436.37.25
Fax: (31) 10-436.10.04

or use the Response Form (Item 3)

Biotechnology and Cancer Research

The eventual understanding and curing of cancer "will be largely due" to the existence of gene technology

"The most important milestone was the recognition that cancer is always attributable to a programming error in the cells genetic code", writes Max Birnstiel, one of the pioneers of genetic research, founder and head at the Institute for Molecular Pathology in Vienna. His belief is that we will succeed one day in understanding and curing cancer, and it will be largely due to the existence of gene technology. Birstiel, who is one of the leading figures of a new generation of cancer researchers, expressed his views lucidly in a major brochure Genes and Cancer – Biotechnology in the Service of Cancer Research published by the Deutsches Krebsforschungszentrum, Heidelberg, in collaboration with the Imperial Cancer Research Fund, London, supported by the European Commission.

Showing Europeans new methods in the overall fight against cancer, at genetic level

The article based on his views goes on to discuss the use of the tools of the genetic engineers to seek the molecular events that regulate the growth of healthy cells, but which have got out of control in tumour cells. This article is one of more than 20, designed to show Europeans how new methods are being used in the overall fight against cancer. Examples illustrate possibilities, some already in the pipeline, for the prevention, diagnosis and treatment of cancer.

Illustrated to the highest standards, the brochure covers subjects such as gene based treatments for cancer, ethical issues raised by cancer genetics, the inevitability of multicellular organisms developing cancer, and how gene diagnosis will radically change the way in which we deal with cancer in the future.

The public urged to take a critical look at the potentials of gene technology and set limits in good time

On ethical aspects, Gordon Dunstan, Emeritus Professor of Moral and Social Theology in the University of London, writes that dealing with genetically modified human hereditary material resembles a balancing act. In order to find a social equilibrium, the public should take a critical look at the potentials of gene technology and set limits in good time. The brochure, of around 60 pages, is published in both German and English.

Details: Deutsches Krebsforschungszentrum

Press and Public Relations Division
Im Neuenheimer Feld 280
D - 69120 Heidelberg
Tel.: (49) 6221-43.36.56
Fax: (49) 6221-42.29.95

For limited numbers, English only, use the Response Form (Item 4).

Information Service Covering Publicly Funded Research Projects in the EU

Data-base contains 7000 projects from 2300 laboratories

An information service covering ongoing and recently completed publicly funded research in the Member States of the EU, under the title BIOREP, has three main objectives. These are: to further scientific contacts; to identify trends; and, to assist in the coordination and planning of research projects.

The data-base contains in excess of 7000 projects from over 2300 laboratories and institutes.

Biotechnology topics include: nucleotide sequences, protein sequences, 3-D structures, European Bioinformatics Network, biomaterials repositories, and horizontal services.

Details: Library of the Royal Netherlands Academy of Arts and Sciences
(Library KNAW)
PO Box 41950
NI - 1009 DD Amsterdam
e-mail: harrie.lalieu@library.knaw.nl
Tel.: (31 20) 6685511
Fax: (31 20) 6685079

or use the Response Form (Item 5).
Also available on World Wide Web:
http://www.knaw.nl/www/bibbron.html.

Intellectual Property Rights over Genome Mapping

A workshop to discuss the impact of intellectual property considerations on genome mapping not restricted to human genome was stimulated by applications from the US National Institute of Health and the UK Medical Research Council for patents covering fragmentary cDNA sequences.

Concerns on IPR and genome mapping can be resolved

The workshop, funded by the European Commission and held in Munich, followed claims over raw data that had raised concerns over the potential conflicts between such claims. Those attending the workshop came believing the issues before them were intractable. However, it appeared, after due consideration that this was not the case: most could be reduced to simple forms and should be readily resolvable.

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

I.3. Regulatory Framework

Directive Covers National and International Transport of Genetically Modified Micro-organisms and Biological Agents

Transport of dangerous goods by road with rail to follow Genetically modified microorganisms and biological agents. National and International transport covered

By 1 January 1997 Member States must implement Council Directive 94/55/EC relating to the approximation of the laws of Member States with regard to the transport of dangerous goods by road. This Directive lays down in its annexes specific requirements for the safe transport, national and international, of genetically modified micro-organisms and biological agents, which until now have only been recommended for international transport.

An equivalent proposal to cover the same goods in rail transport is under discussion (COM (94) 573).

Details: S. Prout, DG VII
Fax: (32) 2-296.51.96

II. Member States

Ireland

Increasing Strength for BioResearch Ireland

Industrial revenue almost doubled and client numbers increased by 77%

Specific new activities by BioResearch Ireland reported in its annual report for last year include the establishment of a state of the art GMP facility for production of recombinant proteins: the launch of two latex immunoassay products; and the establishment of a collaboration with biotechnology researchers in Northern Ireland.

The report describes another successful year in which turnover reached a level of IR pounds 6 million. Industrial revenue almost doubled and numbers of clients increased by 77 per cent during the period 1992–94. Client revenue came up to 68 per cent of total income. Other income derives from state investing and R&D grants.

The development and competitiveness of Irish industry

BioResearch Ireland was established in 1988 to commercialize biotechnology research in Irish colleges. Its mission statement is "To develop within Ireland, in partnership with the Universities, an R&D structure in selected areas of biotechnology which will contribute to the development and competitiveness of existing industry, attract overseas industry to Ireland and aid in the establishment of technology-driven start-up companies".

It is now part of FORBAIRT, which was established by the Irish government to facilitate the development of Irish business and to provide a range of scientific and technical services and programmes for enterprises in Ireland.

Details: BioResearch Ireland
FORBAIRT
Glasnevin, Ir - Dublin 9
Tel.: (353) 1 8370177/8370101
Fax: (353) 1 8370176

Italy

Italian Cancer Research Institute Offers Catalogue of Cell Lines Collected from all over Europe

National Institute for Cancer Research collaborates with Advanced Biotechnology Centre

A series of data-bases of biomedical interest, such as human and animal cell lines, human B lymphoblastoid cell lines and synthetic oligonucleotides, has been set up by the National Institute for Cancer Research of Genoa, Italy, (istituto scientifico per lo studio e la cura dei tumori) working together with the Advanced Biotechnology Centre. This latter is an interdisciplinary group of researchers, including medical doctors, biologists and electronic engineers.

Cell Line Data Base for human and animal cell lines

The information has been collected from Italian and European laboratories and cell banks. The data-bases are available on-line, and catalogues have also been produced, available as a printed record and as an electronic catalogue for PCs (IBM compatible).

One of the data-bases, called Cell Line Data Base (CLDB), contains detailed information on the origin, function, optimal culture methods, availability in cell banks and laboratories of human and animal cell lines. The catalogue contains complete information on 2 650 cell lines, including the cell lines collected in the two main European banks, the European Collection of Animal Cell Cultures (Porton Down, UK), and the DSM Collection of Human Cell Lines (Braunschweig, Germany) , and other important collections mainly related to inherited diseases. More than two thirds of the Cell Lines are said not to be described in other commercial catalogues.

Hybridomas and other immunoclones are not described in the CLDB because information in this field is widely available in Europe through the ImmunoClone Data Base. This project, co-ordinated by the Centre Européen de Recherches Documentaires sur les Immunoclones (CERDIC, c/o CICA, 2229 route des Crêtes, Sophia Antipolis, F - 06560 Valbonne, France) and funded by the European Community, involves seven European partners.

Details: Dott.ssa Tiziana Ruzzon
IST
Istituto scientifico per lo studio
e la cura dei tumori
viale Benedetto XV, n. 10
I - 16132 Genoa
Tel.: (39) 10 35341
Fax: (39) 10 352999

The Netherlands

Preparing for the Next Century

Strategic view for the future of the biotechnology industry

Evidence of determination to hold on to its place at the forefront of biotechnology is displayed by the Dutch nation with the production of a high quality document entitled Holland Biotechnology – in preparation

for the future. Beautifully illustrated, the publication, which gives outline profiles of members of The Netherlands Industrial and Agricultural Biotechnology Association (NIABA), gives a strategic view of various aspects of the industry.

Chapters cover the subjects of: research; the environment; plant breeding; animal breeding and reproduction; selected aspects of medical biotechnology; and biotechnology for the agro-food industry.

Clearly, the publication is aimed to some extent at the educated and highly educated layman. It explains that Holland is now entering a push-pull transition stage. For the biopharmaceutical field, this has, it is stated, already become apparent for several years. During that period, more and more novel biotechnological products were introduced into the market. However, for a cluster of agro-food application sectors, the country is now only at the beginning of the same transitional stage. Here, the first products are now leaving the development stage and are being marketed. This follows the necessary approvals for market introduction on the basis of safety assessments for both people and for the environment.

Greatest challenge is to achieve public acceptance

In this transitional stage, the greatest challenge is to achieve public acceptance of biotechnology per se. The publication points out that only when the general public can make free, well educated choices in favour of novel biotechnology products will the market really open up. Holland Biotechnology, in preparation for the future is edited by E. Roelofs and published by Two Rivers.

Details: Two Rivers B.V.
Or. Lelyweg 50b
NI - 2031 CD Haarlem
Tel: (31) 23 420601

For limited numbers, use the Response Form (Item 7).

United Kingdom

British Government Initiative to 'Sell' Biotechnology to UK Industry

Biotechnology means business opportunities for profit and growth. So tersely expressed, this is the theme of an information pack issued by the British Government Department for Trade and Industry (DTI). The kit, which contains a leaflet, a folder, and 14 factfile two-page texts, is clearly aimed at encouraging various sections of British industry to take the subject more seriously.

Market forecast of £60 billion by year 2000

The DTI explains that industrial competitiveness is fundamental to the UK's future economic prospects. The DTI is actively promoting and facilitating improvements in industrial competence through a range of measures. These include the "BMB" (Biotechnology Means Business) project. It states that a market forecast sees biotechnology activity to have grown to in excess of Pounds 60 billion world-wide by the year 2000.

After a three year pilot study, the BMB initiative is addressing identified problems of awareness, technology transfer and implementation. It continues that to transfer technology, advances into practical processes take investment, advice and expertise. A task of the BMB is to steer British business through this process, to introduce biotechnology into business as simply and speedily as possible.

Increasingly stringent environmental legislation

On the subject of the environment, the BMB states that one reason why industry is having to change and innovate at present is the increasingly stringent legislation in the UK, European Community and beyond. New standards of health and safety, labelling , emission control, environmental impact and product quality mean that traditional industry processes are becoming increasingly unacceptable.

New biotechnological solutions, continues the organization, already exist in many areas to meet and exceed the regulatory requirements. Now they are available to be taken up by companies that want to stay competitive. Broadly speaking, biotechnology tends to be "greener" than traditional methods. By using naturally occurring systems to replace more harmful technologies, environmental damage is kept to a minimum.

The initiative includes a helpline, to offer advice, and to point business in the right direction. It is also organising a series of introductory seminars, to enable business to find out more about the potential applications and benefits of biotechnology in manufacturing, quality control and waste treatment.

Information pack available

Details: BMB Initiative
Department of Trade and Industry – LGC
Queen's Road, Teddington
GB Middlesex TW11 OLY
Tel.: (helpline) (44) 1 800 432100
Fax: (44) 1 81 943 7304

GenEthics News and the Splice of Life not to be confused!

The newsletter, GenEthics News, referred to in EBIS Vol 5, no. 1 of June 1995, as being launched by Mr. David King, is not published by The Genetics Forum, as could have been inferred. The Genetics Forum, a public interest group on genetic engineering issues in the UK, requests EBIS to point out that it does, however, publish The Splice of Life, which is aimed to present a lively, challenging and alternative view of the direction being taken by the new biotechnology. Mr. David King, who was reported as having launched GenEthics News, is described by The Genetics Forum as having ceased to work for that organization.

Details: The Genetics Forum
5–11 Worship Street
GB - London EC2A 2BH
Tel.: (44) 171 638.06.06
Fax: (44) 171 628.08.17

III. International Developments

Convention on Biological Diversity: Open-ended *ad hoc* Group of Experts on Biosafety

Meeting in Madrid to prepare for the 2nd COP in Jakarta

At the invitation of the Government of Spain a meeting of the open-ended *ad hoc* group of experts on biosafety met in Madrid from 24–28 July 1995. This *ad hoc* group was established by the first conference of the Parties (COP) to the Convention on Biological Diversity (December 1994) to consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advanced informed agreement, in the field of the transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity. Prior to the meeting a panel of 15 government-nominated experts had met in Cairo from 1–5 May 1995 to prepare a background document for the consideration of the *ad hoc* group. The report of the *ad hoc* Group will be considered by the second COP from 6–17 November 1995, Jakarta, Indonesia.

Worldwide importance attached to biotechnology safety

More than 80 countries and the European Union were represented at the meeting; a host of United Nations bodies and specialized agencies; and a large number of non-governmental and industry groups, indicating the world-wide importance that is now attached to the safety of biotechnology.

Immediate need for international action to achieve safety of LMO's derived from modern biotechnology

The report produced by the open-ended ad hoc Group stresses the immediate need for international action to achieve adequate safety of living modified organisms (LMO's) resulting from modern biotechnology. A large majority of delegates favoured the development of a protocol while some wanted a step-wise approach. Some did not yet have a position on whether there is a need for a protocol or not but all highlighted the urgent need to give attention to the issue of transboundary movement of LMO's resulting from modern biotechnology, including the consideration of the form and scope of advanced informed agreement of such organisms.

EU supports two-track approach of guidelines under UNEP and the consideration of the need for and modalitites of a protocol under the Convention on Biological Diversity

The European Union at the time of writing is developing a common position but common minimum views support the two-track approach of non-binding guidelines in the UNEP context and the consideration of the need for and modalities of a protocol under the Convention on biological diversity.

Details: M. Jörgensen, DG XI
Fax: (32) 2 2969557

The Biosafety Results of Field Tests of Genetically Modified Plants and Microorganisms: Proceedings of the 3rd International Symposium November 13–16 1994, Monterey, California

Monterey: 20 years after Asilomar

Under the auspices of the US-EC Task Force on Biotechnology Research this third International symposium attracted more than 225 participants from 32 nations. The second Symposium had been held in Europe (Goslar, Germany, see EBIS 2.4, page 14). The proceedings of the Monterey Symposium have now been published to ensure that the results of biosafety research are widely available and understandable.

6 Panels address key biosafety issues

Following a keynote address from A.F. Deshayes of France 6 Panels addressed the following topics:

Panel 1. Are risks scale dependant?
Can small-scale results be extrapolated?
Are longer-term effects an issue?

Panel 2. Are there unique risks when testing in centers of diversity?

Panel 3. Are there unresolved issues regarding the possible generation of new viral pathogens from transgenic plants?

Panel 4. Experiences with microorganisms.

Panel 5. Does classical toxicology offer a useful perspective in assessing the food safety of products produced by biotechnology?

Panel 6. Experiences in approaching commercialization of transgenic crop plants .

Panel 7. Experiences with new and unique organisms and products.

Biosafety in China and Japan

Included in the proceedings are the texts of two luncheon addresses on biosafety in China and the safety assessment system of field tests in Japan; the Panel moderators' summaries of the conclusions and the poster presentations made during this important event.

The proceedings are available without charge (limited numbers) (Use the Response Form, Item 8).

Commercialisation of Agricultural Products

A review of national, regulatory policies on the introduction to the market of agricultural products derived through modern biotechnology was the focus of an OECD workshop hosted by the USA at Washington, D.C.

Harmonisation of regulations for introducing new foods to the market

The objectives were: to improve awareness and understanding of the various systems of regulatory oversight developed for agricultural products of biotechnology; identify similarities and differences in the various approaches; and identify the most appropriate role for OECD in further work towards harmonisation of these approaches. Eighty experts in the areas of environmental biosafety, food safety and varietal seed

certification participated, representing 24 countries and other international organizations.

Commonality requirements for safety

Effort was given to "horizontal linkages", in other words, finding commonality in the data requirements that exist within the three review systems, of environmental biosafety, food safety and varietal seed registration and certification. Other effort was given to "vertical" harmonization, within a specific sector of review, such as environmental biosafety or food safety.

Details: OECD
rue André-Pascal
F - 75775 Paris Cédex 16
Tel.: (33) 1-45.24.82.00
Fax: (33) 1-45.24.97.67

Resolution for Changing Legal Framework on Genetic Engineering

ESF = European Science Foundation

A set of guidelines for use when changing the legal framework concerned with genetic engineering has been drawn up by the European Science Foundation, based in Strasbourg.

Points include:

- The legal framework for the contained use of genetically modified microorganisms should differentiate the relevant procedures more effectively in accordance with their risk potential.

- The definition of criteria for operations with such microorganisms would benefit from a new and workable risk assessment based approach which should be developed in consultation with academic and industrial research scientists.

Guidelines on how the legal framework should be changed without compromising safety

The regulations concerning field trials with genetically modified organisms should be simplified. The European Science Foundation, which represents 55 member research councils, academies and institutions devoted to basic scientific research in 20 European countries, underlines that the amendments that they propose in the Resolution do not create any unacceptable increase in risk to human health and the environment.

Scientific case for amending the Directives

The Foundation urges the European Commission to provide for an amendment of the legal framework on genetic engineering. It calls for adaptation of the directives to reflect the state of the art in research and technology reached since the promulgation of the two Council Directives (90/219/EEC and 90/220/EEC) which could effectively improve the conditions for research and industry in the field of strategic importance for Europe.

Details: European Science Foundation
1 quai Lezay-Marmésia
F - 67080 Strasbourg Cédex
Tel.: (33) 88.76.71.17
Fax: (33) 88.76.71.17

or use the Response Form (Item 9).

Response form

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