

EBIS

EUROPEAN BIOTECHNOLOGY INFORMATION SERVICE

Vol.3 no. 4

N E W S L E T T E R

Editorial: Openness — The Case of Biotechnology

Commission increases openness in its workings

As you are probably aware the European Commission has during recent months taken a number of initiatives to increase further openness in its working. It has relaunched its information and communication policy and has taken measures to make wide consultation on its proposals possible, the latter, in order to ensure that the Commission can deliberate in full knowledge of the range of opinions existing in the Community. A number of existing practices have been reinforced such as making greater use of green and white papers, hearings and seminars. A new notification procedure has been introduced which involves the publication of a brief summary of proposed policy initiatives in the Official Journal. Policy initiatives in the legislative programme which should have a more extensive preparation will be highlighted and proposals have been made to the other institutions on improvement of access to documents held by them. Through these mechanisms the Commission aims to obtain the necessary (technical) information and constructive advice.

Continued on page 2

Other pages

I. Community Activities (Commission, Parliament, Council)	
BCC holds Round Table	50
1993 Eurobarometer Survey	51
FP4 Life Sciences and Technologies Programme	53
AMICA Project launched	54
EC/China meeting - transgenic plants	55
Manpower and training needs	57
Commission proposal for BST	58
Standards for biotech in Europe	59
II. Member States	
EFB — Safety in biotechnology Working Party	60
Belgium — Animal cell lines	61
Italy - Biotech' 94	61
The Netherlands — Agricultural biotechnology	61
United Kingdom — House of Lords report	62
III. International Developments	
OECD: scientific basis for safe scale-up	63
WHO: biological standards	64
UNESCO: bioethics	64
UNEP: biodiversity convention	65
UNIDO: ICGB	66
USA: Biotechnology for 21st Century: Realizing the Promise	67
Russia: seeks international advice	68
IV. Books: Reports Received	
Agricultural biotechnology in Developing Countries	69
Russian transgenic plants	70

EUROPEAN
BIOTECHNOLOGY
INFORMATION
SERVICE

**Successful access policy
already in place for
biotechnology**

In the light of these developments, it is worthwhile to consider the present situation on the preparation of files related to biotechnology. Important transparency tools are already in place. EBIS is an example, with a readership which has grown over 3 years to more than 6000. Through the EBIS Response Form it is possible to obtain relevant policy documents. Several hundred Response Forms are returned each issue and some 3000 documents have been mailed so far this year through EBIS. Furthermore, there is BIODOC, the documentation centre in Square de Meeus, Brussels, where information on biotechnology published over recent years is held and made available to interested persons. Numerous newsletters for the various EC research programmes are also produced.

**Legislative proposals widely
debated.**

Openness also applies to the preparation of legislative proposals. A good example of this has been the development of criteria for the application of simplified procedures for the release of genetically modified plants (see EBIS 3.3). Quite a number of consultative meetings were held with representatives from Member States, Industry, non-governmental organisations and academia before the Commission tabled its proposals to the Committee of Representatives of the Member States. Another example is the preparation of the legislation on novel foods. Numerous Committees and expert groups have been consulted (Food Advisory Committee, Advisory Committee on Distribution, Consumer Consultation Council and several national experts). The Commission's Biotechnology Coordination Committee (BCC) has held several Round Tables to discuss various aspects of its biotechnology policy with non-governmental organisations and industrial associations, the latest of which is reported in this issue (pages 50 and 51).

**BCC holds several Round
Tables**

**EFB = European Federation of
Biotechnology; ESNBA =
European Secretariat of National
Bioindustry Associations; FOE =
Friends of Earth; Greenpeace;
SAGB = Senior Advisory Group
for Biotechnology
Commission will listen,
maintain dialogue and find a
useful way forward**

Based on past experience, it is clear that Europe's citizens rightly expect Community policies to be open and the product of wide consultation. The Commission considers that each public authority and interest Group such as EFB, ESNBA, FOE, Greenpeace, SAGB has to be responsible for defending their own corner and protecting their own interests. It is up to the Commission to listen, to maintain dialogue and to find a useful way forward. Proposals for further transparency initiatives in the field of biotechnology where so many interests and sectors are involved would be welcomed. Understanding, trust and acceptance by the public will only be built on openness, transparency and dialogue which are all EBIS objectives.

I. Community Activities (Commission, Parliament, Council) —

Commission Holds Round Table on the Community's Regulatory Framework

**BCC round table for an open
exchange of views**

On 28 September 1993 Commission staff met with a number of representatives from industry, trade unions, consumer and environmental organisations and academia to discuss the EC's regulatory framework for biotechnology.

**Developments with the 90/219
and 90/220 Directives and with
product legislation**

The Commission gave an overview of recent developments related to the Directives on the deliberate release of genetically modified organisms (Dir. 90/220/EEC) and the contained use of genetically modified microorganisms (Dir. 90/219/EEC).

The Commission's proposal for a Commission Decision establishing the criteria for simplified procedures for experimental releases of genetically

modified plants had been given a unanimous favourable opinion by the Committee of Member States.

The next step towards simplification of the procedures would be the submission of specific proposal(s) for simplified procedures by the Member States, which would be judged against the established criteria. It was expected that the adoption of specific simplified procedures could take place in time for the next planting season.

The Commission also reported on another major area of activity concerning the review of the Annexes of Directives 90/219/EEC and 90/220/EEC. Work had already started in collaboration with experts from Member States, Industry and Academia with the aim of adapting them to technical progress and the needs of the users.

Working within the existing framework to simplify procedures where it is safe and responsible to do so

Mr. David Williamson, Secretary-General of the Commission and Chairman of its Biotechnology Coordination Committee identified the Commission's main priorities as follows:

- (1) to ensure full implementation in all Member States of existing legislation;
- (2) to act within the existing legislative framework to simplify procedures wherever this is possible, i.e., when experience suggests it is responsible to do so.

In so doing, the Commission was implementing the policy commitments made in the 1991 Communication on competitiveness for biotechnological industries.

For a report of the Round Table, use the Response Form (Item 1).

Second Eurobarometer survey on awareness and attitude about biotechnology

Through the Commission's Eurobarometer survey, the horizontal activities of the Biotechnology Programme have financed the second EC-wide public opinion poll on biotechnology, organised by INRA (International Network of Research Associates).

One of the major goals was to identify trends with respect to the first biotechnology survey of March 1991 (see EBIS 4, July 1991, p. 15). Again, 12,800 persons have been interviewed: 1000 per Member State, except Luxembourg (500), plus an extra 1000 for the former East Germany and 300 for Northern Ireland.

The questionnaire was identical to that used in 1991 with two exceptions:

- (a) the block of questions concerning people's factual knowledge was modified in order to have a better tool to measure the possible correlation between knowledge and attitude,
- (b) questions have been added on people's ethical concerns.

A first analysis shows the following results:

- People were asked whether they believe in a positive contribution from some modern technologies to life and living conditions. There was a modest decrease in all cases (on a scale from -100 to + 100) - with the exception of biotechnology: here the affirmation value dropped from 55 to 45 in Europe as a whole, and in Germany even further from 44 to 17. Only Denmark is maintaining its rather sceptical value of 26 points.

- People were confronted with 12 scientific/technological statements such as "It is possible to change the hereditary characteristics of plants, enabling them to create their own defence against certain insects" or "There are test tube babies which develop entirely outside the mother's body" and were asked whether the statements are true or false. To 9 questions a majority of people gave correct answers. Though the issue of test tube babies provokes much public awareness and a lot of discussion, a majority of people gave incorrect answers to the question concerned. This may open speculation as to whether public attitudes are based on feelings rather than factual knowledge.
- People were confronted with 7 different applications of biotechnology relating to plants, microorganisms, food, medicines, etc, and were asked whether (a) research in the field should be promoted, (b) research may invoke risks to human beings or the environment and (c) research needs to be controlled by the government. In all cases where the awareness of risks increased from 1991 to 1993 in Europe (i.e. in all cases except "Farm Animals") then the support for research diminished (except for "medicine" where a higher risk perception stimulated the support for research). Strongest rejection comes from Germany. In all cases there is some increase in risk perception, combined with a decrease of readiness to support research. Germany and Europe as a whole (with the only exception of "food") have a decreasing demand for government control, whereas Denmark wishes for stronger control in all cases. In the light of generally held higher risk perception, this cannot mean that people outside Denmark think there is no need for control. It may reflect the considerable decline in people's confidence in public authorities (from 20 to 17 in Europe as a whole. In Germany even further, from 28 to 16. But an increase from 39 to 45 in Denmark). The reduced demand for public control therefore, may result from a reduced trust in those who do control.
- As to the trust of people in the various organisations which act as source of information, the ranking order is unchanged (percentage of people who mention the source in question as the most reliable one). However, there is a polarisation: in all cases high ranking organisations improved their position, whereas low ranking organisations lost some of the confidence formerly placed in them. The columns for Germany and Denmark underline what has been said in the last paragraph.

Who do you trust mostly to tell you the truth about biotechnology ? (% mentioning)

	EC 12		D		DK	
	1991	1993	1991	1993	1991	1993
1. ENVIRONMENTAL ORGANISATIONS	52.6	60.8	64.2	72.0	47.4	44.7
2. CONSUMER ORGANISATIONS	52.3	55.5	63.6	71.0	63.8	60.1
3. SCHOOLS UNIVERSITIES	37.1	38.5	34.1	31.4	38.4	48.2
4. ANIMAL WELFARE GROUPS	29.1	32.2	36.0	40.8	25.5	21.8
5. PUBLIC AUTHORITIES	20.4	16.8	28.2	16.3	38.8	44.9
6. RELIGIOUS ORGANISATIONS	9.7	8.2	12.1	10.9	1.9	1.7
7. INDUSTRY	6.0	5.6	6.0	4.0	5.8	4.8
8. TRADE UNIONS	5.2	5.2	5.7	6.8	4.4	4.6
9. POLITICAL ORGANISATIONS	4.9	4.0	7.3	5.1	3.0	3.0

- Regarding research into biotechnology involving human beings as well as animals and plants, at least three out of four interviewees declare that "there should be clear ethical rules" indicating when research "may not in any way" be undertaken.

The questionnaire, the names of the institutes involved, the various technical details (such as sampling method) and an in-depth analysis of the results achieved will be found in the full report which is available in English or French.

Use Response Form (Item 2).

Details:

O. Diettrich DG XII/E-1

Tel.: (32) 2 29 55 033; Fax: (32) 2 29 55 365

I.1. Research and Related

Commission Reveals Specific Programmes under FP4

Working Document as an aid to advance discussions and establish dialogue

The Commission has produced a Working Document, COM(93)459 final, which reveals its current plans for the contents of the specific programmes under the 4th Framework Programme (1994-1998). An introduction to the Working Document explains that the Commission considers that presenting overall guidelines and plans at this stage should help to advance discussions on FP4 and to establish a constructive dialogue on the content of the specific programmes.

Indicative breakdown between three areas of life sciences and technologies

The section on Life Sciences and Technologies suggests an indicative break down between the three areas that will be addressed as follows:

- Biotechnology (46-50%)
- Biomedical and health research (15-19%)
- The application of life sciences and technologies to agriculture and fisheries (including agro-industry, food technologies, forestries and rural development) (33-37%) amounting to a total of 1265 MECU.

Between 4 and 8% will be allocated to horizontal demonstration activities, and between 1 and 3% to ethical, social and legal aspects.

Ethical, social and legal aspects

To obtain a copy of "Life Sciences and Technologies" section, use the Response Form (Item 3).

Biotechnology Research Programme

Deadline for Biotech Third Call is 15 December, 1993

In EBIS 3.3, p. 34, we incorrectly gave a deadline of 12 January 1994 for the Biotechnology Third Call. The correct deadline is 15 December 1993 as was published in the O.J. No C. 168, p. 17, 19 June 1993.

Proposals evaluated under Second Call.

Proposals received under the Second Call have recently been evaluated and 108 were selected with 467 participants.

Details:

E. Magnien, DGXII-E/1 - SDME 2/84

Tel.: (32) 2 29 59 347; Fax: (32) 2 29 55 365

Agriculture and Agro-Industry Research, including Fisheries (AIR)

Proposals for research and technology development projects and concerted actions are invited for all areas and topics of the AIR Work Programme. The deadline for applications is 14 January 1994.

Details:

F. Rexen, DGXII-E/2. Tel.: (32) 2 29 63 164, Fax: (32) 2 29 64 322

D. Dessylas, DG VI F II/3. Tel.: (32) 2 29 58 612; Fax: (32) 2 29 63 029

W. Brugge, DG XIV C/2. Tel.: (32) 2 29 55 137; Fax: (32) 2 29 57 862.

Finding Partners for the AIR and biotech programmes

It is often difficult to find the right partner in another country for CEC research programmes particularly for small and medium sized enterprises. In order to improve the situation, the RTD Partners Database has been developed on CORDIS (the Community Research and Development Information Service). Since RTD-Partners was launched in 1992, more than 7.600 requests for partners has been entered in the database from organisations located in EC and EFTA countries and a considerable and growing number of organisations consult the database each month.

At the request of many CORDIS users, including the Value Relay Centres, the RTD-Partners data collection team is currently focusing its activities on the third BIOTECH and the AIR (Agriculture and Agro-Industry Research) calls for proposals. The RTD-Partners team is working in collaboration with these programmes to ensure that they are covered extensively and that the database contains a sufficient number of high quality entries to help participants find appropriate partners. In addition, as both these programmes have closing dates about the same time there is sufficient opportunity to ensure that suitable partnerships can be formed.

Each RTD-Partners record allows those seeking partners to give a profile of their organisation including contact details, type and size of organisation and information on their areas of expertise. It also allows those seeking partners to give precise information as to the type of collaboration they are seeking. This can include reference to a specific programme or programmes, specific project interest themes within programmes and type of collaboration sought e.g. participation in calls for proposals, joint venture agreements, etc. An organisation can also specify the type of partner that they are seeking including the type of organisation, the country or the specific expertise sought.

For further information on submitting an entry to the RTD-Partners database please contact:

Allie Menzies,
RTD-Partners Team,
Longman Cartermill Technology Centre, St Andrews KY16 9EA, Scotland, UK.
Tel.: (44) 334 77 660; Fax: (44) 334 77 180

For a password to CORDIS or information on searching the RTD-Partners database please contact:

CORDIS Customer Service Unit, BP 2373, L-1023 Luxembourg.
Tel.: (352) 34 98 12 40; Fax: (352) 34 98 12 48

Or contact your local Value Relay Centre.

“Plant Molecular Biology for an Environmentally Compatible Agriculture”

On 1 November 1993 the Community project with the above title has been launched under the Biotechnology Programme. The 4 signatories of the contract were: John Innes Foundation (UK), Agricultural and Food Research Council (UK), Max-Planck-Gesellschaft zur Förderung der Wissenschaften e.v. (D) and Institut National de la Recherche Agronomique (F) but 117 different laboratories will participate in the project.

This large shared-cost research project provisionally coordinated by the John Innes Institute will receive advice and guidance from a high level multinational scientific board drawn from 8 Member States and known as the AMICA Board.

This mechanism aims at allowing the project leaders themselves to manage coordination of the project while deriving maximum benefit from the integration of the different research groups.

Details:

A. Beadle
John Innes Research Institute
Colney Lane, Norwich NR4 7UH U.K.
Tel.: (44) 60 35 25 71; Fax: (44) 60 35 68 44

Fourth EC Pig Map Meeting, University of Ghent, Belgium, 17–19 June 1993 —

Linkage and physical maps of the porcine genome on target for completion

The Pig Gene Mapping project is a focused collaborative project set up under the BRIDGE Programme as a European Laboratory without Walls (15 laboratories in 9 EC and EFTA countries) plus collaborators working in a further 7 laboratories and 4 countries. The meeting reflected the rapid progress that is possible when a number of laboratories work together on a set of agreed common aims. The main aims of Pig Map are the production of linkage and physical maps of the porcine genome and the project is on target to achieve these aims within its three year time scale.

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

EC/China Meeting on Transgenic Plants

Ten European experts in field release of GMOs met with fourteen Chinese scientists

A workshop on "Application of Agricultural Biotechnology and Safety Considerations" was held under the EC/China Science and Technology Programme at Sanya City, Hainan Island, China, from August 29 to September 4, 1993. Ten European scientists with expertise in the field release of genetically modified organisms met with fourteen Chinese scientists from several leading Chinese institutions. The lectures focused on the release of transgenic organisms and their application in agriculture. Biosafety aspects were especially considered in plans for future cooperative research. It was agreed that harmonised biosafety procedures would benefit both China and the EC, and that an exchange of scientists and scientific experience will help to achieve this goal.

Harmonised biosafety procedures to be achieved in topics of special interest

Topics of special interest were resistance to viruses and fungi in transgenic plants (e.g. papaya, sugar beet, tobacco), insect resistant plants and transgenic microorganisms for practical use in agriculture. Both sides exchanged their experience and identified fields of mutual interest for cooperation in the future.

Details:

Prof. Dr. Rudolf Casper, Workshop Coordinator,
Biologische Bundesanstalt für Land- und Forstwirtschaft,
Institut für Biochemie und Pflanzenvirologie,
Messeweg 11/12, D-38104 Braunschweig
Fax: (49) 531 299 3006.

CEBC — The China—E.C. Biotechnology Centre

The China—E.C. Biotechnology Centre (CEBC) was formed between the Commission of the European communities and the State Science and Technology Commission of the Peoples Republic of China.

The centre became operational in November 1991, situated in Beijing. It plays a triple role and acts as:

- an information exchange/relay centre servicing the biotechnology research communities of both China and the EC (creating, improving and facilitating links and contacts between the scientific communities);
- the coordination and dissemination body in China of all joint China—EC scientific and technical cooperation activities in the field of biotechnology;
- the focal point of assistance for biotechnology industries and companies in China and the EC wishing to establish contacts.

For those of you unable to reach Beijing to visit the centre yourselves, the CEBC publishes a quarterly newsletter - The CEBC Newsletter.

This collects relevant information on the centre's activities, and reports on Chinese and European developments and is available free from the Commission:

Mr. V. Bontosoglou, DG XII
SDME 2/103
B 1049 Brussels
Tel.: (32) 2 2959410;
Fax: (32) 2 296 3308

or: Mr. Luc Vandebon
China-EC Biotechnology Centre
B 7 Zaojunmiao — Haidan District
10081 Beijing, China.
Tel.: (86) 1 408 2084; Fax: (86) 1 532 4342

Financing Innovation under the SPRINT Programme

Since 1984, the Commission of the European Communities through the SPRINT programme have initiated several activities to promote the financing of innovation, amongst which are support for the establishment of the European Venture Capital Association (EVCA), and more recently the Investment Fora and Technology Performance Financing.

Investment Fora aim at introducing innovative small and medium-sized companies from several Member States seeking funding, to financiers also from several Member States seeking opportunities for investment. They are usually two-day events at which a selected number of SMEs give short presentations about their activities to potential investors, notably venture capitalists, but also development finance companies, investment banks and large corporations. The fora are structured to allow adequate time for private meetings between entrepreneurs and investors, in addition to the opportunity for informal discussion during social events. Around 40 companies usually give presentations at each event. The fora also serve to make other EC finance schemes such as Seed Capital, Eurotech Capital and Venture Consort known and facilitate access to them.

SPRINT has recently organised together with the European Venture Capital Association (EVCA) three experimental Fora in Düsseldorf, Amsterdam and Strasbourg. A number of small firms on one side and venture capitalists, investment companies and financial institutions on the other, were invited to attend. These three Fora proved to be highly successful, resulting in the participating firms raising several million ECU in funding within six months of the event.

On the strength of the early Fora, the Commission launched two Calls for Proposals one in 1990 and one in 1992. As a result of the Calls, a number of organisations were chosen to implement the events till the end of 1995. They include, together with the EVCA, innovation agencies in EC Member States, such as ANVAR (Agence Nationale de la Valorisation de la Recherche) in France; CDTI (Centro para el Desarrollo Tecnológico Industrial) in Spain and ENEA (Ente per le Nuove Tecnologie, l'Energie e l'Ambiente) in Italy; as well as national venture capital associations in the host countries and private sector organisations such as ECOTEC Research & Consulting Ltd. Symbion Kobenhavns Forskerby, and International Research Centre for Industrial Cooperation (APRI).

Technology Performance Financing (TPF) is a system through which banks advance funds needed to acquire new industrial technology or services and are paid in function of the results obtained. TPF is based on the system known as "performance contracting" which has been successfully tested in the USA where it is widely used by energy-intensive companies when buying energy-saving technology. The TPF scheme has extended this principle to include other industries where companies might be reluctant to take on new processes because of the perceived technology risk.

TPF means that a supplier would install a new technology and then receive payments from the acquirer, over a 2 to 3-year-period, according to how well the technology has performed against predefined targets. The better the equipment performs, the more the acquirer pays, however "no cure, no pay", also holds.

A key feature of the TPF scheme is the involvement of a third party source of finance. It provides unsecured advance funding to the supplier firm for bridging the gap between installing the equipment with the acquirer and being repaid through a stream of performance payments from the firm acquiring the technology.

The Commission is supporting the scheme by underwriting a proportion of the risk. Typically, the bank will advance a substantial part (e.g. between 50 to 80%) of the cost of the project and will be paid back in several instalments over a period of 2 to 3 years. Payment schedules will be negotiated in function of predetermined targets proving the performance of the technology or services supplied. If the technology does not work as well as stipulated, users need not pay the full amount.

Funding under the TPF scheme is available both to traditional industries looking to incorporate innovative but risky new processes into their plants or systems and to high technology companies which have developed new techniques but are finding resistance from prospective clients. Both the recipient and the supplier must be EC-based firms, and at least one of the two should be an SME.

For the user, the attraction lies in removing the potential risk associated with adopting modern technologies, as well as in reducing the amount of cash needed initially for the project. For the supplier, the main advantage of TPF is a powerful marketing tool for penetrating new markets resistant to change.

Details:

Mr Daniel Janssens,
DG XIII- D4
Tel.: (352) 43 01 34 407; Fax: (352) 43 01 34 544

Or: Jacques Bonnin
SPRINT - Technical Assistance Unit
Tel.: (352) 46 55 88; Fax: (352) 46 55 50

For descriptive brochures on SPRINT Investment Fora and Technology Performance Financing, use the Response Form (Item 5).

I.2. Manpower and Training

FORCE Supports Biotechnology

Public perceptions of biotechnology, communication and company strategy

FORCE is the programme for the development of continuing vocational training under the Task Force "Human Resources, Education, Training and Youth". With support from this programme a Workshop Course on Public Perceptions of Biotechnology, Communication and Company Strategy was held in London, 4-7 October 1993. Topics covered included science communication in its many different forms, written and oral communication and various company experiences and approaches.

It is intended to hold future workshop courses in the Netherlands and Spain.

Details:

Drs P. Osseweijer
Institute for Biotechnology Studies Delft Leiden, NL-2628 BC Delft
Tel.: (31) 15 78 51 40; Fax: (31) 15 78 23 55.

Manpower and Training needs for Biotechnology in North and South Europe in the Nineties

Comett Programme supports BEMET

The proceedings of a conference held by the COMETT II UETP BEMET (Biotechnology in Europe, Manpower, Education and Training — see EBIS 2.1, p. 15) last September have now been published. The aim of the conference was to provide a forum for industry, academia and policy-makers to address the question of North/South European variations in training and manpower needs, science education in schools and higher

education institutions, transnational labour mobility and increased European cooperation in the face of current challenges for Europe in the global environment.

**Few companies in Southern States
Scientists need business management training**

The conference recognised that the private sector in the Southern (less developed) European States is very weak. There are so few companies able to employ biotechnologists that graduates either have to emigrate or change their career paths. A continuing theme was the need for managerial training. It may be more productive to train scientists and technologists in business management than to teach science to managers with backgrounds in economics or law.

To obtain report, use Response Form (Item 6)

I.3. Regulatory Framework

Bovine Somatotrophin (BST)

Marketing and administration of BST may be prohibited for the duration of the application of milk quotas

In its communication from the Commission to the Council and the European Parliament of 16 September 1993 (COM (93) 331 final) the Commission proposes 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.

Council may consider the proposal before end of year

The Council is likely to start discussing the issue before the existing moratorium comes to an end on 31 December 1993.

Cleared by CVMP on scientific criteria

The Commission's proposal points out that in the earlier decision of the CVMP (see EBIS 3.1, p. 7) that two BST containing products satisfied the criteria for authorization of "quality", "safety" and "efficacy" it was recommended that a number of measures should be taken if the product was authorised for use.

Group of ethical advisers could find no ethical objections but required safeguards

Similarly, the Groups of Advisers on ethical aspects of biotechnology (see EBIS 2.1, p. 3) had found that the use of BST to increase lactation in cows is unobjectionable and safe for both humans and animals, provided that a number of measures, rather similar to those identified by the CVMP, are taken care of.

Approval would be contrary to CAP objectives

The Commission, acknowledging that BST satisfies the criteria of quality, safety and efficacy, considers that its approval would conflict with the objectives of the Common Agricultural Policy (CAP), in particular the milk quota scheme introduced since 1984.

BST is a very special case — no message for other biotechnology products

It is under these circumstances that the Commission exceptionally proposes to the Council of Ministers that the present moratorium should be extended for another seven years, the date on which the present milk quota system expires. In this respect the Commission made reference to SEC(91)629 concerning "Promoting the competitive environment for the industrial activities based on biotechnology within the Community" which stated that "It is not the intention to have another systematic assessment in addition to the three criteria. The Commission will normally follow scientific advice. The Commission reserves the right however, to take a different view in the light of its general obligations to take into account other community policies and objectives". We may conclude therefore that BST is a very special case which has required "exceptional procedures". It sends no message as to the regulation of biotechnology products in general.

US FDA approves BST product without requiring labelling

Meanwhile, the US Department of Health and Human Services has recently announced that its Food and Drug Administration (FDA) has approved the new animal drug sometribove, a recombinant bovine somatotrophin product, for increasing milk production in dairy cows. The FDA will not require special labelling of these food products.

To obtain a copy of COM(93)331 final and opinion of Group of Advisers on Ethical aspects of biotechnology on the ethical implications of the use of performance enhancers in agriculture and fisheries, use the Response Form (Items 7 and 8).

Standards for Biotech in Europe

Commission mandate to CEN: 54 standards

EBIS 2.2 (May 1992) reported that the Commission was preparing a mandate for work on biotechnology by the European Standardisation Committee (CEN). A mandate has been prepared and work is now in progress on no fewer than 54 standards in biotechnology with financial support from the Commission.

18 European countries work in TC 233

The work is overseen by Technical Committee TC 233 chaired by Mr. B. Ager. The secretariat is supported by AFNOR, the French standards body and organisation. A well-established procedure exists for the various phases of publication, consultation and voting that lead ultimately to adoption of a European standard. Member countries are the 12 of the European Community, plus the 6 of the European Free Trade Area.

Voluntary standards complement legislation

The work on standards is designed to complement in practical and up-to-date details the general Community legislation. Standards are normally voluntary and recognised as a non-statutory instrument to define technical specifications, codes, methods, etc.

Links with US ASTM and international science

The CEN work is developing links with standards work in other countries, particularly in the USA, when industrial standards are developed through the ASTM (American Society for Testing and Materials), Committee E48 (Biotechnology). Where it touches questions of definition, classification, nomenclature and taxonomy the experts involved (often academics) are expected to be in touch with the relevant international scientific developments.

Up-to-date and realistic

Through its extended international network of experts involved in current research and practice, CEN ensures that its work is up-to-date and realistic. Community legislation can thus be brief and robust, and avoid seeking to enshrine in the concrete of legislation details specific to perceptions and technologies prevailing when legislation was drafted.

4 sub-groups

The CEN work is being pursued through 4 sub-groups, titles and convenors as follows:

1. Laboratory equipment. Convenor: R. Clark, UK.
2. Large-scale production. Convenor: Mme F. Normand-Plessier, F.
3. Field release. Convenor: A. Deshayes, F.
4. Equipment (20 standards). Convenor: P. Hesselink, NL.

For fuller details, please contact the Convenors, the TC chairman or the AFNOR secretariat at the addresses below. For a fuller overview of the work and a list of the 54 standards being developed, see the articles by Brian Kirsop (UK) cited below.

Recent articles

Articles by Brian Kirsop: "Development of European Standards in Biotechnology", *Pharmaceutical Technology International*, Sept 1993, pp. 36-44. "European Standardisation in Biotechnology", *Trends in Biotechnology*, Sept 1993, pp. 375-377.

Details:

Secretariat:
Sophie Schmitt,
Chimie et Ecologie
63, Boulevard des Invalides
75007 Paris
Tel.: (33) 1 43 06 63 27
Fax: (33) 1 43 06 18 65

CEN TC
Chairman: Brian Ager
SAGB,
Avenue E. Van Nieuwenhuysse, 4, bte 1
B-1160 Brussels
Tel.: (32) 2 67 67 285
Fax: (32) 2 67 67 288

II. Member States

European Federation of Biotechnology (EFB)

EFB bringing together academic and industrial scientists

The EFB is a federation of 60 Learned Societies throughout Europe. It has some 10 working parties (e.g. Safety, Public Perception, Education, Environmental Biotechnology) usually combining scientists from both industrial and academic backgrounds.

Safety in biotechnology working party seeks personal corresponding members

The Working Party "Safety in Biotechnology" met on 21 September 1993 at Amsterdam under the chairmanship of H. Lelieveld of Unilever. The Working Party wishes to have more personal corresponding Members who are kept informed on activities and developments in the area of Biosafety.

Details:

Working Party Secretary
O. Doblhoff
Institute for Applied Microbiology
University of Agriculture
Nussdorfer-Lände II
A-1190 Vienna, Austria
Tel.: (43) 1 36 92 924 40 201 464
Fax: (43) 1 36 92 924 400

Critical Issues affecting bioproducts recovery

The Working Party on Downstream Processing has recently published a book on Recovery of Bioproducts giving the current state of the art. It identifies key areas where improvements are required in order to achieve more cost-effective processes. Other issues covered include bio-safety, validation, effluent treatment and equipment and systems standardisation.

Available at price UK £ 25 from:
SCI Publication Department
14/15 Belgrave Square
London SW1 8XPS
Fax: (44) 71 823 16 98

"Patenting Life" paper available

The Task Group on Public Perception of Biotechnology has produced a briefing paper entitled "Patenting Life" as the first in a series.

To obtain "Patenting Life", use the Response Form (Item 9) .

Belgium

BCCM Patent Deposits of Animal Cell Lines and Genetic Material

BCCM = Belgian Coordinated Collections of Microorganisms

Since 31 August 1993, the Belgian Coordinated Collections of Microorganisms (BCCM) is the third European centre recognised as an international authority for the deposit of animal cell lines, including human cell lines, genetically modified cell lines and hybridomas, within the framework of the international patent legislation (Budapest Treaty).

Scope for deposit of plasmid and other genetic materials

Moreover, the scope for deposits of genetic material has been broadened to any kind of plasmid or genetic material, including for example RNA and oncogenes. The material — recombinant or natural — may be presented either within a host or in purified form, as long as its preservation does not cause any major technical or biosafety problem.

Details on the practical procedures can be obtained from:

The LMBP Collection,
Laboratory of Molecular Biology, University Ghent.
Tel.: (32) 9 264 51 45; Fax: (32) 9 264 53 48

Italy

BIOTECH '94: Biotechnology Against AIDS
From Basic Science to Diagnosis and Therapy
11-13 April 1994, Florence.

Details:
CLAS International, Via Pace, 8, 25122 Brescia
Tel.: (39) 30 37 72 712; Fax: (39) 30 29 32 82

The Netherlands

Agricultural Biotechnology — Future Developments

Recently the Dutch Minister of Agriculture outlined his views on future developments of agricultural biotechnology in the Netherlands.

The Minister proposed in a white paper that a three track approach to agricultural biotechnology should be taken, namely to increase dialogue between the public and the government on biotechnology including reinforced efforts to facilitate public debate on the issues at stake; a continued policy on risk assessment of biotechnological applications and a strengthened innovation policy.

Dialogue between public and government needed

The note expresses the importance of consulting with public interest groups at an early stage in the preparation of policy measures. This is of prime importance for biotechnology where so many different sectors are involved.

Product legislation at national level if insufficient community progress

It is recognised that the prime responsibility for regulatory oversight of biotechnology is at Community level. The Minister stressed the urgent need for product legislation and will make efforts to progress the adoption of such legislation at EC level. National legislation will be considered if insufficient progress is made at the Community level.

Innovation to be encouraged

Further incentives for the development of biotechnology is necessary. Research programmes will be funded and priority areas will include the development of disease-resistant plants and nitrogen fixation. Additional financial resources will be allocated to improve the biotechnology research infrastructure and to stimulate public discussion on the ethics of biotechnology and the potential risks.

Budget defined

A total budget of 41 million DFL for 1993, 1994 and 1995 has been allocated to implement the policies concerned.

Details: Ministry of Agriculture,
Nature Conservation and Fisheries,
PO Box 20401, NL-2500 EK The Hague
Tel.: (31) 70 37 92 023; Fax: (31) 70 34 77 619

United Kingdom

Regulation of the United Kingdom Biotechnology Industry and Global Competitiveness: House of Lords Report

UK House of Lords Select Committee on Science and Technology, HL Paper 80. HM Stationery Office, London, 92 pp.; £ 21.00. Volume II - Oral Evidence, and written Evidence received after 30th April 1993, HL Paper 80-II; 264 pp; £ 27.30.

An Independent S&T opinion

The UK House of Lords Select Committee on Science and Technology has issued a report on biotechnology. The report resulting from their extended enquiry into the above topic was released in mid-October following much written and oral evidence.

Vol. I: Facts, opinions, conclusions and recommendations

After a short introduction and executive summary, there is a simple description of biotechnology — description of its applications and economic value, a summary of regulations governing biotechnology, a review of the evidence received and its bearing on competitiveness, an opinion and a summary of conclusions and recommendations.

Vol. II: 264 pages of evidence

A second bulky volume records the oral and written evidence.

The question: Do regulations damage UK competitiveness?

The Committee's enquiry was prompted by allegations that the regulations governing contained use and deliberate release in biotechnology were likely to place UK industry at a competitive disadvantage, particularly in comparison with the US and Japan.

Answer: Investment and I.P.R. also matter

The competitiveness of UK biotechnology is governed by the level of investment in biotechnology and by intellectual property rights as much as, if not more than, regulation.

Regulation critically reviewed

But they also review critically the UK regulations and the Community Directives on which they are based.

Early fears excessive: More selective approach advocated

Their finding is that early fears relating to GMOs in contained use turned out to be unfounded. As a general principle, except where pathogens are involved, they consider separate regulation of GMOs in contained use is unnecessary over what is required by good laboratory practice; and deliberate release of GMOs, except where bacteria or virus vectors, live vaccines or modification of the genome of animals are involved, is not inherently dangerous.

Excessively precautionary approach ignored scientific advice

The UK regulations and EC Directives are therefore said to have taken an excessively precautionary line and the Committee criticises the Community's treatment of scientific advice at early stages of the development of the Directives.

Report calls for exemptions and simplifications

The report calls on the UK government to seek amendment of the EC Directives; and recommends making full use of the possibilities for simplifying procedures for safe organisms. Exemption categories should be developed by experts; existing questionnaires for field release simplified; applications processed in 30 days; academic research exempted from fees.

Public understanding and perceptions emphasised

The report emphasises promoting the public understanding of biotechnology, advocating that because of its implications for competitiveness, the Department of Trade and Industry should be ultimately responsible for ensuring that public perceptions are based on reason and knowledge.

III. International Developments

OECD

Scientific Basis for Safe Scale-up: the OECD "Preamble" Document

"Blue Book" experts work towards applications

The OECD Group of National Experts (GNE) on Safety in Biotechnology was responsible for the 1986 "Blue Book" on recombinant DNA safety considerations. Since 1988 it has worked to update and further develop scientifically sound principles and practices for the application of rDNA organisms.

A "preamble" to set the context

Work is in progress on scientific considerations relating to the scale-up for large-scale field trials of various classes of organisms: agricultural crop plants, bio-fertilisers, etc, but in June 1991, the GNE decided to develop a "preamble" document to set the various initiatives in a general overall context. Safety in biotechnology is achieved by appropriate application of risk/safety analysis and risk management.

Risk/biosafety analysis and "familiarity"

These terms are carefully defined and discussed. Risk/safety analysis is based on the characteristics of the organisms, the introduced traits, the environment into which the organism is introduced, the interactions between these, and the intended application. Knowledge of, and experience with any or all of these provide familiarity, which plays an important role in risk/safety analysis. Familiarity is not synonymous with safety; rather, it means having enough information to be able to judge the safety of the introduction or to indicate ways of handling the risk.

Risk management

Risk management refers to the application of appropriate management to minimise scientifically identified risks. The document, entitled "Preamble to Reports on Scientific Considerations pertaining to the Environmental Safety of the Scale-up of Organisms developed by Biotechnology" is available free of charge, in English or French, from the Biotechnology Unit in the Directorate for Science, Technology and Industry at:

OECD, 2, rue André Pascal, 75775, Paris Cedex 16
Tel.: 33.1.65.26.93.35; Fax: 33.1.65.26.18.25

or use the Response Form (Item 10).

WHO International Laboratory for Biological Standards

Development and establishment of international standards for biological substances

The National Institute for Biological Standards and Control (NIBSC) is a WHO International Laboratory for Biological Standards. A major aspect of its work is the development and establishment of International Standards for biological substances, an activity which is underpinned by appropriate research and development projects e.g. on the design of novel bioassays.

The Institute also undertakes on behalf of the UK Department of Health and the WHO batch release testing of biologicals including vaccines and products derived from human blood.

Services available from NIBSC include:

- (i) preparation of biological reference materials, including filling into ampoules to high reproductivity and exacting specifications;
- (ii) freeze drying;
- (iii) pilot studies to assess candidate reference materials;
- (iv) testing of biological products.

For further information please contact (in confidence):

The Director, NIBSC, Blanche lane, South Mimms,
Potters Bar, Hertfordshire EN6 3QG U.K.
Tel.: (44) 707 654 753; Fax: (44) 707 646 854

United Nations

UNESCO Holds First Meeting of International Committee on Bioethics, 15-16 September, 1993

UNESCO seeks international agreement on human genome

The United Nations Educational, Scientific and Cultural Organisation has set itself an ambitious task: "the exploratory study of the conditions for the possible drafting of an international instrument for the human genome."

International Committee on Bioethics (ICB) — Chair: Noelle Lenoir

Its chosen instrument, an International Committee on Bioethics, of 47 eminent lawyers, scientists and others; who met in Paris under the chairmanship of Mme Noelle Lenoir, member of France's Constitutional Council, and author of the report which preceded the three laws now in debate in the French Parliament.

Federico Mayor defends research freedom

UNESCO Director-General Federico Mayor opened the first meeting with a speech emphasising the need to maintain freedom of research and access to knowledge as well as to control abuses. Mme Lenoir presented the report of the Scientific and Technical Orientation Group, which had worked since December 1992.

Report recommends action, to define status of knowledge, protect man, inform the public

The report concludes that "the time has come to draft an international standard-setting instrument, based on ethical guidelines, concerning:

- the status of knowledge
- protecting the human being
- safeguarding the human species
- educating, training and informing the public."

Patent complexities, risk of stigmatisation?

There was some dissent as to the ICB's ability to address the inter-continental complexities of patent laws and the rationale for focusing on human genome research when existing and simpler science and technology can be and is unethically exploited. But the Committee commands great expertise, among its own members or by invitation, and UNESCO may succeed in developing an instrument commanding respect, without stigmatising the new techniques or knowledge.

Details:

George B. Kutukdjian, UNESCO
Place de Fontenoy, 7, 75007 Paris Cedex
Tel.: (33) 1 45 68 38 14; Fax: (33) 1 45 06 07 72

Biodiversity Convention Debates**Follow-up to Convention on Biological Diversity with biotechnology implications**

The Convention on Biological Diversity was adopted at the "Earth Summit" in Rio de Janeiro, June 1992. Debate on its ratification and follow-up, on its implementation and implications, is pre-occupying policy-makers worldwide, and these policy debates have many implications for biotechnology (see EBIS 3.1, p. 10). We offer below a short selection of the more recent very numerous articles and publications relating to the activities triggered by the Convention, and the issues surrounding it. Beyond the general consensus on the central aim of conserving biological diversity, the issues in debate concern:

EC BRIDGE Programme research

1. funding the Global Environment Facility, and the mechanism for controlling the finance and the choice of scientific priorities;
2. scientific aspects of bio-diversity: how will national inventories be made, how will the international scientific communities (particularly specialists in taxonomy, nomenclature and systematics) be involved cf. the UNESCO — ICSU — SCOPE "Diversitas" project; see EBIS 5, p. 6 for a description of the biodiversity research under the EC BRIDGE Programme;
3. ownership of, and access to, germplasm, and rights (patents or other) over its exploitation, linked with questions of patents in biotechnology relevant to such use (a problem highlighted by the reluctance of the previous US administration to sign the Convention);
4. consideration of the need for a binding international safety protocol covering GMOs harmful to conservation and bio-diversity.

Relevant publications and reports

Of these issues, the third especially concerns Article 16. On germplasm and its exploitation, World Resources Institute has in May 1993 produced the book "Biodiversity Prospecting: Using Genetic Resources for

Sustainable Development", in conjunction with INBIO of Costa Rica; Rainforest Alliance; and ACTS, the African Centre for Technology Studies (see below). The report offers guidelines to policy-makers, industry and researchers on the design of organisations, legislation and contracts for biodiversity prospecting.

A 4-page article in "Biotechnology & Development" (BDM) no. 15, June 1993 (see EBIS 3.1, p. 9), summarises the same issues: "Are the interests of the drug companies compatible with those of the tropical developing countries?". Their article reviews the Merck-INBIO agreement; the US National Cancer Institute's Letter of Intent; and the Biotics-Polybiotika agreement. The last is a specific example of the model agreement developed by Biotics (with Commission co-finance) in the mid-80s for collaborative exploitation of phyto chemical resources.

Differing approaches to biosafety issues

On biosafety, Article 19 of the Convention is open-ended, and the UNEP Panel 4 report divided; between those advocating worldwide extension of a mechanism similar to the EC field release Directive 90/220, and those fearing stigmatisation of biotechnology, and resulting delay to the diffusion in developing countries of the much needed technologies.

"Conference of the Parties" to be held

The panel reports are addressed to the Executive Director of UNEP, Canadian Elizabeth Dowdeswell, who is required to convene a first "Conference of the Parties" (to the Convention); and in preparation for that Conference, an Intergovernmental Committee on the Convention on Biological Diversity has been created. The first meeting, held in Geneva on 11-15 October 1993, will be reported in a future issue of EBIS.

African Centre for Technology Studies (ACTS)

The African Centre for Technology Studies, ACTS, has played a prominent role; organising on 26-29 January 1993 (in co-operation with the Stockholm Environment Institute) an international conference on the Convention — see BDM 14 (March 1993) for a report. Director of ACTS, Calestous Juma, has authored significant books such as "The Gene Hunters: Biotechnology and the Scramble for Seeds" (1987: Zed Books and Princeton University Press) and co-edited "Innovation and Sovereignty: the Patent Debate in African Development" (1989: ACTS). More recently, ACTS has produced a series of "Biopolicy International" booklets, of which the following (all at \$ 7.50 / Kshs 50.00) are particularly relevant:

- No. 2: Genetic Resources and Sustainable Agriculture Creating Incentives for Local Innovation and adaptation, by W.V. Reid;
- No. 3: Conservation and Use of Agro-Ecological Diversity, by J.I. Cohen;
- No. 7: Property Rights, Biotechnology and Genetic Resources, by M.H. Khalil, W.V. Reid and C. Juma.

Address:

A C T S, P.O. BOX 45917, Nairobi, Kenya
Tel.: 25 42 74 40 47/40 95; Fax: 25 42 74 39 95

ICGEB Activity Report — 1992

ICGEB evolves to formal autonomy

The launching of the International Centre for Genetic Engineering and Biotechnology was completed during 1992 and with national ratifications of its status accumulating, this Activity Report forecasts ICGEB autonomy in 1993. Close links will remain with its parent, UNIDO (The United Nations Industrial Development Organisation).

Ambitious research programmes in Trieste and New Delhi

The 117-page report describes components of both Research Programmes. At Trieste, molecular and cellular biology, genome studies, virology, microbiology, protein structure and function, molecular pathology and molecular immunology; at New Delhi, mammalian biology, plant biology and recombinant gene products.

**Collaboration with 11 countries
Involvement in biosafety**

Also described are the Collaborative Research Programme (projects in 11 countries), the Training programme of Fellowships, meetings and courses, and scientific services including biosafety (ICGEB assisted the UNIDO secretariat in developing their Voluntary Code of Conduct on Release of GMOs in the Environment).

Report available free

The report is well produced and gives a comprehensive view of this ambitious and important initiative. Copies of the report (free) can be requested from UNIDO.

Details:

UNIDO's Biotechnology and Genetic Engineering Unit,
Industrial Technology Development Division,
P.O.BOX 300, 1400 VIENNA
Tel.: (43) 121131; Fax: (43) 12307355; Telex: 134412 UN A

USA

Biotechnology for the 21st century — A report by the FCCSET Committee on life science and health

Presidential initiative in biotechnology research

This 90-page report by the Federal Coordinating Council for Science, Engineering and Technology (FCCSET) of the Office of Science and Technology Policy (OSTP) describes the presidential initiative in biotechnology research. The stated goal of the initiative is to sustain and extend US leadership in biotechnology research for the 21st century to enhance the quality of life for Americans and the growth of the US economy.

Four strategic objectives have been developed

The 12 agencies participating in the Biotechnology Research Initiative have developed an integrated research strategy and identified four strategic objectives:

- extend the scientific and technical foundations for the future development of biotechnology;
- ensure the development of the human resource foundations for the future;
- accelerate the transfer of biotechnology research activities to commercial applications;
- realize the benefits of biotechnology to the health and well-being of the population and the protection and restoration of the environment.

4.3 billion US dollars to sustain and extend US leadership in biotechnology research

The Biotechnology activities of the 12 Federal Agencies are included with a FY 94 budget of \$ 4.3 billion. The Biotechnology Research Subcommittee (BRS) has proposed that research related to health and the environment be highlighted in FY94.

Details:

Office of Recombinant DNA Activities, Building 31, Room 4 B II
National Institutes of Health, Bethesda, MD 20892.

Russia

Russian Federation seeks international advice on biotechnology regulation

Russia's National Committee elaborates GMO law for February 1994

Russia's Ministry of Science and Technology Policy has established a National Committee for Elaboration of Legislation for Work with Genetically Modified Organisms (NCLWG). This Committee is chaired by Professor K.G. Skryabin, Director of the Centre for Bioengineering of the National Academy of Sciences; and includes representatives of various interests, including the Ministries of Agriculture and of Ecology.

Agriculture, Science and Ecology Ministries involved

They have been asked to draft a law by end of February 1994, for consideration by the new Parliament of the Russian Federation.

ICGEB brings international experts to Moscow

The Vienna-based International Centre for Genetic Engineering and Biotechnology, at Russia's request, organised on 30th September-1st October in Moscow an international meeting at which Russian scientists and senior political figures - including Vice-Ministers for Science and Technology, for Ecology and for Agriculture - exchanged information and discussed biotech safety and regulatory issues with a group of experts.

Vice-Minister outlines R&D programmes, stresses international links for S&T and for regulation

In a separate meeting, the experts were welcomed by Professor K.M. Dynmayev, first Vice-Minister of Science and Technology Policy, who stressed the importance of international cooperation in R&D and summarised the five main federal programmes in Life Sciences and Technologies:

- New methods of bio-engineering/biotechnology
- Genetics: fundamental problems
- Equipment and reagents, including a teaching programme
- Human genome (with EC, US and HUGO links)
- Bio-diversity (linked to the decisions at the Rio Earth Summit, June 9 — i.e. the Convention on Biological Diversity).

Referring to the group under Professor Skryabin, he emphasised Russia's wish to develop regulations in cooperation with the international community, compatible with international practice, Professor Dynmayev also mentioned the urgency of addressing public information aspects.

Public information debate includes the Church

Debate has been wide-ranging, including also the Church. Public reassurance was a recurrent theme in the sessions which followed, held in the spacious premises of the Shemyakin Institute of Bioorganic Chemistry.

History of regulation; BST on the market

Various speakers referred to the long history of the development of regulations in the former Soviet Union, including the procedures through which products such as bovine somatotropin had been evaluated prior to authorization.

Yeltsin Adviser emphasises risk and no secrecy

A significant intervention was the speech by Professor Yablokov, Adviser on Ecology to President Yeltsin. While biotechnology was not the most important aspect in ecology, it was essential to determine levels of risk, both to men and environment. He noted that in the West, the possible risks of biotechnology became of primary consideration, more than radio-activity. The need for legislation in Russia was absolutely imperative — there would soon be a new Parliament. He stressed the Government's commitment to no-secrecy of information about ecological risks of biotechnology. The international visitors presented their diverse experience.

Common aspects included an emphasis on the dynamic character of the development of biotechnology, and the consequent need for regulations to be flexible and adaptable in scope and in detail. There was general recognition of the need to move towards a sectoral approach, and of the absence of scientific basis for treating rDNA organisms differently from other biological entities.

Flexibility, product and sectoral approach

The consensus was for a product and risk-based approach, considering process only so far as relevant to risk assessment. The pros and cons of multiple laws and of a single law were debated. The Russians were clearly keen to learn from and avoid mistakes that had been made elsewhere.

Transgenic animals, law on variety rights

Other contributions touched upon work on transgenic animals (so far, agricultural species); and upon the recent Russian law establishing property rights for animal and plant varieties (Russia is not a signatory of UPOV, the International Union for the Protection of Plant Varieties).

Documentation for ICSU-COBIOTECH centre and UNIDO-ICGEB-BINAS node

Extensive documentation was exchanged. The Centre for Bio-Engineering is an information centre for Co-Biotech, the Biotechnology Committee of the International Council of Scientific Unions; and has also been designated as a node of the UNIDO/ICGEB Biosafety Information Network and Advisory Service (BINAS). The UNIDO-led guidelines on field release have been translated into Russian.

A report of the meeting was agreed. For this or other information, contact:

Professor K.G. Skryabin,
Director Bio-Engineering Centre
Vavilova Str. 34/5, 117334 Moscow
Tel/fax: (7) 95 135 06 71
E.mail: skryk @ biengi msc su

For details of ICGEB, BINAS, etc, contact:

Dr. George Tzotzos,
ICGEB Science coordinator
Vienna Office, V.I.C., P.O.BOX 300, A-VIENNA
Fax: 43 12 30 73 55; Tel.: 43 12 11 31 ext 43 36

IV. Books Received

Agricultural biotechnology in Developing Countries, A Cross Country Review by John Komen and Gabrielle Persley. ISNAR. 45 pages.

ISNAR country studies: Agricultural biotechnology in developing countries

The International Service for National Agricultural Research with funding from the World Bank and the Governments of Australia and the Netherlands, has undertaken a number of in-depth studies of biotechnology in selected developing countries. ISNAR also conducted, with Australian support, a 4-year study (1988-1992) titled "Agricultural biotechnology: Opportunities for International Development".

"Intermediary Biotechnology Service" implements CGIAR-BIOTASK recommendation

The present report is the first of a series, planned by the "Intermediary Biotechnology Service" (IBS) whose establishment resulted from a recommendation by the Biotechnology Task Force (BIOTASK) of the

Consultation Group on International Agricultural Research (CGIAR). IBS offers a demand-driven, problem-oriented advisory service to make available the expertise of advance biotechnology institutes to the developing countries.

Building biotech capability for half of mankind

Developing countries are investing in infrastructure and human resources to support national biotechnology programmes and adopting policies to facilitate biotechnology R&D in both the public and the private sectors.

This report provides a short, well-organised and informative comparative description of the different approaches taken by the governments of the following 10 countries: China, Colombia, Egypt, India, Indonesia, Kenya, Malaysia, the Philippines, Thailand and Zimbabwe. Between them, they include half the world's population.

Three conditions for success in agro-biotechnology

The report analyses the institutional organisation adopted in the various countries and describes how governments address the issues constraining further development of biotechnology. Major conditions identified for productive programmes include:

- close collaboration between new biotechnology and conventional agricultural research (especially plant breeding) to ensure that new techniques are taken through to new products and field application;
- minimal duplication of expensive equipment and services;
- an effective working environment for well-trained scientists and adequate financial resources.

Institutional arrangements compared

Possible institutional arrangements include:

- establishing a national biotechnology agency to coordinate and fund biotechnology within existing institutions and to determine national policies;
- stimulating research at designated centres of excellence;
- creating a national biotechnology institute.

The report discusses the advantages and disadvantages in the context of specific countries and emphasises the importance of private sector involvement and finance.

For information about IBS and availability of this succinct and valuable report, contact:

Dr. Joel Cohen,
Project Manager, IBS, ISNAR,
P.O.Box 93373,
2509 AJ The Hague,
The Netherlands
Tel.: (31) 70 349 61 00; Fax: (31) 70 381 96 77

Plant Biotechnology and Molecular Biology

Russian plant science

The following three reports, all on the above subject, are available on request to the CO-BIOTECH Information Centre, at the Bio-Engineering Centre of the Russian Academy of Sciences:

1. First Symposium "Trends in Plant Biotechnology", USSR, November 20-22, 1991, 223 pp.
2. Second Symposium "Trends in Plant Biotechnology", Russia, May 18-20, 1993, 482 pp.
3. "Plant Biotechnology and Molecular Biology, the Latest Bioengineering Methods", Moscow, 1993, 105 pp.

Editor-in-chief for each of the collections of papers is Academician K.G. Skryabin, Director of the Centre.

Symposium reveals Russian transgenic plant research

The two symposium reports comprise the collected abstracts, in Russian and in English, of the papers presented, almost all from scientists in research institutes of the countries formerly comprising the USSR.

The 1991 Symposium lists 71 papers organised into five sections:

1. transgenic plants resistant to viruses, herbicides and insects (53 papers);
2. plant cell technologies (40 papers);
3. chromosome technology (2 papers);
4. plant molecular biology (21 papers);
5. problems of transgenic plant regulations (2 titles, no abstracts).

The 1993 Symposium lists 217 papers organised into five sections:

1. transgenic plants (58 papers);
2. plant molecular biology (37 papers);
3. plant cell technologies (82 papers);
4. plant chromosome technologies (34 papers);
5. progress in plant molecular biology and bioengineering in CIS (4 titles, 2 abstracts).

The third report is a review containing nine articles, including illustrations, on current problems of modern plant gene and cell engineering, together with a "Chronicle" section giving information on the Biotechnological Academy of Research, the CO-BIOTECH Information Centre and the Institute of Cell Biology and Genetics of the Academy of Sciences of Ukraine.

The reports are available without charge but subject to availability of stocks from:

Professor K.G. Skryabin,
Bio-Engineering Centre,
Vavilova Str. 34/5,
117334 Moscow
Russia
Tel/Fax: (7) 95 135 06 71

Response form

To order items mentioned in the text, please tick below and fax or post page to editor at address below:

1. BCC Round table Report
2. 1993 Eurobarometer survey (indicate French or English)
3. Life Sciences and Technologies in FP4
4. Fourth Pig Map meeting report
5. SPRINT descriptive brochures
6. Manpower and training needs report
7. Commission communication on BST
8. Opinion of Group of Ethical Advisers
9. "Patenting Life" briefing paper
10. OECD "preamble" document

European Biotechnology Information Service

Volume 3, issue 4
December 1993

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

Your name and address (please print clearly)

Name _____

Address _____

Editorial Board

A. Van der Meer (Secretariat General), O. Rohte, K. Schreiber (DG III),
J. Connell (DG VI), J. Kioussi (DG XI), M. Lex (DG XII)

Editor

M.Lex DG XII/E-1 SDME 2/65
Commission of the European Communities
Rue de la Loi, 200
B-1049 Brussels, Belgium
Tel.: (32) 2 29 65 619, or (32) 2 29 56 736
Fax: (32) 2 29 55 365, or (32) 2 29 64 322

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