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EBIS

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NEWSLETTER

Editorial: Biotech in Europe and in the US

BCC comparative report on EC/US regulatory frameworks indicates similarities

This issue (page 2) reports on a study being carried out by the Commission Biotechnology Coordination Committee (BCC) to compare the EC and US regulatory frameworks and biotechnology research efforts. This fact-finding exercise has revealed that, contrary to popular perception, overall procedures in the EC and the US are remarkably similar in respect of deadlines, data requirements and risk assessment. Furthermore, at the present stage of biotechnology development, practical experience indicates that most field releases carried out in the EC and the US were covered by the respective regulatory frameworks.

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Other pages

EUROPEAN BIOTECHNOLOGY INFORMATION SERVICE

Commission of the European Communities

Differences in EC/US regulatory frameworks revealed

The differences between the EC and the US are in the approval of the pre-marketing, R&D stages where the US scope is different and provides greater flexibility. At the marketing stage, the major difference identified is that the US has no equivalent to the Community's commitment to the "one door, one key" procedure (see Commission Communication on industrial policy for biotechnology, April 1991, EBIS 3, page 3).

Worries about "brain-drain" and loss of R&D capital to US

On the research front it is clear that R&D expenditure in the US is far greater than in the Community and its Member States combined. Without increased Community funding and improved Community/Member State collaboration the European Science base could further suffer. The "brain-drain" of skilled researchers and R&D capital remains of real concern.

New US administration to "remove obstacles and reduce cost of regulatory compliance"

American biotechnologists now worry that the new US administration may change direction in its approach to biotechnology regulations. Recently, a first re- assuring indication was given in the President and Vice-President's 22 February 1993 statement "Technology for America's Economic Growth".

The Clinton administration acknowledges that "Regulatory policy can have a significant impact on the rate of technology development in energy, biotechnology, pharmaceuticals, telecommunications and many other areas". They commit themselves to "review the nation's regulatory 'infra-structure' to ensure that unnecessary obstacles to technical innovation are removed and that priorities are attached to programs introducing technology to help reduce the cost of regulatory compliance".

Meanwhile, in the Community work has started on how the inherent flexibility of the EC Directive on Deliberate Release of GMOs to the environment can be exploited by introducing simplified procedures in those cases where sufficient experience with the release of GMOs has been obtained.

Apologies to all our readers for the delay in producing EBIS 3.1. We plead pressure of other work and hope to do better in 1993.

I. Community activities (Commission, Parliament, Council)

I.1. BCC compares EC/US regulations and research

BCC compares US and EC regulations and research

The latest report from the Commission's Biotechnology Coordination Committee (BCC) compares the regulation of biotechnology and Research and Development efforts in the EC and the US. It is an interim report of a consultative nature and comments from interested persons should be sent to the BCC secretariat (see below).

The report considers only EC and US regulations on releases of plants, microorganisms and microbial pesticides. It is intended to continue the study by comparing regulations on food, animals, intellectual property and contained use of microorganisms.

US: Regulation in existing statutes
EC: Combination of horizontal and product legislation

In the US the agencies have mostly included biotechnology in the scope of existing statues whereas in the EC, genetically manipulated organisms (GMOs) are regulated by a combination of horizontal legislation and product-based sectoral legislation. To market a product the risk assessment currently takes place under the Deliberate Release Directive 90/220/EEC, Part C, or in future for a number of products a similar more specific

risk assessment will be carried out as an integral part of specific product legislation (the "one door/one key" procedure). Novel foods, pesticides, pharmaceuticals and seeds are all in the pipeline. In the US, there is no such "one door/one key" commitment and it appears that the regulations of several agencies e.g. FDA, USDA and EPA may be involved.

Difference in scope at pre-marketing stage and greater flexibility in the US

The BCC's preliminary findings indicate that at the pre-marketing or R&D stage there is a remarkable similarity between the US and EC as far as risk assessment of an environmental release is concerned. However, in the US the scope of the regulations is different and within that defined scope there exists greater flexibility.

Coordinated US research strategy and higher funding

On the R&D front, the US is clearly spending much more than the Community and its member states combined and has a clearly defined national strategy through its Federal Coordinating Council for Science Engineering and Technology (FCCSET).

The comparative strength of community achievements and infrastructure in the life sciences could be at risk in the longer term, leading to the departure from Europe of highly trained and skilled biotechnologists and/or R&D capital. However, reliable data on all aspects of the Community's public and private sector research expenditure is not readily available. The deficiency of research statistics is symptomatic of deeper institutional and political problems in Europe's responses to the challenge of biotechnology.

Report available seeking comments

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

Please send comments on the report to :

A. Van der Meer
Secretariat General
Commission of the European Communities
rue de la Loi, 200
B-1049 Brussels
Tel. (32)2-2962670
Fax (32)2-2965995

Eurobarometer Survey re. Environmental Worries

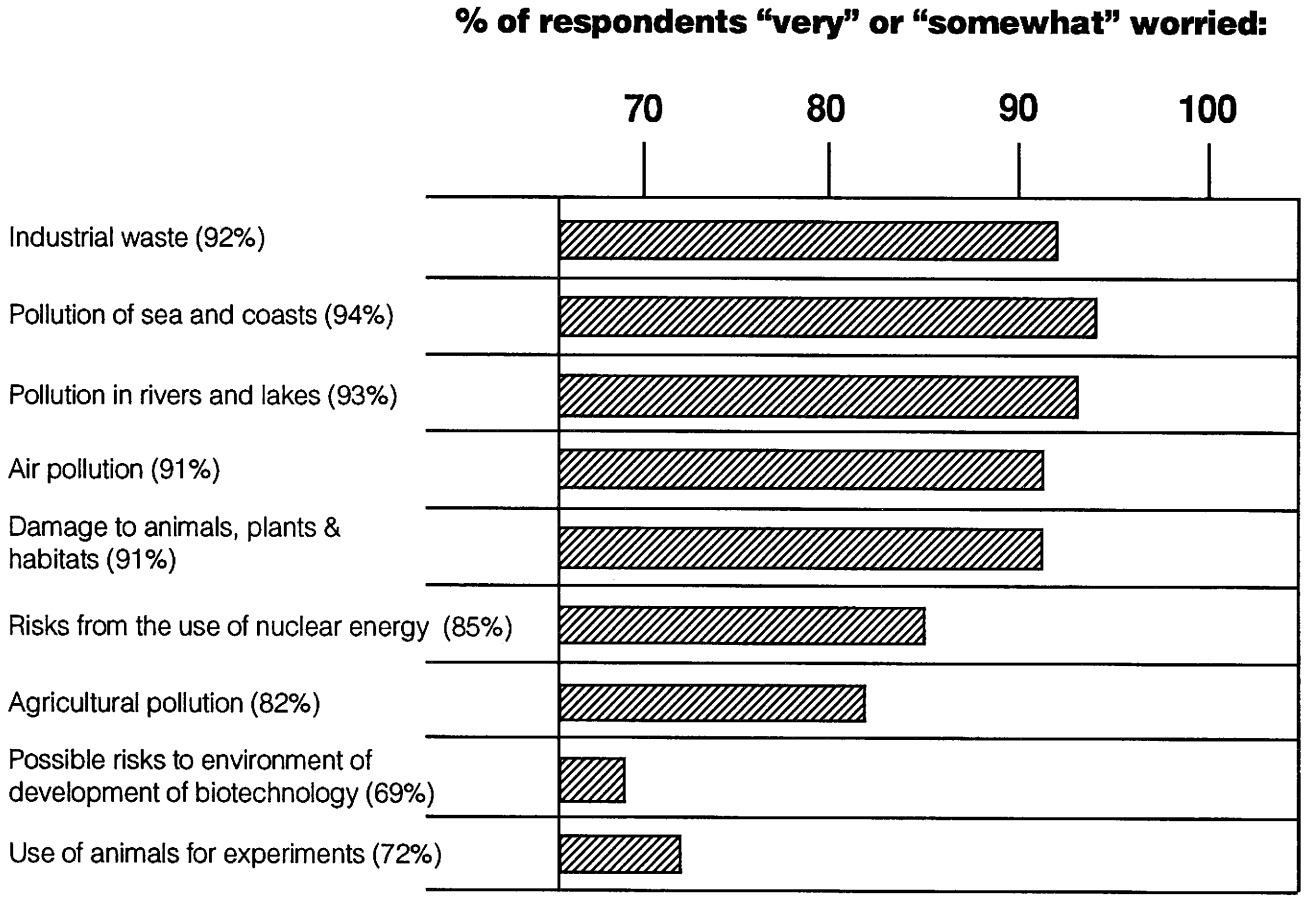
In EBIS 2, 4 p. 4, we incorrectly attributed to EUROSTAT the publication of the Spring 1992 Eurobarometer survey: our apologies. See below for correct details.

The full report sets in context the relative concern about biotechnology; respondents were asked this question about 13 "problems":

> "Now, thinking about (OUR COUNTRY), are you very worried, somewhat worried, not very worried or not at all worried about the following problems?".

70% of respondents worried about biotechnology

Thus prompted, for every "problem" over 50% of respondents expressed themselves "very" or "somewhat" worried; results as follows for the top ten:



The full report may be ordered from Eurobarometer contractor:
INRA, (EUROPE),
18 avenue R. Vandendriessche,
B-1150 Brussels.
Tel.: (32)2-7724444
Fax: (32)2-7724079.

Parliament returns to debate of Commission communication

Commission's April 1991 communication still under debate

The European Parliament's Committee on Energy, Research and Technology (CERT) has returned to the debate of the Commission's communication on biotechnology based on a report drafted by the rapporteur Mrs. Breyer (German, Green Party). Meanwhile, the Commission has reported on the progress made in implementing the proposals made in its communication (see EBIS 2.4, page 3, BCC Takes Stock: Biotechnology after the 1991 communication).

Resolution of Parliament opposing "oncomouse"

This debate followed the recent resolution of the Parliament opposing the granting of a patent on the "oncomouse" and calling on the European Patent Office not to respond favourably to any further applications for animal patents.

Parliamentary rapporteur's report available

For a copy of Mrs. Breyer's report and of the Resolution, use the Response Form (Item 2 and 3).

I.2. Research and Related

BRIDGE Progress Report 1992

BRIDGE contractors report progress

BRIDGE will run from 1990-1993. The 1992 Progress Report has now been published covering the following areas :

Information Infrastructure:	processing and analysis of biological data.
Enabling Technologies:	Protein design;
	molecular modelling;
	biotransformation;
	genome sequencing.
Cellular Biology:	Industrial microorganisms;
	plants and associated microorganisms;
	animal cells.
Pre-Normative Research:	In vitro evaluation of the activity of molecules;
	safety assessment of GMO's.

To obtain the report (limited numbers), use the Response Form (Item 4) or the Office for Official Publications of the European Communities L-2985 Luxembourg.

Biotechnology of extremophiles

A first meeting on this topic is being planned under the BIOTECH research programme to be held at Hamburg, Germany on 2-6 May 1993.

Details:
Prof. Dr. G. Antranikian
Technische Universität
Hamburg - Harburg
Arbeitsbereich 2-09
D-2100 Hamburg 90
Tel. (49)4077183117; Fax (49)4077182909.

BRIDGE biosafety research results

Assessment of possible risks of GMO releases

Significant BRIDGE resources (10 MECU) have been committed to the assessment of risks that may be associated with the release of GMOs into the environment. Sixty-two laboratories from the EC and EFTA countries are working on 14 transnational projects. The first meeting of these biosafety researchers took place from 6-9 December 1992 at Wageningen, The Netherlands.

Report of research results available

The report of this meeting is now available. The topics covered include the following :

- Analysis of gene transfer between microorganisms and plants.

- Fate of genetically engineered microorganisms and genetically engineered DNA sequences in some environmental hot spots.

Wide range of safety issues addressed

- The effects of selection on gene stability and transfer in populations of bacteria in soil.
- Safety assessment of the deliberate release of two model transgenic crop plants, oil-seed rape and sugar beet.
- Stability, genetic transfer and ecology of fungi used as biocontrol agents.
- Assessment of environmental impact from the use of live recombinant virus vaccines.
- Biosafety of genetically-modified baculoviruses for insect control.

Research results to help in the technical adaptation of the regulatory framework

It is hoped that the results of such research will play a positive role in the development and implementation of the Community's regulatory framework ensuring safety for man and the environment.

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

Craft scheme available for biotech SMEs

CRAFT = Cooperative Research Action for Technology
BRITE = Basic Research in Industrial Technologies for Europe
EURAM = European Research on Advanced Materials

CRAFT is a scheme run by the BRITE-EURAM II Industrial and Materials Technologies programme to help Small and Medium Sized Enterprises (SMEs) participate in Community Research activities. CRAFT helps a group of SMEs (with support of up to 50% of total costs) to join together and contract a research programme to a third party (e.g. research organisation, university or company). Biotechnology is one of the topics supported by the programme.

Details :

M. Truffert
Commission of the European Communities DGXII
BRITE/EURAM (CRAFT)
Rue Montoyer, 75
B-1040 Bruxelles
Tel. (32)22962599; Fax (32)22958046
or your National Euro Information Centre

I.3. Regulatory Activities

Biotech patents: EC debate moves to Council

Four-year "first reading"

The European Parliament in October 1992 completed after 4 years the contentious first reading of the Commission's proposal for a Council Directive on the legal protection of biotechnological inventions. The Parliament accepted in principle the main aims of the proposal, to clarify and harmonise throughout the Community the patent law as applied to biotechnology, and consistency with the European Patent Convention. In its amendments, it has demanded more explicit clarification of the exclusions from patentability (allowed under the EPC if contrary to public order and morality).

Consistency with European Patent Convention (EPC)

No patent on humans

Transgenic patents: not if suffering is inflicted with no benefit

Farmers privileged — if Council agrees

Exclusion would apply to "the human body or parts of the human body per se; processes for modifying the genetic identity of the human body for a non-therapeutic purpose which is contrary to the dignity of man; and processes for modifying the genetic identity of animals which are likely to inflict suffering or physical handicaps upon them without any benefit to man or animal". The Commission in its amended proposal to Council has incorporated the above-quoted elements. Regarding the "farmer's privilege" (for sowing farm-saved seeds from his harvest), the Commission, "though initially opposed to the amendment has finally accepted it to allow the Council to discuss it as part of a continuing cooperation procedure" (under the provisions of Article 100A).

The 37-page amended proposal, COM(92)589 final-SYN 159, of 16 December, is available on request (use Response Form, Item 6).

Bovine Somatropin (BST)

CVMP = Committee for Veterinary Medicinal Products

At its meeting on 26/27 January 1993, the EC Committee for Veterinary Medicinal Products (CVMP) completed its evaluation of the two applications for marketing authorization submitted by Monsanto and Eli Lilly for veterinary medicines based on BST.

Consensus agreement on traditional criteria of quality, safety and efficacy

The CVMP reached a consensus conclusion that the two products do satisfy the traditional criteria for authorization of quality, safety and efficacy.

A number of safeguards specified

The Committee also specified a number of safeguards including the requirement for veterinary prescription, to ensure that the two products are used safely and effectively. Of course, this CVMP conclusion does not lift the Council's current moratorium on BST products which extends until 31 December 1993. The next step will be for a Commission report and proposals to the Council and Parliament (see EBIS 2.1. page 4) by 31 June 1993.

To obtain the final reports of the CVMP for each of the two products, use the Response Form (Item 7).

II: Member States

Belgium

Biotechnology industry development in Belgium

Directory of Biotechnology

A report has been published by the Ministry of Technology Development of Belgium's Walloon Region in cooperation with the Belgian Bioindustries Association (BBA) which lists and describes the companies, universities, Institutes and Research Centres involved in biotechnology in Wallonia and Brussels. In a foreword to the report Mr. P. Crooy, chairman of the BBA describes the growth of the association since it was created by 4 companies in 1986. It now has 52 members reflecting the thrusting and innovative development of biotechnology in Belgium.

Directory available in French and English without charge from Belgian Bioindustries Association, rue de Crayer, 6, 1050 Brussels.
Tel. (32)26460564.

Germany

Instructions for shipping non-infectious and infectious biological substances

Transport regulations for biological substances

The Commission under its BRIDGE biotechnology research programme has supported the Information Centre for European Culture Collections based at Braunschweig, Germany to produce a report "Instructions for shipping non-infectious and infectious biological substances". The report gives an overview of the different regulations governing the shipment of biological materials and provides a code of good practice. It should be of interest to any laboratory or culture collection sending biological specimens in the post.

It is available without cost from :

Information Centre for European Culture Collections
Mascheroder Weg 1b
2 D-3300 Braunschweig
Tel. (49)531618715; Fax (49)531618718.

Italy

Biotech Ria 93, 2-4 June 1993, Florence. The impact of biotehnology on autoimmunity

International biotechnology meeting

The main topics covered will include:

- Molecular mechanisms of autoimmunity,
- Diagnostic markers in autoimmune disease,
- Infection and autoimmunity,
- Clinical aspects of autoimmune disease Infection and autoimmunity,
- Clinical aspects of autoimmune diseases,
- Therapeutic advances in autoimmune disease.

A satellite meeting on "Signal transduction and second messenger pathways" will be held on 3 June 1993.

Details:

Clas International
Via Pace, 8
I-25122 Brescia
Tel. (39)303772712; Fax (39)30293282

Advanced biotechnology centre

New biotech centre, 16,000 M^2

The National Cancer Research Institute (IST) has promoted in Genoa an "Advanced Biotechnology Centre" of 16,000 M^2, situated in the University/ Hospital/IST complex. 10,000 M^2 are equipped laboratory facilities.

An incubator for interested companies

The Centre will form the first nucleus in the "Genoese Science Park for Biotechnology", involving the laboratories of the University, the National Research Council, and other scientific Institutes in the creation of a critical mass of researchers, including also the presence of companies having related interests.

Technology transfer, large-scale facilities

Facilities are included for training, conferences, and technology transfer; large-scale facilities are available by specific agreements; the facilities conform to latest national and international regulations for biological and biotechnological research.

Multi-disciplinary basic research, to clinical trials

Basic research activities at the centre will include: molecular biology; developmental biology; biochemistry; bioengineering; genetics; immunology. The centre intends through its proximity to the hospital to become involved in drug development, from research projects to clinical trials.

For details, write to:

IST-ABC
Viale Benedetto XV, 10
I-16231 Genoa
Tel. (39)10-352823 - 3534521 - 3534515; Fax (39)10-355573

The Netherlands

Biotechnology and Development Monitor to continue

Key issues and news of biotechnology in developing countries

Biotechnology and Development Monitor (BDM) has since September 1989 produced 12 excellent issues covering key issues and news items relating to biotechnology in developing countries. Distributed gratis, it has seen demand grow from a few hundred to 4000 ; and has gained a reputation for excellence.

Resource for science policy-makers, advisers in developing countries

BDM is not a specialised scientific publication, but a resource for science policy-makers and advisers in developing countries, international agencies, and in all other circles having related interests.

Follow-up project over next two years

It is therefore welcome news that the Directorate-General for International Cooperation (DGIS) of The Netherlands Ministry of Foreign Affairs has agreed to fund a follow-up project over the next two years. In its future development, publication will be based on a network of institutes in different regions of the world ; and publication will be trilingual, in English, French and Spanish.

Further details available

For further details, contact Editor Professor Gerd Junne, Biotechnology & Development Monitor, University of Amsterdam, Department of International Relations and Public International Law, Oudezijds Achterburgwal 237, 1012 DL Amsterdam. Tel. (31)205252177; Fax (31)205252086.

United Kingdom

New regulations on contained use and release of genetically modified organisms

2 EC Directives implemented

The 90/219/EEC and 90/220/EEC Council Directives have been implemented in new regulations which came into force on 1 February 1993.

The Genetically Modified Organisms (Deliberate Release) Regulations 1992 cover both releases made for research purposes and the marketing of products to ensure protection of the environment and human health and safety.

Plants and animals in contained use covered

They complement two sets of new Regulations on the contained use of GMOs covering microorganisms and "larger" GMOs, such as plants and animals.

Copies of the Genetically Modified Organisms (Deliberate Release) Regulations 1992, SI 1992 Nr. 3280 and the Genetically Modified Organisms (Contained Use) Regulations 1993, SI 1993 Nr. 3280 are available at price UK£ 4 from HMSO 49 High Holborn London WC1V 6HB. Tel. (44)718739090 Fax (44)718738200.

Resistance to new technology, past and present. 5-7 April 1993

An international conference comparing public response to civil nuclear power, information technology and biotechnology.

Details: Martin Bauer
Science Museum Library
London SW7 5NH
Tel. (44)71-9388241;
Fax (44)71-9388213.

III. International Developments

After UNCED: Biotech, biodiversity and genetic resources

"Earth Summit", Rio, June 1992, underlined biotechnology in "Agenda 21"

UN Sectretary-General reviewing S&T across all agencies

The United Nations Conference on Environment and Development (UNCED), or "Earth Summit", of June 1992, emphasised the essential role of biotechnology. The ambitious, 40-chapter "AGENDA 21", outlining the actions needed over the years 1993-2000, includes chapter 16, "Environmentally sound management of Biotechnology". The UN Secretary-General is currently reviewing the whole spectrum of UN involvement in Science and Technology, across all the many agencies concerned — food and agriculture (FAO), health (WHO), industrial development (UNIDO), development (UNDP) environment (UNEP), education, science and culture (UNESCO), and others.

Biodiversity Convention: Will Clinton sign?

Also signed at the Rio conference was the Convention on Biological Diversity, again underlining the role of biotechnology in the sustainable exploitation of genetic resources ; but with controversy in the negotiations concerning intellectual property rights (I.P.R.) on technology, and rights of access to and utilisation of germplasm. The new US administration has to consider whether they can reverse the previous refusal, without damage to US biotech interests.

Biodiversity Convention follow-up: Panels on science, cash, rights and safety law

UNEP has follow-up responsibilities for the Biodiversity Convention, and Expert Panels are advising the new Executive Director, Canadian Elizabeth Dowdeswell on science priorities; the financial mechanism for the new fund envisaged by the Convention; technology transfer, I.P.R. and germplasm; and whether a binding international protocol is needed on the safe transfer and use of modified organisms — perhaps a chance for the benefits of the European Community legislation to be extended worldwide. The Panels meet in Nairobi (December 1992 and February 1993) and Montreal (March 1993). International conferences on the same topics include that at the African Centre for Technology Studies (ACTS) 26-29 January ("National Interests and Global Imperatives") and Trondheim, 24-28 May, when the

Panels and conferences prepare for the intergovernmental meeting, September 1993

government of Norway hosts the "Norway/UNEP Conference on Biodiversity". These meetings lead up to the first meeting of the Intergovernmental Committee on the Convention on Biological Diversity, the ICCBD, at UNEP in September 1993.

Details :

UNEP activities: Mr. Hamdallah Zedan
Coordinator for Biodiversity and Biotechnology, UNEP
P.O. Box 30552,
Nairobi, Kenya
Fax (254-2)226886 or 219270.

For ACTS, contact Dr. Calestous Juma
P.O. Box 45917, Nairobi, Kenya.
Tel 254(2)741651/744047; Fax. 74399.

F or ACTS Biopolicy Institute
Witmakersstraat 10
6211 JB Maastricht, The Netherlands
Tel. (31)43258499; Fax (31)258433

UNESCO creates Bioethics Unit

Unit for exchange of information and formulation of international instruments

The United Nations Educational, Scientific and Cultural Organisation, under the draft Programme and Budget for 1994-1995, "Social Change, Peace and Human Rights", will give increased attention to the exchange of information on bioethics, and study the possibility of formulating international instruments in this area.

Focus on human genome and genetic heritage

Head of the new Bioethics Unit is George B. Kutukdjian, who will assist the International Consultative Committee of Bioethics to be established by UNESCO this year. Director-General Federico Mayor proposes focussing on issues concerning the human genome and protection of the genetic heritage. The committee will evolve from a Task Force headed by Noëlle Lenoir, of France's Constitutional Council, author of the French national reports (see EBIS 4 page 9).

UNESCO is at Place Fontenoy, Paris 7.

Biotech in OECD

100 National Experts from 24 countries convene in Paris, December 1992

Twice a year, most recently in December 1992, the hotels of Paris benefit from the influx of a hundred biotechnology experts for the week-long working group meetings and plenary session of the Group of National Experts on Safety in Biotechnology (GNE), of the Organisation for Economic Cooperation and Development (OECD).

More publications in the pipeline: Food safety, crop plants

Working documents are restricted, but the OECD published reports on biotechnology are well-known since 1981; and new publications are in the pipeline on a broad range of topics, including safety of biotech foods, scale-up release of crop plants, a historical review of plant breeding methods, rDNA biofertilisers, monitoring methods for organisms in the environment etc.

From rDNA to sectoral pre-occupations

Further upstream may be work on biopesticides, biofeeds, bio-mining, and transgenic animals: at OECD as elsewhere, the trend is from general consideration of rDNA methods to sector-specific deliberation. The published reports are the concrete outputs of a process whose greater importance may be the provision of a multinational forum where the 24 developed countries of the Pacific Basin and North Atlantic/Western Europe discuss their common problems and their differences, and hammer out

Key concepts: Familiarity, substantial equivalence, the Dutch "Preamble"

concepts such as "substantial equivalence" and "familiarity" that are fundamental for biotech safety assessment. Of basic importance is a "Preamble" statement of principles, reflecting a strong Dutch initiative,and a long debate to reach consensus; to appear shortly. Happily, the continuing record of biotech is reducing the need to focus only on safety; the OECD's

Biotechnology for a clean environment

contributions have included patent law, the role of government agriculture; and an expert group on "Biotechnology for a Clean Environment" may report next year. In addition to the various reports in progress, and the planning of specialist workshops (aquatic biotech, live vaccines), the December '92 GNE meeting was invited to start reflecting upon the whole future mandate for the OECD biotech activities. A similar invitation was

Towards a new mandate at CSTP, October 1993

extended via the Environmental Policy Committee on 12th January: the request to Member States is to offer a coherent response, in spite of the inevitable plurality of interested Ministries. A new mandate should be finalised at the October 1993 meeting of the GNE's parent body, the Committee for Scientific and Technological Policy.

If you want information on published reports, or the name of your National Coordinator, contact the Biotechnology Unit, Directorate for Science, Technology and Industry, OECD, 2 rue André Pascal, 75775 Paris Cédex 16; or by fax (33)145241825, in (almost) any convenient language.

Australia

Response to "Genetic Manipulation: The Threat or the Glory"

Australia's S&T Minister responds to Parliament's report

EBIS 2.3 page 16 noted the appearance of a major report prepared by the Standing Committee on Industry, Science and Technology of Australia's House of Representatives. The government's official response has been published on 15 October by Ross Free, Minister for Science and Technology.

GMAC (advisory) to be replaced by authority (GMA)

The Government will establish a Genetic Manipulation Authority (GMA) to regulate GMO releases, including field trials; the current GMAC (Genetic Manipulation Advisory Committee) will be replaced by a Research Committee (GMRC), which will have legislatively defined powers to approve contained R&D, taking into account wider aspects such as ethical issues proposed by the GMA.

Flexible and responsive

Although maintaining a GM (i.e. technique-based) focus, the Minister's statement emphasises that "the regulatory approach should be flexible and responsive enough to respond to new developments and applications of the technology for some years. However, the technology is developing

Community attitudes may change: Familiarity, risks and benefits

rapidly. Community attitudes may well change as the technology becomes more familiar and risk levels are accepted as worth taking for the benefits".

Annual report, 7-year review

Annual reports to Parliament will list releases. After seven years, the Government foresees "a thorough review of the type and level of regulatory control needed".

For further information contact : Mr. Brian Delroy, Director, Biotechnology Section, Dept. of Industry, Technology & Commerce, GPO Box 9839, Canberra ACT 2601. Tel. (61)62761182; Fax (61)62761206. (For copies of statement, use the Response Form, Item 8)

Baltic States

Biobalt: Biotechnology in Estonia, Latvia and Lithuania

Integrating Baltic States into world biotech

The International Network Biobalt is organised at Tallinn Technical University (TTU), and aims by coordinated efforts of the three countries to promote integration of the Baltic States into the world biotechnological community. Scientific and commercial co-operation with the Scandinavian states and other European countries are emphasised.

An international network, supported by UNESCO and EFB

BIOBALT aims to create a permanent international network, including organisation of workshops, symposia and conferences. This process is supported by UNESCO (the UN Educational, Scientific and Cultural Organisation), and the European Federation of Biotechnology ; further support from the EC Commission, foundations and companies is sought.

Biobalt 1992 abstract book: Names, institutions, activities

In view of travel difficulties, the BIOBALT 1992 conference was conducted "extramurally" by publishing and distributing the submitted abstracts as a book. The book also contains comprehensive lists and descriptive keywords for the biotechnology centres and institutions in the three countries, indicating a highly developed range of products and services.

The Abstract Book is available on request to Professor Ado Köstner, TTU BIOBALT, Ehitajate tee 5, Tallin EE0108, Estonia ; Telephone (7) 0142-532116; Fax (7)0142-532446.

Japan

Global framework towards the sound development of biotechnology

JBA publishes bilingual report

The Japan Bioindustry Association has published in a bilingual report (115 pages English, 102 pages Japanese) the papers and panel discussion of a 1992 Symposium with the above title.

Pro-biotech but balanced: A rational and open approach

The tone of the report is strongly pro-biotech, but with a recognition of the need for balance, for a rational approach to risk assessment, and for open and comprehensible efforts at public information by universities, government and industry.

International outlook

An international outlook, corresponding to the title, is effectively achieved by the selection of speakers ; indicated below, with their titles:

Basic Major Issues Japan Faces in its Biotechnology Policy, Yoshihiko Nishizawa (Japan).

National Biotechnology Policy in the United States: A Discussion of Regulation, Henry I. Miller (USA).

Biotechnology Policy within the European Community, Nigel J. Poole (UK).

Biotechnology in a Global Economy, Kevin W. O'Connor (USA).

The Role of OECD for the Sound Development of Biotechnology, Bruna Teso (France).

Biotechnology Policy in Local Administration, Makoto Umeda (Japan).

Panel Discussion. Moderators : Ryuichiro Tsugawa (Director, Ajinomoto Co. Inc.) — Fujio Ishikawa (Executive Director, JBA).

Panel discussion

The editing of the Panel Discussion obviously gave difficulties, but in spite of these, the issues debated are clearly indicated, contemporaneous and important.

Enquiries about copies of the report should be addressed to:

Japan Bioindustry Association
10-5, Shimbashi 5-chome Minato-ku
Tokyo 105
Japan
Tel. (813)34333545; Fax (813)34591440

Sweden

"Genetic Engineering — A Challenge"

The Swedish government in 1990 authorized the Ministry of Justice to set up a Parliament Committee on genetic engineering (Genteknikberedningen). Its report, "Genetic Engineering — A challenge" was delivered in September 1992. A 25-page summary in English has been published, and can be ordered from the address below.

Risks related to organisms

The report gives basic information about the nature and use of genetic engineering, noting scientific opinion that it is not the method itself that can lead to risks, but the organism and the result of the modification. The report describes the evolution and present rules relating to various aspects, including ethical, e.g. in public health or in research on fertilised eggs.

Ecological uncertainties; risks as part of ethical analysis

The uncertainties of GMO field releases are emphasised, the Committee taking the view that the assessment of risks should be part of the ethical analysis, since "it is ethically false to base a decision on poor foundations if the decision can be postponed until the foundations have improved. It is also ethically unacceptable to assert that the foundations for a decision are better than they are".

Human rights, nature conservation and moral responsibility

The Committee treats carefully the ethical questions relating to the use of genetic engineering, emphasising human rights to modify nature, but also the "doctrine of nature conservation" and the need for moral responsibility.

EC Directives, but no need for an umbrella law

EC directives 90/219 (contained use of GMMs) and 90/220 (field release of GMOs) are carefully reviewed, with reference to possible Swedish membership of the EC; although they refrain from proposals in these respects.

There is no reference to the EC's April '91 communication, but the report emphasises regulation by the laws that currently include provisions on organisms and products in the respective fields, and sees no need "for a so- called umbrella law, i.e. a law with common rules to be applied to the entire area of genetic engineering".

Intellectual property: Preference for use-linked protection, not product patents

Intellectual property issues are competently reviewed, with attention to international developments, and no changes proposed to Swedish law. But the Committee expresses the view that "in international negotiations concerning the protection of biotechnological inventions..., Sweden should actively promote the argument that only use-linked product protection should be given for genes and micro-organisms taken from nature".

The booklet can be ordered from : Allmänna Förlaget, Kundtjänst, 10647 Stockholm ; Tel. (46)87399630; Fax (46)87399548.

IV. Books Received

"Technology and Transition: A survey of biotechnology in Russia, Ukraine and the Baltic States", by Anthony Rimmington with Rod Greenshields. Pinter Publishers, London. 227 pages. UK£47.50.

Success in microbiology, lagging in genetic engineering

The book is balanced in describing the successes (microbial protein, lysine production), and the relative failure to keep up with genetic engineering and recombinant products. It particularly highlights the appalling pollution inflicted on the environment and local population by the badly-run single-cell protein plants. The alternative structures emerging in the transition to a market economy are described, in the countries indicated by the title.

Enzymes from Lithuania

Of particular interest is the success of Lithuania in enzyme production, thanks to the energies of Professor Janulaitis.

Directory of R&D and production centres

Of special value is the Directory of biotechnology R&D and production centres, with contact details.

Opportunities for foreign contact

Special emphasis is given to the opportunities for foreign contact and investment; a list is given of contracts, joint ventures and collaborations with Western companies.

Biosafety: The safe application of biotechnology in agriculture and the environment

ISNAR helps agricultural research in developing countries

The mandate of the International Service for National Agricultural Research (ISNAR) is to assist developing research systems. In this 39-page booklet, they provide a practical guide for policymakers and research managers, on the safe use of biotechnology products within their countries. It is a masterpiece of clear communication, treating the issues with balance and perspective; the result will be appreciated no less in developed than developing countries.

Biosafety, balance and perspective

The document suggests a series of steps to establish a national biosafety system, starting with a national committee to establish policies and procedures.

5 Principles

The authors advocate maximum use of existing institutions, personnel and legislation. They summarise five key principles:

Risk-based, product not process

1. Regulatory review should focus on the characteristics and identified risks of the biotechnology product, not the process by which it is created.

Efficiency and effectiveness

2. For those biotechnology products that require review the review process should be designed for efficiency and effectiveness while assuring the protection of public health and environmental safety.

Integrated into the overall system

3. Regulatory requirements for modern biotechnology should be integrated into the overall regulatory system which governs the release of new products in the agricultural sector.

Familiarity

4. The degree of familiarity with the behaviour of similar organisms when released into the environment should determine the level of regulatory oversight required. This may range from minimal to extensive, depending on the degree of hazard identified.

Flexible adaptation to advances

5. Regulatory programs should be flexible and capable of adapting quickly to the new knowledge and understanding produced by the rapid advances in biotechnology.

Using OECD, UN, and NRC references

The booklet reviews the evolution of the biosafety and regulatory debate, underlining the significance of other work such as that of OECD, the UNIDO/UNEP/WHO/FAO Working Group on Biosafety, and the US National Research Council.

Authors from 3 continents

The authors are from three continents: Gabrielle Persley, biotechnology manager at the World Bank, previously project manager of the WB/ISNAR/ Australian study on biotechnology in the service of world agriculture; Val Giddings, senior geneticist with the biotechnology programme of the US Dept. of Agriculture, Animal and Plant Health Inspection Service, and previously project manager for the US Congress Office of Technology Assessment Report on "Field Testing of Engineered Organisms: Genetic and Ecological Issues"; and Calestous Juma, Founding Executive Director of the African Centre for Technology Studies in Nairobi, author of several books including "The Gene Hunters".

Single copies of "Biosafety" are available free from ISNAR to professionals in developing countries working in the area of agricultural research policy, organization or management.

For others, copies may be purchased from:
Winrock International Agribookstore,
1611 North Kent Street,
Arlington VA 22209-2134 USA.
Price: US$ 8.95 plus shipping.

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