

Introduction

The purpose of the OECD Biotechnology Update is to provide up-to-date information on the diverse activities at OECD related to biotechnology. Published approximately every six months, the newsletter is mainly intended for delegates to OECD meetings who are familiar with OECD's work. However, we hope that it also serves a purpose to the wider biotech community.

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FUTURE EVENTS

- ◆ OECD 2nd Task Force on Biological Resource Centres, Paris, 25-26 March 2002 (Contacts: Iain Gillespie, Yoshiyasu Yabusaki)
- ◆ The Workshop on Sulfur in Higher Plants, Montpellier, France, 11-14 April 2002 (Contact: Françoise Coudert)
- ◆ OECD Ad Hoc Expert Meeting on Impact of New Technologies on Health Care, Paris, 12 April 2002 (Contacts: Iain Gillespie, Elettra Ronchi)
- ◆ OECD Working Group on Human Health Related Biotechnology, Paris, 6 May 2002 (Contacts: Elettra Ronchi, Iain Gillespie)
- ◆ OECD Working Party on Biotechnology, Paris, 7 May 2002 (Contact: Iain Gillespie)
- ◆ OECD Workshop on Biotechnology Statistics, Finland, 13-15 May 2002 (Contacts: Andy Wyckoff, Iain Gillespie)
- ◆ European Workshop on The Role of Biotechnology in Industrial Sustainability, hosted by the Ministry of Flanders Administration of Science and Innovation, Antwerp, Belgium, 16-17 May 2002 (Contact: Iain Gillespie)

- ◆ BIO 2002, Toronto, Canada, 9-12 June 2002 (Contact: Iain Gillespie)
- ◆ Working Group on Harmonisation of Regulatory Oversight in Biotechnology, Paris, 12-14 June 2002 (Contact: Peter Kearns)
- ◆ Beyond Antimicrobials—the Future of Gut Microbiology, Aberdeen, UK, 12-15 June 2002 (Contact: Françoise Coudert)
- ◆ Task Force for the Safety of Novel Foods and Feeds, Paris, 17-19 June 2002 (Contact: Peter Kearns)
- ◆ OECD Seed Schemes: Advisory Group, Working Groups and Annual Meeting, Santa Cruz, Bolivia, 24-28 June 2002 (Contact: Jean-Marie Debois)
- ◆ International Workshop on Embryo Genomics in Farm Animals, Quebec, Canada, 19-21 July 2002 (Contact: Françoise Coudert)
- ◆ 7th World Congress on Genetics Applied to Livestock Production, Montpellier, France, 19-23 August 2002 (Contact: Françoise Coudert)
- ◆ Remote Sensing for Agriculture and Environment, Kifissia, Greece, mid-September 2002 (Contact: Françoise Coudert)
- ◆ New Vaccines against Helminthes—Parasites of Animals, Hydra, Greece, 15-19 September 2002 (Contact: Françoise Coudert)
- ◆ Dissemination of GMO's in Agro-Ecosystems, Austria, September 2002 (Contact: Françoise Coudert)
- ◆ OECD Scheme for the Control of Forest Reproductive Material Moving in International Trade: Biennial Meeting of Representatives of the National Designated Authorities, Paris 1-3 October 2002 (Contact: Jean-Marie Debois)
- ◆ OECD Workshop on Infectious Diseases and Risk, Lisbon, Portugal, 6-8 October 2002 (Contacts: Elettra Ronchi, Iain Gillespie)
- ◆ OECD Working Group on Human Health Related Biotechnologies, Paris, 4 November 2002 (Contacts: Iain Gillespie, Elettra Ronchi)

- ◆ OECD Working Party on Biotechnology, Paris, 5 November 2002 (Contact: Iain Gillespie)
- ◆ OECD Task Force on Biological Resource Centres, Paris, 6-7 November 2002 (Contacts: Iain Gillespie, Yoshiyashu Yabusaki)
- ◆ An interdisciplinary Dialogue: Agricultural Production and Integrated Ecosystem Management of Soil and Water, New South Wales, Australia, 15-16 November 2002 (Contact: Françoise Coudert)
- ◆ The Global Forum on Agriculture—Biotechnology in the Agro-Food Sector, Paris, 18-19 November 2002 (Contact: Alexandra Trzeciak-Duval)



THE INTERNAL CO-ORDINATION GROUP FOR BIOTECHNOLOGY (ICGB)

OECD has been undertaking work on biotechnology-related projects – including safety issues – since 1982.

In the meantime, biotechnology has had an increasing impact on the programmes of different sectors at OECD such as: agriculture; science, technology, and industry; environment; and trade. So in 1993, an Internal Co-ordination Group on Biotechnology (ICGB) was established to facilitate internal co-ordination among these sectors.

Michael Osborne, the Director of OECD's Advisory Unit on Multidisciplinary Issues, chairs the ICGB. Peter Kearns is the Secretary.

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LMOs AND THE ENVIRONMENT: AN INTERNATIONAL CONFERENCE

27-30 November 2001

Raleigh-Durham, North Carolina

The LMOs Conference held in Raleigh-Durham was attended by close to 250 participants from approximately 20 OECD Member countries and an additional 25 non-Member countries. The

participants were drawn from government, industry, academia and civil society. Dr. Rita Colwell, Director, National Science Foundation, USA, co-chaired the meeting with Calestous Juma, Director of Science, Technology and Innovation Program at the Centre for International Development and Senior Research Fellow at the Belfer Centre for International Development at Harvard University. Donald Johnston, Secretary-General of the OECD was also in attendance and presented some important points in his opening address. He noted that the “key challenges were to achieve a balance between scientific opportunity and safety, to identify gaps in our knowledge and to determine what more needs to be done to address these gaps.

The conference brought together a wide range of participants to discuss environmental issues important in the development, research and commercialization of LMOs. A lot of discussion centered on environmental risk and risk assessment. Due to their potential, these organisms have also renewed an interest in ecological research with an aim toward a better understanding of how ecosystems function.

General agreement as to the issues in assessing, managing and communicating the risks and benefits were reached, including the need to continually account for new developments and to improve the public’s understanding of these, and other, scientific advancements. Participants also identified a need to continue international co-operation amongst OECD countries and between OECD and non-OECD countries, in order to harness the potential benefits offered by this technology. It was also, generally, agreed that there is a need to strengthen the scientific and technological capabilities in developing countries and to foster appropriate partnerships.

For additional information on the outcome of the workshop, please consult the draft rapporteur’s report found at the website indicated below. A final document is being prepared by the Rapporteurs with input from those who were in attendance.

Web site: LMOs and the Environment
www1.oecd.org/ehs/raleigh/index.htm

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HARMONIZATION OF REGULATORY OVERSIGHT IN BIOTECHNOLOGY

At the 11th Meeting of the Working Group, held in Paris, 14-16 January 2002, the OECD Guidance for the Designation of a Unique Identifier for Transgenic Plants was finalised by members of the Working Group. This document provides guidance for the creation of an alphanumeric code to be designated to a product of biotechnology. The significance of this document is important, in that, it aims to prevent confusion that can arise in the OECD database when two products are similarly named.






With an awareness of the differences in safety assessments between plant and microbial taxonomy, a sub-set of the Working Group, the Sub-Working Group on Micro-organisms (SWGM) called for an adapted approach for the creation of consensus and guidance documents on micro-organisms. This adaptation has already produced projects in the areas of taxonomy, detection, pathogenicity and gene transfer, as well as, individual microorganisms such as *Pseudomonas* and Baculovirus. The SWGM has also been working towards increasing its collaboration with other groups within the OECD. In this regard, members of the Biopesticides Steering Group (BPSG), a sub-set of the Working Group on Pesticides will be joining the Working Group at its upcoming meeting in June 2002 (12th-14th). It is hoped that through a mutual discussion of their projects that future means of collaboration can be established.

The Working Group continues to develop its consensus documents that include technical information used in the regulatory review of biotechnology products. The information used in these documents is mutually acceptable among OECD Member countries. Upcoming publications are indicated below.



Future events:

- ◆ 12th Meeting of the Working Group for the Harmonisation of Regulatory Oversight in Biotechnology, Paris, 12-14 June 2002

Recent publications:

-  *Consensus Document on the Biology of Pinus Strobus L. (Eastern White Pine)*
-  *Consensus Document on the Biology of Picea Sitchensis (Bong.) Carr. (Sitka Spruce)*
-  *Report of the Workshop on the Environmental Considerations of Genetically Modified Trees*
-  *Consensus Document on Information Used in the Assessment of Environmental Applications Involving Baculoviruses*
-  *OECD Guidance for the Designation of a Unique Identifier for Transgenic Plants*

Upcoming Publications:

-  *Module II: Glufosinate Ammonium (Phosphinothricin) metabolite and residue situation in genetically modified glufosinate-tolerant plants*
-  *Consensus Document on the Biology of Prunus sp. (Stonefruits)*

Web site: BioTrack Online
<http://www.oecd.org/biotrack>

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**SAFETY OF NOVEL FOODS AND FEEDS**

At the 5th Meeting of the Task Force, held in Paris from 10-12 December 2001, the OECD Secretariat emphasised that a major assignment for the group was to develop a new programme of work for 2003-2005. Discussion on the proposal will take place at the next meeting to be held in June 2002 (17th-19th).

A Steering Committee has been formed to develop a workshop that will be hosted by the Russian Federation. This workshop will bring together OECD and non-OECD countries in the spirit of information sharing on the processes of assessing genetically engineered products. A case study, produced by the lead country, Canada, will be used to illustrate the various stages one goes through when evaluating the dossiers of prospective product approvals. This outreach project on the Safety of

Novel Foods and Feeds is expected to take place some time in mid-2002.

Preliminary responses from the biomarkers, research activities and post-market surveillance survey have been collected. Responses from eleven countries were obtained; however, it was decided that more time would be given to receive any additional responses. The deadline for new submissions is the end of February 2002. The United Kingdom, which has led this project, would like to present results of their own study on these issues at the next Task Force meeting (17-19 June 2002). It is possible that future work for the Task Force could arise out of the observations.



The Task Force also continues its work regarding the safety/risk assessment of animal feedstuffs with the production of a document entitled, Considerations for the Safety Assessment of Animal Feedstuffs derived from Genetically Modified Plants. It is hoped that this comprehensive document will be declassified at the next meeting of the Task Force.


The Task Force is also continuing its work on consensus documents, which are complementary to those of the Working Group, and which identify the critical nutrients and critical toxicants associated with major crop plants. There have been 5 documents published in the new Series on the Safety of Novel Foods and Feeds, which are listed below. Other documents are nearing completion and should be published in the summer of 2002.

Future event:


- ◆ 6th Meeting of the Task Force for the Safety of Novel Foods and Feeds, Paris, 17-19 June 2002


Recent publications:

-  *Consensus Document on Compositional Considerations for New Varieties of Sugar Beet: Key Food and Feed Nutrients and Anti-Nutrients*
-  *Consensus Document on Compositional Considerations for New Varieties of Potatoes: Key Food and Feed Nutrients, Anti-Nutrients and Toxicants*

 *Report of the OECD Workshop on the Nutritional Assessment of Novel Foods and Feeds, Ottawa, Canada, February 2001*

Upcoming publication:

 *Consensus Document on Compositional Considerations for New Varieties of Maize (Zea Mays): Key Food and Feed Nutrients, Anti-Nutrients and Secondary Plant Metabolites*

 *Consensus Document on Compositional Considerations for New Varieties of Bread Wheat (Triticum Aestivum): Key Food and Feed Nutrients, Anti-Nutrients and Toxicants.*

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MOLECULAR CHARACTERIZATION

The Task Force for the Safety of Novel Foods and Feeds and the Working Group on the Harmonisation of Regulatory Oversight in Biotechnology have been discussing how best to work together on the subject of molecular characterisation as it relates to safety assessment. The four main countries involved from both groups, Canada, the Netherlands, Belgium and the United States, have planned an upcoming teleconference call, with co-ordination by the Secretariat to discuss the prospect of future collaborations and the potential for a workshop on this issue. Canada will be preparing a short introductory paper on the main points to be addressed in this area.



OECD'S SEED CERTIFICATION AND FOREST REPRODUCTIVE MATERIAL CONTROL SCHEMES

Three criteria - distinctness, uniformity and stability - are the basis for identifying crop seed varieties and constitute the backbone of seed development and commercialisation. Reliability of forest reproductive material rests upon local

identification, selection and breeding work. Genetic purity is a component of the sustainability issue, especially when hybridisation and genetic modifications are involved.

The **OECD Schemes for Seed Certification** have developed since the late 1950s to regulate international trade as well as counter season multiplication of seed between the northern and southern hemispheres. They are implemented by a total of fifty-two member and non-member countries across all continents, and four more countries have submitted an application. Their essential purpose is to harmonise the assessment and certification of identity and purity of cultivars (cultivated crop plant varieties). Most species, including all basic staples, are eligible and more than 25 000 varieties from all participating countries appear on the annually published *OECD List of Varieties Eligible for Certification*. Current issues in discussion are, among others, the quality and monitoring of seed control and the handling of the accidental presence of GMOs in non-GM seed varieties. A Working Group on Genetically Modified Seed Issues was established at the 2000 Annual Meeting of National Designated Authorities. OECD labels and certificates could become available for "hosting" LMO information.

A new **OECD Scheme for the Certification of Forest Reproductive Material** is being introduced.

Future event:

Annual Meeting of National Designated Authorities and meetings of the Working Groups on GM Seed Issues and Accreditation, Santa Cruz de la Sierra, Bolivia, 25-29 June 2002.


Publications:

. List of Varieties Eligible for Certification, 2001.

. OECD Seed Schemes 2000.

Web site: <http://www.oecd.org/agr/code/>

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**AGRICULTURE COOPERATIVE RESEARCH
PROGRAMME ON
BIOLOGICAL RESOURCE MANAGEMENT
FOR SUSTAINABLE
AGRICULTURAL SYSTEMS**

In recognition of the great importance of agriculture as an aspect of sustainable development, 27 OECD Member countries have agreed to participate in a Co-operative Research Programme on Biological Resource Management for Sustainable Agricultural Systems. A new five-year programme (2000-2004) was established on 1 January 2000. The programme's aim is to intensify fundamental research in biotechnology, with new emphasis on research integrating socio-economic and scientific concerns as well as risk assessment. It seeks to reinforce international scientific co-operation and to facilitate the exchange of information on current research. The four themes of the current Programme are:

- New agricultural products for sustainable farming and industry;
- Quality of animal products and safety of food;
- Enhancing environmental quality in agricultural systems;
- Connecting scientific progress to sustainable and integrated agro-food systems.

The Programme promotes two types of activities:

- **Fellowships:** 92 applications were received for the year 2002 and 58 scientists were awarded a fellowship. Information on the Programme and application forms are available on the Programme website: <http://www.oecd.org/agr/prog/>. The new deadline for submitting applications has been set for 31 October 2002 (for fellowships commencing in 2003)
- **Grants for Workshops:** Information on how to apply for subsidies and proceedings of workshops held in previous years are available on the Programme's website (see below).

Future events:

- Workshop on Sulphur in higher plants - 11-14 April 2002, Montpellier (France)

- Workshop on Innovative soil-plant systems for sustainable agricultural practices - 3-7 June 2002, Izmir (Turkey)
- Beyond antimicrobials - the future of gut microbiology - 12-15 June 2002, Aberdeen (UK)
- International workshop on embryo genomics in farm animals - 19-21 July 2002, Quebec (Canada)
- Genetics applied to livestock production - 19-23 August 2002, Montpellier (France)
- Remote sensing for agriculture and environment - mid-September 2002, Kifissia (Greece)
- News vaccines against Helminth-parasites of animals - 15-19 September 2002, Hydra (Greece)
- The dissemination of GMOs in Agro-Ecosystems - 27-28 September 2002, Grossrussbach (Austria)
- An interdisciplinary dialogue: Agricultural production and integrated ecosystem management of soil and water- 12-16 November 2002, Balina (Australia)

Web site: <http://www.oecd.org/agr/prog/>

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**MODERN BIOTECHNOLOGY AND
AGRICULTURAL MARKETS**


The report *Modern Biotechnology and Agricultural Markets: A Discussion of Selected Issues*, prepared by the Directorate for Food, Agriculture and Fisheries, synthesises the main economic issues on both the supply and demand side arising from the use of modern agricultural biotechnology in agriculture.

Impacts of biotech crops on agricultural markets and trade continue to be part of the ongoing analysis for the agricultural outlook process. An analysis of the impacts of biotech crops on trade and international markets is to be presented to the working group on commodities in spring 2002.

Recent Publications:

 *Modern Biotechnology and Agricultural Markets: A Discussion of selected Issues*

Available for free at: <http://www.oecd.org/>
under biotechnology/biological resources and
agriculture

 OECD (2000), *OECD Agricultural Outlook
2000-2005 and OECD Agricultural Outlook
2001-2006*

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**BIOTECHNOLOGY FOR INFECTIOUS
DISEASES
ADDRESSING THE GLOBAL NEEDS
LISBON, 7-9 OCTOBER 2002**

A high level workshop on: Biotechnology for Infectious Diseases: Addressing the Global Needs will be held in Lisbon, 7-9 October 2002.

Recent outbreaks and global events have revealed the vulnerability of OECD countries to infectious diseases, bring a renewed understanding of the global impacts of infectious diseases. The Portugal 2002 workshop will help identify the key challenges to S&T and R&D.. It will ask the question: can biotechnology help address these challenges? It will take a holistic view, integrating research, economics and policy. The workshop presents an opportunity to develop an OECD-wide approach in response to recent G8 statements on the need for “sustained action and coherent international co-operation to fully mobilise new and existing medical, technical and financial resources in the fight against infectious diseases”.

The workshop's main goals are:

1. To review the risks, including economic impacts, posed by infectious diseases, especially new and emerging diseases, and neglected diseases;
2. To review new trends in S&T and their potential to fight against infectious diseases and anticipate risks;
3. To take stock of the opportunities and limitations of biotechnology and bioinformatics for surveillance, detection, diagnosis and therapy;

4. To address the risk and costs of failure, explore case studies and consider options for best practice in or by OECD countries to improve access to and uptake of technology;

5. To address the significant socio-economic implications of the widening technological gap between developed and developing countries in the fight against infectious diseases, and the need to develop adequate policies to incentivise R&D for neglected diseases

The first Steering Group Meeting was held on 8 February 2002 at OECD Headquarters. It was attended by representatives from 12 countries, the WHO, the EC and BIAC, as well as several invited experts.

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INCENTIVE MEASURES

The OECD Working Group on Economic Aspects of Biodiversity (WGEAB), a subsidiary body of the Environmental Policy Committee, recently approved a new mandate which will run until 31 December 2004. Three areas are the basis of the new mandate: the creation of markets for biodiversity products and services, distributive issues related to biodiversity conservation in the context of incentive measures, the development and use of biodiversity indicators. Keeping with the WGEAB's successful tradition, the main project, market creation, is expected to yield a handbook on the issue by the end of the mandate.

Regarding the previous mandate, a compendium of valuation studies on biodiversity benefits was recently published, a handbook on valuation is being published in March 2002 and a study on market creation for biodiversity products and services soon after. This forms part of WGEAB's contribution to the Convention on Biological Diversity (CBD) in its work on Incentive Measures (article 11).

The handbook on valuation is based in part on 9 OECD country case studies. These country case studies are available as general distribution. Together with the handbook, they provide an in-depth discussion on biodiversity values and reviews all major valuation methods. The focus is valuation use for policy making and incentive design.

Finally, a number of case studies related to market creation are already available as general distribution. A series of regional training seminars on incentive measures are being planned for the first half of 2002, and a side event describing OECD work on economic aspects of biodiversity will take place in the CBD's Conference of the Parties (COP6) in collaboration with IUCN.

WGEAB also works on access and benefit sharing of genetic resources (ABS). As such, it is completing a detailed analysis of the economic aspects of ABS and their legal ramifications.

Future events:

- Regional training seminars in West Africa and Mexico (May / June 2002)
- 14th Meeting of the Working Group on Economic Aspects of Biodiversity, Paris, 16-17 May 2002

Recent publications:

- 📖 *Saving Biological Diversity: Harnessing Markets for Conservation and Sustainable Use (forthcoming 2002)*
- 📖 *Handbook of Biodiversity Valuation: A Guide for Policy Makers (March 2002)*
- 📖 *Valuation of Biodiversity Benefits: Selected Studies (2001)*
- 📖 *Handbook of Incentive Measures for Biodiversity: Design and Implementation (1999)*
- 📖 *Saving Biological Diversity: Economic Incentives (1996)*
- 📖 *Economic Issues in Benefit Sharing: Concepts and Practical Experiences [ENV/EPOC/GEEI/BIO(98)7/FINAL]*
- 📖 *Issues in the Sharing of Benefits Arising out of the Utilisation of Genetic Resources [OCDE/GD(97)193]*

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BIOTECHNOLOGY FOR SUSTAINABLE INDUSTRIAL DEVELOPMENT

The Task Force on Biotechnology for Sustainable Industrial Development, led by Canada and supported by other Member countries, held its sixth meeting in Seville, Spain, on 19-20 February 2002. The Task Force confirmed that the recent

publication, *The Application of Biotechnology to Industrial Sustainability*, has been well accepted and had good public interest from Member countries. A "primer" booklet, which will introduce the benefits of the inclusion of biotechnological steps in production processes, will be published and distributed freely primarily on the Web.

Based on the general consensus that the development of renewable bioproducts and eco-efficient bioprocesses would contribute to the realisation of a more bio-based global economy, the Task Force discussed its future direction. A proposal of its next phase plan will be submitted to the Working Party on Biotechnology in May 2002.

Future event:

- International Conference, The Role of Biotechnology in Industrial Sustainability, hosted by Ministry of Flanders Administration Science and Innovation on 16-17 May 2002 in Antwerp, Belgium (www.innovation.flanders.be/conference_industrial_biotechnology).

Recent publication:

- The Application of Biotechnology to Industrial Sustainability, OECD 2001

Forthcoming publication:

- A "primer" on "The Application of Biotechnology to Industrial Sustainability"

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BIOLOGICAL RESOURCE CENTRES

After the completion of the previous Task Force with publication of the report, *Biological Resource Centres: Underpinning the Future of Life Sciences and Biotechnology*, a new follow up Task Force led by France was established to implement the recommendations of the report.

The new Task Force held its first meeting on 19-20 November 2001, attended by 12 Member countries as well as six non-member country Experts. The Task Force agreed a proposal by the Chairman to establish three Focus Groups. The three groups would tentatively cover the following topics; Accreditation and Quality Criteria (quality;

qualifications of staff, expertise; training; research; "at risk" collections), International Linkages (communication; assistance; exchange; data interoperability standards; non-duplication of standards), and Harmonisation (legal aspects around biosafety; security; IPRs; ethics; biodiversity and "at risk" collections; funding). Electronic Discussion Groups (EDGs) have been set up and will be used by the Focus groups to discuss their topics. A more detailed terms of reference for each Focus Group will be confirmed at the next meeting of the Task Force in March 2002.

Future event:

- 2nd meeting of the Task Force on BRCs will be held in Paris on 25-26 March 2002.

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XENOTRANSPLANTATION

Xenotransplantation is about the transplantation of organs, tissues or viable cells from one species to another - in particular, from animals to humans. As such, it is yet another example of scientific progress confronting society with a controversial and emotionally charged issue that is in need of a coherent policy framework.

A Consultation was held in Paris at OECD Headquarters on 4-6 October 2000 and was attended by over 60 participants from around the world, representing countries currently hosting xenotransplantation clinical trials; countries not actively engaged in xenotransplantation research but interested in its potential public health impact; and relevant international bodies such as the Council of Europe and the European Commission.

The consultation brought together some 60 participants from countries currently hosting xenotransplantation clinical trials, engaged in xenotransplantation research and others who have banned the use of the technology but are aware of its global implications.

A report has been published which summarises the topics, issues and considerations discussed at the OECD/WHO Consultation on Xenotransplantation Surveillance and can be downloaded from our web site: <http://www.oecd.org/biotechnology/> – under

the theme “Scientific, Industrial and Health Applications of Biotechnology”.

Recent publications:

- 📖 *Xenotransplantation: International Policy Issues*, OECD 1999
- 📖 *The OECD Observer*, “Challenges in Tissue Transplantation”, No 213, OECD 1998
- 📖 Plans drawn up for xenotransplantation watchdog Source: Nature ; 12 October 2000, vol.407, pp.666
- 📖 <http://www.oecd.org/media/release/nw00-104a.htm>- News Release

Web site:

<http://www.oecd.org/biotechnology> - under the theme “Scientific, Industrial and Health Applications of Biotechnology”

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SAFE DRINKING WATER

Technology development has much to contribute to water security in the 21st century, especially the protection of drinking water. Recently, the OECD has held workshops on the potential use of biotechnology for conserving water, and on molecular technologies aimed at improving the quality of drinking water. Work has also focused on:

- frameworks and data needs to improve our capacity to assess human health effects, outbreak of water-borne diseases, and adverse incident recognition and management in the context of drinking water;
- information needs, efficiency of current management approaches and both conventional and new molecular technologies for assessing water quality at the various stages from raw water to drinking water, as part of efforts to improve risk assessment and management related to these supplies (study carried out in co-operation with WHO soon to be published as a guidance document). Taking this work further, an expert meeting will be held in Mexico late 2002. The meeting will offer an update on:

- Health risks and less well defined hazards of waterborne and water transmitted diseases.
- Critical evaluations of new methodological approaches and surveillance activities.
- New approaches for risk prevention and preparedness for outbreaks.
- Best practices for information sharing to protect public health.

Forthcoming Publication:

- Safe Drinking-water: improving the assessment of microbial safety

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**GENETIC TESTING
SURVEY ON MOLECULAR GENETIC
TESTING LABORATORY PRACTICES**

The OECD launched a pilot phase for a survey on molecular genetic testing laboratory practices, with the support and co-operation of its Member countries, the European Commission and the European Molecular Quality Genetics Network, on 8 January 2002. The pilot of the survey includes over 350 laboratories from nine countries (Italy, Portugal, USA, Canada, UK, Austria, Finland, Switzerland and Japan).

The objectives of the survey are to get an overview of: *a)* the settings in which genetic testing is being offered as a clinical service; *b)* what types of tests and how many are being performed; *c)* the qualifications of the Directors of the laboratories performing genetic testing; *d)* what quality assurance methods are being utilised; and *e)* what measures are taken when deficiencies are uncovered. The findings will be used to identify areas for international cooperation in developing standards, proficiency testing and interpretative guidelines; and will facilitate international collaboration among disease-specific consortia, particularly for testing for rare diseases.

A Steering group meeting to assess preliminary survey responses, key issues and challenges will take place on 18 March 2002 in Seville, Spain, hosted by the European Commission at the IPTS.

This meeting is being held the day before the IPTS Workshop on "*Genetic testing services, quality assurance and harmonization needs in the EU.*"

Future event:

- 2nd Steering Group meeting on Quality Assurance and Proficiency Testing Schemes for Molecular Genetic Testing in OECD countries will be held in Seville, Spain on 18 March 2002.

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AGEING

While undoubtedly one of the greatest accomplishments of the 20th Century, the increased longevity and lower fertility of OECD populations means that one quarter to one third of the working age population will be over sixty five by 2025. This ageing of OECD countries creates enormous social and health care challenges, especially since this segment of the population is most vulnerable to chronic illness and disability. Not surprisingly, countries are searching for ways to promote healthy ageing. What solutions can biotechnology offer?

A Workshop on Healthy Ageing and Biotechnology was held on 13-14 November 2000 in Tokyo, Japan. It assembled a cross disciplinary group of experts for a lively discussion on the impacts of biotechnology on the ageing process and the economics of elderly health care. Scientists identified the major opportunities being created by biotechnology in our understanding and ultimately our ability to slow the ageing process. Policymakers debated the research, regulatory, health care, and social choices countries must make now in order to ensure that efficient new technologies are affordable, equitable, and available.

Sponsored and generously supported by the Ministry of Health and Welfare of Japan, the workshop was organised by the Biotechnology Unit of the Directorate for Science Technology and Industry at the OECD with the co-operation of the Directorate of Education, Employment, Labour and Social Affairs.

Conference proceedings as well as a summary of the Key Points and Policy Conclusions can be found on the workshop web site below. A volume of select papers is being compiled and edited by Dr. Marc Weksler and Dr. Hiroshi Yoshikura. A Summary Report of the meeting will be published over the course of the winter 2001-2002.

Web site:

<http://www.oecd.org/biotechnology/> - under the theme “Scientific, Industrial and Health Applications of Biotechnology”

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GENETIC INVENTIONS, IPRS, AND LICENSING PRACTICES

The Berlin Workshop on Genetic Inventions, Intellectual Property Rights and Licensing Practices brought together over 100 public and private sector experts from 18 OECD countries meeting. The meeting was held under the auspices of the German Federal Ministry for Education and Research and the OECD’s Working Party on Biotechnology. It aimed to review empirical evidence and studies of the impacts of patenting and licensing of genetic inventions on access to the technology by researchers, companies and within healthcare systems.

Speakers and participants concluded that patents and effective licensing regimes make technology available and are essential for the successful development of new therapeutic applications of biotechnology. There is much private sector good practice in licensing of diagnostic genetic tests. But in some cases the system falls short of public and private sector goals to utilise new biotechnologies in health care systems.

Available surveys show that the concerns of the 1990s that exponential growth in the number and complexity of biotechnology patents would bring about breakdown of the patent system and so prevent access to inventions by researchers and health services have not materialised. Patents in biotechnology are broadly doing what they should do, stimulating research and entry of new technology into markets. But continued vigilance is necessary to ensure this remains the case internationally.

The conference heard that some difficulties occur around licensing of patents related to genetic tests. Clinical laboratories often fall shy of concluding licensing agreements with holders of such patents, though the defining reasons for this remain to be clarified. The conference heard of a number of potential tools that might be available to improve access and market penetration without undermining the patent system and within the confines of member-country health service budgets. Further detailed analysis by the private and public sectors and international organisations is necessary to determine what approaches might work best.

The conference heard that most if not all OECD countries operate formal or informal research exemptions that work reasonably in most cases. However, the transition between “research” and “commercial” use and subsequent requirements for licensing agreements needs to be clarified. Participants also emphasised the need for improved international harmonisation of the legal and judiciary frameworks which shape patent and licensing practices for genetic inventions, and they identified implementation of the European Directive on Biotechnological Inventions as being instrumental in helping achieve this.

The Working Party on Biotechnology will issue a published Report on the findings of the Berlin Workshop. The Agenda and presentations are available on the Biotechnology Unit’s external website (www.oecd.org/sti/biotechnology). The WPB will consider follow-up work on related topics for next year’s work programme.

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BIOTECHNOLOGY STATISTICS IN OECD MEMBER COUNTRIES

The web page <http://www.oecd.org/EN/countrylist/0,,EN-countrylist-617-nodirectorate-no-no-633-27,FF.html> contains data that countries have given us about biotechnology statistics in their country. If there are any updates available or data corrections please send them to Andrew Devlin (andrew.devlin@oecd.org). The biotechnology statistics compendium that was released as STI working paper 2001/6 and contains biotechnology statistics for Member countries is

located on www.oecd.org/sti/working-papers. This compendium presents the range of indicators that can be produced from existing biotechnology statistics.

On November 6 the Working Party on Biotechnology met and provisionally adopted the statistical definition of biotechnology with the understanding that the concerns and suggestions made at the meeting would be discussed at the 3rd Ad Hoc meeting on biotechnology statistics. A room document on biotechnology indicators and public policy was then presented. Delegates were invited to comment on the room document before the end of 2001.

Preparations are continuing for the 3rd Ad Hoc NESTI meeting on biotechnology statistics. The Finnish Government is sponsoring this event to be held on May 13-15 in Espoo. Issues to be discussed include:

- the statistical definition in light of four countries which have conducted pilot surveys.
- how to classify biotechnology commodities, firms, R&D and patenting.
- a model survey on R&D and a special module model survey.
- biotechnology indicators addressing user needs
- a framework for measuring biotechnology statistics.

To date 17 Member countries and three non-member countries have expressed an interest to attend.

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BIOLOGICAL INFORMATICS

The Global Biodiversity Information Facility (GBIF) became operational on 1 March 2001. It had been endorsed by Science Ministers of the OECD member countries, based on a recommendation of the OECD Megascience Forum. GBIF is now an independent internationally funded research organisation, open to all countries. Its goal is to link numerous and highly diverse biodiversity databases, with special emphasis on information about species. The results will be fully accessible to anyone via the internet (www.gbif.org). The GBIF secretariat has been established in Copenhagen, and

substantive work will begin before the end of the year.

Web site: <http://www.gbif.org>

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ECONOMIC AND POLICY ASPECTS OF MODERN AGRICULTURAL BIOTECHNOLOGY IN NON-MEMBER COUNTRIES

Work on developing an analytical framework for the evaluation of the economic benefits and costs and the classification of policy approaches of selected developing countries is advancing. In addition, the institutional and infrastructural constraints to the effective dissemination of information on agricultural technologies are being examined. The Business and Industry Advisory Committee (BIAC) to the OECD has agreed to provide help in filling any information and data gaps, where possible, in order to ensure the completion of this work. The report is expected to be available in early 2003.

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WHO'S WHO IN BIOTECH AT OECD

Michael OBORNE (SGE/AU)

Chairman of the ICGB
Director Multidisciplinary Issues

Peter KEARNS (ENV/EHS)

Secretary to the ICGB
Harmonisation of Regulatory Oversight in Biotechnology
Safety of Novel Foods and Feeds

Dan BILLER (ENV/ECO)

Economic Aspects of Biodiversity

Bénédicte CALLAN (STI/STP)

Ageing
Genetic Inventions, IPRs and Licensing Issues

Françoise COUDERT (AGR/PROG)
Agriculture Co-operative Research Programme

Jean-Marie DEBOIS (AGR/COD)
OECD Seed Schemes
Forest Seed and Plant Scheme

Andrew DEVLIN (STI/EAS)
Biotechnology Statistics

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Head of Biotechnology Unit

Linda FULPONI (AGR/TM)
Agricultural Biotechnology: Economic Issues

Wayne JONES (AGR/PTA)
Economic Aspects of Food Safety

Masahiro MIYAZAKO (ENV/EHS)
Harmonisation of Regulatory Oversight in
Biotechnology
Safety of Novel Foods and Feeds

Evdokia MÖISÉ (ECH/TLR)
Intellectual Property Rights

Elettra RONCHI (STI/BIO)
Human Health-Related Activities

Michael RYAN (AGR/NME)
Agricultural Biotechnology: Economic Issues

Kees Van GOOL (STI/BIO)
Economist

Andy WYCKOFF (STI/EAS)
Biotechnology Statistics


Yoshiyasu YABUSAKI (STI/STP)
Biological Resource Centres
Sustainable Industrial Development



THE WORLD WIDE WEB

OECD's web site continues to grow and includes much material on biotechnology and related topics. In addition, the web site now allows visitors to tailor the OECD site to their needs. By selecting the themes that interest them, visitors can personalize their homepages at My OECD to present the news, events, and documentation strictly related to their chosen themes. Visitors can also choose to receive automatically the Biotechnology Update through My OECD.

- For more information about OECD's work on biotechnology see:
<http://www.oecd.org/biotechnology/>
- For more information about the industrial, scientific and health applications of biotechnology at the OECD, see:
<http://www.oecd.org/biotechnology/> under the theme "Scientific, Industrial and Health Applications of Biotechnology."

 Hard copies of some publications can also be obtained free-of-charge from the ICGB Secretariat

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ENDNOTE: A BRIEF GUIDE TO THE OECD

The Organisation for Economic Co-operation and Development (OECD) has 30 Member countries. Its principal aim is to promote policies for sustainable economic growth and employment, a rising standard of living, and trade liberalisation. By sustainable economic growth the OECD means growth that balances economic, social and environmental considerations.

The OECD is an institution that enables its Member countries to discuss and develop both domestic and international policies. It analyses issues, recommends actions, and provides a forum in which countries can compare their experiences, seek answers to common problems, and work to co-ordinate policies.

The Council of OECD is the highest decision-making body of the Organisation. Normally, its participants are the Ambassadors of the Member countries to OECD. It is chaired by OECD's Secretary-General. However, once a year it meets at the level of Ministers. Amongst other things, the Council decides on the annual budget of Organisation as well as the content of the programme of work.

In addition to the Council, there are around 200 specialised Committees and other bodies (including Working Parties, Working Groups, Task Forces, etc.), which undertake the Organisation's programme of work. The governments of the Member countries nominate the participants to all these groups.

The list below shows the main OECD bodies that have activities related to biotechnology:

OECD Council

Committee for Agriculture (COAG)

- ◆ Seeds Scheme
- ◆ Co-operative Research Programme

Committee for Scientific and Technological Policy (CSTP)

- ◆ Working Party on Biotechnology
- ◆ Task Force on Biological Resource Centres
- ◆ Biological Informatics Working Group
- ◆ Task Force on Biotechnology for Sustainable Industrial Development
- ◆ Working Group on Human-Health-Related Biotechnologies

Environment Policy Committee (EPOC)

- ◆ Working Group on Economic Aspects of Biodiversity

Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology (Joint Meeting)

- ◆ Working Group for the Harmonisation of Regulatory Oversight in Biotechnology
- ◆ Task Force for the Safety of Novel Foods and Feeds



