

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 is also useful to the wider biotech community.

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OECD BIOTECH AND 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 related to their chosen themes. Visitors can also choose to receive automatically this newsletter, *Biotechnology Update*, through **My OECD**.

- OECD's web site is: <http://www.oecd.org>
- 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."

- OECD's BioTrack web site (covering biosafety) is found at: <http://www.oecd.org/biotrack/>

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

FUTURE EVENTS

- ◆ 7th Meeting of the Task Force on Biotechnology for Sustainable Industrial Development, Ottawa, Canada, 5-6 March 2003. (Contacts: Iain Gillespie and Yoshiyasu Yabusaki)
- ◆ Expert Group on Impact of New and Emerging Health-Related Technologies, OECD, Paris, 17-18 March 2003. (Contact: Kees Van Gool)
- ◆ Steering Group on Mexico 2003 Expert Meeting on Emerging Risks to Water Supplies, OECD, Paris, 24-25 March 2003. (Contact: Elettra Ronchi)
- ◆ Steering Group on Genomics and Informatics – Privacy and Security, OECD, Paris, 27-28 March 2003. (Contacts: Bénédicte Callan and Iain Gillespie)
- ◆ Steering Group on Intellectual Property Rights and Genetic Inventions, OECD, Paris, 7 April 2003. (Contacts: Bénédicte Callan and Iain Gillespie)
- ◆ 4th meeting of the Task Force on BRCs will be held in Washington, United States, in May 2003 (date to be confirmed). (Contacts: Iain Gillespie and Yoshiyasu Yabusaki)
- ◆ OECD Working Group on Human Health Related Biotechnology, Paris, 4 June 2003. (Contacts: Elettra Ronchi and Iain Gillespie)
- ◆ OECD Working Party on Biotechnology, Paris, 5-6 June 2003. (Contact: Iain Gillespie)
- ◆ 4th Steering Group meeting on Quality Assurance and Proficiency Testing Schemes for Molecular Genetic Testing in OECD countries, Brussels, Belgium, November 2003. (Contact: Elettra Ronchi)

- ◆ OECD Working Group on Human Health Related Biotechnology, Paris, 4 November 2003 (Contacts: Elettra Ronchi and Iain Gillespie)
- ◆ OECD Working Party on Biotechnology, Paris, 5-6 November 2003 (Contact: Iain Gillespie)
- ◆ OECD Working Group on Harmonisation of Regulatory Oversight in Biotechnology, Paris, 24-26 November 2003. (Contact: Peter Kearns)
- ◆ OECD Task Force for the Safety of Novel Foods and Feeds, Paris, 15-17 December 2003. (Contact: Peter Kearns)

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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HARMONISATION OF REGULATORY OVERSIGHT IN BIOTECHNOLOGY

At the 12th Meeting of the Working Group on Harmonisation of Regulatory Oversight in Biotechnology, held in Paris June 12-14 2002, a draft Programme of Work for the period 2003-2005 was finalised. It was approved by the parental body, the Joint Meeting, which met in November 2002. The three main project areas are: 1) facilitating harmonisation: the next steps; 2) outreach projects; and 3) consensus documents. Within the first area, new projects have been proposed on: parameters for

environmental risk and safety assessment; the next generation of biotechnology-derived crops; and the risk and safety assessment of transgenic fish.

Outreach activities constitute the second area of work, and include BioTrack Online. This website, focusing on information related to the regulatory oversight of products of biotechnology, is used by governments, industry and other stakeholders. Information available on the site includes regulatory developments of countries, a product database, field trials, and consensus documents. Other outreach activities comprise the contribution of BioTrack to the Cartagena Protocol and the work of the Steering Group on BioTrack with regard to cooperation with non-member economies.

The third priority area for the Working Group is the continued development of consensus documents, which provide technical information used in the regulatory review of biotechnology products. The information described in these documents is mutually acceptable among OECD Member countries. The focus of the documents is the biology of organisms (such as plants and micro-organisms) or introduced novel traits. Upcoming publications are indicated below.

Also at the 12th meeting of the Working Group, presentations describing the activities of the Biopesticides Steering Group (BPSG) and the sub-working group on microorganisms were made by the chairs of these groups in order to discuss opportunities for linkage between them. One area of possible collaboration that was agreed upon involved Test Guidelines in the area of health assessments.

The sub-working group on micro-organisms held its second meeting on 23-25 September 2002 in Bilthoven, in the Netherlands. The interest of this forum is to address safety and risk assessment issues specific to the use of micro-organisms (mainly bacteria) in biotechnology, as opposed to those issues surrounding transgenic plants, often the focus of Working Group discussions. The dominant topics discussed at Bilthoven were taxonomy, detection, horizontal gene transfer, and pathogenicity. OECD guidance documents on the first two topics are currently at advanced stages of preparation.

Very recently, the Working Group held its 13th session in Paris (10-12 February 2003). One of the

main objectives of this meeting was to discuss initial arrangements for a Workshop on future activities of the Working Group, which will be hosted by the US, Canada and Mexico, probably in October 2003. The reasons for organising such a workshop are (1) to identify priority areas of future work in risk/safety assessment and (2) to review the scope, purpose and usefulness of Consensus Documents, a cornerstone of the work of the Working Group.

Future event:

- 14th Meeting of the Working Group for the Harmonisation of Regulatory Oversight in Biotechnology, Paris, 24-26 November 2003.

Recent Publications:

- ☞ *Consensus Document on the Biology of Prunus Spp. (Stone Fruits)*
- ☞ *Module II: Herbicide Biochemistry, Herbicide Metabolism and the Residues in Glufosinate-Ammonium (Phosphinothricin)-Tolerant Transgenic Plants*
- ☞ *Guidance for the Designation of a Unique Identifier for Transgenic Plants*

Upcoming Publications:

- ☞ *Consensus Document on the Biology of Maize*
- ☞ *Consensus Document on the Biology of Citrus*
- ☞ *Consensus Document on the Biology of Cotton*
- ☞ *Report on the Questionnaire on Monitoring/Detection/Identification of Transgenic Products*

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SAFETY OF NOVEL FOODS AND FEEDS

At the 6th Meeting of the Task Force on the Safety of Novel Foods and Feeds, held in Paris June 17-19 2002, the Programme of Work for the 2003-2005 period was finalised. As with the Working Group on Harmonisation in Biotechnology, the three main project areas are: 1) facilitating harmonisation: the next steps; 2) outreach projects; and 3) consensus

documents. Proposals for new projects in the first area were considered for discussion and prioritisation during the recent 7th session of the Task Force (13-14 February 2003) and include: exotic fruits and vegetables; food containing bioactive compounds; transgenic fish; and marker genes. In addition, the development of trait documents is being considered, for example on herbicide tolerance and viral resistance, to complement trait documents of the Working Group but from the perspective of food and feeds safety.

With regard to outreach activities, the Task Force contributes to the BioTrack Online Information System by working to ensure that information on the product database is linked to existing decision documents for food and feed approvals on national web sites. As well, the Task Force initiated a capacity-building project by organizing a workshop held in the Russian Federation in September 2002 on the Safety of Novel Foods and Feeds. This highly successful project is described in more detail below.

Finally, the third area of focus is the development of consensus documents, which provide current information important to food and feed safety assessment, and that act as a technical tool as well as a general guide and reference source for regulatory officials and for industry and other parties. Task Force documents identify the critical nutrients and toxicants associated with major crop plants, complementing the consensus documents of the Working Group on Harmonisation in Biotechnology. Draft documents on Rice, Sunflower and Cotton are under development and proposals for new work on Tomato and Mushroom were agreed. Recent and forthcoming publications are indicated below.

Future event:

- 8th Meeting of the Task Force for the Safety of Novel Foods and Feeds, Paris, 15-17 December 2003.

Recent Publications:

- ☞ *Consensus Document on Compositional Considerations for New Varieties of Maize: Key Food and Feed Nutrients, Anti-nutrients and Secondary Plant Metabolites*
- ☞ *Consensus Document on Compositional Considerations for New Varieties of Potatoes:*

Key Food and Feed Nutrients, Anti-nutrients and Toxicants

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

Upcoming Publications:

- ☞ *Consensus Document on Compositional Considerations for New Varieties of Bread Wheat: Key Food and Feed Nutrients, Anti-nutrients and Toxicants.*
- ☞ *Questionnaire on Biomarkers, Research on the Safety of Novel Foods and the Feasibility of Post-Market Monitoring*
- ☞ *Considerations for the Safety Assessment of Animal Feedstuffs Derived from Genetically Modified Plants*

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

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OECD WORKSHOP ON THE SAFETY OF NOVEL FOODS AND FEEDS

Hosted by the Russian Federation and held under the auspices of the Task Force for the Safety of Novel Foods and Feeds together with the Centre of Co-operation with Non-Members (CCNM), a workshop was held in Moscow from 16 to 18 September 2002, in order to bring together experts from OECD countries to work with invited participants from the Russian Federation, countries of the former USSR, and Baltic States. The workshop introduced and promoted discussion on the various concepts being applied worldwide in the safety assessments of novel foods and feeds. A hands-on approach focusing upon a central case study that uses the Codex guidelines was employed in order to provide regulators with practical training in the evaluation of dossiers over a three-day period. Topics covered include Substantial Equivalence, Molecular Characterization, Nutritional Aspects, Toxicity, Allergenicity, Unintentional Effects, and Comparison of International Approaches. The approaches

discussed were consistent with those described in international consensus. The workshop was highly successful and participants indicated that they were pleased with the organisation of the workshop, the high level of expertise of the facilitators, the detail of information presented, and the depth of the subsequent discussions.



UNIQUE IDENTIFIER FOR TRANSGENIC PLANTS

The OECD Guidance for the Designation of a Unique Identifier for Transgenic Plants was published in February 2002. The unique identifier, a simple alphanumeric code designated for each biotechnology product approved for commercial use, is important for the retrieval of detailed information in the OECD Product Database, as well as interoperable systems such as the Biosafety Clearing-House (created by the Secretariat of the Convention on Biological Diversity). It was designed to ensure lack of duplication (and lack of confusion) between different products while maintaining flexibility and user-friendliness for applicants. To date, unique identifiers have been provided for 27 approved transgenic products.

The application of the unique identifier can be seen in an updated version of OECD's Product Database at: <http://www1.oecd.org/scripts/biotech/>



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 trade. 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 cultivated crop plant varieties. Most species, including all basic staples, are eligible and 30 000 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, including in the framework of the CBD-Cartagena Protocol.

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

Future events:

- Meeting of the Working Group on GM Seed Issues (*April 2003, to be confirmed*)
- Annual Meeting of National Designated Authorities, and meetings of the Working Groups on GM Seed Issues and Accreditation, Paris, France, 9-12 September 2003.

Publications:

- 📖 *List of Varieties Eligible for Certification 2002/2003*
- 📖 *OECD Seed Schemes 2000*

Web sites: <http://www.oecd.org/agr/seed>
<http://www.oecd.org/agr/forest>

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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, 26 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:** 106 applications were received for the year 2003 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 2003 (for fellowships commencing in 2004).
- **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:

Congresses for 2003

- International conference on the molecular biology and biotechnology of ciliates and anaerobic protozoa, Nijmegen (Netherlands) 4-6 March 2003.
- Conference on enzyme and environment: Ecology, activity and application, Praha (Czech Republic) 14-17 July 2003.
- What risk analysis is appropriate? Options for future policy making towards integrated agro-food systems, Maastricht (Netherlands) 15-17 July 2003.

- The genus *Mus* as a model for evolutionary studies, Brno (Czech Republic) 27 July-1 August 2003.
- 14th European Congress on poultry nutrition, Lillehammer (Norway) 10-14 August 2003.
- Organisation of the 16th International symposium on environmental biogeochemistry. "Biogeochemical shaping of the earth system: past, present and future", Aomori Prefecture (Japan) 1-6 September 2003.
- Drying timber for value-added products, Athens (Greece) 2-4 October 2003.
- Conference on biological resources and migration, Marburg (Germany) 7-10 October 2003.
- Virus resistant transgenic papaya: A case study on the social and economic impact of a transgenic product in US and its application to lesser developed countries, Hawaii (U.S.) 21-23 October 2003.
- Risk assessment of food obtained from cloned livestock, Paris (France) October or November 2003.
- Challenges and risks of GMOs.

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Recent Publications

- 📖 *Second international workshop on mammary gland biotechnology. Cloning and stem cells vol.4 -1- publishers Mary Ann Liebert Inc.*
- 📖 *Resilience of the subsurface ecosystem to anthropogenic disturbances. Biodegradation vol. 13 N°1. 2002*
- 📖 *Allelopathy from molecules to ecosystems 2002. Edited by Manuel J. Reigosa and Nuria Pedrol - Science Publishers Inc. NH.USA ISBN 1-57808-254-4*
- 📖 *Beyond antimicrobials - The future of gut microbiology. Reproduction, Nutrition, Development 42 (suppl.1) S1-S98. June 2002. INRA.EDP Sciences 2002*

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



**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 was held in Lisbon, 7-9 October 2002.

The objectives of the conference were to:

- Review the risks, including economic impacts, posed by infectious diseases, especially new and re-emerging/unexpected diseases and neglected diseases.
- Assess new trends in S&T and their potential to address infectious diseases (naturally occurring or deliberately released), anticipate risks and take stock of opportunities and limitations of biotechnology and bio-informatics for surveillance, detection, diagnosis and therapy.
- Explore appropriate case studies and consider options for best practice in or by OECD member countries to improve access to, and uptake of, appropriate technology and information systems.
- Consider options for policies and strategies to encourage R&D for emerging and neglected diseases, with a special session on the needs of developing countries; and look for synergies between different lines of research.

The conference brought together a wide range of stakeholders, including policy makers, scientists, researchers and industry representatives. Over 100 delegates attended from 30 OECD member countries and non-member countries, as well as representatives from the World Health Organization (WHO) and the European Commission.

The Conference confirmed the potential of new advances in genomics and bioinformatics. Case studies showed specific areas (*e.g.* management of drug resistance, diagnostics, surveillance for early warning) where new advances can most readily add value and contribute to global infectious disease management and control. However, for biotechnology to be able to deliver its full potential, a number of barriers need to be overcome. Some of these barriers are scientific but many others are economic and political.

In consultation with the WHO and other relevant international organisations, the Secretariat is considering a number of future activities or next steps.

Recent publication:



Rapporteurs' Report:

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

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**ECONOMIC ASPECTS OF
BIODIVERSITY**

The OECD Working Group on Economic Aspects of Biodiversity (WGEAB), a subsidiary body of the Environmental Policy Committee, is now well into its new mandate and has begun exploring issues in: the creation of markets for biodiversity products and services, the distributive impacts related to biodiversity conservation in the context of incentive measures, and the development and use of biodiversity indicators. Initial documents in all of these areas have been discussed by the Working Group but a decision was taken to focus exclusively, for now, on completing a handbook of market creation in time for the next COP meeting in early 2004. Once that work is completed, the Working Group will turn its attention to the issue of distributive impacts of biodiversity policy. In the interim, however, there will also be ongoing development of a specific agenda for work on biodiversity indicators.

Regarding work that was left over from a previous mandate, the WGEAB also continues to work on access and benefit sharing of genetic resources (ABS). Revisions have been made to an earlier document containing a detailed analysis of the economic aspects of ABS and their legal ramifications. Further revisions are foreseen in response to recent discussions.

A book will be published shortly which will explore existing markets for biodiversity conservation and sustainable use. This book will form an important basis for the aforementioned handbook on market creation for biodiversity.

Future events:

- 16th Meeting of the Working Group on Economic Aspects of Biodiversity, Paris, 27-28 May 2003

Recent publications:

- 📖 *Harnessing Markets for Biodiversity: Towards Conservation and Sustainable Use (forthcoming 2003)*
- 📖 *Handbook of Biodiversity Valuation: A Guide for Policy Makers (March 2002)*
- 📖 *Valuation of Biodiversity Benefits: Selected Studies (2001)*

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GENETIC INVENTIONS, IPRS, AND LICENSING PRACTICES

A report entitled “Genetic Inventions, IPRs, and Licensing Practices: Evidence and Policies” was published in December 2002 and can be downloaded from our website (please see address below). This publication is an in-depth report on the debates and conclusions of WPB Berlin Workshop on Genetic Inventions held in January 2002. The publication presents data on the patenting and licensing of genetic inventions. Recent studies and expert testimonies shed light on the impact of patents for genetic inventions on the on access to the technology by researchers, companies and within healthcare systems.

While the Workshop concluded that there is no systematic breakdown in the licensing of genetic inventions, several issues were flagged for continued monitoring and possibly action. In particular, the licensing of patented genetic testing and the proliferation of patents with “reach through rights” were identified complicating access to technology. The report discusses some of the remedies being considered and suggests that Member countries take a targeted approach to those areas where the patenting and licensing of genetic inventions pose documented challenges.

Recent publication:

- 📖 *Genetic Inventions, IPRs, and Licensing Practices: Evidence and Policies*

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

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AGEING

A report entitled “Healthy Ageing and Biotechnology: Policy Implications and New Research” was published in December 2002 and can be downloaded from our website (please see address below). This publication is based on the presentations of speakers at the Workshop on Healthy Ageing and Biotechnology held in November 2000 in Tokyo, Japan. The publication discusses the impacts of biotechnology on the ageing process and the economics of elderly health care. Scientific contributions identify the major opportunities created by biotechnology in our understanding and ultimately our ability to slow the ageing process. Economic and policy contributions discuss what tradeoffs must be made among the research, regulatory, health care, and social policies in order to ensure that efficient new technologies for healthy ageing are affordable, equitable, and available.

Recent publication:

- 📖 *Healthy Ageing and Biotechnology: Policy Implications and New Research*

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

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THE IMPACT OF NEW AND EMERGING HEALTH-RELATED TECHNOLOGIES

This project on the new and emerging technologies aims to assess ways in which Member countries can manage health-related technological change. It is guided by Member country experts and is part of the wider OECD Health Project.

The project consists of three parts:

A) Conduct a survey on how decisions on health technology are made, the role of health technology assessment (HTA) and how decisions are translated into practice. This part of the project aims to assess the impact of decision and implementation processes using common indicators.

B) Consider how member countries could address some of the broader policy challenges in health-technology decision-making and assessment. The broader policy challenges considered in this part of the project include (1) dealing with uncertainty, (2) how results can be transferred between settings and countries, (3) how implementation of HTA can be improved, (4) the impact on R&D, and (5) how decision-makers could deal with bio-medicines, including genetic tests and services.

C) On the basis of information gathered during the first two parts of the project, draw up principles of good practice. This will be achieved through an international experts' workshop to be held in the second half of 2003.

The survey is intended to capture the decision-making and implementation experiences for a number of case study technologies in a wide range of Member countries. Experts, together with the Secretariat, are in the process of finalising the survey instrument and selecting case studies technologies for analysis. The project is due for completion early 2004.

Future event:

- Expert Group on Impact of New and Emerging Health-Related Technologies, OECD, Paris, 17-18 March 2003.

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Web site: <http://www.oecd.org/biotechnology/> under the theme "Scientific, Industrial and Health Applications of Biotechnology"



BIOTECHNOLOGY FOR SUSTAINABLE INDUSTRIAL DEVELOPMENT

There are a number of drivers that are leading to the emergence of a knowledge-based economy, one of which can be defined as bio-based economy. The

bio-based economy uses renewable bio-resources, highly efficient bioprocesses and eco-industrial clusters to produce sustainable bio-products, jobs and income. Key amongst these drivers toward more bio-based economy is scientific and technological developments in life science and biotechnology.

The Task Force on Biotechnology for Sustainable Industrial Development concluded its future activity comprising the following four work streams and was agreed by the Working Party on Biotechnology, in November 2002:


- develop a shared vision of a more bio-based economy through scenario building;
- measure where industrial biotechnology is used, and trends and opportunities for future development;
- consider indicators to identify and quantify the benefits of industrial biotechnology, and;
- take concrete and proactive steps to raise the political and public profile of the potential benefits of industrial biotechnology.

Future event:

- 7th Task Force meeting will be held on 5 and 6 March 2003 in Ottawa, Canada.

Recent publications:

 *The Application of Biotechnology to Industrial Sustainability, OECD 2001*

 A "primer" on "The Application of Biotechnology to Industrial Sustainability" (free download from our website)

Web site: <http://www.oecd.org/biotechnology/> under the theme "Scientific, Industrial and Health Applications of Biotechnology"

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BIOLOGICAL RESOURCE CENTRES

At its 3rd meeting in Paris in November 2002, the Task Force reviewed and discussed on recent progresses of the three established Focus groups.

- Focus group 1: Accreditation and Quality Criteria;
- Focus group 2: International Linkages, and;
- Focus group 3: International Laws and Policies.

It was agreed that some of the outcomes of the Task Force (common accreditation standards, international linkages, gap analysis of international laws and policies, biosecurity, and financial stability) would be submitted to the proposed CSTP Ministerial meeting. Further progresses will be expected at the next Task Force meeting in May 2003.

Interest on global BRC network recommendations have been generated from experts in non-member countries in Asia, Africa and South America. These experts have been invited to attend the Task Force meetings.

Recent publication:

📖 *Biological Resource Centres: Underpinning the Future of Life Sciences and Biotechnology* (free download from our web site)

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

Future event:

- 4th meeting of the Task Force on BRCs will be held in Washington, United States, in May 2003 (date to be confirmed).

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SAFE DRINKING WATER

Inadequate drinking water supply, water quality and sanitation are among the world's major causes of preventable morbidity and mortality. Children are particularly at risk. Approximately 4 billion cases of diarrhoea per year cause 2 million deaths, mostly among children under five.

The problem is not limited to developing countries. In OECD member countries, waterborne outbreaks,

particularly from protozoan parasites, occur all too frequently and are a growing concern.

Thus, despite substantial advances in recent years, access to safe drinking water is still a major public health challenge. Contributing factors include the discharge of greater quantities of wastewater, the ageing of water treatment infrastructures and the increasing occurrence of organisms resistant to conventional disinfection treatments.

A joint OECD/WHO expert group has reviewed methods for improving the microbiological safety of water. A guidance document resulting from this co-operative effort is currently in press.

An OECD workshop on Emerging Risks to Water Supplies will be held in Cuernavaca, Mexico, July 28-30, 2003.

Forthcoming Publication:

📖 *Assessing microbial safety of drinking-water: improving approaches and methods*

Future event:

- Emerging Risks to Water Supplies- Cuernavaca, Mexico- 28-30 July, 2003.

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GENETIC TESTING SURVEY ON MOLECULAR GENETIC TESTING LABORATORY PRACTICES

The OECD completed in May 2002 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. The pilot of the survey included over 350 laboratories from nine countries (Italy, Portugal, USA, Canada, UK, Austria, Finland, Switzerland and Japan).

The objectives of the survey were 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 results of this pilot survey have provided important insights on a number of issues. These include the first documentation of the practice of referring genetic testing specimens across national boundaries and of differences in the practices of laboratories with regard to the requirements for reporting results, written informed consent and confidentiality policies. These results will need further investigation and discussion in order to provide guidance to policy makers and others responsible for the practice of molecular genetic testing. A large-scale survey of 18 OECD countries is planned for 2003.

Future event:

- 4th Steering Group meeting on Quality Assurance and Proficiency Testing Schemes for Molecular Genetic Testing in OECD countries to be held in Brussels in November 2003 (date to be confirmed)

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BIOTECHNOLOGY STATISTICS IN OECD MEMBER COUNTRIES

OECD has developed the first set of internationally comparable statistics on biotechnology. 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. Efforts continue to further develop the data and expand the available range of international indicators.

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BIOTECHNOLOGY INNOVATION SYSTEMS

The Working Party on Technology and Innovation Policy of the Committee on Scientific and Technological Policy has launched a set of case studies that investigate the policy-relevant differences in the innovation patterns of different

technological fields/sectors, with a view to draw policy implications concerning R&D funding, industry-science relations, and framework conditions for innovation.

One of these case studies is on pharmaceutical biotechnology. It is carried out by an Expert Group of volunteer countries led by Germany and the Netherlands. The cross-country comparative analysis addresses the following main questions:

Drivers of innovation. What are the primary determinants of innovation in pharmaceutical biotechnology? What is the role of demand side factors: market actors (lead users, patient organisations, consumers, etc.), societal needs and concerns? How does government regulatory and health policies shape innovation patterns?

Characteristics of innovation processes and systemic linkages. What are the key sources of new knowledge? How is biotechnology positioned in the overall innovation system, *e.g.* in terms of knowledge flows and spillovers? What is the structure and dynamics of the networks generating knowledge, technologies and products which are formed by biotech firms, public research organisations, clinical research organisations, hospitals, and medium-sized and large industrial companies? What are the relative contributions of industry, government, and universities in funding and conducting R&D? How can knowledge flows among industry, government, and universities be characterized (*e.g.* public/private research partnerships, patents and licensing, mobility of scientists and engineers, consulting,)? How is the balance between these mechanisms changing over time?

Globalisation. How globalised are R&D and innovation networks? What are the primary forces that motivate globalisation (*e.g.* market access, proximity to sources of science and technology, lower cost labour) and how are those forces changing over time? What are the primary mechanisms for globalising R&D and innovation (*e.g.* collaborative research, establishment of new foreign R&D facilities, mergers and acquisitions of foreign firms)?

The study aims to develop recommendations on how governments could enhance the efficiency of biotechnology innovation systems, with a specific

emphasis on R&D funding, public/private partnerships, IPRs and product-related regulation.

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OECD GLOBAL FORUM ON KNOWLEDGE ECONOMY: MODERN AGRICULTURAL BIOTECHNOLOGY IN NON-MEMBER COUNTRIES

The Workshop on modern agricultural biotechnology, under the auspices of the OECD Global Forum on Knowledge Economy, was held on 18 and 19 November 2002. The primary objective of the Workshop was to examine and debate the economic and policy dimensions of modern agricultural biotechnology in developing and emerging economies. Following presentations from a selected number of non-member countries, the Workshop discussed methodologies for assessing the impacts of modern animal and crop biotechnologies in developing and emerging economies, as well as a proposed typology of policies and countries based on their infrastructural and institutional capacities for biotechnology uptake and use in agriculture. Delegates from many of the OECD member countries participated in the Forum, as well as policymakers and experts from 14 non-member countries, international organisations and BIAC.

The papers from the Meeting and presentations are available on the OECD website. Based on oral and written comments received by the Secretariat, the two core framework papers have been revised and have been sent to the Committee for Agriculture for information. The revised papers will be published in April 2003.

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WHO'S WHO IN BIOTECH AT OECD

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Intellectual Property Rights and Genetic
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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
- ◆ Ad Hoc Group on OECD Health Project, IEA, Paris, 23-25 April 2003

