

Introduction

This newsletter provides up-to-date information on OECD activities related to biotechnology. It is mainly intended for delegates to OECD meetings who are already familiar with certain aspects of OECD's work. We hope that it is also informative for the wider biotech community.



INDEX

OECD BIOTECH AND THE WORLD WIDE WEB.....	1
FUTURE EVENTS	2
OECD'S INTERNAL CO-ORDINATION GROUP FOR BIOTECHNOLOGY (ICGB)	2
MINISTERIAL DISCUSSIONS AT OECD	3
HARMONISATION OF REGULATORY OVERSIGHT IN BIOTECHNOLOGY	3
SAFETY OF NOVEL FOODS AND FEEDS	4
BIOTRACK ONLINE	5
BIOSECURITY: PREVENTING ABUSE OF RESEARCH AND RESOURCES IN THE BIOSCIENCES	5
THE BIOECONOMY: ITS LONGER-TERM FUTURE AND POTENTIAL IMPACTS	6
BIOTECHNOLOGY FOR SUSTAINABLE INDUSTRIAL DEVELOPMENT	6
BIOLOGICAL RESOURCE CENTRES.....	7
SAFE DRINKING WATER.....	7
OECD TO DEVELOP BEST PRACTICES FOR QUALITY ASSURANCE OF LABORATORY PRACTICE IN MOLECULAR GENETIC TESTING	8
OECD ASKS "WHAT'S DIFFERENT ABOUT PHARMACOGENOMICS?"	8
BEST PRACTICE GUIDELINES FOR THE LICENSING OF GENETIC INVENTIONS	8
BEST PRACTICE IN GOVERNANCE AND MANAGEMENT OF HUMAN GENETIC RESEARCH DATABASES	9

OECD'S SEED CERTIFICATION AND FOREST REPRODUCTIVE MATERIAL CONTROL SCHEMES	9
CO-OPERATIVE RESEARCH PROGRAMME: BIOLOGICAL RESOURCE MANAGEMENT FOR SUSTAINABLE AGRICULTURAL SYSTEMS'	10
STRENGTHENING WORK ON BIOTECHNOLOGY, INNOVATION AND HEALTH.....	11
BIOTECHNOLOGY STATISTICS IN OECD MEMBER COUNTRIES.....	12
ECONOMIC IMPACTS OF BIOTECHNOLOGY..	12
STUDY OF INNOVATION SYSTEMS.....	12
BIOMASS AND AGRICULTURE.....	13
WHO'S WHO IN BIOTECH AT OECD	13
CONTACT POINT:	14
MEDIA ENQUIRIES:	14
ENDNOTE: A BRIEF GUIDE TO THE OECD	14



OECD BIOTECH AND THE WORLD WIDE WEB

OECD's web site includes much material on biotechnology, biosafety, and related topics. The web site 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 future editions of this newsletter through *My OECD*.

- OECD's web site is at:
<http://www.oecd.org>
- OECD's biotechnology portal:
<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.”

- The BioTrack information system (which covers biosafety) is found at:
<http://www.oecd.org/biotrack/>

📖 *Hard copies of many OECD publications can be obtained free-of-charge from the ICGB Secretariat.*



FUTURE EVENTS

- ◆ Workshop, “Promoting Responsible Stewardship in the Biosciences: Avoiding Potential Abuse of Research and Resources”, Frascati, Italy, 17-19 September 2004 (Registration Closed). (Contact: Chris Deane)
- ◆ Expert meeting on best practice guidelines for the licensing of genetic inventions, Vienna, Austria, 4-5 October 2004. (Contact: Iain Gillespie)
- ◆ 9th Meeting of the Task Force for the Safety of Novel Foods and Feeds, Paris, 11-13 October 2004. (Contact: Masahiro Miyazako)
- ◆ Steering group meeting on quality assurance and proficiency testing schemes for molecular genetic testing in OECD countries, Paris, 13-14 October 2004. (Contacts: Elettra Ronchi)
- ◆ Steering group meeting on pharmacogenomics, Paris, France, 15 October 2004. (Contact: Elettra Ronchi).
- ◆ Workshop, “Innovation in Healthcare: Examining the Links Between Policy Makers and Innovators”, 15-16 November, Berlin, Germany. (Contact: Barbara Slater)
- ◆ 9th Meeting of the Task Force on Biotechnology for Sustainable Industrial Development, Paris, 25-26 November 2004. (Contact: Chris Deane)
- ◆ 7th meeting of the Task Force on Biological Resource Centers, Paris, 29-30 November 2004. (Contact: Chris Deane)

- ◆ The OECD Expert Workshop on Atlantic Salmon. Moscow, Russia, November 2004. (Contact: Mar Gonzalez)
- ◆ OECD Working Group on Human Health - Related Biotechnology, Paris, 30 November 2004. (Contacts: Elettra Ronchi and Barbara Slater)
- ◆ OECD Working Party on Biotechnology, Paris, 1-2 December 2004. (Contact: Iain Gillespie)
- ◆ 16th Meeting of the Working Group for the Harmonisation of Regulatory Oversight in Biotechnology, Paris, 23-25 February 2005. (Contact: Peter Kearns)
- ◆ Workshop on Industrial Biotechnology and the Biobased Economy, April 2005 (tbc) (Contact: Chris Deane)
- ◆ Workshop on Pharmacogenomics, Autumn 2005 (tbc). (Contact: Elettra Ronchi)



OECD’S INTERNAL CO-ORDINATION GROUP FOR BIOTECHNOLOGY (ICGB)

OECD and its member countries have been undertaking work on biotechnology – including biosafety issues – since 1982.

In the meantime, biotechnology continues to have 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 and the International Futures Programme, chairs the ICGB. Peter Kearns, Head of Biosafety Programme, is the Secretary.

Contact: Peter.Kearns@oecd.org



MINISTERIAL DISCUSSIONS AT OECD

Biotechnology has hit the agenda of two sets of ministerial discussions at OECD over the past few months. Science Ministers from OECD countries (as well as China, Israel, the Russian Federation and South Africa) met on 29 & 30 January to discuss the theme “Science, Technology and Innovation for the 21st Century”, Ministers endorsed the paper “Biotechnology for Sustainable Growth and Development” (available as a free download at www.oecd.org/biotechnology) which sets out a strategy for moving towards a biobased economy. Subsequently, the first ever meeting at OECD level of health ministers (13-14 May) endorsed the elements of this strategy that relate to biotechnology, innovation and health and to getting the most out of the human genetics revolution. These perspectives were underlined during discussions with senior figures from industry and from civil society during a ministerial round table on health technology and innovation held on 13 May as part of the annual OECD Forum.



HARMONISATION OF REGULATORY OVERSIGHT IN BIOTECHNOLOGY

OECD’s Working Group on Harmonisation in Biotechnology comprises delegates from the 30 Member countries of OECD and the European Commission. Delegates are from those government ministries and agencies, which have responsibility for the environmental risk/ safety assessment of products of modern biotechnology. The Working Group also includes a number of observer delegations and invited experts who participate in its work. They include: Argentina; Russia; Slovenia; the United Nations Environment Programme (UNEP); the Secretariat of the Convention on Biological Diversity (SCBD); the United Nations Industrial Development Organisation (UNIDO); and the Business and Industry Advisory Committee to OECD (BIAC).

The focus of OECD’s programme on the harmonisation of regulatory oversight in biotechnology is on environmental safety assessment of transgenic organisms. One of the most important products of the work are *biosafety consensus documents* which address the biology of crop plants (for example, maize, soy bean, and rice)

or other organisms, such as micro-organisms, which are used in applications of modern biotechnology. Other documents address traits that are used in these applications, such as herbicide tolerance. These documents contain technical information which national authorities believe is important in safety/ risk assessment and are used in the regulatory review of biotechnology products. This information is said to be mutually acceptable among the OECD member countries. To date, 20 consensus documents have been published.

The 15th Meeting of the Working Group on Harmonisation of Regulatory Oversight in Biotechnology was held 16-18 June. One of the main items was a discussion on setting priorities for drafting future consensus documents as well as other new projects. At the same time, there has been an increasing interest in the biosafety consensus documents beyond the OECD member countries. For this reason, the Working Group thought it important to have a clear and authoritative explanation on the role they play in risk/ safety assessment, as well as a description of how they are developed. So for these reasons the Working Group completed a document, *An Introduction to the Biosafety Consensus Documents*, which will be published shortly.

The Working Group also continued to develop three projects: parameters for environmental risk/ safety assessment; work related to transgenic fish; and the role of information, from molecular characterisation, in safety assessment. This latter project is being carried out in coordination with the Task Force for the Safety on Novel Foods and Feeds.

Future events:

- Workshop on the biology of Atlantic Salmon, Moscow, Russia, November 2004.
- 16th Meeting of the Working Group for the Harmonisation of Regulatory Oversight in Biotechnology, Paris, 23-25 February 2005.

Recent Publications:

- 📖 *Consensus Document on the Biology of European White Birch*
- 📖 *Consensus Document on the Biology of Zea mays (Maize) (Also available in Japanese)*
- 📖 *Guidance Document on the Use of Taxonomy in Risk Assessment of Micro-organisms: Bacteria*

📖 *Guidance Document on Methods for the Detection of Micro-organisms introduced in the Environment: Bacteria*

In addition, hard copies of the proceedings of the international conference, *LMOs and the Environment*, are still available upon request.

Upcoming Publications:

- 📖 *An Introduction to the Biosafety Consensus Documents of OECD's Working Group for Harmonisation in Biotechnology*
- 📖 *Consensus Document on the Biology of Sunflower*
- 📖 *Consensus Document on the Biology of Citrus*
- 📖 *Consensus Document on the Biology of Cotton*

Web site: *Harmonisation of Regulatory Oversight in Biotechnology* available on BioTrack Online: <http://www.oecd.org/biotrack>

Contacts: Peter.Kearns@oecd.org
Mar.Gonzalez@oecd.org
Masahiro.Miyazako@oecd.org



SAFETY OF NOVEL FOODS AND FEEDS

The main goal of OECD's programme on the Safety of Novel Foods and Feeds is to promote harmonisation in the safety assessment of novel foods and feeds, including the products of modern biotechnology. Its outputs are used by governments, industry and other stakeholders.

The major output of this programme is also the development of consensus documents that provide information on compositional components related to food and feed safety, for example, major nutrients and toxicants of specific food crops. The programme also addresses other emerging issues that will promote and facilitate harmonisation in the safety assessment of novel foods and feeds. An important recent publication is *Considerations for the Safety Assessment of Animal Feedstuffs derived from GM Plants*.

The 9th meeting of the Task Force for the Safety of Novel Foods and Feeds, which will be held October

2004, will focus on the current and potential uses of consensus documents. An important aim will be to encourage a dialogue between members and non-member countries in order to identify future crop consensus documents of interest to both.

Other projects which will be discussed include: "Food Containing Bioactive Compounds", "Exotic Fruits and Vegetables", and the "Molecular Characterisation Project". The latter is being done in coordination with the Working Group on Harmonisation of Regulatory Oversight in Biotechnology. The relevance of information from molecular characterisation to both environmental and food risk/ safety assessment, indicates the value of collaboration between food safety assessors and environmental safety assessors.

Future event:

- 9th Meeting of the Task Force for the Safety of Novel Foods and Feeds, Paris, 11-13 October 2004.

Recent Publications:

- 📖 *Considerations for the Safety Assessment of Animal Feedstuffs derived from GM Plants (Also available in Japanese)*
- 📖 *Report on the Questionnaire on Biomarkers, Research on the Safety of Novel Foods and Feasibility of Post-Market Monitoring*
- 📖 *Consensus Document on Compositional Considerations for New Varieties of Bread Wheat*
- 📖 *Consensus Document on Compositional Considerations for New Varieties of Cotton*
- 📖 *Consensus Document on Compositional Considerations for New Varieties of Rice*

Upcoming Publications:

- 📖 *Consensus Document on Barley*
- 📖 *Consensus Document on Sunflower*
- 📖 *Consensus Document on Forage Legumes*

Web site: *Safety of Novel Foods and Feeds* available through BioTrack Online: <http://www.oecd.org/biotrack>

Contacts: Peter.Kearns@oecd.org
Mar.Gonzalez@oecd.org
Masahiro.Miyazako@oecd.org



BIOTRACK ONLINE

The BioTrack Online information system is the mechanism by which the Working Group for Harmonisation in Biotechnology and the Task Force for the Safety of Novel Foods and Feeds make available the results of their work. As such, BioTrack focuses on information related to the regulatory oversight of products of modern biotechnology. It includes details of regulatory contacts in OECD member countries, as well as information on major regulatory developments. It allows access to documents published by the Working Group and Task Force including the consensus documents. It also includes a database of products which have been approved in OECD member countries (mainly transgenic crops) as well as a database of field trials

Recently, there has been much activity related to the Product Database which contains information on those transgenic crops which have been approved for commercial use. Within this database, most transgenic crops have been allocated a “*unique identifier*”, in fact to date; unique identifiers have been provided for 97 approved transgenic products. These unique identifiers are designated following “*The OECD Guidance for the Designation of a Unique Identifier for Transgenic Plants*”, which was published in February 2002. The Unique Identifier (UI) is a simple alphanumeric code designated for each biotechnology product approved for commercial use. It 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 (SCBD)].

The OECD Secretariat has had a successful co-operation with the SCBD in assisting in the implementation of the pilot phase of the Biosafety Clearing House (BCH) which is called for as part of the Cartagena Protocol on Biosafety. This co-operation was the subject of a Memorandum of Co-operation, which has led to interoperability between information in the Product Database (including unique identifiers) and the BCH. Now that the BCH is in its operational phase, a new Memorandum is being drafted.

Web site: Product Database and Unique Identifiers:
<http://www2.oecd.org/biotech/>

Web site: *BioTrack Online*

<http://www.oecd.org/biotrack>

Contacts: Peter.Kearns@oecd.org
 Mar.Gonzalez@oecd.org
 Masahiro.Miyazako@oecd.org



BIOSECURITY: PREVENTING ABUSE OF RESEARCH AND RESOURCES IN THE BIOSCIENCES

Rapid advances in the biological sciences greatly contribute to the improvement of human welfare. They also constitute a very real potential for harm, as they could be misused to produce dangerous agents and toxins. It is urgently important to maintain a healthy research environment, ensuring responsible oversight of dual-use research within the scientific communities, industry and government bodies.

The International Futures Programme (IFP) is holding a high-level meeting in Frascati, Italy, on 17th-19th September this year to explore ways of avoiding potential abuse of research and resources in bioscience. High-ranking government officials and academics will tackle many aspects of the open access versus security dilemma, with a view to shedding light on key questions and future options.

The roundtable discussion will be organised in five sessions. The first explores the risks and opportunities of biological research, including possible misuse. The second emphasises the importance of open research systems with responsible access to resources, and the balance to be struck between openness and caution. The third reviews current governmental and non-governmental arrangements for governance of bioscience research and attempts to draw lessons concerning directions in future oversight. The fourth looks at possibilities of assuring responsible conduct through voluntary arrangements among stakeholders. The final session will draw conclusions concerning the adequacy of formal and informal tools to manage the threat posed, and possible next steps to create greater awareness of the issues.

Recent publication

📖 *The Security Economy, 2004. ISBN 92-64-10772-X*

Contact: Michael.Oborne@oecd.org



THE BIOECONOMY: ITS LONGER-TERM FUTURE AND POTENTIAL IMPACTS

Recent advances in the life sciences are making a reality of the prediction that this will be the century of biotechnology. A wide range of R&D activities are maturing at a remarkably rapid pace. New treatments and drugs, genetically modified foods, biologically controlled production processes, new materials, biologically based computing – 20 or 30 years from now, these and many other applications may well become part of our everyday lives, improving health, the environment, and industrial, agricultural and energy production, and affecting our societies as profoundly as information technologies have already done.

What's more, biotechnological techniques, materials and devices could – especially if they converge with other technologies such as IT, bioinformatics and nanotechnologies – transform the way a whole host of products are designed, manufactured and used. That transformation of industry and consumption could provide significant opportunities for sustainable growth in both developed and developing countries. It could also lead to far-reaching changes in economic activity and society, as well as to some complex policy challenges.

A workshop to be organised by the International Futures Programme (IFP) in 2005 will be assessing just how pervasive and widespread biotechnological applications are likely to be, the prospects for convergence over the next two to three decades, the likely impact on the economy, and the implications for policy.

Contacts: Michael.Oborne@oecd.org
Iain.Gillespie@oecd.org
Chris.Deane@oecd.org



BIOTECHNOLOGY FOR SUSTAINABLE INDUSTRIAL DEVELOPMENT

The ability of biotechnology to lower costs and reduce the environmental impact of industry has been illustrated by the OECD 2001 report *The Application of Biotechnology to Industrial Sustainability*.

Using biobased products and processes offers the prospect of reducing reliance on finite resources of fossil fuels and developing an economy that is increasingly based on renewable resources, producing lower carbon emissions and helping to mitigate climate change.

Advances in genomics, proteomics, metabolomics and pathway engineering are producing new generations of technologies that create the potential for using renewable biomass as feed-stock for industrial products and processes across a broad range of sectors.

To enable the transition to a biobased economy, an examination of the policy challenges and of the impact of existing policy frameworks is essential. Efforts to develop the evaluation frameworks, statistics, tools and indicators necessary to help deliver coherent policies that support the transition to a biobased economy were endorsed by OECD Science and Technology Ministers in January 2004.

The Task Force on Biotechnology for Sustainable Industrial Development have used scenarios to further progress on a report that will support and enable the development of a biobased economy. A Task Force workshop held in June 1-2, 2004 advanced the development of a survey instrument and other elements that will contribute to this report, which will be delivered in 2005.

Future event:

- 9th Task Force meeting will be held on 25-26 November 2004.
- Workshop on Industrial Biotechnology and the Biobased Economy, April 2005 (tbc)

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

Contact: Chris.Deane@oecd.org



BIOLOGICAL RESOURCE CENTRES

Biological resources are the foundation of all biological sciences research. They provide the source material for scientific investigation, leading to many of the discoveries on which biotechnology is founded. Ensuring the proper maintenance and exchange of biological resources is essential to the future advancement of biotechnology and its capacity to contribute to sustainable growth.

Biological resource centres (BRCs) are both service providers and repositories of the living cells, genomes of organism, and information relating to heredity and the functions of biological systems. BRCs contain collections of cultural organisms (e.g. micro-organisms, plant, animal and human cells) replicable parts of these (e.g. genomes, plasmids, viruses, cDNAs), viable but not yet culturable organisms, cells and tissues, as well as databases containing molecular, physiological and structural information relevant to these collections and related bioinformatics.

A global network of biological resource centres is a crucial part of the infrastructure that underpins advances in the biological sciences and their capacity to contribute to sustainable growth. Since 1999 the Working Party in Biotechnology, through the establishment of its task force on BRCs has been building international cooperation in this area.

Efforts to continue work in developing the instruments for the establishment of a Global Biological Resources Network were endorsed by OECD Science and Technology Ministers in January 2004. These instruments are at an advanced stage of development and work is on-target to culminate in 2006. In light of its progress, the task force on BRCs, at its 6th meeting in March 2004, restructured its internal working groups to meet the demands of the next phase in developing the necessary instruments.

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

Future event:

- 7th meeting of the Task Force on BRCs will be held in Paris on 29-30 November 2004

Contact: Chris.Deane@oecd.org



SAFE DRINKING WATER

The OECD held an expert meeting on “Emerging Risks to Water Supplies: Best Practice for Improved Management and Preparedness to Protect Public Health” in Cuernavaca, Mexico 28-30 July 2003.

The theme of the Cuernavaca meeting arose out of a growing awareness that the increasing demands being placed on water supply for drinking, irrigation and sanitation continue to lead not just to shortages of water but also to the emergence and re-emergence of health risks to the public through water-borne disease. This is true for all countries, whether highly industrialised, economies in transition, or developing countries, and in many the risk of deliberate biological contamination of drinking water by terrorists remains a real threat.

In view of the above issues, the focus of the meeting was on two main topics:

- Facing water shortage, and how to effectively implement and manage water improvement, focusing particularly on wastewater re-use.
- Risk reduction and preparedness efforts.

Experts at the meeting called for international commitment to establish a new, inclusive, mechanism that will foster best practice and good governance in water hygiene and sanitation and develop common methods of working for national emergency response systems that deal with outbreaks of waterborne disease. A useful way forward would be for countries to develop common approaches in risk communication and establish a laboratory network.


The Secretariat is refining proposal for further action to bring back to future WPB.

The Report from the meeting is scheduled for publication towards the end of 2004.

Recent Publication:

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

Contact: Elettra.Ronchi@oecd.org



OECD TO DEVELOP BEST PRACTICES FOR QUALITY ASSURANCE OF LABORATORY PRACTICE IN MOLECULAR GENETIC TESTING

In 2003 the OECD ran a large-scale survey on molecular genetic testing laboratory practices across 18 OECD countries. These countries are Austria, Belgium, Canada, Czech Republic, Finland, France, Germany, Italy, Japan, Norway, Portugal, United Kingdom, United States, Spain, Sweden, Switzerland and Turkey. The survey was completed October 31, 2003.

The short-term objectives of the survey are to determine what quality assurance (QA) practices are being undertaken in clinical laboratories that offer molecular genetic testing (MGT) and to compare these practices across OECD countries. The project's longer-term goals are to facilitate:

- Identification of areas for international co-operation in developing standards, proficiency testing and interpretative guidelines.
- Development of international guidelines based on general principles.
- International collaboration among disease-specific consortia, particularly for testing of rare diseases.

The survey was designed to assess personnel qualifications, reporting and QA practices, and the policies of MGT laboratories with regard to informed consent, confidentiality of results and specimen retention. In addition, information was collected about transborder flow of specimens and the impact of patents.

822 laboratories submitted a completed response for an overall response rate of 65%. In May 2004 delegates to the Working Party on Biotechnology agreed that the survey had raised awareness about the need for action at international level and that further work on drawing out best practices in quality assurance at OECD level was needed. This will be carried out over the period 2005-2006.

The report on the survey is scheduled for publication early in 2005.

Contact: Elettra.Ronchi@oecd.org



OECD ASKS “WHAT’S DIFFERENT ABOUT PHARMACOGENOMICS?”

The Working Party on Biotechnology is embarking upon the planning for a workshop on pharmacogenomics for the second half of 2005. The workshop will aim to reach OECD-wide agreement on challenges to regulatory systems (supply and demand-side) and the otherwise efficient working of health systems that may result from the pharmacogenetics/ genomics revolution. Efforts will be made to agree common approaches to addressing identified challenges.

Contact: Elettra.Ronchi@oecd.org



BEST PRACTICE GUIDELINES FOR THE LICENSING OF GENETIC INVENTIONS

Licensing practices are rapidly changing as companies, public institutions, governments, and civil society come to terms with the complexities of intellectual property protection and access to genetic inventions.

Where problems have arisen with access to genetic inventions, they have been with the licensing system rather than the patent system *per se*. This was the conclusion of the Working Party on Biotechnology (WPB) workshop on genetic inventions held in Berlin in January 2002 and of the subsequent report ‘*Genetic Inventions, IPRs and Licensing Practices: Evidence and Policies*’ (OECD 2002).

In 2003 the WPB established an Expert Group to develop OECD guidelines for the licensing of genetic inventions to facilitate best practice in this field. The Expert Group is in the process of developing these guidelines that are intended to serve as voluntary, non-binding recommendations to those engaged in the licensing of genetic inventions.

The expert group next meets in October 4-5, 2004 in Vienna, Austria.

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

Contacts: Iain.Gillespie@oecd.org



BEST PRACTICE IN GOVERNANCE AND MANAGEMENT OF HUMAN GENETIC RESEARCH DATABASES

OECD’s Working Party on Biotechnology held a workshop on “Human Genetic Research Databases – Issues of Privacy and Security” in Tokyo, Japan on 26th and 27th February 2004.

Around sixty high-level experts from OECD countries and Estonia participated in the workshop, which focused on privacy and security issues associated with human genetic research databases that contain human genetic and genomic information collected for research purposes. The aim of the workshop was to help participating countries to:

- Gain an understanding of current practices internationally for the acquisition and maintenance of human genetic and genomic data and information;
- Identify any challenges in the management of genetic databases (including issues about their storage, use, transfer, disposal and abolition) that need to be resolved; and
- Identify good management practices for human genetic research database management, where such good practices exist.

The workshop concluded that:

- Human Genetic Research Databases (HGRDs) are an invaluable tool for research into the genetic basis of disease.
- There remains no expert consensus on whether genetic information should be treated as distinct from other medical information, though the perception of many that it has led to an increasing impact of that perception on policy making. Further

efforts are required to avoid inappropriate consequences arising from such perceptions.

- Public – and more particularly, patient – trust in the development, management and governance of HGRDs remains an essential element of the enabling environment for health research and innovation in this field. (The workshop considered a number of practical approaches to assure public engagement and trust).
- Clear procedures must be in place for informing patients about the way that data based on their genetics might be used in HGRDs. Participants questioned whether current approaches to informed consent were sufficient to assure patient privacy and achieve an appropriate balance with research access. Whether or not such a balance is achieved in public policy will affect how successful genetic science is as a driver for innovative products and processes and delivery of better health.
- The OECD should develop principles of best practice for the management and governance of Human Genetic Research Databases.

The full report of the HGRD Tokyo workshop will be completed during 2004 and subsequently published.

The Working Party on Biotechnology will begin work on developing best practice in this area shortly.

Contacts: Kenji.Takezawa@oecd.org



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. Identification and minimum purity criteria are a component of sustainability, 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, particularly between the northern and southern hemispheres. They are implemented by a total of fifty-two member and non-member countries across all continents and three more countries have submitted an application to join. Their essential purpose is to harmonise certification with a view to facilitating international seed trade. Over 185 species, including all basic staples, are eligible and 33 000 varieties from all participating countries appear on the latest *OECD List of Varieties Eligible for Certification*. Some current issues in discussion have been the changing role of government in seed control, the impact of biotechnology and advanced breeding methods on seed certification (cotton, oilseed rape). Working Groups on Accreditation and on Genetically Modified Seed Issues have been established. Contacts have been made with the Secretariat on the Convention on Biological Diversity (CBD) on issues related to compliance in the Cartagena Protocol.

Similarly, contacts has been made with the International Foundation for Organic Agriculture (IFOAM) on organic seed standards.

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

Future events:

- Meeting of the Working Groups on Accreditation and GM Seed Issues (6 September 2004 in Budapest, Hungary)
- Annual Meeting of National Designated Authorities (8-10 September 2004, Vienna, Austria)

Publications:

- ☞ *List of Varieties Eligible for Certification 2003/2004*
- ☞ *OECD Seed Schemes "2004"*

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

Contact: Jean-Marie.Debois@oecd.org



CO-OPERATIVE RESEARCH PROGRAMME: 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:

- 1 New agricultural products for sustainable farming and industry;
- 2 Quality of animal products and safety of food;
- 3 Enhancing environmental quality in agricultural systems;
- 4 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/>.
- **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).

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
- 📖 *4th European Congress of Mammatology, the genus mus as a model of evolutionary studies - a symposium in honour of Louis Thaler (published by Biological Journal of the Linnean Society). ISBN 80-903329-0-0*
- 📖 *14th European Symposium on Poultry Nutrition: Proceedings from 2003 conference published by the World's Poultry Science Association. (No isbn ref.)*
- 📖 *International symposium on Environmental Biogeochemistry, "Biogeochemical Aspects of Earth System and Bioremediation of Polluted Environments. Published by ISEB 16 ISBN4-9901886-0-8.*
- 📖 *"Biological Resources and Migration" published by Verlag Springer. ISBN 3-540-21470-4*
- 📖 *Concerns and Responses to Food Safety, Health and Environmental issues: published by Reproduction Nutrition Development, June 2004 (ISSN0926-5287)*

Forthcoming publications linked to 2003 conferences

- 📖 *International Conference on the Molecular Biology and Biotechnology of Ciliates and Anaerobic Protozoa (to be published by OECD)*
- 📖 *What risk analysis is Appropriate? Options for Future Policy Making towards integrated Agro-Food Systems (to be published by OECD).*
- 📖 *Publication of proceedings on conference on "Virus resistant transgenic papaya: a case study on the social and economic impact of a transgenic product in the US, and its application to lesser developed countries. (to be published by Pieroglyph 2004)*
- 📖 *Publication of proceedings on conference on "Risk assessment of Food obtained from cloned livestock" to be published by INRA 2004 France.*

Forthcoming publications linked to 2004 conferences:

- 📖 *Crop Fertility and volunteerism: A threat to Food Security in the Transgenic Era? Bellagio, Como Italy, 24-29 May 2004*
- 📖 *Anticholinesterasa agents, health and sustainable agriculture. A specialized session of the VIIIth International Meeting on Cholinesterases, Perugia, Italy ,26-30 September 2004*
- 📖 *Phytoremediation: Environmental and Molecular Biological Aspects, Keszthely, Hungary, 9-12 September 2004*
- 📖 *Nutrition and food safety, Headquarters of the Société Scientifique d'Hygiène alimentaire, Paris France, 17-18 June 2004*
- 📖 *Rhizosphere 2004: Perspectives and Challenges - A tribute to Lorenz Hiltner, Munich Germany, 12-17 September 2004*
- 📖 *Improving the Balance Between Economic Agricultural Production and Environmental Quality through Enhanced Decision Making, Hawaiï, United States, 9-11 November 2004*

Contacts: Liliane.Shettle@oecd.org
Caroline.Keogh@oecd.org



STRENGTHENING WORK ON BIOTECHNOLOGY, INNOVATION AND HEALTH

OECD member country science ministers and health ministers have endorsed a strengthening of the work of the Organisation on biotechnology, innovation and health. A number of activities are under way to meet this invitation:

(i) A process is in place to develop *case studies* of particular biotechnologies in the human health area which will focus on experience in different OECD countries relating to the challenges met in bringing products to the market and seeing appropriate subsequent diffusion and uptake;

(ii) The report of the technology part of OECD's health project, "*Health Technologies and Decision Making*" will be released shortly (watch 'What's New' at www.oecd.org/biotechnology). This reports on a study of decisions on uptake of different health technologies (including

biotechnology) are reached in case study OECD countries and sets out some of the challenges posed by biotechnologies for decision makers in ensuring that successful innovations are not unduly restricted in entering the marketplace and diffusing within health systems. These challenges will be addressed further by a forthcoming OECD workshop in Berlin (see below);

(iii) The relevant OECD committees are actively considering how the Organisation's contribution to ensuring more successful delivery of biotechnology innovations that deliver better health can be enhanced. Watch this space for news.

Future event:

- Workshop, "Innovation in Healthcare: Examining the Links Between Policy Makers and Innovators", 15-16 November, Berlin, Germany.

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

Contacts: Barbara.Slater@oecd.org
Iain.Gillespie@oecd.org



BIOTECHNOLOGY STATISTICS IN OECD MEMBER COUNTRIES

In May 2004 the OECD held the 5th *ad hoc* Meeting on Biotechnology Statistics. Key issues addressed at this meeting include: further development of the biotechnology statistics framework, which is expected to be released by the end of 2004; presentation of an inventory of biotechnology statistics collected by official sources, to be released as an STI Working paper later this summer.

The *ad hoc* Meeting on Biotechnology Statistics, under the aegis of the National Experts group on Science and Technology Indicators (NESTI), is taking a one-year reflection period, during which time a steering group will elaborate a new set of objectives, to be presented at the 2005 NESTI meeting.

Forthcoming working paper:

📖 *Biotechnology Statistics in OECD Member Countries: An Inventory (STI Working Paper 2004)*. This paper will be available at: www.oecd.org/sti/working-papers

Contact: Brigitte.Vanbeuzekom@oecd.org



ECONOMIC IMPACTS OF BIOTECHNOLOGY

An OECD workshop was held in May 2004 on measuring the Economic Impacts of Biotechnology. The workshop was intended as a first step to measure impacts, in response to growing demand by policy makers for quantitative measures of the importance of biotechnology for economic performance. The workshop included three sessions, one focusing on the biotechnology sector and its impacts in the economy, the second focusing on the role of biotechnology innovation, and the third examining the overall impacts of biotechnology and the work that could be undertaken in this area to further advance our understanding. The workshop showed that biotechnology is forcing a rethinking of the statistical toolbox. A more tailored approach to measuring impacts, distinguishing between key fields of application (health, agro-food, industrial processing, etc.) might offer the best way forward. Next steps on how to measure the impacts of biotechnology will be considered in the near future.

Contact: Brigitte.Vanbeuzekom@oecd.org



STUDY OF INNOVATION SYSTEMS

The Working Party on Technology and Innovation Policy of the Committee on Scientific and Technological Policy (CSTP) has launched a set of studies investigating the sectoral dimensions of innovation systems. The *Case Studies in Innovation* are aimed at identifying the specificities of the processes of knowledge creation, diffusion and exploitation in selected fields of technology or industry sectors while adopting the overall

framework of the National Innovation Systems approach. They are expected to contribute to the development of innovation policies in member countries by assisting them to balance generic policies for innovation with more customized policies that account for sector-specific characteristics and requirements.

One of these Case Studies is devoted to *Pharmaceutical Biotechnology*. Participating countries (Belgium, Finland, France, Germany, Japan, the Netherlands, Norway and Spain) have contributed to the work of the Focus Group by providing national reports on their respective national biopharmaceutical innovation system. These reports, authored by national experts, are available on the OECD project website (see the link below). Based on these reports and on inputs provided by the OECD Secretariat the Focus Group lead countries (the Netherlands, Germany and Norway) are in charge of finalising a Synthesis Report.

After presenting a draft synthesis to the Working Party on Technology and Innovation Policy in June 2004, lead countries are presently working on finalising the report. In addition to brief chapters on national biopharmaceutical innovation systems in participating countries, this synthesis includes a comparative analysis of the structure, dynamics and performance of national biopharmaceutical innovations systems, the openness of these systems, the role of selected demand-side factors in innovation, as well as systemic imperfections. Finally, the report will draw conclusions concerning innovation policies. The Synthesis Report is scheduled for publication towards the end of 2004.

Web site: <http://www.oecd.org/sti/innovation>
 OECD project website: see item "Sectoral Case Studies in Innovation" under "Don't miss".

Contacts: Jean.Guinet@oecd.org
 Gernot.Hutschenreiter@oecd.org



BIOMASS AND AGRICULTURE

A report on "*Biomass and Agriculture: Sustainability, markets and policies*" was published in September 2004, with further information provided on the OECD website (see address below). This report is the proceedings of an OECD

Workshop on Biomass and Agriculture held in June 2003 in Vienna, Austria. The Workshop covered two broad themes: the contribution of agricultural biomass to sustainability, and policy approaches, including market-based initiatives, impacts and options for developing agricultural biomass. Each theme was explored in depth supported by specific country examples, with background to the discussions provided by general overview papers. In this report there is a wealth of material relating to agricultural biomass, bioenergy and biomaterials in OECD countries, contributing to the current debate on agricultural biomass, particularly in the context of agricultural policy reform, sustainable development, and developments in the biobased.

Publication: September, 2004

📖 *Biomass and Agriculture: Sustainability, markets and policies*

Web site: <http://www.oecd.org/agr/env>
 Under "New Publications"

Contact: Kevin.Parris@oecd.org



WHO'S WHO IN BIOTECH AT OECD

Michael OBORNE (SGE/AU)
 Chairman of the ICGB
 Director Multidisciplinary Issues and the International Futures Program

Peter KEARNS (ENV/EHS)
 Secretary to the ICGB
 Head of Biosafety Programme
 Harmonisation of Regulatory Oversight in Biotechnology
 Safety of Novel Foods and Feeds

Chris DEANE (STI/BIO-SGE/AU)
 Biological Resource Centres
 Sustainable Industrial Development
 Biosecurity

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

Helen FISHER (PAC/COM)
 Contact for Media Enquiries

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

Iain GILLESPIE (STI/BIO)
Head of Biotechnology Unit
Working Party on Biotechnology
Health Technology and Innovation

Maria del Mar GONZALEZ (ENV/EHS)
Harmonisation of Regulatory Oversight in
Biotechnology
Safety of Novel Foods and Feeds

Jean GUINET (STI/STP)
Innovation Systems and Technology Policy

Gernot HUTSCHENREITER (STI/STP)
Innovation Systems and Technology Policy

Wilfrid LEGG (AGR/PE)
Agriculture and Environment

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

Dirk PILAT (STI/EAS)
Economic Impacts of Biotechnology

Elettra RONCHI (STI/BIO)
Quality Assurance of Genetic Testing
Pharmacogenomics
Safe Drinking Water

Christina SAMPOGNA (STI/BIO)
Intellectual Property Rights & Biotechnology
Licensing Guidelines
Patent Pools
Human Genetic Research Databases

Liliane SHETTLE (AGR/CMU)
Cooperative Research Programme

Barbara SLATER (STI/BIO)
Biotechnology, Innovation and Health
Innovation Case Studies
Health Technology Assessment

Kenji TAKEZAWA (STI/BIO)
Human Genetic Research Databases: Issues of
Privacy and Security

Brigitte VAN BEUZEKOM (STI/EAS)

Biotechnology Statistics

Andy WYCKOFF (STI/EAS)
Biotechnology Statistics



CONTACT POINT:

- Peter Kearns
Secretary, ICGB
OECD
2 rue André-Pascal
75775 PARIS Cedex 16
France
Tel: (33-1) 45 24 16 77
Fax: (33-1) 45 24 16 75
E-mail: Peter.Kearns@oecd.org

MEDIA ENQUIRIES:

- Helen Fisher
OECD, Communications
2 rue André-Pascal
75775 PARIS Cedex 16
France
Tel: (33-1) 45 24 80 97
Fax: (33-1) 45 24 94 37

E-mail: Helen.Fisher@oecd.org



ENDNOTE: A BRIEF GUIDE TO THE OECD

The Organisation for Economic Co-operation and Development (OECD) is an intergovernmental organisation with 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. Its members are the Ambassadors of the Member countries to OECD. It is chaired by OECD's Secretary-General. Once a year, it meets at the level of Ministers from member countries. 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, and Task Forces), 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
- ◆ Working Group on Human-Health-Related Biotechnologies
- ◆ Task Force on Biological Resource Centres
- ◆ Task Force on Biotechnology for Sustainable Industrial Development

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 (ad interim)

- Meetings of Experts on New and Emerging Health Related Technologies (NEHRT)

