ORGANISATION DE COOPÉRATION ET DE DÉVELOPPEMENT ÉCONOMIQUES

OECD OCDE

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

No. 15, July 2005

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. The contents of this newsletter have been provided by those members of the OECD secretariat who are responsible for the various activities. Members of the secretariat can be contacted via the e-mail address: icgb@oecd.org. Alternatively, individuals can be contacted via e-mail using the form firstname.lastname@oecd.org .

This edition is now available on the Internet as a "live-link" version.

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

OECD and its member countries have been addressing issues related to biotechnology since 1982.

Since that time, 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, the Internal Co-ordination Group on Biotechnology (ICGB) was established to facilitate co-ordination among these sectors.

Michael Oborne, the Director of OECD's Advisory Unit on Multidisciplinary Issues and the International Futures Programme, chairs the ICGB. Peter Kearns, the Head of OECD's Biosafety Programme, is the Secretary.

Contact: Peter Kearns

OECD LAUNCHES SURVEY ON THE BIOBASED ECONOMY

OECD has launched a survey to assess what progress is being made by governments, industry and others towards realising a biobased economy. The findings of this survey will be included in a 2006 OECD policy report. Participation in the survey (http://www.oecd.org/sti/biotechnology/biobasedeconomy) is open to all. Responses are invited by 15 August 2005.

WWW.BIOSECURITYCODES.ORG: A NEW INTERNATIONAL FUTURES PROGRAMME WEBSITE

The OECD's International Futures Programme (IFP) has launched a new website dealing with security issues and the biosciences:

http://www.biosecuritycodes.org

The website provides a comprehensive information portal for general biosecurity information as well as more focused information on codes of conduct and regulatory oversight mechanisms for the life sciences.

Why this site?

In September 2004, the International Futures Programme of the OECD convened a meeting in Frascati, Italy that brought together 55 selected participants from government, industry, academia, public research organizations, scientific societies, and the science publishing field to discuss promoting responsible stewardship in the biosciences and avoiding the potential abuse of research and resources. Following the meeting, it was clear that there was room to build further international consensus in the biosecurity field. Legal structures, governmental apparatuses, and definitions vary widely between countries, and there was a call for better, more transparent information. Participants agreed that a web-based source of information was needed.

What will you find on the site?

Biosecurity and regulatory oversight of the life sciences are established through a complex combination of national, international, and organizational statutes. The relative complexity of jurisdictions and lack of understanding of how these mechanisms interact often means that there is poor global perspective on biosecurity issues. The site fills this gap by providing key information on governmental, institutional, academic, and private sector biosecurity actors as well as worldwide biosecurity legislation, events, terminology, and background materials.

How can this site help me stay up to date on biosecurity events and issues?

You may sign up for a mailing list by emailing webmaster@biosecuritycode.org with your name, title, and company/organisation in order to receive periodic email notifications of updates to the site as well as to receive all the information about the latest biosecurity events around the world.

How can I get involved?

The site is "work in progress" and will be continually updated. Biosecurity is a rapidly developing field, and the IFP will require help in identifying interesting and pertinent information to add to our site. Interaction is encouraged, and comments about the content or any potential omissions can be sent to webmaster@biosecuritycode.org.

Recent publication:

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

Contact: Michael Oborne
David Sawaya

THE BIOECONOMY: ITS LONGER-TERM FUTURE AND POTENTIAL IMPACTS

The International Futures Programme (IFP) are preparing a workshop for 2 November 2005, which aims to assess 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.

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 is 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.

For further details please consult the document *The Bioeconomy in 2030: A Policy Agenda*
http://www.oecd.org/dataoecd/47/19/35070283.pdf

Contacts: Michael Oborne
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GUIDELINES FOR THE LICENCING OF GENETIC INVENTIONS MOVE TOWARDS COMPLETION

National experts have agreed how the comment received during public consultation on the Guidelines should be incorporated. The Guidelines have now begun the clearance process through the relevant OECD internal bodies. It is hoped that they may be agreed and adopted by the end of 2005.

ECONOMIC IMPACT OF NEW AND EMERGING INFECTIOUS DISEASES ON OECD ECONOMIES

OECD work is beginning on addressing the burden that the emergence of infectious diseases has on the global economy, with a particular focus on the economies of OECD countries. The work is intended to complement work

done elsewhere on the impact of such diseases on developing country economies and goes hand in hand with analysis of options for overcoming market failure in the delivery of new diagnostic, therapeutic and preventative technologies.

HARMONISATION OF REGULATORY OVERSIGHT IN BIOTECHNOLOGY

The main focus of OECD's Working Group on Harmonisation of Regulatory Oversight in Biotechnology is on environmental risk/ safety assessment of transgenic (genetically modified) crops. The work aims to ensure that the information used in risk/ safety assessment, as well as the methods used to collect such information, is as similar as possible. This improves mutual understanding amongst countries, increases the efficiency of the risk/safety assessment process and avoids duplication of effort, while reducing barriers to trade.

The participants of the Working Group are mainly from those government ministries and agencies, which have responsibility for the environmental risk/ safety assessment of products of modern biotechnology. There are also a number of observer delegations and invited experts who participate in the work. They include: Argentina; Russia; Slovenia; the Secretariat of the Convention on Biological Diversity (SCBD); and the Business and Industry Advisory Committee to OECD (BIAC). During the last couples of years, there has been increased participation of other non-member countries such as Brazil, Chile, China, Egypt and India, under the auspices of OECD's Global Forum on the Knowledge-based Economy.

The publication of *consensus documents* continues to be a major output of the work. Typically, consensus documents compile information on the biology of specific crop plant species which is for use in environmental risk/ safety assessment. Many documents have focused on those major crop plants which are important in modern biotechnology such as maize, soy bean and rapeseed. Other documents cover traits that are used in genetic modification such as herbicide tolerance. Some documents have addressed other types of organism used in applications of modern biotechnology such as bacteria. All consensus documents include information which national authorities believe is important in risk/ safety assessment and can be used in the regulatory review of transgenic organisms. To date, 27 consensus documents have been published. A recent publication, *An Introduction to OECD's Biosafety Consensus Documents,* describes the purpose of these documents as well as the process by which they are drafted, reviewed and brought to publication.

In addition, the Working Group organised an Expert Workshop on the biology of Atlantic salmon. This workshop was held in Moscow, 29 November - 1 December 2004. This was the first occasion for the Working Group to address environmental safety issues related to a transgenic animal. A major feature of the Workshop was the participation of experts from key non-member countries (Chile, China, India, Russia and Tanzania), who have had experience with transgenic fish. The report of this event will be published.

The experts presented a wide range of information on the biology and ecology of Atlantic salmon, as well as details of recent developments in salmon breeding and aquaculture. The main outcome was the conclusion that the Working Group could use a similar safety approach as it has used with transgenic plants, through the drafting consensus documents. The Working Group is now organising a second OECD Expert Workshop to start drafting an operational plan for a consensus document on Atlantic salmon. This Workshop will be held in Trondheim, Norway, the 12th-14th October 2005.

The 17th meeting of the Working Group will be held at OECD Headquarters, 24-26 October 2005. In addition to a discussion of a number of draft consensus documents and projects, the Working Group will agree on the Programme of Work for 2006-2008.

Future events:

- OECD Expert Workshop on the Biology of the Atlantic salmon. Trondheim, Norway, the 12th-14th October 2005
- 17th Meeting of the Working Group for the Harmonisation of Regulatory Oversight in Biotechnology, Paris, 24-26 October 2005.

Recent Publications:

- *An Introduction to the Biosafety Consensus Documents of OECD's Working Group for Harmonisation in Biotechnology*
- *Guidance Document on Methods for Detection of Micro-organisms Introduced into the Environment: Bacteria*
- *Consensus Document on the Biology of Sunflower*
- *Consensus Document on the Biology of Citrus*
- *Consensus Document on the Biology of Cotton*

Upcoming Publication:

- *Consensus Document on the Biology of Papaya*
- *Consensus Document on the Biology of Western White Pine*
- *Consensus Document on the Biology of Oyster mushroom*
- *Report of the OECD Expert Workshop on the Biology of Atlantic salmon (salom salar), Moscow 29 November-1 December 2004.*

Web site: http://www.oecd.org/biotrack

Contacts: Peter Kearns
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Masatoshi Kobayashi

BIOTRACK ONLINE

OECD's BioTrack Online information system (http://www.oecd.org/biotrack) is the mechanism by which the Working Group on Harmonisation in Biotechnology and the Task Force for the Safety of Novel Foods and Feeds make available the outputs of their work. But it allows access to much more than the documents containing risk/safety assessment information published by the Working Group and Task Force. It also includes a Product Database of transgenic products which have been approved for commercial use in OECD member countries (mainly transgenic crops) as well as a database of small-scale field trials. There are also details of regulatory contacts in OECD member countries, as well as information on major regulatory developments such as laws, regulations and guidelines.

A major output of this work is unique identifiers for transgenic crop plants. Unique identifiers are important for the accurate retrieval of information on specific transgenic products from OECD's Product Database (http://www.oecd.org/biotrack/productdatabase) as well as linked national and international databases. A unique identifier is a simple alphanumeric code designated for each product approved for commercial use. These

identifiers are designated following "*The OECD Guidance for the Designation of a Unique Identifier for Transgenic Plants*", which was published in February 2002. To date, 97 identifiers have been provided for approved transgenic crop plants.

The work on the databases involves co-operation with the Secretariat of the Convention on Biological Diversity (SCBD) in the implementation of the Biosafety Clearing House (BCH) which is part of the Cartagena Biosafety Protocol. This co-operation has been established through a Memorandum of Co-operation (MOC) between OECD and the SCBD.

Web site: *Product Database and Unique Identifiers*
http://www.oecd.org/biotrack/productdatabase

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

Contact: Masatoshi Kobayashi

SAFETY OF NOVEL FOODS AND FEEDS

OECD's Task Force for the Safety of Novel Foods and Feeds was established in 1999. The main goal of the Task Force is to promote harmonisation in the safety assessment of novel foods and feeds, including products of modern biotechnology. Delegates to the Task Force are from those ministries and agencies, which have responsibility for the safety of products (including those derived from modern biotechnology) from a human food and animal feed safety perspective. In addition to the OECD member countries, the Task Force also includes a number of observer delegations and invited experts who participate in its work. They include: Argentina; Russia; Slovenia; FAO; and the Business and Industry Advisory Committee to OECD (BIAC).

The main output of the Task Force is its food and feeds safety consensus documents. These documents provide information that is important in the risk assessment of transgenic (genetically modified) foods. To this end, the documents compile information on the major nutrients, toxicants, anti-nutrients and allergens of specific food crops. To date 11 consensus document have been completed and published, and others are been drafted.

Food safety issues associated with new crops and foods/feeds have become an increasingly global issue. The need to meet health and safety standards needs the participation of worldwide expertise. During the 9th meeting in October 2004, the Task Force hold a special focus session on the uses of consensus documents. This was an opportunity for delegations to exchange their experiences in the use of published documents as well as identifying needs for future work. Non members' participation (Brazil, Latvia, South Africa, and Thailand) to this dialogue was possible through the Global Forum on the Knowledge-based Economy (GFKE). This is important since the dialogue showed that the consensus documents are used by non-members as well as member countries.

Accordingly, non-member countries participation has been increasing within the Task Force and this has been reflected in the Programme of Work 2006-2008. The outcome expected is to broaden the expertise inputs within the document as well as addressing foods and feeds products that are of great interest for them. In fact, the acting role from key non-member countries is also increasing. During the 10th meeting of the Task Force, which was held in Paris, 20-22 June 2005, Thailand proposed to start drafting a first draft of a consensus document on papaya, and South Africa is currently working on an operational plan for a document on cassava. Both proposals were welcomed by the Task Force.

Future event:

- 11th Meeting of the Task Force for the Safety of Novel Foods and Feeds, Berlin, Germany, 6-8 March 2006.

Recent Publications:

🕮 *Consensus Document on Compositional Considerations for New Varieties of Alfalfa and Other Temperate Forage Legumes: Key Feed Nutrients, Anti-Nutrients and Secondary Plant Metabolites*

Upcoming Publication:

🕮 *An Introduction to the Food/Feed Safety Consensus Documents of the Task Force.*

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

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DRAFT GUIDELINES FOR THE LICENSING OF GENETIC INVENTIONS

Biotechnology and genetics research have been subjects of extensive investment by both the public and private sectors, with the products and processes emerging from these efforts making a significant and increasing contribution to human health and health care. Moreover, biotechnological, including genetic, innovations have been the subject of intellectual property rights for decades. Over the last decade, as the number of such innovations has increased, their use in and importance for the human health care field has also grown.

In this light, the OECD has undertaken work in the field of licensing and biotechnological inventions, with a particular focus on development of draft guidelines for the licensing of genetic inventions. The need for these was highlighted during an expert workshop examining issues related to intellectual property, licensing practices and genetic inventions. OECD work to develop draft guidelines was subsequently endorsed by the OECD Committee on Scientific and Technological Policy meeting at Ministerial level in January 2004 and by OECD Health Ministers at their meeting in May 2004.

The draft guidelines offer principles and best practices for the licensing of intellectual property rights that relate to genetic inventions used for the purpose of human health care. They are targeted at those involved with innovation and the provision of services in health, and particularly at those involved in the licensing of such inventions. Overall, the draft guidelines seek to foster the objectives of stimulating genetic research and innovation while maintaining appropriate access to health products and services.

The OECD Secretariat has revised the draft guidelines in light of the comments received from consultations held in February and March 2005. These will now be put to the relevant internal OECD bodies for adoption. It is hoped that the agreed Guidelines will be issued before the end of 2005. Information concerning this project may be obtained on our website.

Website: http://www.oecd.org/sti/biotechnology/licensing (in English)
http://www.oecd.org/sti/biotechnologie/licences (in French)

Contact: Christine Sampogna

THE IMPACT OF PHARMACOGENOMICS ON HEALTH SYSTEMS

In 2004, the OECD Working Party on Biotechnology (WPB) announced it will review what could best be done to advance the efficiency, utility and use of genomic knowledge for the delivery of safer medicinal products and better health. The announcement followed statements made by OECD Science and Health Ministers at their meetings in January and May 2004 that the challenge from increased understanding and use of human genetics had to be met in order to achieve the dual goals of economic growth and better public health.

One of the areas to be addressed in 2005 is pharmacogenetics. Pharmacogenetics is the study of the impact of heritable traits on pharmacology (pharmacokinetics and pharmacodynamics) and toxicology. An extension of pharmacogenetics is pharmacogenomics, which is based on the discovery that genetic polymorphisms have the potential to affect a drug's mechanism, including its efficacy. The commitment is to deliver by 2006 a policy report addressing challenges and opportunities to health systems from pharmacogenetics

The policy report will draw on discussion at a workshop on Pharmacogenetics set to take place in Rome, 17-20 October, 2005. The workshop hopes to accomplish three main goals:

- Communicate the status of pharmacogenetics internationally, analyse and raise awareness on the anticipated impacts on innovation, health delivery and health care systems.
- Review and address regulatory issues and challenges that may arise in translating pharmacogenetics into useful products for targeted therapies and diagnostics.
- Identify and explore initiatives and strategies relevant for pharmacogenetics development and implementation to improve public health across OECD countries.

Future events:

- An international perspective on pharmacogenetics: The intersection between innovation, regulation and health delivery, Rome, Italy, 17-19, 2005.

Contact: Elettra Ronchi

GUIDELINES ON BEST PRACTICES IN MOLECULAR GENETIC TESTING LABORATORIES

On the basis of a comprehensive analysis of quality assurance practices in molecular genetic testing in 18 OECD countries, member countries reached agreement in 2004 to develop international best practice guidelines. The decision comes at a time of international convergence of opinion on the need for a broad international framework that will foster best practice and good governance in molecular genetic testing laboratories. For example, the European Parliament called, also in 2004, for an opinion on the need for legislation in the area.

The approach agreed by OECD member country experts – and by the Organisation's governing body – is to develop broad guidelines for action, within the scope of which national or regional initiatives – including, if deemed appropriate, national legislation – might subsequently be developed.

These guidelines will offer short and succinct principles and best practices that relate to quality assurance systems, result reporting, education and training, and insofar as possible, clinical validity and utility. The guidelines should facilitate application of best practice in relation to human genetic and genomic testing, guarantee an international approach to exchange of clinical samples and data facilitating access to rare disease testing, and help meet the general objectives of OECD member countries in relation to best practices in health care.

The summary report of results from the OECD survey can be downloaded from our website.

Website: http://www.oecd.org/sti/biotechnology

Contact: Elettra Ronchi

BEST PRACTICE IN GOVERNANCE AND MANAGEMENT OF HUMAN GENETIC RESEARCH DATABASES

The OECD held a workshop on "Human Genetic Research Databases (HGRDs) – Issues of Privacy and Security" in 2004. With the participation of over sixty experts, the main goals of the workshop were 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 Tokyo Workshop is expected to be published shortly. The OECD governing body has agreed that best practices guidelines for management and governance of Human Genetic Research Databases should be developed based on the work of the carried out at the Tokyo workshop. A steering group met in May 2005 to discuss and recommend the way forward for the work on best practices for HGRDs.

Forthcoming Publication:

📖 *Report of Tokyo Workshop on Human Genetic Research Databases*

Website: http://www.oecd.org/sti/biotechnology

Contact: Christina Sampogna

BIOTECHNOLOGY, INNOVATION AND HEALTH

The links between innovation, productivity, health and wealth are recognised by OECD countries. Investing in and encouraging innovation is a priority for many jurisdictions as is the affordability, quality and sustainability of health-care systems. The apparent tension between these two goals can be mitigated, however. The challenge for policymakers is to encourage innovation that addresses health needs and priorities; maximises access to the benefits; and manages risks in a way that is beneficial both to innovators and health systems.

A workshop on "Biomedicine and Innovation in Healthcare: Examining the Links Between Policy Makers and Innovators" was held in Berlin, Germany, on 15-16 November 2004 in Berlin to explore two questions: (1) How can OECD countries deliver greater convergence between healthcare priorities and the direction of innovation?; and (2) What tools need to be developed to ensure that decisions taken in OECD countries capture the benefits of, and contribute to fostering, innovations in human health-related biotechnologies?

The medical biotechnology sector has developed over the last decades at an unprecedented speed and is already influencing the provision of medical care. New and emerging biotechnologies offer many opportunities that are likely to change the way society understands and treats disease. While there is wide recognition that the contribution of innovation needs to be fostered, many also believe that the situation for how biotechnological innovations are used within health systems is for the moment sub-optimal. Policy makers and health system managers in all countries face many challenges in making decisions regarding the uptake of efficient and effective technologies into health systems. The limitations of current approaches to health technology assessment are identified and analysed in the forthcoming OECD report, *Health Technologies and Decision Making*.

As countries make major investments in biotechnology-related innovation there is a need to develop accompanying policy tools to ensure that the benefits of research and development can be appropriately used to improve the health of citizens. To respond to this challenge, several projects have been launched in 2005 which, when taken together, seek to identify different ways of building partnerships that link researchers, industry, governments, policy makers, and health system managers so that the fruits of innovation are quickly and appropriately taken into health systems and reach those that need them. The projects include:

- A survey of health and innovation policies which will: (1) explore the policies in place to create an innovation-friendly atmosphere for health-related technologies, (2) explore conditions across the whole innovation cycle that affect biomedicine; (3) gather information on different tools and approaches to evaluate such biomedicines; and (4) collect information on a number of case study biomedicines.
- Case studies identifying and analysing incentives and barriers to the uptake and diffusion of specific health related biotechnologies.

- A workshop and an analytic report on new biotechnology research and innovation models for health which will explore the conditions and factors common among these models that move discovery more quickly, efficiently, and appropriately and achieve better health outcomes.
- A scoping of possible indicators for biotechnology, innovation and health.

Forthcoming publication:

🕮 *Health Technologies and Decision Making*

Website: http://www.oecd.org/sti/biotechnology

Contact: Bénédicte Callan

THE OUTLOOK FOR INDUSTRIAL BIOTECHNOLOGY

Advances in biotechnology are driving a gradual change towards wider and more technologically- sophisticated use of biobased alternatives and bioprocesses across a range of industries. The transformative ability of biotechnology, applied to industrial processes is delivering profitability and environmental gains hand-in-hand, and the influential report The Application of Biotechnology to Industrial Sustainability (OECD, 2001), prepared by the OECD Task Force on Biotechnology for Sustainable Industrial Development, has resulted in much discussion and some action towards delivering a more resilient, more sustainable and more biobased economy.

The focus at OECD on industrial biotechnology is to identify the potential contribution of biotechnology to sustainable growth and development and identify and appraise policy options for supply and demand side interventions that can drive efficient economy transition. The programme is fully integrated with work on developing statistics and economic indicators for biotechnology.

The Task Force have launched a survey to assess what steps governments, industry and other relevant actors are taking towards realising a biobased economy, and to highlight the barriers and drivers and identify what best practices exist in policy development internationally, to drive sustainable growth and development in line with a biobased economy. The survey is open to respondents until 15 August 2005 at http://www.oecd.org/sti/biotechnology/biobasedeconomy.

The findings of this survey will be included in a 2006 policy report and recommendations on managing the transition to a biobased economy.

From 2006, OECD plans to publish a regular Outlook for Industrial Biotechnology that will draw on policy analysis, statistics and development of economic indicators for such applications of biotechnology.

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

Upcoming Publication:

🕮 *Policy Implications for Developing a Biobased Economy*

Contact: Chris Deane

DEVELOPING A GLOBAL NETWORK OF 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.

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.

Science and Technology Ministers from OECD countries last year called on the Organisation to complete development of the instruments to establish a Global Biological Resource Centre Network.

Such a network once established will:

- Make a major contribution to security by putting in place a system of quality control and tracking for maintenance and supply of dangerous pathogens;
- Provide a one-stop-shop for access to high quality biological resources for use by bio-industry;
- Help sustain the future of existing repositories of ex situ genetic resource, and thus make an invaluable contribution to the conservation of biodiversity.

Relevant experts interested in participating in the work of the Task Force on Biological Resource Centres should contact their relevant national contact points for OECD's Working Party on Biotechnology.

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

Contacts: Kenji Takezawa
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BIOTECHNOLOGY STATISTICS IN OECD MEMBER COUNTRIES

In May 2005 the OECD released **A Framework for Biotechnology Statistics**. The development and application of biotechnology has the potential for far-reaching economic, social and environmental impacts. It is therefore important to outline a statistical framework to guide the measurement of biotechnology activity. This Framework is intended to provide the basis for statistical compilation work within OECD member countries and those non-member countries wishing to adopt the standards.

The focus of the Framework is on biotechnology R&D and the application of biotechnology techniques to produce goods or services. For simplicity, these are referred to in this Framework as key biotechnology activities. End uses

of biotechnology, for instance the use of products produced using biotechnology in manufacturing, agriculture or private consumption, are of increasing policy interest but are beyond the scope of this document. However, many of the statistical standards articulated here will be relevant to such uses.

Under the auspices of the OECD's National Experts on Science and Technology Indicators (NESTI) group, five Ad hoc Meetings on Biotechnology Statistics have been held to date. The Framework is based on the methodological work produced by these meetings (held from 2000 to 2004). It is hoped that publication of the Framework will encourage further statistical work in this field and stimulate debate leading to further improvements in biotechnology statistics. The Framework is available online, at http://www.oecd.org/sti/biotechnology/framework

The OECD released a biotechnology statistics inventory last year, available at: http://www.oecd.org/sti/biotechnology/inventory. The aim of the inventory was to provide an accurate assessment of the current state of biotechnology statistics collections in OECD member and observer countries. It was compiled on the basis of information provided by officials in the respective countries. Now, as a follow-up to the biotechnology statistics inventory, the Secretariat will prepare a new compendium of available biotechnology statistics. This compilation will be released in the last quarter of 2005.

Web sites: http://www.oecd.org/sti/biotechnology/framework; http://www.oecd.org/sti/biotechnology/inventory

Contact: Brigitte van Beuzekom

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: Dirk Pilat

OECD'S SEED CERTIFICATION AND FOREST REPRODUCTIVE MATERIAL CONTROL SCHEMES

Three criteria: distinctness, uniformity and stability are the basis for defining crop varieties and constitute the backbone of agricultural seed development and trade. Identification and minimum purity criteria are a component of sustainability, especially when hybridisation and genetic modifications are involved. Reliability of forest reproductive material rests upon local identification, regions of provenance, selection and breeding work.

The **OECD Seed Schemes** have been developed since the late 1950s to regulate international exchanges as well as "counter season" multiplication of seed, particularly between the northern and southern hemispheres. They are implemented by member and non-member countries across all continents (Uganda became the 53rd participant in January 2005), and some other applications to join have been submitted. The Schemes' essential purpose is to harmonise certification with a view to facilitating international seed trade. Over 187 species including all basic staples and 35 000 varieties appear on the latest *OECD List of Varieties Eligible for Certification*. Amongst the issues under discussion are the changing role of government in seed control and testing including accreditation of authorised private field inspectors and laboratories, the impact of biotechnology and advanced breeding methods on seed certification, the certification of seed mixtures (herbage species, hybrid maize, swede rape), the seed lot size and homogeneity.

The mandate of the Working Group on Genetically Modified Seed Issues, established some years ago, is being revised. To assess better the current and future needs of international certification in this respect, a Workshop on Modern Biotechnology and Seed Certification will take place next September in Paris. The four sub-themes will be Identity, Purity, Quality and Government Roles, to be handled with all stakeholders' prominent representatives.

Contacts have been developed with the Secretariat of the Convention on Biological Diversity (CBD) on issues related to compliance in the Cartagena Protocol on Biosafety. Similarly, contacts have been made with the International Federation of Organic Agriculture Movements (IFOAM) on standards for organic seeds.

A new **OECD Scheme for the Certification of Forest Reproductive Material** is being introduced. In 2004, a database of basic reproductive material (forest stands, etc.) available in participating countries was set up on the website.

Future events:

- Meeting of the Advisory Group (26 Sept. 2005, Paris, France);
- Workshop on Modern Biotechnology and Seed Certification (27-28 Sept. 2005, Paris)
- Annual Meeting of National Designated Authorities (29 Sept.-1 Oct. 2005, Paris)

Publications:

- 🕮 *List of Varieties Eligible for Certification 2004/2005*
- 🕮 *OECD Seed Schemes "2005"*

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

Contact: Jean-Marie Debois

CO-OPERATIVE RESEARCH PROGRAMME (CRP): BIOLOGICAL RESOURCE MANAGEMENT FOR SUSTAINABLE AGRICULTURAL SYSTEMS'

The rationale of this OECD programme which gathers 26 OECD countries recognises that agriculture and food production are heavily dependent on the application of science and that policies in these areas need to take account of the scientific dimension. It further recognises that policy makers are often confronted by conflicting scientific

evidence and public concerns, emphasising the need for policies to be based on sound science. The objectives of the Programme for the period 2005-2009, under a renewed mandate by Council, are thus the following: to provide a sound scientific knowledge base to agricultural policy-making; to contribute to an informed public debate on current and emerging agro-food issues and to help resolve conflicting views in Member countries; and to promote scientific understanding and standards between major regions of OECD.

Operational features of the Programme involve supporting and promoting international cooperation and networking in the field of basic and applied research. In this respect it awards **fellowships** to scientists from an OECD Member country to conduct research projects in a foreign country (OECD Member) and **supports financially workshops** to address agro-food issues that are high on the science/policy agenda of OECD Member countries. The CRP strategy emphasises the need to engage a range of scientific disciplines including the natural sciences, social sciences and the humanities in an interactive dialogue. Three themes will be addressed by the Programme during its mandate period:

1 The Natural Resource Challenge;
2 Sustainability in practice;
3 The Food Chain

A Conference on **"Challenges and opportunities in agri-food research" was held on 18-20 May 2005**, in Rome, Italy , with the support of the Italian Ministry of Agricultural and Forestry Policies and the Italian Council for Agricultural Research. It brought together leading keynote speakers from academia, agro-business and NGOs as well as policy makers and researchers to discuss current and future opportunities and challenges in the management of biological resources. Among the key cross-cutting themes emerging was the underlying importance of sustainability – in its economic, environmental and social contexts – and the issues surrounding its translation into an understandable and acceptable agenda for action. The Conference concluded that research had its role to play and must adopt increasingly cross-disciplinary and cooperative approaches given these interrelations and complexities, as foreshadowed in the three chosen themes for the new CRP. The outputs of the Conference will be used to help refine and focus the contribution to be made by the CRP to agriculture, food and fisheries, through its future programmes of seminars and conferences as well as the topics for research in its international fellowship schemes.

Information on this conference including the Chair's summary and speakers' presentations can be found on the Conference's website https://www.oecd.org/site/0,2865,en_21571361_34690760_1_1_1_1_1,00.html?appId=-1&token=1196247974

Information on the Programme and application forms are available on the Programme website http://www.oecd.org/agr

Recent Publications

- *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, "Biogeochemial Aspects of Earth System and Bioremedication 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)*

Proceedings of conference :"What risk analysis is Appropriate? Options for Future Policy Making towards integrated Agro-Food Systems" (published by OECD ISBN 92-64-10877-7) 2003.

Forthcoming publications linked to conferences held in 2004:

- *Crop Ferality 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, Hawaï, United States, 9-11 November 2004*

Contacts: Liliane Shettle
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OECD BIOTECHNOLOGY AND THE WORLD WIDE WEB

OECD's web site includes much information on biotechnology, biosafety and related topics. The web site allows individual users 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 Biotechnology Update through ***My OECD***.

- OECD's portal is: http://www.oecd.org
- OECD's biotechnology portal: http://www.oecd.org/biotechnology
- For more information on industrial, scientific and health applications of biotechnology, 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

- Meeting of the Advisory Group, 26 September 2005, Paris, France (Contact: Jean-Marie Debois).
- Working Party on Biotechnology, Paris, France, 26-27 September 2005 (Contact: Stella Horsin)
- Workshop on Modern Biotechnology and Seed Certification, 27-28 September 2005, Paris, France (Contact: Jean-Marie Debois).
- Working Group on Human-Health Related Biotechnology, Paris, France, 27-28 September 2005 (Contact: Elettra Ronchi)
- Task Force on Biotechnology for Sustainable Industrial Biotechnology, Paris, France, 28 September 2005 (Contact: Chris Deane).
- Annual Meeting of National Designated Authorities, 29 Sept.-1 Oct. 2005, Paris, France (Contact: Jean-Marie Debois)
- OECD Expert Workshop on the Biology of the Atlantic salmon, 12th-14th October 2005, Trondheim, Norway (Contact: Peter Kearns).
- Workshop on Pharmacogenomics, Rome, Italy, 17-19 October 2005. (Contact: Elettra Ronchi)
- Steering Group Meeting on Guidelines for Quality Assurance of Genetic Tests, Rome, Italy, 20 October 2005 (Contact: Elettra Ronchi)
- 17th Meeting of the Working Group for the Harmonisation of Regulatory Oversight in Biotechnology, Paris, France, 24-26 October 2005 (Contact: Peter Kearns)
- Task Force on Biological Resource Centres, Paris, 25-26 October 2005 (Contact: Kenji Takezawa)
- International Futures Programme Meeting on the Bioeconomy, Paris, France, 2 November (Contact: Michael Oborne)
- Task Force on Biological Resource Centres, Special Meeting on Biosecurity, Paris, 14-15 November 2005 (Contact: Chris Deane)
- Workshop on Delivering the Biobased Economy, Ghent, Belgium, 1-2 December 2005 (Contact: Chris Deane)
- International Futures Programme Workshop (by invitation only) on "Collaborative Mechanisms: Patent Pools", 8-9 December, Venue to be announced. (Contact: Christina Sampogna)
- Workshop on Policy Targets for Health Biotechnology Research Networks, Paris, 14-15 December 2005 (Contact: Benedicte Callan).
- Working Party on Biotechnology, Paris, France, 20-21 February 2006 (Contact: Stella Horsin)
- 11th Meeting of the Task Force for the Safety of Novel Foods and Feeds, Berlin, Germany, 6-8 March 2006 (Contact: Peter Kearns).
- Task Force on Biological Resource Centres, Paris, France, 10-11 April 2006 (Contact: Kenji Takezawa)
- Ad Hoc Meeting on Biotechnology Statistics, Paris, France, 18-19 May 2006 (Contact: Brigitte van Beuzekom)
- Committee on Biotechnology, Paris, France, 1-2 June 2006 (Contact: Stella Horsin)
- Task Force on Biological Resource Centres, Paris, France, 27-29 September 2006 (Contact: Kenji Takezawa)
- Working Party on Biotechnology, Paris, France, 16-17 October 2006 (Contact: Stella Horsin)
- Committee on Biotechnology, Paris, France, 4-5 December 2006 (Contact: Stella Horsin)

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Pharmacogenetics

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

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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. An increasing number of non-member countries participate in a wide range of activities, including some of those related to biotechnology.

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