

## Biotechnology Update Internal Co-ordination Group for Biotechnology (ICGB)

*No. 14, February 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](mailto:icgb@oecd.org). Alternatively, individuals can be contacted via e-mail using the form [firstname.lastname@oecd.org](mailto: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 Osborne, 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 MOVES TO STRENGTHEN CONTRIBUTION TO BIOTECHNOLOGY**

Last year, OECD member country Science and Health ministers called on the Organisation to strengthen its contribution to work in the area Biotechnology. OECD's Secretary-General has proposed to the Organisation's governing body (the Council) that a number of concrete steps should be taken to act on Ministers' wishes. Council is considering these proposals carefully. In December 2004, the Council agreed the new programme of work 2005-2006 and upgraded the DSTI Biotechnology Unit to a full Division to strengthen its work within the OECD.



## **PUBLIC COMMENTS INVITED ON DRAFT INTERNATIONAL GUIDELINES FOR THE LICENCING OF GENETIC INVENTIONS**

The OECD's draft guidelines offer principles and best practices to license intellectual property rights related to genetic inventions used for the purpose of human health care. They target those involved with innovation and the provision of services in health, and those involved in the licensing of such inventions. The Guidelines seek to foster the desired objectives of stimulating genetic research and innovation while maintaining appropriate access to health products and services. Public comments are invited before 11 March 2005. For more information, please go to our website: [www.oecd.org/sti/biotechnology/licensing](http://www.oecd.org/sti/biotechnology/licensing)



## **BIOSECURITY: PREVENTING ABUSE OF RESEARCH AND RESOURCES IN THE BIOSCIENCES**

In September 2004, fifty-five participants selected from government, academia, industry, public research organisations, scientific societies, and the science publishing field gathered in Frascati, Italy for three days to discuss the promotion of responsible stewardship in the biosciences and means of avoiding the potential abuse of research and resources. The meeting was convened by the International Futures Programme of the OECD.

The role of responsible stewardship in helping to achieve a balance between scientific freedom and security concerns was one of the themes raised at a meeting of OECD Science Ministers in Paris in January last year. The OECD Frascati meeting developed this issue further by bringing together a broad range of participants in their personal capacity to address balancing the needs of science with those of security.

Rapid advances in the biological sciences offer significant benefits to mankind while posing new challenges to the scientific and security communities. Whereas biological research has greatly contributed to the improvement of human health, the same methods and materials, technologies, and knowledge bases can also be used to produce potentially dangerous agents and toxins for harmful use. Nevertheless, excellence in scientific research depends on open interactions among researchers, including the exchange of scientific data and methodologies and open access to biological resources.

Whilst this central conundrum is being discussed in other fora, the unique value of the Frascati meeting was to bring together a broad cross-section of international representatives from the three major communities – government, industry and academia – directly affected by the debate about balancing access and security.

The meeting was divided into four sessions. Exploring the balance between openness and precaution in addressing the risks; reviewing legal, administrative and regulatory approaches; examining the roles of the academic and industrial scientific communities; and exploring options and next steps.

The Frascati discussions identified two broad areas for further action in dealing with biosecurity issues on the international level:

- 1) to create an inventory of tools being developed by the science, security, and business communities in selected countries to deal with dual use of bioresearch (codes of ethics, conduct, practice; legal and policy tools);

2) to create a forum or venue in which the science, security and business communities can meet on a scheduled basis to discuss the convergence of different efforts at the national and international level. These efforts include: voluntary codes of practice or governance and an appraisal of the effectiveness of their implementation; education and awareness raising in the science community; and identification of gaps in national and international legislation.

The International Futures Programme is currently exploring ways to continue and deepen this international dialogue among the science, security and industry communities. One idea is to create a Forum of limited mandate and duration that would attempt to guide and to create convergence mechanisms for the many efforts to develop biosecurity tools which are underway in the different stakeholder communities. A key issue would be how to create a leveraging effect with this new temporary body so as to ensure that the OECD effort brings value-added to existing groups.

***Recent publication:***

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

**Contact:** Michael Osborne



**THE BIOECONOMY: ITS LONGER-TERM FUTURE AND POTENTIAL IMPACTS**

In 2005, the International Futures Programme (IFP) will be preparing a workshop that 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.

The scoping of this project will begin early 2005.

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## HARMONISATION OF REGULATORY OVERSIGHT IN BIOTECHNOLOGY

It is now 10 years since OECD's Working Group on Harmonisation of Regulatory Oversight in Biotechnology first began its work. The participants 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 three years, there has been increased participation of other non-member countries through the work of OECD Global Forum on the Knowledge-based Economy.

The main focus of the Working Group 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 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.

Recently, the Working Group organised an expert workshop on the biology of Atlantic salmon. It 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 (genetically modified) 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 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 will take into account the results of the Workshop when it considers the next steps at its next meeting.

The 16<sup>th</sup> meeting of the Working Group will be held at OECD Headquarters, 23-25 February 2005. In addition to a discussion of a number of draft consensus documents, the Working Group will also begin to prepare a draft Programme of Work for 2006-2008. A key issue will be to identify the next steps to strengthen the participation of non-member countries in the work.

### ***Future events:***

- 16<sup>th</sup> Meeting of the Working Group for the Harmonisation of Regulatory Oversight in Biotechnology, Paris, 23-25 February 2005.

- 17<sup>th</sup> 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*

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

**Contacts:** Peter Kearns  
Mar Gonzalez  
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://www2.oecd.org/biotech/>) 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://www2.oecd.org/biotech/>

**Web site:** *BioTrack Online*

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

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## SAFETY OF NOVEL FOODS AND FEEDS

OECD's Task Force for the Safety of Novel Foods and Feeds was established in 1999. Delegates to the Task Force are from those ministries and agencies, which have responsibility for the safety of transgenic products, 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 goal of the Task Force is to promote harmonisation in the safety assessment of novel foods and feeds, especially products of modern biotechnology.

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. During 2004, the Task Force completed and published its 10th consensus document, which was on Barley. It was an opportune time, therefore, for the Task Force to hold a special focus session on the consensus documents at its 9th meeting in October 2004. This was an opportunity for delegations to exchange their experiences in the use of published documents as well as identifying needs for future work.

A number of non-member countries (Argentina, Brazil, Latvia, Slovenia, South Africa, and Thailand) were able to participate in this dialogue through the Global Forum on the Knowledge-based Economy (GFKE). This is important, as food safety issues associated with new crops and foods developed through modern biotechnology have become an increasingly global issue. The dialogue showed that the consensus documents are used by non-members as well as member countries; in fact, a number of non-members expressed their willingness to participate in drafting future documents. One of the results of this discussion was the drafting of a document, *Introduction to OECD's Food and Feed Safety Consensus Documents*, which will be completed during 2005.

### **Future event:**

- 10th Meeting of the Task Force for the Safety of Novel Foods and Feeds, Paris, 20-22 June 2005.

### **Recent Publications:**

- 📖 *Consensus Document on Compositional Considerations for New Varieties of Cotton (Gossypium hirsutum and Gossypium barbadense): Key Food and Feed Nutrients and Anti-Nutrients*
- 📖 *Consensus Document on Compositional Considerations for New Varieties of Rice (Oryza sativa): Key Food and Feed Nutrients and Anti-Nutrients.*
- 📖 *Consensus Document on Compositional Considerations for New Varieties of Barley (Hordeum vulgare L.)*

### **Upcoming Publication:**

- 📖 *Consensus Document on Forage Legumes*

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

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## **OECD LAUNCHES PUBLIC CONSULTATION ON BEST PRACTICE GUIDELINES FOR THE LICENSING OF GENETIC INVENTIONS**

Biotechnology and genetics research have been the subject 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. Specifically, the OECD has been developing draft Guidelines for the Licensing of Genetic Inventions (“draft Guidelines”).


The need for draft Guidelines was highlighted during an expert workshop examining issues of pertaining to intellectual property, licensing practices and genetic inventions, and 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. These draft Guidelines 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.

At this stage, the OECD Secretariat would like to draw on as wide a range of views with respect to the draft Guidelines and is seeking comments via an electronic consultation process. Information and documents are available on our website. Comments may be submitted before March 11, 2005 on the website or via e-mail to: [\*\*licensing.guidelines@oecd.org\*\*](mailto:licensing.guidelines@oecd.org).

**Web site:** [www.oecd.org/sti/biotechnology/licensing](http://www.oecd.org/sti/biotechnology/licensing) (in Eng.),  
[www.oecd.org/sti/biotechnology/licences](http://www.oecd.org/sti/biotechnology/licences) (in Fr.)

### ***Upcoming Publication:***

 *Guidelines on Licensing Genetic Inventions*

**Contact:** Christina Sampogna



## **OECD ANNOUNCES WORKSHOP TO ADDRESS POLICY CHALLENGES FROM THE USE OF PHARMACOGENOMICS**

In 2004, the OECD Working Party on Biotechnology 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.

An OECD workshop on Pharmacogenetics is now set to take place in Rome, 17-20 October, 2005. The workshop should accomplish three main goals:

- Analyse and raise awareness on the extent of expected impacts on innovation and health care systems;
- Review and address regulatory issues and challenges that may arise in the context of pharmacogenetics;
- Identify and explore initiatives and frameworks relevant for pharmacogenetics development and implementation across OECD countries.

**Contact:** Elettra Ronchi



## **OECD ON TARGET TO DEVELOP BEST PRACTICES FOR QUALITY ASSURANCE IN MOLECULAR GENETIC TESTING**

On the basis of a comprehensive analysis of quality assurance 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 has recently called 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.

Meantime, a report on the OECD survey of current quality assurance practices, personnel qualifications and policy and practice on informed consent and confidentiality is expected to be published very shortly.

Results of the survey, document the steady growth of molecular genetic testing and its widespread availability. Results also show that molecular genetic testing is provided under widely varying conditions and regulatory frameworks across the participating 18 countries.

**Upcoming Publication:**

📖 *Report on Quality Assurance and Proficiency Testing for Human Genetic Testing*

**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 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 now be developed based on the Tokyo discussions.

A steering group will meet in mid-2005 to discuss how to take work forward on best practices for HGRD.

**Web site:** [www.oecd.org/sti/biotechnology](http://www.oecd.org/sti/biotechnology)

***Upcoming Publication:***

📖 *Tokyo Workshop proceedings on Human Genetics Research Database*

**Contact:** Christina Sampogna



**OECD COUNCIL PRIORITISES WORK ON BIOTECHNOLOGY, INNOVATION AND HEALTH**

During their meetings in 2004, OECD member country science ministers and health ministers called for more effort on biotechnology, innovation and health.

In the 2005-2006 Programme of Work Budget, the OECD Secretary-General allocated funds from the Organisation's Central Priority Fund (CPF) to take forward work in this area.

Work will focus on:

- i) Assessing how greater convergence can be encouraged between the direction of innovation and healthcare priorities (and vice-versa);
- ii) Comparison of research and innovation models for health innovation;
- iii) Identification of best practices for delivering a coherent and efficient health innovation system for biomedicines.

These themes were first at a workshop on "Biomedicine and Other, Innovation in Healthcare: Examining the Links Between Policy Makers and Innovators" held in Berlin, Germany, on 15-16 November 2004.

A report of the Workshop will be published in the Summer.

**Web site:** <http://www.oecd.org/biotechnology/>

Under the theme "Scientific, Industrial and Health Applications of Biotechnology"

***Upcoming Publication:***

📖 *Berlin Workshop proceedings - Biomedicine and other Innovation in Healthcare*

**Contact:** Stella Horsin



**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 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 OECD Task Force expects to launch a survey of policy measures for the biobased economy shortly followed by a policy workshop later in 2005.

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

**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



## **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 included: further development of the biotechnology statistics framework, which is expected to be released in early 2005; presentation of an inventory of biotechnology statistics collected by official. 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.

The Biotechnology Statistics Inventory is now available online, at [www.oecd.org/sti/biotechnology/inventory](http://www.oecd.org/sti/biotechnology/inventory). The paper edition of the inventory [STI Working Paper 2004/8] was released in September 2004. The aim of the inventory is to provide an accurate assessment of the current state of biotechnology statistics in OECD member and observer countries. It was compiled on the basis of information provided by officials in the respective countries (and Eurostat). By having his repository online it will be more accessible and also easier to update more frequently.

**Web site:** [www.oecd.org/sti/biotechnology/inventory](http://www.oecd.org/sti/biotechnology/inventory)

**Contact:** Brigitte Vanbeuzekom



## **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'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 53<sup>rd</sup> 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 current 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.

Contacts have been developed with the Secretariat of the Convention on Biological Diversity (SCBD) on issues related to compliance in the Cartagena Protocol on Biosafety. Similarly, contacts have been made with the International Foundation for Organic Agriculture (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: Seeds Schemes (March 2005, Paris, France)
- Annual Meeting of National Designated Authorities (27-30 Sept. 2005, Paris, France)

### ***Publications:***

- 📖 *List of Varieties Eligible for Certification* 2004/2005
- 📖 *OECD Seed Schemes “2004”*

**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

### ***Future event:***

*A Conference on "Challenges and opportunities in agri-food research" will be held on 18-20 May 2005, in Rome, Italy, with the support of the Italian Ministry of Agricultural and Forestry Policies, Ministry of the Environment and the Protection of the Territory, and the Italian Council for Agricultural Research. Its purpose is to launch the new OECD Co-operative Research Programme through a broad-ranging debate on challenges and opportunities in the agri-food sector and thereby to ensure that the new Programme is of relevance to policy related work in the OECD.*

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, "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)*

*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 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  
Caroline Keogh



## **THE BUSINESS AND INDUSTRY ADVISORY COMMITTEE TO THE OECD (BIAC)**

This is the first occasion on which the Business and Industry Advisory Committee to the OECD (BIAC) has made a contribution to the Biotechnology Update.

The Business and Industry Advisory Committee to the OECD (BIAC) was created in March 1962 as an independent organisation officially recognised by the OECD as being representative of the OECD business community. BIAC's members are the major industrial and employers' organisations in the 30 OECD member countries. Via its 34 standing committees and policy groups, BIAC mirrors all economic policy issues the OECD covers, and their impacts on both member and an increasing number of non-member countries. BIAC's main objectives are to reflect business priorities in OECD work and provide members with information on OECD activities and their implications for business.

Triggered by a G-8 request to the OECD to carry out a study on the implications of biotechnology, BIAC became active in this area in 1999 and shortly afterwards created a formal biotechnology committee. Since then, BIAC has continuously expanded both its membership and the scope of its activities to contribute to the wide range of OECD biotechnology-related projects. The BIAC Biotechnology Committee now has over 100 members representing the range of sectors dealing with biotechnology. The Committee is currently chaired by Richard Johnson from Arnold & Porter (US), who is assisted by 4 vice-chairs, representing the various sectors involved.

Members of the BIAC Biotechnology Committee participate in both the meetings of the OECD Working Group on the Harmonisation of Regulatory Oversight in Biotechnology and its Task Force for the Safety of Novel Foods and Feeds. BIAC attaches major importance to the development of consensus documents that

include technical information used in the regulatory review of biotechnology products. BIAC is actively involved in the development of these documents and brings important technical expertise to the table.

Likewise, BIAC is an active participant in the OECD Working Party on Biotechnology and its Working Group on Human Health-Related Biotechnologies and continues to underline the importance of biotechnology at the highest OECD level. In 2004, BIAC participated in the consultation with OECD Science Ministers underlining the important role OECD has in developing policies that will help better utilisation of the potential that biotechnology has in contributing to sustainable growth. BIAC endorsed Ministers' call upon OECD to strengthen its work in this area and focus on enabling innovation in health biotechnology and on the contribution that industrial biotechnology can make to a more bio-based economy. BIAC remains actively involved in discussions in these areas and also contributes to work on the economic impact of biotechnology, on bio-security, and on best practice guidelines for the licensing of genetic inventions.

BIAC believes that the OECD's high-quality analytical work and integrated analysis make the Organisation perfectly suited for a leadership role in the area of biotechnology. As the official representative of the private sector to the OECD, BIAC has a unique role to play in this dialogue. In partnership with the OECD, BIAC provides a useful forum for industry to help ensure that biotechnology policy and regulatory structures make the benefits of biotechnology accessible to all in a safe, efficient and sustainable manner.

**Contact:** Hanni Rosenbaum



## 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

- ◆ 16th Meeting of the Working Group for the Harmonisation of Regulatory Oversight in Biotechnology, Paris, France, 23-25 February 2005. (Contact: Peter Kearns)
- ◆ Meeting of the Advisory Group: Seeds Schemes, Paris, France, March 2005. (contact: Jean-Marie Debois)
- ◆ Steering group meeting on Quality Assurance and Proficiency testing schemes for Molecular Genetic Testing in OECD countries, Paris, France, April 2005. (Contact: Elettra Ronchi)
- ◆ Steering group meeting on Pharmacogenomics, Paris, France, 19-21 April 2005. (Contact: Elettra Ronchi).
- ◆ Conference “Challenges and opportunities in agri-food research”, Rome, Italy, 18-20 May 2005. (contact: Caroline Keogh)
- ◆ Steering group meeting on Biotechnology on Innovation and Health, Paris, France, May 2005. (Contact: Stella Horsin).
- ◆ Meeting of the Task Force on Biological Resource Centres on Biosecurity to be held in Paris, France, in May 2005. (Contact: Chris Deane)
- ◆ Workshop (by invitation only) on “Collaborative Mechanisms: Patent Pools”, May/June 2005, Venue to be announced. (Contact: Christina Sampogna)
- ◆ 10th Meeting of the Task Force for the Safety of Novel Foods and Feeds, Paris, France, 20-22 June 2005.(Contact: Peter Kearns)
- ◆ Annual Meeting of National Designated Authorities, Paris, France, 27-30 September 2005. (contact: Jean-Marie Debois)
- ◆ 17th Meeting of the Working Group for the Harmonisation of Regulatory Oversight in Biotechnology, Paris, France, 24-26 October 2005. (Contact: Peter Kearns)
- ◆ Committee on Biotechnology to be held in Paris France the 2-3 June 2005.
- ◆ Working Party of National Experts of Science and Technology Indicators, Reykjavik, Iceland, 13-17 June 2005.
- ◆ Workshop on Pharmacogenomics, Rome, Italy, 17-19 October 2005. (Contact: Elettra Ronchi)
- ◆ Workshop on Biobased Economy, Autumn 2005 (Contact: Chris Deane)
- ◆ Committee on Biotechnology to be held in Paris, France, 14-15 December 2005.



## 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)

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

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Agricultural Biotechnology: Economic Issues

**Iain GILLESPIE** (STI/BIO)

Head of Biotechnology Division

Working Party on Biotechnology/ Committee on Biotechnology

**Maria del Mar GONZALEZ** (ENV/EHS)

Harmonisation of Regulatory Oversight in Biotechnology

Safety of Novel Foods and Feeds

**Masatoshi KOBAYASHI** (ENV/EHS)

BioTrack Online

Harmonisation of Regulatory Oversight in Biotechnology

Safety of Novel Foods and Feeds

**Wilfrid LEGG** (AGR/PE)

Agriculture and Environment

**Dirk PILAT** (STI/EAS)

Economic Impacts of Biotechnology

**Elettra RONCHI** (STI/BIO)

Quality Assurance of Genetic Testing

Pharmacogenomics

**Christina SAMPOGNA (STI/BIO)**

Intellectual Property Rights & Biotechnology  
Licensing Guidelines  
Patent Pools  
Human Genetic Research Databases

**Liliane SHETTLE (AGR/CMU)**

Cooperative Research Programme

**Kenji TAKEZAWA (STI/BIO)**

Human Genetic Research Databases  
Biological Resource Centres  
Biotechnology, Innovation and Health

**Brigitte VAN BEUZEKOM (STI/EAS)**

Biotechnology Statistics

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Biotechnology Statistics



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The Business and Industry Advisory Committee to the OECD



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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

