

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

No. 18, September 2007

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 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 Executive Secretary.

Contact: Peter Kearns



IMPLEMENTATION OF OECD GUIDELINES ON LICENSING OF HEALTH CARE GENETICS

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 impact on health care has grown substantially.

Some governments, patient groups and healthcare providers have become concerned about how certain genetic inventions have, in certain circumstances, been licensed and exploited, particularly for diagnostic genetic services in the human health care field.

In order to address these concerns, OECD member countries adopted [Guidelines for the Licensing of Genetic Inventions](#) as an OECD Council Recommendation in February 2006.

The 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 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 Guidelines seek to foster the objectives of stimulating genetic research and innovation while maintaining appropriate access to health products and services. Current efforts at the OECD are focusing on assessing implementation and inputs of these guidelines.

These Guidelines may be obtained on our website.

Web site: www.oecd.org/sti/biotechnology/licensing (English)
www.oecd.org/sti/biotechnologie/licences (French)
www.oecd.org/sti/biotechnology/licensing (Japanese)
www.oecd.org/sti/biotechnologie/licensing (Italian)

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GUIDELINES ON THE CREATION AND GOVERNANCE OF HUMAN GENETIC RESEARCH DATABASES

Scientists have known for years that complex diseases, such as cancer, heart disease, stroke, and diabetes, arise from a combination of lifestyle, environmental, genetic and random factors. Large-scale study of populations may contribute significantly to science's understanding of the complex multi-factorial basis of disease and to improvements in prevention, detection, diagnosis, treatment and cure. As a result of developments in biotechnology and bioinformatics, the opportunity to store and analyse increasingly large amounts of genetic data have rendered possible the creation of large-scale population databases.

Large-scale population databases which contain a significantly broader range of information about individuals also raise a number of issues and concerns. While some of these are not new, the increasing breadth and scope of such databases amplifies them. Moreover, the combination of a broader set of genetic data and personal information in these databases raises new issues about the use of such information, especially in a non-clinical or non-research context. As such databases will increasingly be international in scope, and cover populations from numerous jurisdictions, new sets of questions will also arise.

A report, entitled *Creation and Governance of Human Genetic Research Databases*, was published in October 2006. It provides an overview of the complex issues which need to be considered or addressed, in recognition of the significant contribution that human genetic research databases could play in translating scientific advances into innovation in health.

Considerable work is also underway to elaborate OECD Council guidelines on the establishment, management and governance of human genetic research databases. The guidelines are being developed by OECD member countries and their national experts. The aim of these guidelines is to develop principles and best practices on the numerous issues that arise with respect to HGRDs. The wide range of issues include funding mechanisms, governance structure, privacy and confidentiality policies, commercialisation consideration, security of databases, etc. The aim is to carry out public consultations on these draft Guidelines in early 2008.

When completed, they will complement existing OECD instruments, namely *Guidelines for the Licensing of Genetic Inventions* and *Guidelines on Quality Assurance In Molecular Genetic Testing*.

Web site: www.oecd.org/sti/biotechnology

Recent Publication:

 *Creation and Governance of Human Genetic Research Databases*, Paris: OECD, 2006

Contact: Christina Sampogna



COLLABORATIVE MECHANISMS FOR THE MANAGEMENT OF INTELLECTUAL PROPERTY (IP)

Recently, both industry and governments have considered factors and mechanisms for encouraging collaboration amongst diverse interests in order to stimulate innovation, foster R&D and promote access and diffusion of technology and information. Previously, some collaborative mechanisms have been employed within other areas, such as information technology. However, there is increasing consideration and discussion about their potential use within the life sciences.

Although the discussion of using such mechanisms in the life sciences is fairly recent, certain organisations have recommended that governments, the public sector and the private sector consider the development and use of collaborative mechanisms, within the life sciences and the field of biotechnology. The organisations that have made such recommendations include the Australian Law Reform Commission, the Canadian Expert Working Party on Human Genetic Materials, Intellectual Property and the Health Sector (Canadian Biotechnology Advisory Committee), the United States National Academies of Science (US), and the OECD. Consideration of these types of mechanisms is also occurring within the private sector, wherein companies, such as Pfizer, GlaxoSmithKline and Affymetrix, are also studying the use of such mechanisms for fostering innovation.

A high-level roundtable was organised with experts from diverse backgrounds and experiences including private sector, public sector, finance, biotechnology/pharmaceutical/science, management, legal (IP, anti-trust/ competition), research/academia, etc. Generally, the roundtable focused on the diverse types of collaborative mechanisms and the manner in which they may be employed to facilitate access to and use of biotechnological innovations for purposes of research, commercialisation and the provision of products/services. An analytical report is in publication that draws on the roundtable discussion and provides an overview of the issues pertaining to collaborative mechanisms and their application in the life sciences. Release date is expected to be October 2007.

Forthcoming Publication:

 *Collaborative Mechanisms for the Management of Intellectual Property*, Paris: OECD, 2007

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COUNTERFEITING AND PIRACY OF PHARMACEUTICALS

The OECD report on Counterfeiting and Piracy of Pharmaceuticals is now in publication. Counterfeiting and piracy of pharmaceutical products is an opportunistic crime endangering the lives of patients and consumers. This report examines the nature of counterfeiting and piracy activities from the health and safety, public security, business and intellectual property perspective.

The report examines the diverse definitions of counterfeit pharmaceuticals, the nature and scope of counterfeiting activities, the modes of operation, assess the trends and magnitude, evaluate the impacts on patients/consumers, especially public health implications, on the private sector and on governments, and analyse measures employed for combating counterfeiting of pharmaceuticals (including, technology, legislative and regulatory mechanisms, education and risk communication, enforcement, securing of distribution/supply chain, and international cooperation). It is expected to be released by November 2007.

Forthcoming Publication:

 *Counterfeiting and Piracy of Pharmaceuticals*, Paris: OECD, 2007

Contact: Christina Sampogna



THE BIOECONOMY TO 2030: DESIGNING A POLICY AGENDA

The bioeconomy is the set of economic activities relating to the invention, development, production and use of biological products and processes. While still relatively small, development is occurring rapidly. In the future, biotechnology is expected to contribute significantly to the overall economy and society as a whole. It will do this by improving health outcomes, nutrition, energy efficiency, the environment, and industrial processes, as well as enhancing sustainability and improving human welfare more generally. But the

promise of biotechnology and the bioeconomy must be nurtured and fostered by judicious policy choices ranging from long term investment to appropriate regulatory frameworks. Consumer understanding, confidence and acceptance of the new possibilities are also necessary to the growth that pervasive and generic biotechnology will provide.

The International Futures Programme (IFP) of the OECD specialises in analysing key long-term trends to help governments map strategy and projects. Due to the rapid increase in biological innovation, growing strategic interest in the bioeconomy (in OECD and non-OECD areas) and its potential for significant global economic, social and environmental benefits, the IFP has launched a two-year project on The Bioeconomy to 2030: Designing a Policy Agenda.

Through the collaborative work of the Steering Group made up of industry and government agencies, IFP Staff, the Science, OECD staff from Technology and Industry Directorate, the Trade and Agriculture Directorate, as well as external experts, the project will pursue several objectives:

- Assess the long-term prospects of the bioeconomy over the next thirty years and its economic and social implications.
- Improve the indicators and metrics that are needed to monitor the development of the bioeconomy.
- Identify the most critical issues that may affect the medium- and longer-term prospects for the bioeconomy (e.g. technical, financial, human capital, and regulatory bottlenecks).
- Explore the value chain, emerging new business models and scope for co-operation among stakeholders.
- Identify where policies and regulations are increasingly out of step with biotechnology development and propose options for a more dynamic policy framework.
- Seek ways to make the concept of the bioeconomy and its potential more robust and concrete.
- Further other work on the bioeconomy within the OECD

Following a year-long consultation process, the IFP has brought together a Steering Group comprised of representatives from governments, the private sector and research institutions, to help guide the project. The first phase of the project (complete) was aimed at establishing an analytical baseline and produced documents that analyse the biotechnology market and product structure, the regulatory tools and frameworks in biotechnology, and current OECD work on biotechnology statistics and indicators.

The project is currently in the prospective phase. This includes projections and scenarios that examine the future of biotechnologies in health, agriculture, and industry as well as work which will focus on emerging business/economic models, value chains, legal and regulatory policies, and improving the institutional framework. In early 2008, conclusions and policy recommendations will be drawn out of this body of work.

For further details please consult the project brochure: <http://www.oecd.org/dataoecd/7/51/37504590.pdf>

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AN ECONOMIC ASSESSMENT OF BIOFUEL SUPPORT POLICIES

The Ministerial Council of the OECD, at its meeting in May 2007, decided that OECD and IEA should collaborate in further work on issues related to the production and use of biofuels, including the promotion of increased use of biofuels. A report of the results of this work would be presented prior to the 2008 OECD Ministerial Council, expected to take place in May 2008. For this work to be useful in assisting governments to improve the performance of their policies, and to be convincing in the debate with existing vested interests, the economic assessment of biofuel policies will be undertaken in close co-operation between different Directorates of the OECD and the International Energy Agency IEA. It also seems important to make use of the expertise of the European Council of the Ministers of Transport (ECMT).

The study finds it's rational in the fact that policies promoting the production and biofuels have in many countries, in both the OECD area and other parts of the world, developed rapidly in recent years. This project

aims at providing up-to-date factual information on developments in biofuel markets and policies, as well as on the nature of the production and use processes involved. The economic and environmental characteristics of biofuel markets and related production processes will also be discussed. Based on that information, the project will help to assess the outcomes of alternative future policy scenarios and their implications in both economic and environmental terms, so that governments have information they might find helpful in taking decisions on where they want to go with their future biofuels policies.

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BIOFUELS: LINKING SUPPORT TO PERFORMANCE

The Joint Transport Research Centre of the OECD and the International Transport Forum held its Round Table on biofuels on 7/8 June 2007 to examine recent research findings on the well-to-wheels CO₂ mitigation potential of biofuels, the scale of subsidies for biofuels and some of the unintended impacts of promoting biofuels, on markets and on the environment. Potential trade in biofuels was addressed on the basis of an examination of the economic and environmental performance of Brazilian ethanol and biodiesel.

Volumetric production targets for biofuels and subsidies as currently formulated fail to provide incentives to contain costs, to avoid environmental damage or even to ensure greenhouse-gas emission reductions are delivered. The Round Table examined the potential of certification systems to regulate the market for biofuels and reviewed developments in California, the Netherlands, Germany and the United Kingdom. Despite the difficulties in establishing certification and assurance systems – in terms of credibility, stakeholder acceptance, barriers to trade and an inability to influence potential indirect impacts such as deforestation – the round table concluded that certification is essential if consumption of biofuels is to continue to be subsidised. Otherwise, although there may be progress towards biofuel targets, there will be disappointment in the higher level objective of reducing greenhouse gas emissions and unwelcome side effects for other sustainability goals.

From a transport sector perspective, much greater greenhouse gas emissions reductions could be achieved with the USD 13-15 billion a year currently spent in OECD countries on tax subsidies for biofuels if the support were directed to improving the efficiency of road vehicles and their use on the road.

The presentations and summary can be found on: <http://www.cemt.org/JTRC/index.htm>

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19TH ROUND TABLE ON SUSTAINABLE DEVELOPMENT: BIOFUELS: IS THE CURE WORSE THAN THE DISEASE?

The Round Table on Sustainable Development met on 11/12 September 2007 to discuss the economic potential and environmental impact of biofuels and the effectiveness of policies that influence their development. The Round Table is an independent body, housed at OECD, which serves as a forum for international dialogue among senior representatives from governments, businesses, academia, intergovernmental organisations and OECD secretariat.

The background paper written in support of the meeting was produced in close cooperation with the IEA and the International Institute for Sustainable Development. It discussed the technical and economic potential of different technologies to produce biofuels, government policies influencing biofuels production and prices, the opportunities and barriers to international trade, the consequences of government policies on agricultural

markets, the environment and energy security and the cost effectiveness of these policies. Finally the paper discussed the merits of certification systems to ensure a more sustainable production of biofuels and some suggestions for an alternative policy agenda.

The background paper and agenda can be found on: www.oecd.org/sd-roundtable. A chairman's summary will be published in due course.

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HARMONISATION OF REGULATORY OVERSIGHT IN BIOTECHNOLOGY

The main focus of OECD's *Working Group on Harmonisation of Regulatory Oversight in Biotechnology* (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 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; Russian Federation; Slovenia; the Secretariat of the Convention on Biological Diversity (SCBD); and the Business and Industry Advisory Committee to OECD (BIAC). During the last couple of years, there has been increased participation of other non-member countries including Brazil, Cameroon, Chile, China, India, Philippines and South Africa, under the auspices of OECD's Global Forum on the Knowledge-based Economy.

Major progress has been seen recently in a project on *Environmental Consideration of Risk/ Safety Assessment of the Release of Transgenic Plants*. This project intends to provide a comprehensive package of information elements to be used in considerations during risk/ safety assessment of transgenic plants. A steering group on this project held a second meeting at the Finnish Environment Institute in Helsinki at the end of August. The key components and structure of a document to be drafted as an outcome of this project were deliberated there, based on the Draft Operational Plan which has been adopted by the Working Group and a first draft of the document provided by the lead country Canada before the meeting. The second draft is expected to be completed in May 2008.

Major progress since the last publication of this newsletter has also been made on the project of *Unique Identifier for Transgenic Micro-organisms*. This is a project to develop a unique identification system for transgenic micro-organisms (bacteria) that have gone through the regulatory process leading to commercial application for release into the environment. This builds on existing guidance for the unique identifier for transgenic plants ([http://appli1.oecd.org/olis/2002doc.nsf/linkto/env-jm-mono\(2002\)7-rev1](http://appli1.oecd.org/olis/2002doc.nsf/linkto/env-jm-mono(2002)7-rev1)). In June 2007, the Sub-working Group on Micro-organisms of the Working Group held its workshop at Moscow State University, where they developed a draft questionnaire for stakeholders to gather their views and input on the development of a unique identifier for transgenic bacteria. This workshop was hosted by the Ministry for Education and Science of the Russian Federation, the Russian Academy of Science (RAS) and Scientific Council of RAS on Biotechnology. The developed questionnaire will be discussed at the Working Group to be held in October, and once adopted, it will be distributed or disseminated to stakeholders, and probably to the public through the OECD BioTrack website as well.

The publication of Consensus/ Guidance Documents continues to be a major output of the work of the Working Group. Amongst other things, a Consensus Document on the introduced trait of "Bt" was recently published. This covers proteins with insecticidal property derived from *Bacillus thuringiensis*. The Bt trait is involved in a large portion of commercial crops and the drafting process of this document raised intensive discussions for many years in the Working Group. This shows that the resultant document is important for risk assessors, risk managers and researchers concerned.

To date, 29 Consensus Documents including those for the biology of crops, trees and micro-organisms, and for selected traits that may be introduced into crop species, as well as the other variety of documents useful for risk/ safety assessment, have been published. All of them are available through the website (<http://www.oecd.org/biotrack>).

As announced in the last edition of this news letter, a special edition of the journal of *Environmental Biosafety Research* on the OECD workshop on "Beyond the Blue Book – Framework for Risk/ Safety Assessment of Transgenic Plants" was published (ISSN 1635-7922, Volume 5(4)). In this issue, you can find large amount of information relevant to risk/ safety assessment framework of transgenic plants, namely the foundation, current practices and potential way forward for risk/ safety assessment. An article on the overview of the workshop has been put on the website (<http://www.oecd.org/dataoecd/7/55/39018232.pdf>).


During the last meeting of the Working Group in February, a potential new project on *Adventitious Presence* – now called *Low Level Presence* – of transgenic seeds in conventional bulk shipments was discussed. As agreed at the last meeting, this potential project will be discussed again during the 20th meeting of the Working Group in October. A revised proposal will be prepared by the Bureau of the Working Group before the meeting. It is worth noting that a parallel project on low level presence of transgenic crops is currently being undertaken by a Task Force of the Codex Alimentarius Commission from a food safety perspective – so close co-ordination will be necessary with FAO/WHO.

Future events:

- 20th Meeting of the Working Group for the Harmonisation of Regulatory Oversight in Biotechnology, Paris, 24-26 October 2007.

Recent Publications:

 Consensus Document on the Biology of the native North American Larches

 Consensus Document on Safety information on Transgenic Plants Expressing *Bacillus Thuringiensis* – Derived Insect Control Proteins

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

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BIOTRACK ONLINE

BioTrack Online information system is a 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, especially the Consensus/ Guidance Documents of both groups. It also includes information on various workshops and conferences organised by the OECD, and a database of transgenic products (mainly crops) which have been approved for commercial use in OECD member countries (Product Database).

The major activity related to BioTrack Online recently focused on is the progress on the development of the unique identification system for transgenic micro-organisms as mentioned above. Once the system is developed, it will be used for each product accommodated in the Product Database.

Other progress has been made on co-operation between FAO and OECD on a web-based database for information on safety assessment of transgenic foods. This project was developed in response to a request from the Codex *ad hoc* Task Force on Food Derived from Biotechnology. Currently some IT experts of both organisations are discussing the feasibility of introducing interoperability between the *FAO Global Portal on Food Safety, Animal and Plant Health* and *OECD's Product Database*.

Web site: BioTrack Online
<http://www.oecd.org/biotrack>
Product Database and Unique Identifiers
<http://www.oecd.org/biotrack/productdatabase>

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SAFETY OF NOVEL FOODS AND FEEDS

The Task Force for the Safety of Novel Foods and Feeds (Task Force) was established in 1999 to address aspects of the safety assessment of foods and feeds derived from genetically engineered crops. The main focus of the work of the Task Force is to ensure that the types of information used in risk/ safety assessment, as well as the methods used to collect such information, are as similar as possible amongst countries.

Consensus Documents

The main output of the food and feeds programme is **consensus documents** on compositional considerations of specific food/feed crops. The Task Force consensus documents a compile common base of scientific information on the major components of specific crop plants, such as key nutrients, toxicants, anti-nutrients and allergens that may be useful in assessing the safety of specific crops with respect to human food and animal feed safety. This information is of value in the safety assessment of new (genetically engineered) varieties because typically such safety assessment involves a comparison of these components between the new variety, and existing traditional varieties. These documents are not legally binding, but because they are agreed upon consensus by member countries, they are highly valued during the risk/ safety assessment process.

To date, eleven consensus document addressing major crops have been completed and published: Low Erucic Acid Rapeseed (Canola); Soybean; Sugar Beet; Potatoes; Maize; Bread Wheat; Rice; Cotton; Barley; Alfalfa and other Temperate Forage Legumes; and Sunflower. In addition, the Task Force recently published the first consensus document on a mushroom (*Agaricus bisporus*), using the same structure as in the crop plant documents; a consensus document on Tomato will soon be completed; and three documents are being prepared on Papaya, Cassava, and Sweet Potato.

The Task Force also develops documents on important topics in safety assessment, such as 'Considerations for the Safety Assessment of Animal Feedstuffs Derived from Genetically Modified Plants'. Although this document does not deal with a specific crop, it is complementary to the other consensus documents.

The Task Force has recognised that, over time, some of the earlier consensus documents may become outdated and may no longer reflect the latest data and information available on the levels of key constituents in the crops. For this reason, the Task Force established a process for revising the earliest consensus documents it published, and the two earliest documents: Low Erucic Acid Rapeseed (Canola) and Soybean, are currently being updated.

Finally, the Task Force published the document *An Introduction to the Food/Feed Safety Consensus Documents of the Task Force*, which explains, amongst other things, i) why the Task Force decided to prepare consensus documents as part of its programme of work; ii) the purpose and use as a practical contribution to the risk/safety assessment of foods and feeds derived from transgenic organisms; and iii) the process by which consensus documents are drafted and brought to final publication.

Outreach and non member economies engagement

As modern biotechnology has become an increasingly global issue, the need to meet environmental and health safety standards goes beyond OECD member countries. One of the main features of the Task Force has been the increasing participation of non-member economies and invited experts to its work. The Task Force benefits from the participation of delegations from: Argentina, Brazil, China, Latvia, the Russian Federation, Slovenia, South Africa and Thailand. Their participation has been possible through the Global Forum on the Knowledge-based Economy (GFKE) under the auspices of OECD's Centre for Co-operation with non-members. The Task Force continues to involve more actively the expertise and interests of non member economies. This broadens the expertise that is available to the Task Force, while addressing a wider range of food and feed products that are of global interest. As a consequence, Thailand and South Africa have now started to work on three consensus documents on compositional considerations for papaya,

cassava, and sweet potato. These crops are of high importance for their respective countries, as well as many other OECD members countries and non-members economies. These three consensus documents are being drafted in co-operation with delegations from OECD member countries.

Participation also involves the Codex Alimentarius Commission, the United Nations (U.N.) Food and Agriculture Organization (FAO); the U.N. World Health Organization (WHO); and the Business and Industry Advisory Committee to OECD (BIAC).

OECD work on the risk/safety assessment of modern biotechnology

The Task Force on the Safety of Novel Foods and Feeds complements the work on the risk/safety assessment of modern biotechnology undertaken by the Working Group on Harmonisation of Regulatory Oversight in Biotechnology (Working Group), which addresses environmental safety concerns (see *Harmonisation of Regulatory Oversight in Biotechnology*).

Currently, the Task Force is carrying out jointly with the Working Group on Harmonisation of Regulatory Oversight in Biotechnology a project on Molecular Characterisation for Transgenic Plants. The first draft has recently being completed and it is currently under discussion by both the Working Group and the Task Force.

In addition, a Brochure on the ***OECD work on the risk/safety assessment of modern biotechnology***, which aims to capture activities of both the Task Force and Working Group, has been finalised and will soon be available.

Finally, the OECD work also complements other international activities such as those undertaken by the Codex *ad hoc* Task Force on Food Derived from Biotechnology (see *Biotrack*).

Future events:

- 14th Meeting of the Meeting of the Task Force for the Safety of Novel Foods and Feeds, Paris, 8-10 April 2008.

Recent Publications:

- 📖 *Consensus Document on Compositional Considerations for New Varieties of the Cultivated Mushroom *Agaricus bisporus*: Key Food and Feed Nutrients, Anti-Nutrients and Toxicants*
- 📖 *Consensus Document on Compositional Considerations for New Varieties of the Sunflower: Key Food and Feed Nutrients, Anti-Nutrients and Toxicants*

Upcoming Publication:

- 📖 *Consensus Document on Compositional Considerations for New Varieties of Tomato (*Lycopersicon esculentum*): Key Food and Feed Nutrients, Anti-Nutrients and Toxicants*
- 📖 *Brochure on the OECD work on the risk/safety assessment of modern biotechnology*

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

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HIGH LEVEL FORUM ON MEDICINES FOR EMERGING AND NEGLECTED INFECTIOUS DISEASES

The OECD held a High Level Forum in June 2007, at Noordwijk-aan-Zee in the Netherlands, on “Medicines for Neglected and Emerging Infectious Diseases: Policy Coherence to Enhance their Availability.

Participants at the HLF, which included Ministers and high level representatives from OECD and non-OECD countries, agreed a Noordwijk Medicines Agenda (NMA): a consensus document identifying promising actions governments could take to improve the availability of medicines, vaccines and diagnostics for neglected and emerging infectious diseases.

The NMA focussed on how to improve the innovation system, which at present is failing to deliver a robust pipeline of new medicines, vaccines and diagnostics for the neglected diseases that primarily affect the developing world. The NMA called on governments to show political leadership and to join with a wide variety of stakeholders in multiple sectors to intensify collaborative efforts and promote coherent policies.

Specifically, the NMA proposes actions that could make the health innovation system for infectious diseases more open and networked; that encourages more collaborative use and access to knowledge and IP; that makes it easier for a wide variety of global actors including biotechnology firms, pharmaceutical companies, academic institutions to contribute their skills and infrastructures in a low risk, low cost manner; that enhances the certainty there will be a viable market for end products; that improves policy coherence so that availability and accessibility go hand in hand. Going forward, OECD countries could explore what are the R&D needs for the infectious diseases that primarily affect the developing world; what is the ideal mix of the tools and research models to meet different public health needs; and how one could support and improve the research models being used to better prioritise and accelerate R&D in infectious diseases.

The HLF was a joint project of the Directorate of Science Technology and Industry and the Development Cooperation Directorate with cooperation from the Development Centre. There was close collaboration with the WHO and WHO/TDR in its planning, and it is hoped the NMA will be a useful input to deliberations at the WHO Intergovernmental Working Group on Public Health, Innovation and IP.

Publications

- 📖 *The Noordwijk Medicines Agenda*, Paris: OECD 2007. www.oecd.org/sti/biotechnology/nma
- 📖 Benedicte Callan and Iain Gillespie, "The path to new medicines" *Nature Outlook*, September 13, 2007, vol. 449, pp 164-165.
- 📖 Jack Radisch, *WHO Bulletin*, "More medicines for neglected and emerging infectious diseases", Volume 85, Number 8, August 2007.
- 📖 Lyndon Thompson and Rory Clarke, "Neglected Diseases: Towards Policies without Borders," *OECD Observer*, July 2007, vol. 262, pp. 19-21.

Forthcoming Publications

- 📖 *Innovation Strategies and Policy Options for Increasing Availability of Medicines for Emerging and Neglected Infectious Diseases*, Paris: OECD, 2007.
- 📖 *Policy Coherence for the Availability and Accessibility of New Medicines for Neglected Infectious Diseases*, The Development Dimension Series, Paris: OECD, 2007.

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OECD COUNTRIES AGREE GUIDELINES ON QUALITY ASSURANCE IN MOLECULAR GENETIC TESTING

In May 2007 OECD member countries adopted Guidelines for Quality Assurance in Molecular Genetic Testing. The Guidelines offer Principles and Best Practices for the quality assurance of molecular genetic testing offered in a clinical context. They seek to assist both OECD and non-OECD Member countries in the development and introduction of appropriate quality assurance procedures to:

- Promote minimum standards internationally for quality assurance systems and molecular genetic testing laboratory practices.

- Facilitate mutual recognition of quality assurance frameworks.
- Strengthen international cooperation and facilitate, where appropriate, the cross-border flow of samples for clinical purposes in accordance with recognised principles for their handling, storage, safety, privacy and confidentiality.
- Increase public confidence in the governance of molecular genetic testing.

The Guidelines address genetic testing for variations in germ line DNA sequences or products arising directly from changes in heritable genomic sequences that predict effects on the health, or influence the health management, of an individual. They focus on molecular genetic testing for the diagnosis of a particular disease or condition and predictive genetic testing often carried out before any clinical signs of the disease or condition appear. They are relevant to tests for heritable DNA variants that predict the response profile of an individual to a drug or course of therapy and that affect susceptibility to disease, patient prognosis, counselling, treatment and family planning. They do not address testing carried out only for research purposes.

The OECD Council agreed the Guidelines should be promoted and asked to be informed of the results of this promotion process, including information on the implementation of the guidelines as well as on their impact. They are an important contribution to international soft-law and practice.

The Guidelines are available on the web (in English, French and Japanese, a Chinese version is forthcoming). Website: <http://www.oecd.org/sti/biotechnology>

Publications

- 📖 *OECD Guidelines for Quality Assurance in Molecular Genetic Testing*. Paris: OECD, 2007.
- 📖 *Genetic Testing: A clinical practice survey and recommendations for improving quality standards*. Paris: OECD, 2007.
- 📖 *Quality Assurance and Proficiency Testing for Molecular Genetic Testing: Summary Results of a Survey of 18 OECD Member Countries*. Paris: OECD, 2005.

Contact: Benedicte Callan



PHARMACOGENETICS

A new Report on *Pharmacogenetics: Opportunities and Challenges for Health Innovation and Care* will be available in Autumn 2007. The report examines the challenges facing pharmacogenetics at across the health innovation cycle and into the clinic. The report reviews the impact to date of pharmacogenetics on both pharmaceutical R&D and clinical care. It concludes that the widespread adoption of pharmacogenetics is not yet guaranteed and that governments have a role to play in creating an “enabling” environment.

Pharmacogenetics can improve both the drug discovery process. It is useful in both identifying and validating new drug targets. In clinical trials, pharmacogenetics can help stratify patients who respond to a new potential medicine appropriately, adversely or not at all. It can also improve the quality and efficacy of the medicines ultimately developed. In clinical care, pharmacogenetics may enable doctors to prescribe more effective interventions and improve their use of evidence-based medicine. Pharmacogenetics can help identify those individuals most likely to benefit from a therapy and those most likely have an adverse reaction, allowing doctors to optimise treatments for individuals.

But, in 2007 the number of pharmacogenetics-based diagnostics on the market is still limited with less than a dozen products commercially available. A number of scientific, regulatory, and economic challenges need to be overcome if pharmacogenetics is to be taken up more widely by healthcare systems.

Public policy and coordinated international action may be necessary to: (1) validate biomarkers; (2) run the prospective studies necessary to apply pharmacogenetics to existing medicines; (3) create the incentives to apply pharmacogenetics broadly in the drug development process; (4) increase transparency about how

pharmacogenetics will be accepted by regulatory authorities; (5) understand the economic and health impacts of pharmacogenetics on health care systems; (6) educate and make information available to health care providers about pharmacogenetic assays, their interpretation and treatment options.

Forthcoming Publication

📖 *Pharmacogenetics: Opportunities and Challenges for Health Innovation and Care*. Paris: OECD, 2007.

Contacts: Iain Gillespie
 Benedicte Callan



BIOMARKERS AND TARGETED THERAPIES

Scientific advances in biotechnology are ushering in a new era of medicine: targeted therapies and personalized medicine are coming of age. Traditional medicine manages a disease through standard treatments, without taking account of existing variability between individuals or groups of population. Personalized medicine, in contrast, adapts treatments to the profile of each individual. This revolution in biomedicine is due, in large part, to the discovery of biomarkers.

A biomarker is a biological indicator which can be used to monitor the presence or absence of a disease; the progression of a disease; the effect of a treatment; and the toxicity of a drug. Biomarkers are important because they will help deliver safer and more effective drugs to patients and they will be a part of the solution to the pharmaceutical sector's R&D productivity problems.

Despite the growing enthusiasm for biomarkers and the large number and types of actors involved in developing them, biomarker identification, validation, and use in drug discovery and clinical practice, is still in its early stages. The OECD has selected a number of issues related to the development and uptake of biomarkers and for which policy actions may be necessary in the near future. These include (1) Ensuring the standardisation and interoperability of data coming from biomarker research; (2) Understanding the use of biomarkers in the innovation cycle and their acceptance by regulatory authorities; (3) Analysing the uptake and economic impacts of biomarkers on health systems.

Over the course of 2007-2008, the Secretariat and a steering group of interested countries under the WGHRB will develop a number of analytical papers addressing the three broad themes above. The analytical papers will be discussed and their policy recommendations validated through an expert meeting. A policy report is planned for delivery in the autumn of 2008.

Contacts: Marie-Ange Baucher
 Benedicte Callan



EMERGING RESEARCH MODELS FOR THE DELIVERY OF HEALTH INNOVATION

A new Policy Report on *Emerging Research Models for the Delivery of Health Innovation* will be available at the end of 2007. The Report explores the major elements (tools, practices, incentive structures) underpinning new models, or approaches to organising health innovation, in order to improve the efficiency with which laboratory discoveries are translated into new medical treatments. It also identifies where governments may have a role in facilitating the transition to such new models. The Report is based on four case studies and an Expert Workshop held in Paris in November 2006.

Across the OECD there are dozens of initiatives that take a holistic or bench-to-bedside perspective on the delivery of health innovation. The tools used include the creation of novel organisational networks and structures to increase flows of information among all stages of the innovation cycle; the smarter use of

information technology and the better exploitation biological and health data for both R&D and clinical practice; the creation of new and convergent scientific infrastructures and platforms; strategies and financing for improving the translation of discoveries into potential products; and the modernisation of clinical trials and regulations.

This describes the range of novel initiatives which share a common goal of more rapidly and effectively bringing biomedical products and processes from invention to market. It illustrates their commonalities and differences through case studies. And it explores whether we are in fact seeing the emergence of more efficient models for health innovation that can nimbly service the smaller targeted-therapy markets of the future.

Policy choices that could help facilitate such a transition are also discussed and include: the need for vision and leadership to effect a change in culture about health innovation; the creation of a knowledge market for the valorisation and exchange of a variety of health related data and technologies; the use of new models to leverage IP in collaborations; validating proof models and the modernisation of regulatory processes; exploiting opportunities from technological convergence in health innovation; analyzing how the value chain is changing in health innovation and policy interventions to deliver on such new value chains; accurate metrics of spending on health innovation and delivery.

Forthcoming Publications

📖 *Emerging Research Models for Health Innovation*. Paris: OECD, 2007.

Contacts: Bénédicte Callan
Jack Radisch



KNOWLEDGE MARKETS

A workshop on the application of Knowledge Markets to health innovations is scheduled for late spring/early summer 2008. The Workshop will explore what knowledge markets are, where there are experiments in the health sector, and what the challenges are to their widespread use.

Knowledge markets encompass a number of different mechanisms where buyers and sellers can trade a variety of knowledge intensive goods and services. Knowledge markets can include things like IP exchanges and patent pools; networking, matching or brokering services; clearing houses; and auctions. Increasingly, there is interest in applying the concept of knowledge market to the life sciences.

Enormous amounts of data, information and knowledge are created throughout the health innovation cycle, much of which remains privately held. In isolation, the information may not be of great value or the producer may not fully be able to exploit it. But in combination with other information, it could arguably have greater value and strategic impact. Proprietary information might provide valuable insights to other companies that are pursuing different research tracks, helping them to avoid similar pitfalls (and thus from wasting resources) or redirecting them toward goals that were formerly unrealizable. Knowledge markets could also serve the needs of companies when meeting regulatory requirements—for example, by enabling them to avoid the costs of conducting repetitive clinical and preclinical tests.

The Workshop will explore what benefits health sector knowledge markets could bring to both innovators and the public. Knowledge markets are a way of better identifying, accessing and using and creating value from existing intellectual assets. The workshop will identify where knowledge markets could help increase transparency, reduce duplication, deliver scale economies, create new value, create new sources of finance, and facilitate networking and collaboration. It will identify the difficulties of developing knowledge markets in the life sciences and what role public policy may have.

Contacts: Bénédicte Callan
Iain Gillespie



OECD INNOVATION STRATEGY: HEALTH BIOTECHNOLOGY CONTRIBUTIONS

The OECD Innovation Strategy offers an excellent opportunity to synthesize the many health-related biotechnology studies and policy recommendations produced over the past few years about how to create an environment that is supportive of health innovation, facilitates access to innovations so that they best serve the public good, and includes a receptive end-market for innovations. The Working Group on Human Health Related biotechnology has decided to synthesize its work and deliver a simple, concise summary of the most important trends and best policy practices in health innovation. A steering group or task force will be asked to review what advice should be included about the essential conditions for generating health-related innovations and to assess what are commonly agreed policy recommendations at this important point in the biotechnology and health sectors. The WGHRB will feed its messages into different modules of the OECD Innovation Strategy. It may also decide to produce a stand alone report if there is interest among Member countries.

Contacts: Iain Gillespie
Bénédicte Callan



CASE STUDIES ON THE UPTAKE AND DIFFUSION OF HEALTH RELATED BIOTECHNOLOGIES

A new Report on *The Uptake and Diffusion of Health Related Biotechnologies* will be available in autumn 2007. The Report identifies the range of incentives and barriers that are affecting the uptake and into the health care sector of health biotechnologies which differ in their stage of development, from innovations that are relatively mature to those that are still very new on the market. The case studies include: monoclonal antibodies as diagnostics and as therapeutics; genetic testing DNA micro-arrays; and a drug delivery technology illustrating the convergence of bio- and nano-technologies.

For each technology, the report identifies its clinical utility and factors stimulating and/or inhibiting its diffusion. The report makes clear that institutional frameworks and technology co-evolve, and that even when breakthroughs occur diffusion cannot be expected if the necessary institutional adjustments are not made. A striking finding is that in many cases the technology itself has progressed far faster than the institutional mechanisms that are needed support widespread diffusion and uptake.

Forthcoming Publication

 *The Uptake and Diffusion of Health Related Biotechnologies: Case Studies*. Paris: OECD, 2007.

Contact: Bénédicte Callan



SYNTHETIC BIOLOGY

Today, scientists are going beyond sequencing and manipulating genes, they are building life from scratch. Synthetic biology refers to the design and construction of new biological parts, devices and systems which do not exist in the natural world and to the redesign of existing biological systems to perform specific tasks. Basically, synthetic biology breaks down biological processes (e.g. protein production from a gene) to then builds systems that perform a particular desired function (e.g. oscillators which can produce protein on demand).

Scientists predict that within 2-5 years it will be possible to synthesize any virus. In 5-10 years simple bacterial genomes will be routinely synthesized and the construction of designer genomes commonplace.

These “designer genomes” will be inserted into empty bacterial cells thus giving birth to new living and self-replicating organisms. Other synthetic biologists hope to reconfigure the genetic pathways of existing organisms to perform new functions such as the manufacture high-value drugs or chemicals.

Synthetic biology is a powerful and transformative technique which merges biology and engineering. It opens up enormous scientific, commercial, and health opportunities. The promise of synthetic biology needs to be better understood, the variety of players involved identified, and their -- potentially conflicting -- research norms and business strategies explored.

Synthetic biology will undoubtedly also raise policy challenges for governments if the maximum benefits are to be realised. These include social, economic, and legal challenges, as well as biosecurity and safety concerns. Parallels to past experience with transformative technologies in the life sciences may be drawn (genetic engineering and bio-nano). The OECD is in an ideal position to forge a common understanding in the policy community of the issues to be aware of (research needs, community building, safety and security concerns, regulatory implications, market pathways, public understanding). Moreover, the OECD can launch an early dialogue on what reasonable and responsible conduct might entail in this field and thus assure that the economic and social benefits of this new technology are safely encouraged.

The OECD is beginning to work in this exciting area and a workshop to be held in 2008 is now in the planning stages.

Contacts: Iain Gillespie
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BIOSECURITY

The threat of bioterrorism gives rise to the need for security measures in legitimate bioscience facilities that work with, store or transfer dangerous biological material to protect them from being lost or stolen and subsequently misused for malevolent ends.

The OECD Committee on Scientific and Technological Policy (CSTP) agreed “Best Practice Guidelines on Biosecurity for BRCs” (Biological Resource Centres) in March 2007. The Guidelines on Biosecurity contain a framework on Risk Assessment to guide BRCs in classifying pathogens, for example, according to one of four biosecurity risk levels, and robust Risk Management measures that may be applied as a function of a particular pathogen’s biosecurity risk level. The Guidelines are available on the OECD website.

See: <http://www.oecd.org/dataoecd/6/27/38778261.pdf>

Publication

 *OECD Best Practice Guidelines on Biosecurity for BRCs*, Paris: OECD, 2007.

Contact: Jack Radisch



BIOLOGICAL RESOURCE CENTRES

Delivery and implementation of the Best Practice Guidelines for Biological Resource Centres

Biological Resource Centres (BRCs) are considered to be one of the key elements for sustainable international scientific infrastructure, which is necessary to underpin successful delivery of the benefits of biotechnology, whether within the health sector, the industrial sector or other sectors, and in turn ensure that these advances help drive growth.

“OECD Best Practice Guidelines for BRCs” comprised of the report of the Task Force on BRCs, were agreed by OECD member countries in March 2007.

The Best Practice Guidelines comprise two main parts. Part I sets out the background and rationale to the project as well as describing the methodology used for the articulation of best practice guidelines. A number of general recommendations (principally related to the implementation and review of the best practice guidelines) are set out in the last chapter. Part II of the report comprises the best practice guidelines themselves. Four sets of best practice guidelines are included dealing with (i) general quality aspects, (ii) biosecurity-related issues, (iii) specific guidelines for BRCs holding and supplying micro-organisms, and (iv) specific guidelines for BRCs holding and supplying human-derived materials. Finally, optional best practice guidelines are provided on the establishment of national certification system related to the best practices. See: <http://www.oecd.org/dataoecd/7/13/38777417.pdf>.

The upcoming International Culture Collections Conference (ICCC-11) (to be held on 7-11 October 2007 in Goslar, Germany) will include sessions on implementation of the guidelines by culture collections in practice. See: http://www.iccc11.de/index.php?contentleft_id=2

Further work on Global Biological Resource Centre Network (GBRCN)

A Workshop is planned for 13-14 December 2007, in Paris, entitled “*The Global Biological Resource Centres Network – Networking the Networks*”. The workshop will be mainly aimed at developing recommendations and consensus on practical measures towards establishment of an inclusive, virtual global network of BRCs, drawing on existing networking practice.

Publication

 *OECD Best Practice Guidelines for Biological Resource Centres*, Paris: OECD, 2007.

Web site: http://www.oecd.org/document/36/0,3343,en_2649_33703_38777060_1_1_1_1,00.html

Contacts: Kiyokazu Nakase
Alexandre Bartsev



BIOTECHNOLOGY FOR SUSTAINABLE INDUSTRIAL DEVELOPMENT

The transformative ability of biotechnology applied to industrial process in delivering profitability and environmental gains hand-in-hand, and the influential report “The Application of Biotechnology to Industrial Sustainability” (OECD, 2001: <http://www.oecd.org/dataoecd/61/13/1947629.pdf>), prepared by the OECD Task Force on Biotechnology for Sustainable Industrial Development, has prompted action in several countries towards delivering a more resilient, more sustainable and more biobased economy. The focus at the 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 transition towards bio-based economy.

Current focus is on supply-side limitations for industrial biotechnology – including on capital supply, human resources and globalisation of R&D. A Workshop to validate the findings of this work is planned to coincide with the 2008 World Congress on Industrial Biotechnology. The Task Force is also reviewing the utility of green and other sustainability indices for biobased products.

Delegates to the WPB also acknowledged increased importance of sustainable industrial biotechnology and agree to organise a thematic discussion on the achievements, trends and potential of industrial biotechnology with invited speakers at the next WPB meeting to be held on 12-14 November 2007.

Contact: Kiyokazu Nakase
Alexandre Bartsev



BIOTECHNOLOGY STATISTICS IN OECD MEMBER COUNTRIES

Preparatory work has started on the future edition of OECD Biotechnology Statistics. The OECD is developing a biotechnology questionnaire to harmonise the OECD's collection of biotechnology statistics. The data questionnaire for the next publication will be sent out in December 2007 to the delegates of the OECD Ad hoc Meeting on Biotechnology Statistics and those of the Working Party of National Experts on Science and Technology Indicators (NESTI), with responses requested by May 2008.

Web site: <http://www.oecd.org/dataoecd/51/59/36760212.pdf>

Contact: Brigitte van Beuzekom



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

2006 was the 20th anniversary of the publication of the Blue Book. With this in mind, the OECD organised a number of activities or events during 2006 designed to take stock of OECD work related to safety in biotechnology and to identify future needs, especially with respect to non-member countries. The OECD workshop: *Beyond the Blue Book – Framework for Risk/Safety Assessment of Transgenic Plants* was one of the most important of the 2006 events and was organised with the following objectives in mind:

- 1 To discuss the history and evolution of the conceptual framework for the evaluation of transgenic plant products in the environment and OECD's role in the development of that framework;
- 2 To discuss the current contribution of OECD's Working Group on the Harmonisation of Regulatory Oversight in Biotechnology to risk/safety assessment practice; and
- 3 To discuss the future role of OECD with respect to current risk assessment issues and needs.

Conferences co-sponsored by the Programme for 2007 are:

- *OECD Workshop on Bioenergy Policy Analysis, Umea, Sweden 22-24 January 2007*
- *Forest Research Management in an Era of Globalisation, Arlington, Virginia, USA 18-19 April 2007*
- *Modelling Global Land Use and Social Implications in the Sustainability Assessment of Biofuels, Copenhagen, Denmark 4-5 June 2007*
- *International Workshop on Campylobacter, Helicobacter and Related Organisms (CHRO 2007), Rotterdam, Netherlands 2-5 September 2007*
- *Frontiers in Transgenesis: A vision for new and safer sources of food, pharmaceuticals and energy, St. Louis Missouri 26-28 September 2007*
- *Improvement of Plant Performance for Sustainable Agricultural Development in Wetlands, Sendai, Japan 23 November 2007*

The OECD Workshop on Bioenergy Policy Analysis, organised by the OECD Trade and Agriculture Directorate in Co-operation with the Cooperative Research Programme and the Swedish Ministry of Agriculture, Food and Fisheries, was held in Umea, Sweden, 22-24 January 2007. The workshop discussed the relevant issues related to bioenergy policy analysis, ranging from the scientific and environmental background information, objectives and measures of bioenergy policy and the economics of the production and use of bioenergy. It provided many insights into how to organise further work by TAD on the issue of bioenergy. Without going in too much detail, the following are the key points:

- 1 Bioenergy is potentially a very fast field and future OECD work needs to be clearly defined to remain manageable
- 2 Work in the area of bioenergy is of a multidisciplinary nature and tapping in the CRP network and knowledge could be very important and helpful,
- 3 The analytical method of identifying policy objectives and evaluating the economic impacts of alternative policy tools may be a useful model for future work in this area.

Appropriate means of communicating basic facts and analytical findings to both policy makers and the public are key challenges in this area.

Information on the Co-Operative Research Programme and application forms for conference sponsorship or Research Fellowship awards are available on the Programme website:

http://www.oecd.org/topic/0,2686,en_2649_33903_1_1_1_1_37401,00.html

Recent Publications

- 📖 *Aquatic Living Resources Journal of the 8th International Conference on Shellfish Restoration held in Brest, France, in October 2-5, 2005.*
- 📖 *Special Issue on the 9th ISBGMO and OECD Workshop on Beyond the Blue Book; Framework for Risk/Safety Assessment of Transgenic Plants, Environment Biosafety Research, Volume 5(4), October-December 2006*
- 📖 *Abstracts from the 14th International Workshop on Campylobacter, Helicobacter and Related Organisms, Rotterdam, Netherlands, 2-5 September 2007, Zoonoses and Public Health (Formerly Journal of Veterinary Medicine, Series B), Volume 54, Supplement 1 2007;*

Forthcoming publications linked to conferences held in 2006:

- 📖 *Soils and Waste Managements: a challenge to climate change, Gorizia, Italy 15-16 June 2006*
- 📖 *The Role of Rumen biohydrogenation in the production of nutritionally enhanced ruminant derived foods by sustainable means, Madrid, Spain 30 September-1 October 2006*
- 📖 *International Workshop on Domestication, super-domestication and gigantism: human manipulation of plant genomes for increasing crop yield, Tsukuba, Japan 2-4 October 2006*
- 📖 *Forestry: a sectoral response to climate change, Wilton Park, UK 21-23 November 2006*
- 📖 *Mycotoxins from the field to the table, Omaha, Nebraska, USA 28 November-1 December 2006*
- 📖 *Agricultural and societal implications of contemporary embryo-technologies in farm animals, Copenhagen, Denmark 12 January 2005*

Contacts: Carl-Christian Schmidt
Janet Schofield



OECD'S SEED CERTIFICATION AND FOREST REPRODUCTIVE MATERIAL SCHEMES

The following three criteria namely; distinctness, uniformity and stability are used for defining crop varieties and form the basis for agricultural seed development and trade. Identification and minimum purity criteria are important components of sustainability, especially in the case of hybridisation and genetic modifications. For forest reproductive material reliability depends on several factors including local identification, regions or provinces, selection and breeding.

The **OECD Seed Schemes** were developed in 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 55 member and non-member countries across all continents. In essence, the Schemes attempt to harmonise certification with a view to facilitating international trade in agricultural seeds. Over 193 species, including all the basic staples and 39 100 varieties appear on the latest *OECD List of Varieties Eligible for Certification*. Among the emerging issues are the role of government in the control and testing of seeds, the 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), rules for hybrid cotton and hybrid grass seed, and the issue of seed lot size and homogeneity.

Under the broad mandate to assess the current and future needs of international certification, the “Working Group on Varietal Purity and Varietal Identity” established in 2006 have started to develop new definitions and procedures to be introduced into the Schemes.

A new **OECD Scheme for the Certification of Forest Reproductive Material** was introduced in June 2007. This new Scheme clarifies the terminology and improves the rules relating to the “Source-identified” and “Selected” categories (forest seed stands and sources). The Scheme is implemented by 22 countries. Three new countries, Burkina Faso, Serbia and Uganda have applied to join the Scheme. Discussions on the more “advanced” forest reproductive material continue for a possible future extension of the Scheme to cover them at the international level.

Future events:

- Meeting of National Designated Authorities/Forest Reproductive Material (27-28 Sept. 2007, Paris)
- Meeting of the Extended Advisory Group/Agricultural Seed (24 p.m.-25 January 2008, Paris)
- 4th Meeting of the Working Group on Varietal Identity and Varietal Purity (23-24 a.m. Jan.08, Paris)
- 5th Meeting of the WG on Varietal Identity and Varietal Purity (30 June 2008, Chicago, United States)
- Annual Meeting of National Designated Authorities/Agric. Seed (1-2 July 2008, Chicago, USA)

Publications:

- 📖 *List of Varieties Eligible for Seed Certification 2006/2007 (A new Interim List, updated July 2007, is available on the web). Next List 2007/2008 to be issued in Dec. 07.*
- 📖 *“2007” Supplement to the OECD Seed Schemes “2006”*
- 📖 *OECD Forest Seed and Plant Scheme “2007”*

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


Contact: Michael Ryan
Bertrand Dagallier (agriculture seed)
Csaba Gaspar (forest seed)



OECD BIOTECHNOLOGY AND THE WORLD WIDE WEB

OECD's web site includes much information on biotechnology, biosecurity, 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, and Biosecurity, 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/>
- For information on Biosecurity codes of conduct, see: www.biosecuritycodes.org

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



FUTURE EVENTS

- ◆ Frontiers in Transgenesis: A vision for new and safer sources of food, pharmaceuticals and energy, St. Louis Missouri 26-28 September 2007 (Contact: Janet Schofield)
- ◆ Expert meeting on Human Genetics Research Databases, Paris, 15-16 October 2007 (Contact: Christina Sampogna)
- ◆ 20th Meeting of the Working Group for the Harmonisation of Regulatory Oversight in Biotechnology, Paris, France, 24-26 October 2007 (Contact: Masatoshi Kobayashi)
- ◆ 14th meeting of the Task Force on Biotechnology for Sustainable Industrial Development, Paris, 8-9 November 2007 (Contact: Kiyokazu Nakase)
- ◆ Working Party on Biotechnology, Paris, 12-14 November 2007 (Contact: Stella Horsin)
- ◆ Improvement of Plant Performance for Sustainable Agricultural Development in Wetlands, Sendai, Japan 23 November 2007 (Contact: Janet Schofield)
- ◆ OECD/IAVI Workshop on Infectious Diseases, Paris, 26 November 2007 (Contact: Bénédicte Callan)
- ◆ Expert Workshop on Collaborative Mechanisms for Intellectual Property Rights, Paris, 28-29 November 2007 (Contact: Christina Sampogna)
- ◆ Workshop on the "Global Biological Resource Centres Networks – Networking the Networks", Paris, 13-14 December 2007 (Contact: Kiyokazu Nakase)
- ◆ 23rd Working Party on Biotechnology, 18-20 February 2008, Paris, France (Contact: Stella Horsin)
- ◆ 14th Meeting of the Task Force for the Safety of Novel Foods and Feeds, Paris, France, 8-10 April 2008 (Contact: Mar Gonzalez)



WHO'S WHO IN BIOTECH AT OECD

Michael OBORNE (SGE/AU)

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Peter KEARNS (ENV/EHS)

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Harmonisation of Regulatory Oversight in Biotechnology
Safety of Novel Foods and Feeds
Bi-track

Anthony ARUNDEL (SGE/AU)

The Bioeconomy to 2030

Alexandre BARTSEV (STI/BIO)

Biological Resource Centres
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Biomarkers and Targeted Therapy
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Working Group on Human Health Related Biotechnology

Richard DOORBOSCH (SGE/RSD)

Roundtable on Sustainable Development

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Safety of Novel Foods and Feeds
Harmonisation of Regulatory Oversight in Biotechnology

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Collaborative IPR Mechanisms
Human Genetic Research Databases
Counterfeiting of Pharmaceuticals

David SAWAYA (SGE/AU)

The Bioeconomy to 2030
Biosecurity

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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

