



EUROPEAN
COMMISSION

Community Research

BIO 2006 Chicago International Day (09 April 2006)

Programme of the joint delegation of the European Commission (EC), the European Medicines Agency (EMA) and the European Patent Office (EPO)

Hot Topics for the biotechnology industry in Europe

At BIO2006's International Day (09 April 2006), the joint EU delegation will organize four targeted speaking sessions. Each session deals with a 'hot topic', that is highly relevant for the global biotech industry.

In contrast with many other sessions at International Day, the EU sessions will not talk about inward investment, nor focus on a specific country, but they will discuss **developments in the biotechnology industry** in a region that includes the 25 Member States of the **European Union** (plus Candidate States Bulgaria and Romania and Associated States such as Switzerland, Israel, Turkey, Norway, Iceland), representing **the world's largest single market for goods**.

Session I: 12:30 PM – 1:20 PM:

International cooperation in EU research programmes (EC, project presentations)

Session II: 1:35 PM – 2:25 PM

Regulatory issues affecting biotech and pharma companies in Europe (EMA, tissue engineering directive, etc)

Session III: 2:40 PM – 3:30 PM

Protecting biotechnological inventions in Europe (the European Patent Office)

Session IV: The EU International Food and Agriculture Seminar in the Agri-Food track on International Day for 1:35 PM – 2:25 PM

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For the **full programme** of International Day: www.bio.org/events/2006/intlatt.

For **more information** on Europe's presence at BIO 2006 Chicago please see the media fact sheet at www.europa.eu.int/comm/research/eu-bio2006.

Outline of sessions and speakers

Session I: 12:30 PM – 1:20 PM: International cooperation in EU research programmes

How can companies and research institutes benefit from international collaboration? This session will feature world-renowned investigators from leading research institute and companies, who are involved in large scale R&D collaborations. The European Commission manages the world's largest public funding programme for collaborative research in life sciences, amounting to about 1 billion USD annually.

Chair: Christian Patermann, European Commission, DG Research, Director of the Biotechnology, agriculture and food directorate

Speaker 1: Dr. Kathie Olsen, Deputy Director, NSF and US chairperson of EC-US Task Force on Biotechnology Research

Speaker 2: The role of and benefits to companies in collaborative research
Laura van 't Veer, COO of Agendia, The Netherlands, participates in a 40-partner European project TRANS-BIG, Translating molecular knowledge into early breast cancer management.

Speaker 3: The role of top quality academic researchers in creating critical mass in research programmes
Roslyn Bill, School of Life and Health Sciences, Aston University, UK, and coordinator of the E-MEP consortium.

Session II: 1:35 PM – 2:25 PM Regulatory issues affecting biotech and pharma companies in Europe (EMA, tissue engineering directive, etc)

This panel will explain Europe's new pharmaceutical rules governing the marketing of medicines in Europe. The European Commission is proposing new regulation on advanced therapies including tissue engineering. The European Medicines Agency is developing a new set of guidelines which will be ready for public presentation at BIO, they will include hot topics like biosimilars – how will they be treated, clinical trials and biotech, what changes to the orphan drug rules after the current review is over, what services and assistance can biotech companies expect when working with the EMA – Europe's 'FDA'. The EU's Orphan Drugs Regulation is under review and results are expected early 2006.

Chair: Octavi Quintana Trias, European Commission, DG Research, Director of the Health research directorate

Speaker 1: Georgette Lalis, European Commission, DG Enterprise and Industry, Director of the Directorate for Consumer Goods.

Speaker 2: John Purves, Head of Biotechnology/Biological Sector, European Medicines Agency (EMA)

Speaker 3: Stéphane Hogan, European Commission, DG Research, Head of Unit for Biotechnology and Applied Genomics: Technology Platform Innovative Medicines

Session III: 2:40 PM – 3:30 PM

European Patent Law and practice for biotechnology differ in many aspects from US law: the legal basis for patenting biotechnological inventions in Europe will be explained and examples of case-law will be presented.

Chair: Siobhan Yeats, Director JC Biotechnology.

Speaker 1: Ingwer Koch - Director Patent Law Department (on legal aspects)

Speaker 2: Ashok Chakravarty, Examiner – Examiner (on the technical aspects)

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The EU International Food and Agriculture Seminar is scheduled in a parallel Agri-Food track on International Day for 1:35 PM – 2:25 PM

Session title: Coexistence between genetically modified and non-genetically modified based agricultural supply chains: from the seed to the fork.

Description of the session topic:

The EU regulations ensuring the traceability of GMOs & GMO derived products and informing consumers through reliable labelling is at the origin of the coexistence issue. The European Commission's guidelines on coexistence published on 2003 state that "farmers should be able to cultivate the agricultural crops they choose, be it genetically modified, conventional or organic crops". This legal framework is in line with a general international trend to enable reliable coexistence and traceability. Ensuring coexistence is a real challenge for scientists, stakeholders and policy-makers. The session aims at analysing the general framework, as well as the technical and economic feasibility of coexistence in the EU.

Chairman: Emilio RODRIGUEZ-CEREZO, EC JRC IPTS

Topics addressed and speakers:

Speaker 1. Legal frameworks for the cultivation of GM crops in the EU and its Member States.

Andreas Gumbert, EC, DG Agriculture, Environment, GMO and Genetic Resources Unit

Speaker 2. Agricultural measures to ensure coexistence between GM and non GM crops.

Antoine Messéan, INRA - Eco-Innov (France)

Speaker 3. Economic assessment of coexistence measures to ensure coexistence of GM and non GM crops. Manuel GÓMEZ-BARBERO, EC, JRC IPTS