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- Discover the **most important issues affecting major players in the food industry.** You will learn from these key examples.
- Find out about essential legislative developments as soon as they are discussed in the European Commission and Parliament. **You can plan effectively to protect your business.**
- **Gain a global perspective** with the expanded international section.

EU Food Law is read by senior executives in the food industry, national food authorities, and consumer organisations.

'EU Food Law provides thoughtful and thorough analysis of current events and issues, making it a "must read" every week for anyone who deals with food policy or works in the food industry.'

Mette Kahlin, Which? Advocacy Adviser

EU Food Law covers important issues affecting the food industry including:

- health and nutrition claims
 - food safety
 - contaminants
 - food labelling
 - traceability
 - genetically modified food and
 - food and drink advertising
 - food law enforcement
 - hygiene proposals.
- Legislation in related sectors is also monitored such as: packaging and waste law, employment law, consumer policy, competition law, and environmental law.
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Business Information
In A Global Context

Get Essential Information
from the Experts:

European Commission (Belgium)

US Food & Drug Administration
(FDA), Europe Office (UK)

The European Consumers'
Organisation (Belgium)

Federation of Pharmaceutical
Industry (Belgium)

Medical Products Agency (Sweden)

Pharmaceutical Group of the
European Union (Belgium)

Astrazeneca (UK)

Genethon (France)

GlaxoSmithKline Biologicals
(Belgium)

Lützel Klümper Wachenhausen
Rechtsanwälte (Germany)

Sanofi (France)

Covington & Burling LLP (UK)

Ehlers, Ehlers & Partner (Germany)

Eversheds LLP (UK)

Field Fisher Waterhouse LLP (UK)

Four New Square (UK)

NautaDutilh (The Netherlands)

Powell Gilbert LLP (UK)

Sidley Austin LLP (Belgium)

Simmons & Simmons LLP (UK)

Squire Sanders & Dempsey LLP
(UK)

Van Bael & Bellis (Belgium)

White & Case LLP (Belgium)



C5's 2nd Annual Forum on

European Pharma Regulatory Law

Emerging European Regulatory Developments
Affecting the Pharma Sector and Effective
Strategies for Compliance and Risk Management

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21 – 22 September 2011 • Le Plaza Hotel, Brussels, Belgium

Experienced in-house counsel, top legal practitioners, and regulatory experts will provide you with both practical and strategic guidance on the most current regulatory developments impacting on the pharma sector, including:

- Interpreting the Pharmacovigilance rules and the impact on reporting obligations
- The rise of social media: balancing compliance obligations with effective marketing strategies
- Obtaining and maintaining an effective pricing and reimbursement structure
- The do's and don'ts in multi-jurisdiction clinical trials: where are we and where are we going?
- Reviewing your pharma regulatory requirements and the interaction with competition law
- Adopting an effective product labelling model to combat anti-counterfeiting
- Successfully obtaining SPCs and extensions of regulatory data protection: extending your market exclusivity
- Avoiding product liability litigation by reviewing your global labelling practices

Plus, add further practical value to your experience by attending the programme's post-conference workshop on:

Adopting Effective Risk Management Strategies to Avoid Product Liability Claims

Friday, 23 September 2011

Media Partners:



To register call +44 (0) 20 7878 6888 or register online at www.C5-Online.com/pharmaforum

Discount Code: LEX 100

Don't be caught out by the impact of the new nanomaterial definition on legislation. Find out how you can maintain regulatory compliance

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life sciences

NANOMATERIALS: RISKS, REGULATIONS & REWARDS

Navigating global and cross industry regulations and delivering 1st hand experience of successful nanomaterial products

www.informa-ls.com/nanomaterials

7-8 September 2011 • Fira Palace Hotel, Barcelona, Spain

Hear from industry and regulatory experts including:

- **Hermann Stamm**, European Commission, Joint Research Centre, **Institute for Health and Consumer Protection**
- **Jeff Morris**, US Environmental Protection Agency
- **Frans Christensen**, Joint Research Centre (JRC), **Institute for Health and Consumer Protection (IHCP)**
- **Ulrike Frank**, Swedish Chemicals Agency, **Pesticides and Biotechnical Products**
- **Robert Landsiedel**, BASF SE
- **Steffi Friedrichs**, Nanotechnology Industries Association (NIA)
- **David Carlander**, Scientific Committee and Advisory Forum Unit, **EFSA**
- **Anna Gergely**, **Steptoe & Johnson LLP**
- **Michael Schuleit**, **Novartis Pharma AG**
- **Daniel Bernard**, **Arkema**
- **Beate Kettlitz**, **Science and R&D Confederation of the Food and Drink Industries of the EU**
- **Jenny Holmqvist**, **Cefic**
- **Peter Kearns**, **OECD**
- **Jean-Noël Guye**, **AXA Group**
- **Qasim Chaudhry**, **The Food and Environment Research Agency**
- **Gregor Schneider**, **ras materials GmbH**
- **Catherine Mir**, **MEDDTL**

Take home with you:

- ✓ The latest report findings from the REACH Implementation Projects on Nanomaterials (RIP-oNs) and what impact they will have on your exposure testing and material characterisation
- ✓ Insight into the US EPA and the pending nanomaterial regulation including case studies on products which have come to market and reporting systems
- ✓ Regulatory perspective into the developing EU guidance document on nanomaterials in food and feed
- ✓ Knowledge about the national French nanomaterial legislation and its context within European regulation
- ✓ Feedback from nanomaterial and nanotechnology working parties, including the OECD, on the changes they are pushing through to gain comprehensive, applicable and relevant regulation on nanomaterial products
- ✓ A toxicology checklist to ensure relevant testing and regulatory compliance
- ✓ Case studies detailing how companies have successfully launched nanomaterial products, from pharmaceuticals to biocides

Pre-conference workshop – 6 September 2011

The Regulation of nanotechnologies under REACH: Today and Tomorrow

Assess your regulatory rights and obligations under the REACH framework and anticipate how they are likely to evolve in the coming months and years, both within the EU and globally

Choice of two evening seminars

Evening Seminar, Discussion and Dinner – 7 September 2011

Legal Briefing

Led By : **Field Fisher Waterhouse**, Belgium

Evening Seminar , Discussion and Dinner

7 September 2011

Meet the regulators: Ensure nano compliance

Get in depth and reliable answers to your questions. A chance to discuss in a relaxed environment your challenges and brain storm solutions

NEW
FOR 2011

Post-conference workshop – 9 September 2011

Fulfilling your CLP Responsibilities

Implement the new CLP regulation according to the new requirements and have the opportunity to discuss points of concern with your peers.

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Please quote: CQ8105EJRR

REACH and CLP Implementation in Practice

Discussing the Outcome of the 2010 Registration and the Next Steps to Ensure Compliance

Brussels, Belgium

28th - 30th September 2011

Half-Day Interactive Pre-Conference Workshop:

Candidate Listing and Authorisation

Led by:

Senior Representative
Field Fisher Waterhouse

Attending This Premier **marcus evans** Conference Will Enable You to:

- **Benefit** from best practices of leading multinational companies to ensure a smooth preparation for 2013
- **Learn** how to tackle emerging issues and changes post 2010 registration
- **Examine** the obligations on downstream users and how to substantially improve communication in the supply chain
- **Get** familiar with the authorisation process
- **Explore** the recent changes and the complexity of safety data sheets and find ways to make them smarter
- **Identify** the current key compliance elements and apply an efficient strategy to your organisation

Learn from Key Practical Case Studies:

- Learn from the 2010 and establish effective preparation for the 2013 registration from **Umicore**
- Combat challenges of working together in SIEFs and build a strong strategy for 2013 from **Linde AG**
- Understand the authorisation process and its complexity from **Solvay S.A.**
- The role of socio-economic analysis and its importance in the authorisation process from **US Steel**
- Discover ways to make the safety data sheets smarter from **Borealis Group**
- Recognise downstream users obligations and improve the supply chain communication from **Henkel**
- Understand REACH responsibilities for non EU manufacturers from **Norilsk Nickel**

Corporate Business Partner:



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Lessons Learnt from 2010 while Getting Ready for the 2013 Deadline – Finding an Efficient Implementation Strategy for Your Company



In the Chair Day One

Dr. Fridtjof Schucht

Head of REACH and GHS Implementation, Europe
Linde AG

Your Expert Speaker Panel:

Dr. Roger Van der Linden

Group Manager, Product Stewardship and REACH
Borealis Group

Mercedes Viñas

Manager Chemical Regulation
CEPIC - European Chemical Industry Council

Petra Kralova

REACH Director
US Steel

Anja Klauk

Scientific Officer
ECHA

Nobumasa Arashiba

Director, Responsible Care Division
Mitsui Chemicals, Japan

Dr. Marleen Van Den Bergh

Director, Product Stewardship and REACH
Umicore

Dr. Fridtjof Schucht

Head of REACH and GHS Implementation, Europe
Linde AG

Giuseppe Malinverno

General Secretary EUROTOX, Governmental and Regulatory Affairs, EU and Italian Manager
Solvay S.A.

Dr. Dirk Danneels

REACH Initiative Director
Honeywell

Maarten Dankloff

HSE Manager Benelux
ARKEMA

Rob Mason

Head of Compliance Branch
Chemicals Regulation Directorate
Health and Safety Executive

In the Chair Day Two

Dr. Roger Van der Linden

Group Manager, Product Stewardship and REACH
Borealis Group

Hennie Pouwels

Director Safety, Health and Environment
Department Sustainability and Government Affairs
Philips Lighting

Dr. Hermann Onusseit

Technical Director
Henkel

Patrick Verhelle

Product Safety and Compliance Manager, EMEA
Ecolab

Irina Burkova

Head of Standardisation and Product Quality,
Manufacturing Operational Management
Department
Norilsk Nickel, Russia

Maria Baklashova

Chief Specialist
Norilsk Nickel, Russia

Dr. Steve Binks

Director, Hazard Assessment and Communication
EHS Centre of Excellence
GlaxoSmithKline

Lorenzo Zullo

Coordinator, Chemicals and Environment
Legislation and Advocacy
ETRMA - European Tyre and Rubber Manufacturers Association

Koen Naert

Group Environmental Health and Safety
General Manager
Bekaert
Scientific Collaborator Free University
Brussels

Agnieszka Kotze

Senior REACH Specialist HSE, EMEA and India
Afton Chemical

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7-8 September 2011

Hotel Fira Place
Barcelona, Spain

Latest scientific opinion from EFSA:

Herman Fontier • Johann Steinkellner
Aija Kazocina • Mark Egsmose

**Feedback from the
EU Commission**

Jeroen Meeussen
European Commission, Belgium

**Practical advice from
MS experts:**

Darren Flynn
CRD, UK

Tove Jern
Ministry of Agriculture and Forestry, Finland

Maarten Trybou
Federal Public Service of Public Health, Food
Chain Safety and Environment, Belgium

Hara Panagopoulou
Ministry of Rural Development and Food,
Greece

Claude Vergnet
AFSSA, France

Dr Pavel Miná
State Phytosanitary Administration, Czech
Republic

Jacob van Klaveren
RIVM, The Netherlands

Philip Marx-Stoelting
Federal Institute for Risk Assessment,
Germany

Dr Martin Strelake
Federal Office of Consumer Protection and
Food Safety (BVL), Germany

Dr Véronique Poulsen
(ANSES), France

Anne Alix
DGAI-SRPV-BRMMI, France

**Learn from the experiences
of industry leaders:**

Dow AgroSciences • BASF
Bayer CropScience • Syngenta
Makhteshim Agan • DuPont

In Association with:



The New Regulation enters into force June 14th 2011
- hear feedback from 13 regulators



Forum

www.informa-ls.com/agchemforum

Opening Plenary Session:

**Maintaining global food security whilst protecting
biodiversity and human health**

Hear the perspective of a large supermarket, the Crop Protection Association and
Department of Agriculture, Ireland

**3 Conference Streams: Over 50 presentations to
choose from:**

1. Regulatory Frameworks

Ensure successful implementation of The New PPP Regulation
1107/2009, MRLs and The Sustainable Use Directive

2. Human Safety

Hear latest developments in risk assessment methods and review best
practice for toxicology testing and exposure assessment

3. Environmental Safety

Member State, EFSA and industry feedback on honey bees, guidance
documents and risk assessment for ecotox and fate

Pre-Conference Workshop: 6 September 2011

**Consequences of New Efficacy Data
Requirements for Dossier Generation**



Chairman:

Norbert Weißmann, Senior Regulatory Manager Agrochemicals and Biopesticides
- Efficacy, SCC, Germany

Evening Seminar and Conference Dinner: 7 September 2011

Legal Briefing

Seminar Leaders:

Ruxandra Cana, Partner, Field Fisher Waterhouse, Belgium
Claudio Mereu, Partner, Field Fisher Waterhouse, Belgium
Koen Van Maldegem, Partner, Field Fisher Waterhouse, Belgium

Post Conference Workshop: 9 September 2011

Fulfilling your CLP Responsibilities

Workshop Leader:

Dr B.D. Podd, Global Regulatory Affairs Manager, Kimberly-Clark Europe, UK

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Informa Life Sciences' inaugural:

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law within industry

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& need-to-know legal updates on biopharmaceutical
regulatory frameworks, IP and licensing agreements*

Brand
new event
for 2011

www.informa-ls.com/biopharmlaw

11-12 October 2011 • Pestana Chelsea Bridge Hotel • London • UK

Keynote Speakers:

- Gopalan Narayanan, **MHRA**, UK
- Sjoerd Hoekstra, **European Patent Office**, The Netherlands

In House Representatives:

- Marc Christian Bauer, **Amgen**, Switzerland
- Soren Thor Jensen, **Novo Nordisk A/S**, Denmark
- Isabella Fabbri, **Biogen Idec International GmbH**, The Netherlands
- William Haddad, **Biogenics**, USA
- Frank Landolt, **Ablynx**, Belgium
- Douwe Witteveen, **Genzyme**, The Netherlands
- Rob Aerts, **Abbott**, The Netherlands

Private Practice Experts:

- Lincoln Tsang, **Arnold Porter**, UK
- Paul Calvo, **Sterne Kessler Goldstein & Fox**, USA
- Maria Manley, **Bristows**, UK
- Peter Bogaert, **Covington & Burling**, Belgium
- Gareth Morgan, **Winston & Strawn**, UK
- Alex Denoon, **Lawford Davies Denoon**, UK
- Erik Vollebregt, **Greenberg Traurig**, The Netherlands
- David Hull, **Covington & Burling**, UK

Conference Highlights:

- ✓ **Explore the ATMP Regulation with Feedback from the MHRA** - Gopalan Narayanan reviews the ATMP regulation and offers advice to assist with legal implications surrounding advanced therapies
- ✓ **Benefit from Guidance on Biological Medicinal Products Containing Monoclonal Antibodies** - Remain updated and find out how these guidelines will affect biopharmaceutical practice
- ✓ **Examine EU Biosimilar Approval Pathways and Review the US Biosimilar Statute** - Participate in a thought-provoking panel session with feedback from Biogen Idec International and Novo Nordisk
- ✓ **Increase Patent Filing Success and Investigate the Ability of Biopharmaceutical Companies to Protect Innovation** - Hear first-hand advice from the European Patent Office and gain guidance from Abbott and Ablynx on patent challenges
- ✓ **Can Stem Cell Therapies Save Companies from the Patent Cliff?** Innovative sessions address this concept and offer insight into alternative business models stem cell therapies may offer
- ✓ **Ensure that You Avoid Competition Law Pitfalls in Collaboration and Licensing Agreements** - Minimise competition law concerns with key provisions & ensure you know who is regarded as a competitor

Evening Seminar and Networking Dinner: 11 October 2011 Developing a Patent Litigation Strategy for Europe

Led By: Alastair McCulloch, *Partner*, Jones Day, UK &
Christian Paul, *Partner*, Jones Day, Germany

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„Erfolg entsteht im Kopf“:
Prof. Dr. Hans-Dieter Hermann,
Sportpsychologe der
deutschen Fußball-
Nationalmannschaft,
spricht über
„Motivation, Erfolg
und Spitzenleistung“



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17. – 20. Oktober 2011 | Meliá Berlin

CEO-Panel – Montag, 17. Oktober 2011 Diskutieren Sie mit **High-Level-Experten** über **neue Kommerzialisierungsmodelle**



Han Steutel,
European VP & General
Manager Germany,
Bristol-Myers Squibb



Andreas Sander, VP Central
Europe & General Manager
Germany,
ALK-Abello-Arzneimittel GmbH



Dr. Michael Mehler, CEO,
RIEMSER Arzneimittel AG



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Dierk Neugebauer, selbständiger
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- Priv.-Doz. Dr. Marc-Alexander Burmeister, Senior Vice President/
Regional Head Marketing & Sales Central Europe,
B. Braun Melsungen AG, Division Hospital Care
- Kerstin Drinnenberg, Direktorin Sales, **Basilea Pharmaceutica AG**

Frühe Nutzenbewertung nach AMNOG

- Thomas Müller, Leiter Abteilung Arzneimittel,
Gemeinsamer Bundesausschuss
- Dr. Kai Richter, VP Medical, Mitglied der Geschäftsleitung,
AstraZeneca Deutschland GmbH
- Dr. Gerhard Jäger, Director Direct Sales,
Daiichi Sankyo Deutschland GmbH

„Wenn du Sales-Verantwortung hast – hingehen!“

Michael Esther, Verkaufsleiter Deutschland BU Onkologie & Hospital,
Riemser Arzneimittel AG

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Studies**

**Sonderfokus
Medizintechnik**

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Networking**

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Sessions**

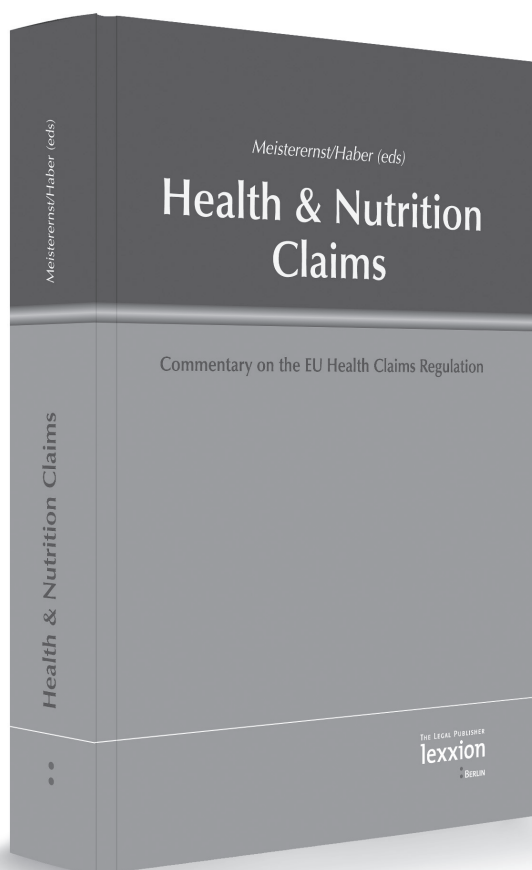
Unsere Kongress-Schwerpunkte in diesem Jahr:

- **Neue Kommerzialisierungsmodelle auf dem Prüfstand**
Collaborative Healthcare, Versorgungsmanagement,
KAM, KOL – Welche Strategien und Kompetenzen sind
im Pharmavertrieb von morgen gefragt?
- **AMNOG & Market Access**
Konsequenzen der frühen Nutzenbewertung für
Produktneueinführungen, Indikationserweiterungen
und den Bestandsmarkt
- **CRM, Closed Loop Marketing, Multi Channel
Management, iPads**
Welchen Beitrag können Social Media und Sales
Technologies für eine passgenaue Zielgruppenansprache
leisten?

Health & Nutrition Claims

Commentary on the EU Health Claims Regulation

Meisterernst/Haber (eds.)



The influence of the regulation on health and nutrition claims on the law on food advertising, on product development work in food enterprises, on the advertising industry, foodstuff monitoring and on nutrition science, cannot be overestimated. The book comments on the Regulation article by article giving an explanation for all the relevant terms, concepts of the law and consequences for the practice. The authors combine legal and scientific expertise. Andreas Meisterernst is a senior partner of a food law firm and lecturer on food law at the Technical University of Munich. Bernd Haber, PhD, is a state-examined food chemist and works for the regulatory affairs department of a multinational food ingredients manufacturer.

Health & Nutrition Claims – Commentary on the EU Health Claims Regulation · *Meisterernst/Haber (eds.)* · Berlin 2010 · 453 pages
Print: € 128.00 · ISBN: 978-3-86965-133-0
E-Book: € 102.40 · ISBN: 978-3-86965-134-7

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Call for Papers: Comparing Risk Regulation in China and Europe

The business worlds of China and Europe have come closer. As awareness about the interdependence of both economies arises, the need for a dialogue between both economies becomes evident. In this respect, the field of risk regulation is on the forefront of such a dialogue. Recent and old crises such as the dioxin scandal in Europe and hazardous toys in China as well as the transnationality of the financial crisis emphasize the intertwined character of risk perception and regulation in both economies, which still lacks adequate research. Local problems and regulatory challenges in China and Europe may furthermore be of interest for a mutual understanding of both regimes. Environmental challenges with emissions, drawing and enforcement of safety standards represent challenges to both economies.

The EU-China risk regulation special issue invites submissions that investigate specific Chinese and European topics within the areas covered by the EJRR from a comparative perspective. Additionally, we are looking for contributions from international scholars and practitioners which evaluate fields covered by the EJRR and especially case notes from the respective jurisdictions.

The EJRR is an international journal that provides an innovative forum for informed and scholarly discussion on how risks are regulated across policy domains. By focusing on institutional, procedural and substantive aspects of risk regulation, the EJRR strikes a balance between the interests of the practitioners, notably those increasingly engaged in regulatory drafting and advice to the industry, and a more theoretical focus, combining normative articles with timely contributions on legislative and judicial developments, new literature and relevant events. The EJRR understands itself as a truly multi-disciplinary journal.

Please send inquiries and article submissions to ejrr-china@lexxion.de
Submission deadline: 2nd April 2012

EJRR Special Issue

edited by

Alberto Alemanno (HEC Paris School of Management)

Gao Xiang (University of Political Science and Law (CUPL), Beijing)

He Mingke (Business School of Beijing Technology and Business University (BTBU), Beijing)

Kai Purnhagen (Ludwig-Maximilians-University, Munich/University of Amsterdam)

Francis Snyder (Peking University School of Transnational Law / London School of Economics (LSE) / CERIC, Université Paul Cézanne (Aix-Marseille III))

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Jonathan Wiener, Duke University, Durham



5th International European Food and Feed Law Conference

Regulation of Innovations

Thursday and Friday, 6 and 7 October 2011

Logenhaus Berlin

PROGRAMME

I. Legislative and scientific approaches

- ▶ Past, present, and future of the precautionary principle
- ▶ The regulation of GMOs
- ▶ The Novel Food Regulation - revision required
- ▶ EFSA and the identification of emerging risks
- ▶ EFSA Guidance on risk assessment of nanotechnology applications in foods/feeds

II. Actual issues

- ▶ The application of nanotechnology
- ▶ Consumer information requirements: impact on competitiveness and innovation
- ▶ Jurisdiction of the ECJ on the novel food regulation
- ▶ Ethical aspects of animal cloning

III. Concepts in practice

- ▶ EU legal requirements for innovative food additives
- ▶ Regulation's impacts on innovation in speciality feed ingredients
- ▶ New additives - the Stevia Case
- ▶ Use of other substances and Regulation 1925/2006
- ▶ Legal frame for nutrigenomics

SPEAKERS

Alberto Alemanno, *Associate Professor of Law, HEC Paris*

Evelyn Breitweg-Lehmann, *Head of Unit, Federal Office of Consumer Protection and Food Safety, Berlin*

Lars Bracht Andersen, *Associate Professor, Department of Law, Aarhus University*

Vittorio Silano, *Chair of the Scientific Committee, European Food Safety Authority (EFSA), Parma*

Bernd Haber, *Head of Global Regulatory Affairs & Quality Data Management/Human Nutrition, BASF SE, Lampertheim*

Isabel Ortiz, *Director, Consumer Information, Diet and Health, FoodDrinkEurope, Brussels*

Barbara Klaus, *Partner, Meyer Meisterernst, Milan, Managing Editor of EFFL*

Caroline Herody, *Head of Regulatory Affairs & Product Service, Adisseo, A Bluestar Company, Antony*

and many more

Visit www.lexxion.eu/conferences for the full programme and registration form! **Closing date: 22 September 2011.**

Or contact Ms Nikola Bock by phone: +49-30-81 45 06-27 · fax: +49-30-81 45 06-22 · e-mail: bock@lexxion.de.

FEEES

Conference 6/7 October 2011

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€ 730,- (reduced fee for EFFL-subscribers)

€ 620,- (reduced fee for full-time academics)

Dinner (optional): € 54,- (incl. wine & water)

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EJRR

EUROPEAN
JOURNAL OF
RISK
REGULATION

A JOURNAL AT THE INTERFACE OF SCIENCE AND LAW

As the European Union is increasingly emerging as de facto global regulator of all kinds of rules concerning the environment, human health and safety, risk regulation is becoming a new lens through which to analyse the European integration process. Indeed, today the most important and widespread form of EU regulation in the internal market is concerned with the government of risk to individuals' health and safety.

The European Journal of Risk Regulation (EJRR) provides an innovative forum for informed and scholarly discussion on how these risks are regulated across policy domains in Europe and beyond. While the central focus of the journal is the European law regulating inter alia Chemicals, Nanomaterials, Pharmaceuticals, Food, Cosmetics, Medical Devices, Pollution, Climate Change, and Public Health, discussion extends to other social sciences, such as sociology, political science, risk analysis, economics, cognitive psychology as well as to the physical and life sciences.

EJRR strikes a balance between the interests of the practitioners, notably those increasingly engaged in advice to the industry and in regulatory drafting, and a more theoretical focus, combining normative articles with timely contributions on legislative and judicial developments, new literature and relevant events.

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