

# EJRR

EUROPEAN  
JOURNAL OF  
RISK  
REGULATION

## SYMPOSIUM ON THE EUROPEAN PARLIAMENT'S ROLE IN RISK GOVERNANCE

The Changing Face of Risk Governance

*Paul Rübige*

The Precautionary Principle: Its Use Within Hard and Soft Law

*René von Schomberg*

The European Parliament and Risk Governance

*Dirk Hudig*

Improving Regulatory Decisions through Targeted Research

*Michael Rogers and Miro Smrīga*

Risk Governance and the Precautionary Principle:

Recent Cases in the ENVI Committee

*Jo Leinen*

Risk Governance and Risk Assessment –

Key Tools for an Effective European Parliament

*Malcolm Harbour*

## ARTICLES

Back to the Future: US-Tuna II and the New Environment-Trade Debate

*Alessandra Arcuri*

Can Science Tame Politics: The Collapse of the EU's New GMO Regime

*Vesco Pascalev*

## REPORTS

Biosimilars: Current Situation and Future Expectations

*Guillermina Forno and Eduardo Orti*

Looking Back to the Future of Regulating Nanotechnologies and  
Synthetic Biology

*Elen Stokes and Diana Bowman*

## CASE NOTES

WTO Appellate Body Report, United States – Clove Cigarettes

*Benn McGrady*

ECJ Case C-225/09 – Fundamental Freedoms and Rights of Patients

*Alexander Weiss*

# Contents

Editorial	143
<i>Alberto Alemanno</i>	
<b>SYMPOSIUM ON THE EUROPEAN PARLIAMENT'S ROLE IN RISK GOVERNANCE</b>	
The Changing Face of Risk Governance: Moving from Precaution to Smarter Regulation	145
<i>Paul Rübzig</i>	
The Precautionary Principle: Its Use Within Hard and Soft Law	147
<i>René von Schomberg</i>	
The Problem of Low and Uncertain Risks – Balancing Risks and Benefits	157
<i>Dirk Hudig</i>	
Improving Regulatory Decisions through Targeted Research: A Case Study on Amino Acids	161
<i>Michael Rogers and Miro Smruga</i>	
Risk Governance and the Precautionary Principle: Recent Cases in the ENVI Committee	169
<i>Jo Leinen</i>	
Risk Governance and Risk Assessment – Key Tools for an Effective European Parliament	174
<i>Malcolm Harbour</i>	
<b>ARTICLES</b>	
Back to the Future: US-Tuna II and the New Environment-Trade Debate	177
<i>Alessandra Arcuri</i>	
Can Science Tame Politics: The Collapse of the New GMO Regime in the EU	190
<i>Vesco Paskalev</i>	
Schizophrenic Stakes of GMO Regulation in the European Union	202
<i>Claudio Mereu</i>	
<b>REPORTS</b>	
<b>Biotechnology</b>	
Biosimilars: Current Situation and Future Expectations	213
<i>Guillermina Forno and Eduardo Orti</i>	
The Product of Nature Doctrine in the Myriad Saga	218
<i>Emanuela Gambini</i>	
<b>Food</b>	
Overview of the Standard of Review for Possible Justifications to Introduce National Food Labelling Rules in the EU	223
<i>Ignacio Carreño</i>	
EU and US Mutually Recognise their Respective Organic Standards and Control Systems as Equivalent	225
<i>Ignacio Carreño</i>	
<b>Nanotechnology</b>	
The Drive towards Nanotechnology Standardization	227
<i>Evisa Kica</i>	
Looking Back to the Future of Regulating New Technologies: The Cases of Nanotechnologies and Synthetic Biology	235
<i>Elen Stokes and Diana Bowman</i>	

Regulatory Impact Assessment	
The Impact of Better Regulation in the Case Law of the European Court of Justice <i>David Keyaerts</i>	241
Pharmaceuticals	
India Grants a Compulsory Licence of Bayer's Patented Cancer Drug: The Issue of Local Working Requirement <i>Enrico Bonadio</i>	247
<b>CASE NOTES</b>	
Appellate Body Report, United States – Clove Cigarettes <i>Benn McGrady</i>	251
Clarifying the Concept of Victim in the Motor Vehicle Driver's Liability Insurance: The ECJ's Judgment in Case C-442/10 <i>Vadim Mantrov</i>	257
Case C-225/09 Commission v Portugal: Fundamental Freedoms Strengthen the Rights of Patients <i>Alexander Weiss</i>	261
<b>BOOK REVIEWS</b>	
The Reality of Precaution – Comparing Risk Regulation in the US and Europe <i>Fabrizio Cafaggi</i>	265
The Financial Crisis in Constitutional Perspective – The Dark Side of Functional Differentiation <i>Giorgio Tosetti Dardanelli</i>	273
Corporate Finance Law. Principles and Policy <i>Timo Fest</i>	275
<b>MISCELLEANEOUS</b>	
Masthead	III
Imprint	V
2 <sup>nd</sup> HEC Paris Workshop on Regulation – Call for Papers	VII
Upcoming Conferences and Events	IX

## MANAGING EDITOR

*Alberto Alemanno*  
HEC Paris, France  
alemanno@hec.fr

## ASSOCIATE EDITORS

### Articles Submission

*Pascal Cardonnel* (Law)  
European Court of Justice, Luxembourg

*Adam Burgess* (Social Sciences)  
University of Kent, Canterbury, United Kingdom

### Book Reviews

*David J. Hornsby*  
University of the Witwatersrand, Johannesburg,  
South Africa

### Case Notes

*Kai Purnhagen*  
Ludwig-Maximilians-University, Munich Risk  
and Insurance Center,  
Munich, Germany

### Reports

*Enrico Bonadio*  
City University London, United Kingdom

## ADVISORY BOARD

*Peter Barton Hutt*  
Covington & Burling LLP, Washington, USA

*Carl Baudenbacher*  
University of St. Gallen, Switzerland  
President of the EFTA Court, Luxembourg

*Marco Bronckers*  
University of Leiden, Netherlands  
VVGB, Brussels, Belgium

*Theofanis Christoforou*  
European Commission Legal Service,  
Brussels, Belgium

*Miguel Maduro*  
European University Institute, Florence, Italy

*Giandomenico Majone*  
European University Institute, Florence, Italy

*Anthony Ogus*  
University of Manchester, United Kingdom

*José Esteve Pardo*  
University of Barcelona, Spain

*Jacques Pelkmans*  
College of Europe, Bruges, Belgium

*Michael D. Rogers*  
Independent Consultant on Risk, Ethics and Law,  
Brussels, Belgium

*Giorgio Sacerdoti*  
Bocconi University, Milan, Italy  
Former Chair of the WTO Appellate Body

*Nicolas de Sadeleer*  
University of Saint Louis, Brussels, Belgium

*Francis Snyder*  
University Paul Cézanne, Aix-Marseille III, France,  
London School of Economics, United Kingdom

*David Vogel*  
University of California, Berkeley, USA

*Denis Waelbroeck*  
Ashurst, Brussels, Belgium  
College of Europe, Bruges, Belgium

*Vern Walker*  
Hofstra University School of Law, New York, USA

*Thomas Werlen*  
Quinn Emanuel Urquhart & Sullivan LLP, London,  
United Kingdom

**EDITORIAL BOARD***Lucas Bergkamp*

Hunton &amp; Williams, Brussels, Belgium

*Susana Borrás*

Copenhagen Business School, Frederiksberg, Denmark

*Morten Broberg*

University of Copenhagen, Denmark

*Fabrizio Cafaggi*

European University Institute, Florence, Italy

*Dirk Detken*

European Food Safety Authority (EFSA), Parma, Italy

*Mary Footer*

University of Nottingham, United Kingdom

*Candido Garcia Molyneux*

Covington &amp; Burling, Brussels, Belgium

*Liana Giorgi*

The Interdisciplinary Centre for Comparative Research in the Social Sciences (ICCR), Vienna, Austria

*Minna Heikkilä*

European Chemicals Agency (ECHA), Helsinki, Finland

*Sebastian Krapohl*

Otto-Friedrich-University, Bamberg, Germany

*Peter Kugel*

Attorney at law, Brussels, Belgium

*Bettina Lange*

University of Oxford, United Kingdom

*Ragnar Lofstedt*

King's College London, United Kingdom

*Benn McGrady*

Georgetown University, Washington, USA

*Sara Poli*

University of Rome 'Tor Vergata', Italy

*Reinhard Quick*

VCI Liaison Office, Brussels, Belgium

*Claudio Radaelli*

Exeter University, United Kingdom

*Andrea Renda*Centre for European Policy Studies (CEPS), Brussels, Belgium  
LUISS Guido Carli University, Rome, Italy*Vincenzo Salvatore*

European Medicines Agency (EMA), London, United Kingdom

*Colin Scott*

University College Dublin, Ireland

*Stijn Smismans*

Cardiff University Law School, Wales

*Geert Van Calster*DLA Piper, Brussels, Belgium  
K.U. Leuven, Belgium*Ellen Vos*

Maastricht University, The Netherlands

*Jonathan Wiener*

Duke University School of Law, Durham, USA

**CORRESPONDENTS****Biotechnology***Justo Corti Varela*

Universidad CEU San Pablo, Madrid, Spain

*Shane Morris*

University College Cork, Ireland

*Maria Weimer*

Maastricht University, The Netherlands

**Food***Ignacio Carreño*

FratiniVergano – European Lawyers, Brussels

*Stéphanie Mahieu*

European Court of Justice, Luxembourg

**Intellectual Property***Enrico Bonadio*

City University London, United Kingdom

**Lifestyle Risks***Jean-Patrick Villeneuve*

Swiss Graduate School of Public Administration (IDHEAP), Lausanne, Switzerland

*Simon Planzer*

University of St. Gallen, Switzerland

**Nanotechnology**

*Joel D'Silva*  
European Association of Chemical Distributors  
(FECC), Brussels, Belgium

*Mihail Kritikos*  
White & Case LLP, Brussels

**Pharmaceuticals**

*Alessandro Spina*  
European Medicines Agency (EMA), London,  
United Kingdom

*Anna Pavlou*  
Sidley Austin LLP, Brussels

**Regulatory Impact Assessment**

*Lorenzo Allio*  
Independent Policy Analyst and Consultant,  
Lugano, Switzerland  
Honorary Research Fellow at the University  
of Exeter, United Kingdom

*Anne Meuwese*  
University of Tilburg, The Netherlands

*Jacopo Torriti*

London School of Economics and Political  
Science, United Kingdom

**Risk Communication**

*Sweta Chakraborty*  
University of Oxford, United Kingdom

**Trade, Investment and Risk**

*Alessandra Arcuri*  
Erasmus University Rotterdam, The Netherlands

*Alexia Herwig*  
University of Antwerp, Belgium

*Lukasz Gruszczynski*  
Polish Academy of Sciences, Warsaw, Poland

**EXECUTIVE EDITOR**

*Cliff Wirajendi*  
Lexxion Publisher, Berlin  
wirajendi@lexxion.eu

**Publisher**

Lexxion Verlagsgesellschaft mbH  
Güntzelstraße 63 · 10717 Berlin · Germany  
Phone: +49 30/81 45 06-0 · Fax: +49 30/81 45 06-22  
www.lexxion.de

**Typeset**

G.K.W. Kuhle Werbung GmbH, Berlin

**EJRR annual subscription\* rates 2012 (4 issues)**

printed version only	367,00 €
printed version + online edition (incl. archive)**	412,00 €
online edition only (incl. archive)**	367,00 €

\* Prices include Postage and Handling. EU Member States: VAT will be added if applicable.

\*\* Single user online access via user name and password.

EJRR is supplied under our terms of sale and supply. Copies of our terms and conditions are available upon request.  
Lexxion Verlagsgesellschaft mbH. VAT Reg.No. DE 209981990.

**For further information please contact**

info@lexxion.de  
Tel.: +49 30/81 45 06-0 · Fax: +49 30/81 45 06-22

**Contributions**

are welcome and should be submitted according to the EJRR author guidelines. Any such contribution is accepted on the understanding that the author is responsible for the opinions expressed in it.

**Photocopying**

All rights reserved. No part of this journal may be reproduced in any form whatsoever, e.g. by photo print, microfilm, or any other means, without prior permission of the publisher. This journal was carefully produced in all its parts. Nevertheless, authors, editors and publisher do not warrant the information contained therein to be free of errors. Readers are advised to keep in mind that statements, data, illustrations, procedural details or other items may inadvertently be inaccurate.

This journal may be cited as [2012] EJRR.

ISSN (Print) 1867-299X · ISSN (Online) 2190-8249