

**European Regulatory Governance (194101160)**

*University of Twente*

*Master European Studies: Regulation, Europe and Innovation Track*

*Master Public Administration: Risk and Regulation Track*

*Master Health Sciences*

*Fall Semester 2013-2014, Quarter 2*

**Convenor**

Dr. Shawn Donnelly

Dept. of Public Administration

RA 4252, Ext. 3259, [s.donnelly@utwente.nl](mailto:s.donnelly@utwente.nl)

**Objectives**

How is European regulation designed, and how do professionals play a role in shaping it and coping with it? This course provides practical experience in all stages of the process, covering all of the main ways that Europe regulates—from strong EU powers, to strong national powers with light coordination, to self-regulation by market participants that the EU tries to change by identifying and promoting best practice.

When dealing with the single market, most European legislation involves delegating the power to regulate to the European Commission, subject to oversight by national governments and the European Parliament, with the input of expert advisory bodies and the opinions of the regulated. This course provides basic reading and instruction on how that happens, and then expects students to study in groups how that works on a specific topic of regulation. Each week has a specific assignment that goes into a final report, ending in a policy presentation / poster session in the final week.

The course therefore trains you to be an expert in how Europe generates rules and how the regulated cope with them. You will learn a variety of different ways, and how to cope with each. The course requires you to apply your expertise, in a specific way, and how regulation is generated and dealt with there, such as financial conglomerates in financial market regulation, employee rights in a company bankruptcy in social policy, or medical devices and pharmaceuticals in the health sector. You will work in a group that works through weekly assignments that you discuss with other groups, to compare how things work in your different cases. By the end of the course, you should have expertise in designing regulation, participating in the process, dealing with the consequences, generating research reports, and presenting findings.

Students must choose one project, and a team in which to follow it, at the beginning of the course. The four project areas to be followed in this year's course, with proposed specific topics are:

1. Financial market regulation
  - a. Financial Conglomerates Directive: FICOD
  - b. Capital Requirements Directive: CRD IV
2. Public administration (Regulation and Innovation)

- a. Promoting Renewable Energy: Directive 2009/28.
- b. Safety of Meat and Animal-Derived Food: Regulation 853/2004.
3. Social policy (Working conditions under employer insolvency).
  - a. Part-Time Work Directive (97/81/EC)
  - b. Working Conditions under Employer Insolvency. Directive 2008/94/EC.
4. Health sciences
  - a. Medical Devices Directives: 90/385/EEC and/or 93/42/EEC
  - b. Pharmacovigilance: Regulation 1235/2010 and Directive 2010/84/EU

### **Literature**

*Core readings* will be provided on the blackboard site in PDF format, which you can then download to read. This syllabus provides selected tips for further reading. Reading on the individual policy areas will start with *primary documents* from the various EU institutions, available through the Legislative Observatory of the European Parliament <http://www.europarl.europa.eu/oeil/home/home.do>. Students will be responsible for identifying and acquiring documents from the other key actors in the policy development process, ranging from national governments and parliaments to EU-level lobbies and NGOs (non-governmental organizations). Finally, students are expected to make diligent use of Google Scholar <http://scholar.google.com> to identify any *key articles* that apply to their case studies. Strategy sessions in class will help clarify what to target and how.

### **Preparation and Grading**

The grade for the course consists of class participation (20%) combined with poster presentation in the last class session (15%) and a group project assignment (65%), to be handed in via Blackboard on Tuesday, 28 January 2014 at 08:00. The project assignment consists of parts that are to be prepared in groups and presented and discussed in the larger class each week before being submitted by the deadline.

#### **Week 1: Regulatory choice, options and challenges in the EU**

Martin Lodge (2008) 'Regulation, the Regulatory State and European Politics,' *West European Politics*, Vol. 31, Nos. 1–2, 280 – 301, January–March.

Christoph Knill and Andrea Lenschow (2003) 'Modes of Regulation in the Governance of the European Union: Towards a Comprehensive Evaluation', *European Integration online Papers (EIoP)* Vol. 7 (2003) N° 1.

#### *Further Reading:*

Giandomenico Majone (2005) *Dilemmas of European integration : the ambiguities and pitfalls of integration by stealth*. Oxford UP.

Giandomenico Majone (1996) *Regulating Europe*. London: Routledge.

Esty, D. and Geradin, D. (eds) (2001) *Regulatory Competition and Economic Integration* (Oxford: Oxford University Press).

Shawn Donnelly (2010) *The Regimes of European Integration: constructing governance of the single market*. Oxford UP.

## **Week 2: Delegation to the European Commission**

Thatcher, M., and A. Sweet Stone (2002). 'Theory and Practice of Delegation to Non-Majoritarian Institutions', *West European Politics*, 25:1, 1–22.

Renaud Dehousse (2008) 'Delegation of powers in the European union: The need for a multi-principals model,' *West European Politics*, Volume 31, Issue 4, 2008, Pages

Arndt Wonka and Berthold Rittberger (2010) 'Credibility, Complexity and Uncertainty: Explaining the Institutional Independence of 20 EU Agencies', *West European Politics* 33, 4: 730-52.

### *Further Reading:*

Pollack, M. (2002). 'Learning from the Americanists (Again): Theory and Method in the Study of Delegation', *West European Politics*, 25:1, 200–219.

Robert Thomson and Rene Torenvlied (2010) 'Information, Commitment and Consensus: A Comparison of Three Perspectives on Delegation in the European Union', *British Journal of Political Science* 41: 139-159.

Thatcher, M. (2002). 'Delegation to Independent Regulatory Agencies: Pressures, Functions and Contextual Mediation', *West European Politics*, 25:1, 125–47.

Thomas Christiansen and (2006) 'The 2006 Reform of Comitology: Problem Solved or Dispute Postponed?' Beatrice Vaccari, *EIPAScope* 2006/3.

Thatcher, M. (2005). 'The Third Force? Independent Regulatory Agencies and Elected Politicians in Europe', *Governance*, 18:3, 347–74.

Gilardi, F. (2002). 'Policy Credibility and the Delegation to Individual Regulatory Agencies', *Journal of European Public Policy*, 9:6, 873–93.

Hood, C., and M. Lodge (2006). *The Politics of Public Service Bargains*. Oxford: Oxford University Press.

Keleman, R.D. (2002). 'The Politics of "Eurocratic" Structure and the New European Agencies', *West European Politics*, 25:4, 93–118.

Majone, G. (2002). 'Delegation of Regulatory Powers in a Mixed Polity', *European Law Journal*, 8:3, 319–39.

McGowan, L., and S. Wilks (1995). 'The First Supranational Policy in the European Union', *European Journal of Political Research*, 28:2, 141–69.

Anand Menon; Stephen Weatherill (2008) 'Transnational Legitimacy in a Globalising World: How the European Union Rescues its States,' *West European Politics*, Volume 31, Issue 3 May 2008 , pages 397 – 416.

Jarle Trondal (2008) 'The anatomy of autonomy: Reassessing the autonomy of the European Commission,' *European Journal of Political Research* 47: 467–488.

Alexander Kreher (1997) 'Agencies in the European Community - a step towards administrative integration in Europe,' *Journal of European Public Policy*, Volume 4, Issue 2 January 1997 , pages 225 - 245

Giandomenico Majone (1997) 'The new European agencies: regulation by information,' *Journal of European Public Policy*, Volume 4, Issue 2 January 1997 , pages 262 – 275.

Thomas Gehring; Sebastian Krapohl (2007) 'Supranational regulatory agencies between independence and control: the EMEA and the authorization of pharmaceuticals in the European Single Market,' *Journal of European Public Policy*, Volume 14, Issue 2 March 2007 , pages 208 – 226.

Matthew Flinders (2004) 'Distributed public governance in the European Union,' *Journal of European Public Policy*, Volume 11, Issue 3 June 2004 , pages 520 – 544.

### ***Project Assignment (1):***

Making reference to a core piece of legislation that defines your project field, or a core policy area that is tied to several pieces of legislation, identify the type of delegation made to the European Commission (to monitor, to issue secondary legislation and regulations, to enforce) and the reasoning for the delegation. Beyond the technical reasons, what are the public policy reasonings, and the likely impact of delegation?

### **Week 3: Comitology**

Adrienne Heritier and Catherine Moury (2011) *Contested Delegation: the Impact of Codecision on Comitology*. *West European Politics* 34, 1: 145-66.

Rhys Dogan (1997) 'Comitology: Little procedures with big implications,' *West European Politics*, Vol.20, No.3 (July 1997), pp.31-60.

C.-F. Bergstrom, Henry Farrell & Adrienne Heritier, 'Legislate or Delegate? Bargaining over Implementation and Legislative Authority in the EU,' *West European Politics*, Vol. 30, No. 2, 338 – 366, March 2007

### *Further Reading:*

Gijs Jan Brandsma & Marianne van de Steeg (2007) 'Accountability in the European Union: the cases of the Comitology Committees and the European Council,' Mimeo, Utrecht School of Governance.

Jens Blom-Hansen (2008) 'The origins of the EU comitology system: a case of informal agenda-setting by the Commission,' *Journal of European Public Policy*, Volume 15, Issue 2 March 2008 , pages 208 – 226.

Lucia Quaglia; Fabrizio De Francesco; Claudio M. Radaelli (2008) 'Committee Governance and Socialization in the European Union,' *Journal of European Public Policy*, Volume 15, Issue 1 January 2008 , pages 155 – 166.

**Project Assignment (2):**

Making reference to the delegation laid out in (1), identify the appropriate comitology committee, the voting procedure, and its application in at least one recent policy area. Document your findings with original documents. How would you best describe the relationship between the Commission and the comitology committee based on the evidence?

**Week 4: Expert advisory committees and supervisory authorities: epistemic power**

Claire A Dunlop (2010) 'Epistemic communities and two goals of delegation: hormone growth promoters in the European Union', *Science and Public Policy*, 37, 3: 205–17.

Åse Gornitzka & Ulf Sverdrup (2011) 'Access of experts: information and EU decision making', *West European Politics* 34, 1: 48-70.

Claudio Radaelli (1999) 'The public policy of the European Union: whither politics of expertise?', *Journal of European Public Policy* 6, 5: 757-74.

*Further Reading:*

Christina Boswell (2006) 'The political functions of expert knowledge: knowledge and legitimation in European Union immigration policy,' *Journal of European Public Policy*, Volume 15, Issue 4 June 2008 , pages 471 – 488.

Volker Schneider; Frank M. Häge (2008) 'Europeanization and the retreat of the state,' *Journal of European Public Policy*, Volume 15, Issue 1 January 2008 , pages 1 – 19.

Lucia Quaglia; Fabrizio De Francesco; Claudio M. Radaelli (2008) 'Committee Governance and Socialization in the European Union,' *Journal of European Public Policy*, Volume 15, Issue 1 January 2008 , pages 155 – 166.

Lucia Quaglia (2008) 'Financial Sector Committee Governance in the European Union', *Journal of European Integration* 4: 563-78.

Åse Gornitzka & Ulf Sverdrup (2008) 'Who consults? The configuration of expert groups in the European union', *West European Politics* 31, 4: 725-50.

**Project Assignment (3):**

Making reference to the same delegated power studied in (1) and (2), identify and describe the Agency, Authority or other official body that is involved in assisting the Commission determine what to do and how to do it as it carries out its delegated responsibilities. To what extent is there a close correspondence between the position of the expert body or authority and the position of the Commission? And the position of key member states? And the position of key private sector lobby groups, either in business or the public interest sector?

**Week 5: Implementation: degrees of discretion in EU regulation and balancing EU goals with national difference**

Knill, C., and D. Lehmkuhl (2003). 'The National Impact of European Union Regulatory Policy: Three European Mechanisms', *European Journal of Political Research*, 41:2, 255–80.

Lee McGowan (2006) 'Europeanization unleashed and rebounding: assessing the modernization of EU cartel policy,' *Journal of European Public Policy* 12:6 December 2005: 986–1004.

Jorgen Gronnegard Christensen (2010) 'EU Legislation and National Regulation: Uncertain Steps Towards a European Public Policy', *Public Administration* 88, 1: 3-17.

*Further Reading:*

A. Héritier et al. (2001) *Differential Europe: New opportunities and restrictions for member-state policies*. Lanham : Rowman & Littlefield.

Knill, C. (2001). *The Europeanization of national administrations: Patterns of institutional change and persistence*. Cambridge : Cambridge University Press.

Jordana, J., D. Levi-Faur and I. Puig (2006). 'The Limits of Europeanization: Regulatory reforms in the Spanish and Portuguese Telecommunications and Electricity Sectors', *Governance*, 19:3, 437–64.

Heritier, A., D. Kerwer, C. Knill, D. Lehmkuhl, M. Teutsch and A.C. Douillet (2001). *Differential Europe*. Lanham, MD: Rowman & Littlefield.

Falkner, G., O. Treib, M. Hartlapp and S. Leiber (2005). *Complying with Europe*. Cambridge: Cambridge University Press.

Claudio M. Radaelli (2005) 'Diffusion without convergence: how political context shapes the adoption of regulatory impact assessment,' *Journal of European Public Policy* 12:5 (October): 924–943.

**Project Assignment (4):**

Making reference to the legislation, documents observed so far, and where available, secondary literature, assess the degree of discretion that is retained by national legislators and competent authorities, or alternatively, self-regulation by private groups in the context of European legislation and delegation in the area you are studying. If possible, assess why this is so and whether it strengthens or weakens the public purpose intent of the European legislation.

**Week 6: Persuasion, Enforcement and Self-Regulation**

Miriam Hartlapp (2007) 'On Enforcement, Management and Persuasion: Different Logics of Implementation Policy in the EU and the ILO,' *Journal of Common Market Studies* Vol. 45, No. 3, pp. 653–674.

Francesco Duina; Tapio Raunio (2007) 'The open method of co-ordination and national parliaments: further marginalization or new opportunities?' *Journal of European Public Policy*, Volume 14, Issue 4 June 2007 , pages 489 – 506.

Lodge, M. (2007). 'Comparing New Modes of Governance in Action: The Open Method of Coordination in Pensions and Information Society', *Journal of Common Market Studies*, 45:2, 343–65.

Christian Hey, Klaus Jacob, and Axel Volkery (2007) 'Better regulation by new governance hybrids? Governance models and the reform of European chemicals policy', *Journal of Cleaner Production* 15: 1859-74.

*Further Reading:*

Hodson, D., and I. Maher (2001). 'The Open Method as a New Mode of Governance: The Case of Soft Economic Policy Co-ordination', *Journal of Common Market Studies*, 39:4, 719–46.

Schaefer, A. (2004). 'A New Form of Governance? Comparing the Open Method of Coordination to Multilateral Surveillance by the IMF and the OECD', Max Planck Institute for the Study of Societies, working paper 5.

Zeitlin, J. (2005). 'Introduction: The Open Method of Co-ordination in Question', in J. Zeitlin and P. Pichot with L. Magnusson (eds.), *The Open Method of Co-ordination in Action: The European Employment and Social Inclusion Strategies*. Brussels: PIE Peter Lang.

David Chalmers and Martin Lodge (2003). *The Open Method of Co-ordination and the European Welfare State*, CARR discussion paper No. 11. London: London School of Economics.

Mark Thatcher (2007) 'Regulatory agencies, the state and markets: a Franco-British comparison,' *Journal of European Public Policy*, Volume 14, Issue 7 October 2007 , pages 1028 – 1047.

Lene Holm Pedersen (2006) 'Transfer and transformation in processes of Europeanization,' *European Journal of Political Research* 45: 985–1021.

***Project Assignment (5):***

Policy areas vary by the degree to which they rely on direct regulation, supervision and enforcement at the European level or the national level. Depending on the degree of decentralization, the EU may rely on the open method of coordination, persuasion, policy learning and best practice rather than command and control regulation. Making reference to how regulation is governed in your project area, how would you characterize European policy and activity? Has it had any effect on the regulatory distinctiveness of individual countries, or the establishment of common standards, and what is the long-term prospect as a result?

**Week 7: Policy Networks and Regulatory Outcomes in the Absence of Rules**

Eberlein, B., and E. Grande (2005). 'Beyond Delegation: Transnational Regulatory Regimes and the EU Regulatory State', *Journal of European Public Policy*, 12:1, 89–112.

Ed Randall (2007) 'Not that soft or informal: a response to Eberlein and Grande's account of regulatory governance in the EU with special reference to the European Food Safety Authority (EFSA),' *Journal of European Public Policy*, Volume 13, Issue 3 April 2006 , pages 402 – 419.

David Levi-Faur (2011) 'Regulatory networks and regulatory agencification: towards a Single European Regulatory Space', *Journal of European Public Policy* 18, 6: 810-29.

*Further Reading:*

Coen, D., and A. Heritier (2005). *Redefining Regulatory Regimes*. Cheltenham: Edward Elgar.

Weber, K. and Hallerberg, M. (2001) 'Explaining Variation in Institutional Integration in the European Union: Why Firms May Prefer European Solutions'. *Journal of European Public Policy*, Vol. 8, No. 2, pp. 171–91.

Dehousse, Renaud (1997) Regulation by Networks in the European Community: The Role of European Agencies. *Journal of European Public Policy* 4:2 , pp. 246-261.

David Bach; Abraham L. Newman (2007) 'The European regulatory state and global public policy: micro-institutions, macro-influence,' *Journal of European Public Policy*, Volume 14, Issue 6 September 2007 , pages 827 – 846.

Sabatier, P.A. (1998). The advocacy coalition framework: Revisions and relevance for Europe. *Journal of European Public Policy* 5: 98–130.

Hans-Peter Kriesi, Edgar Grande, Romain Lachat, Martin Dolezal, Simon Bornschieer & Timotheus Frey (2006) 'Globalization and the transformation of the national political space: Six European countries compared,' *European Journal of Political Research* 45: 921–956.

***Project Assignment (6):***

Networks fill in many of the gaps between countries where common laws, institutions and obligations are weak, and serve to supply certain kinds of cooperation, where these are desired. They also influence future legislation and regulation by engaging with lawmakers and delegated authorities. Is there an identifiable network of public and private actors in your project area? Describe membership, means of interaction, means of connecting with the policy-making process, and impact.

**Week 8: Regulatory Impact Assessments and Regulatory Choice**

Claudio M. Radaelli & Anne C.M. Meuwese (2010) 'Hard Questions, Hard Solutions: Proceduralisation through Impact Assessment in the EU', *West European Politics*, 33:1, 136-153.

C. Radaelli 'Diffusion without convergence: how political context shapes the adoption of regulatory impact assessment,' *Journal of European Public Policy* 12:5 October 2005: 924–943

*Further Reading:*

OECD (2010) *Recommendation of the Council on Regulatory Policy and Governance*.

Robert Baldwin, Martin Cave and Martin Lodge (2012) 'Cost-Benefit Analysis and Regulatory Impact Assessment', in Baldwin, Cave and Lodge, *Understanding Regulation: Theory, Strategy and Practice*. Oxford University Press, 315-37.

***Project Assignment (7):***

All legislation and regulation in the EU requires a regulatory impact assessment. Consider the characteristics, advantages and disadvantages of an RIA in terms of efficiency, objectivity and fruitful contribution to the quality of regulation. Incorporate this into your final report, and present to the rest of the group as a poster presentation in the Atrium of the Ravelijn Building, that is open to the public.