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SOME PARADIGMS OF REGULATION OF RISKS TO SOCIETY*

Regulation of risks to society is one of the most important spheres of action of a modern state, and an important theme in discussions about the role of the state and public administration. The author attempted to identify several paradigms underlying risk regulation by pointing to socio legal challenges for risk regulation in the era of regulatory capitalism.

Risk regulation is a multidisciplinary issue, and legal aspects are not the only source of concern. The study of law in the governance of risk highlights the need for a critical and conceptual approach to risk governance. Each paradigm may have an impact on legal issues in technological risk regulation, and their better understanding should lead to a better understanding of the role of law in the process of risk regulation. Being focused on paradigms as generalisations, this article has been largely cast at a conceptual level; empirical conclusions mostly remained out of its sphere.

Key words: *Regulation. Governance. Risk Regulation. Technological risks.*

1. MULTI-PARADIGMATIC NATURE OF REGULATION OF RISKS TO SOCIETY

We live in a risk society and risks arising from human activities are affecting our everyday life.¹ Regulation of risks to society has a long his-

* This paper is a result of author's research primarily performed at the University of Pennsylvania School of Law, where she was a visiting scholar in 2010, supported through the Junior Faculty Development Program of the Bureau of Educational and Cultural Affairs of the U.S. Department of State, administered through American Councils for International Education. The author is greatly indebted to Professor Cary Coglianese (Director, Penn Program on Regulation) for his support as a faculty sponsor.

tory and expanding scope in areas such as environmental protection, health and safety issues, financial regulation etc. The risk is the driver of the regulatory role of a modern state and governments have always relied on regulation to protect citizens from various risks. Risk is also a major theme in discussions about the role of the state in regulating economic activities. Improvements to regulation of risks improve social welfare of citizens as consumers and can also reduce costs to businesses.

‘Public’ regulation consists of legislative and administrative measures by which the state or the other entity, determines, controls or influences the behaviour of the regulated in order to prevent behaviour which could harm legitimate interests of the society.² The process of regulating any aspect of the economy is based on three main elements: the setting of standards, rules or other norms; monitoring or determining feedback for compliance with the norms; and a mechanism aimed to correct the behaviour which deviates from the norms. Regulation of risks to society assumes the process of risk identification and the regulatory response, notably the introduction of a piece of legislation and/or a set of regulatory measures and approaches which regulators adopt and pursue. In a formal sense, regulation of risks to society is understood as the setting and enforcing product or behavioural standards to control risks.³

In a broader context, risk regulation may be based on an assessment of the impact of risk and risk based systematised decision making procedures that prioritise regulatory activities. A risk-based approach to regulation acknowledges that governments cannot prevent all risks or reduce them to the minimum and that their actions have to be targeted and based on the nature and probability of occurrence of risks.⁴ Risk-based regulation does not only characterise public management framework in assessing the risks that regulated subjects pose to regulator’s objectives and are not applied only in the formulation of regulatory proposals. It also induces the regulated to develop compliance strategies and adopt internal approaches to identify, monitor and manage risks.⁵

¹ U. Beck, *Risk Society: Towards a New Modernity*, Sage Publications, London 1992.

² A.C. Dos Santos, M. E. Gonçalves, M. M. Leitão Marques, *Direito Económico*, Almedina 2001, 191.

³ C. Hood, H. Rothstein, R. Baldwin, *The Government of Risk: Understanding Risk Regulation Regimes*, Oxford University Press, Oxford 2001, 3.

⁴ B. M. Hutter, *The Attractions of Risk based Regulation: Accounting for the Emergence of Risk Ideas in Regulation*, CARR Discussion Paper No. 33, LSE, London 2005.

⁵ R. Fairman, C. Yapp, “Enforced Self Regulation, Prescription and Conceptions of Compliance within Small Businessess: the Impact of Enforcement”, *Law and Policy* 27(4)/2005, 491.

The state has limited resources to address market failures and to achieve policy goals, but bears the ultimate responsibility for risk regulation.⁶ In a risk society, not all risks can be reduced to zero and trade-offs in risk regulation are inevitable.⁷ This is one of the underlying paradigms of risk regulation. New approaches to risk regulation have become pervasive in recent years and have contributed to better policy-making. The recent financial crisis unveiled important policy challenges that have been underscored: the pitfalls of reactive regulation and the need to ensure a balance between efficient market regulation and the protection of the public welfare. This balance might be ensured by a shift from interventionism to ‘regulatory governance’, the interaction among multiple state and non-state actors.⁸ The multitude of interests and regulators is urging for an approach capable of facilitating harmonization of private and public interests through ‘collaborative governance’. The central role still belongs to administrative decision makers, who are acting in the environment marked by competing paradigms. The nagging question is how to keep their actions within the limits of legality or what is the optimal degree of regulation of administrative power. Too much restriction would restrain decision-making with complex procedures and limit the ability of administration to intervene, while too little restrictions could lead to arbitrary and inconsistent decision-making.

In a globalised world, challenges of risk regulation go beyond specific industries and geographical constraints, and transcend the borders between science and the legal order. Global nature of risks is increasingly calling for a convergence in risk regulation and is promoting its transnational character. Due to different legal and cultural contexts, science might serve as a uniform parameter. However, due to scientific uncertainty it is difficult to draw a clear line between scientific and political aspects of decision making. Hence, it appears that technological risks regulation is, albeit faultily, marked by a dichotomy between science (expertise) and democracy, and ultimately between technocracy and participatory democracy.⁹

The paradigms to be considered relate to regulation of risks to society, that is to say issues pertinent to ‘risk regulation’, and not specifically to the concept of risk-based regulation. The analysis is further lim-

⁶ U. Beck: “Risk Society and the Provident State”, in: S. Lash, B. Szerszynski (eds), *Risk, Environment and Modernity: Towards a New Ecology*, Sage Publications, London 1996, 27.

⁷ W. K. Viscusi, *Rational Risk Policy*, Clarendon Press, Oxford 1998.

⁸ OECD, *Regulatory Policies in OECD Countries: from Interventionism to Regulatory Governance*, OECD, Paris 2002.

⁹ E. Fisher, *Risk Regulation and Administrative Constitutionalism*, Hart Publishing, Oxford 2007, 11–13.

ited to issues facing the regulation of technological risks, which are scientifically uncertain, and will exclude business risks and risks to which financial systems are exposed. Being focused on paradigms, this article has been largely cast at a conceptual level, empirical conclusions remaining out of its sphere.

Like all paradigms, the paradigms of risk regulation are both prescriptive and descriptive. As general attitudes on the essence and structure of reality, some of them will reflect more general attitudes towards the role of state and the role of law in a society. The others derive from meta-paradigms and are less abstract and as such favourable to be transposed into a range of principles. Each paradigm may have an impact on legal issues in technological risk regulation, and their better understanding can lead to better understanding of the role of law in the process of risk regulation. Like all paradigms of social sciences, the axioms of which are always the presumptions under scrutiny, they should not be taken for granted. They are neither universal, nor stable, but changeable and evolving. The socio-legal approach to regulation is characterised by a whole range of paradigms,¹⁰ and so is the nature of regulation of risks to society obviously multi-paradigmatic.

2. THE CONCEPT OF RISK AND RISK REGULATORY CONCEPTS

A technological risk is a potential unpredictable outcome. The notion of risk depends on the sphere of its potential manifestation.¹¹ In a formal sense, risk is often defined as a probability of adverse consequences,¹² or the measurable probability that the actual outcome will deviate from the expected (or most likely) outcome.¹³ From an economic perspective, risk may be considered as a public good that needs government intervention.

¹⁰ On the multi paradigmatic nature of social sciences see: I. Lacatos, A. Musgrave (eds), *Criticism and the Growth of Knowledge*, Cambridge 1972. On the multi paradigmatic nature of the sociology of law: S. Bovan, *Paradigmatski koreni sociologije prava osnovi biološke teorije prava* [*The Paradigmatic Origins of Sociology of Law The Basis of Biological Theory of Law*], Beograd 2004, 32 70.

¹¹ For example, in agro food sector, the risk means “*a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard*”, Article 3(9) of the Regulation (EC) 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

¹² C. Hood, H. Rothstein, R. Baldwin, 3.

¹³ OECD, *Public Private Partnerships: In Pursuit of Risk Sharing and Value For Money*, OECD Publishing, Paris 2008, 48.

Operational definitions of risk vary so as the determinations of risk regulation concepts. Many conceptual approaches to risk and its management have been developed over the past three decades. Risk analysis and risk management techniques, as complex regulatory constructs, are being employed in different contexts. For some authors, *risk analysis* is about “identification of potential hazards to individuals and society and the estimation of the likelihood of any particular hazard occurring, using data, statistical analysis, systematic observation, experiment and intuition.”¹⁴ Despite of the obvious contextual differences, countries share methodological approaches to risk regulation. One of them is the three-pillar approach of risk analysis, which is common in OECD countries. This analytical model distinguishes three sequential pillars of risk policy: risk assessment, risk management and review, all being linked to risk communication.¹⁵

Risk assessment is based on scientific process of identification and characterization of risks and hazards, assessment of the probability of occurrence of certain events and exposure to them. Risk assessment is about defining the components of risk in precise, usually quantitative, terms. In assessing risk exposures and potential loss to its occurrence, quantitative methodology is often used within the framework of cost-benefit analysis and regulatory impact assessments to ensure cost-effectiveness of risk reduction. The objective of the first pillar is to identify those actions which could *minimize* risks as much as possible. Particularly important elements of the assessment phase are comparative risk assessments used in determining remediation strategies, where risk assessment is used to point to tradeoffs which emerge when the reduction of one risk induces an increase of another (*risk versus risk tradeoff*).¹⁶ Once risk assessments have been made, they can then be compared and evaluated (risk evaluation).

Risk management assumes the identification and assessment of policy alternatives and the development of strategies to prevent and control risk, primarily in order to decide which is the best option from a standpoint of the society.¹⁷ It means reducing the risks to that level the

¹⁴ O. Renn, “Risk Analysis – Prospects and Limitations”, in: H. Otway, M. Peltu (eds), *Regulating Industrial Risks*, Butterworths, London 1985, 111, at p. 113.

¹⁵ OECD, *Risk and Regulation: Issues for Discussion*, GOV/PGC/REG(2006)1, Paris 2006.

¹⁶ J. Graham, J. Wiener, *Risk Versus Risk: Tradeoffs in Protecting health and the Environment*, Harvard University Press, Cambridge MA 1995.

¹⁷ A range of responses could be classified as follows: a) risk avoidance: not performing an activity that would create the risk (proscription, prohibition); b) risk reduction: developing a strategy to reduce the probability and severity of the impacts of a risk event (licensing, codes and standards, enforcement and compliance strategies); c) risk retention: accepting the loss arising from the risk event (by way of a self insurance, retaining re

society would tolerate, ensuring control, monitoring and public communication of its real consequences.¹⁸ While risk assessment is based on scientific research to define the probability of risk realisation, “risk management, in contrast, is the public process of deciding what to do where risk has been determined to exist”.¹⁹ *Risk review*, based on evaluation, is an essential element of risk policy. Ex post evaluation of the effectiveness of adopted solutions is necessary for future risk analysis, as well as the adaptation of risk management actions.

Risk communication is based on a dialogue with the stakeholders and the society at large. It does not refer only to the phase when risk occurs, but is also of a crucial importance through two previous pillars, to ensure the consistency and transparency of the regulatory process. Information on the nature and extent of risks and its management is fundamental for shaping public opinion and helps to build trust in the proposed responses and in those who are entrusted with the mission to manage them.

Risk regulatory concepts are being used in many different contexts.²⁰ The above listed were predominantly introduced to control public administration and restrain administrative discretion. *Risk regulatory concepts* range from governmental to private regulation. In governmental regulation, a governmental agency is given the mandate to determine an acceptable risk level, which is binding both for those who cause and those who bear risks. On the other end of the spectrum, the private regulation of risk refers to the process where the industry sets the acceptable risk level or the market approach to risk management. In the latter case of the private approach, tort law is used as an instrument of ex-post compensation.²¹ Between the two extremes mixed regulatory concepts assume the combined role of affected parties, government and experts. Acceptable risk level may be negotiated between risk producers and potential bearers; the participants may agree to reduce or internalize risks. Here the

sponsibility for functions within government, etc.); d) risk transfer: another party accepts the risk by contracts (compulsory insurance, derivative transactions, public private partnerships). G. Bounds: “Challenges to Designing Regulatory Policy Frameworks to Manage Risks”, in OECD, *Risk and Regulatory Policy Improving the Governance of Risk*, OECD, Paris 2010, 15, at p. 19.

¹⁸ O. Renn, “Three Decades of Risk Research: Accomplishments and Challenges”, *Journal of Risk Research* Vol 1., 1/1997, 12, at p. 14.

¹⁹ W. D. Ruckelshaus, “Risk in a Free Society”, *Risk Analysis* 4/1984, 157, at p. 157.

²⁰ For an overview of different contexts see: E. Fisher, “Risk Regulatory Concepts and the Law” in: OECD, *Risk and Regulatory Policy Improving the Governance of Risk*, OECD, Paris, 2010, 45, at p. 51–55.

²¹ D. Dewees, M. J. Trebilcock, “The Efficacy of the Tort System and its Alternatives: A Review of Economical Evidence”, *Osgoode Hall Law Journal* 30/1992, 57.

government may determine the legal conditions for negotiating, but is not capable of fixing the strategy of risk management. Risks may be assessed and evaluated by experts, which may be empowered to set standards or to define the minimum acceptable risk levels. The ‘discursive’ concept of risk regulation emphasizes democratic decision making and fair representation of scientific expertise and social interests and values. Opposed to private regulation based on the market approach, this approach is not attempting to weight the different interest, but is committed to developing a common solution to risk.

3. RISK, REGULATORY POLICY AND THE ROLE OF LAW

Risk regulation is a multidisciplinary issue, and legal aspects are not the only source of concern. Although in the era of regulatory governance the law seems to have a marginal role,²² the study of law in the governance of risk highlights a need for a critical approach to risk governance concepts. The governance of risk is the essential part of good governance arrangements and better regulation, and risk regulatory concepts have an important place in good governance arrangements.²³ *Vice versa*, good governance arrangements are fundamental to promoting the successful risk regulation and risk governance.

The need to account for specific regulatory regimes in relation to specific risks, as well as national specificities, should be taken into account when developing principles of governance in the phases of risk assessment and management. Risk regulatory regimes are not directly observable; they represent analytic constructs consisting of two dimensions: the regime context and content.²⁴ Regime context is the broad setting in which regulation takes place, such as types and levels of risk being scrutinised, public preferences and attitudes towards risk and the way the various actors who produce or are affected by the hazard are organised. Regime content is about policy settings, the configuration of state and other organizations directly engaged in regulating the risks. In the given context, the function of law is to shape the content of the regulatory regime.

Even though there is “no integrative theory that provides guidelines on how to model and measure the complex interrelationships among

²² E. Fisher, (2007), 17.

²³ United Kingdom Better Regulation Commission, *Risk Responsibility and Regulation – Whose Risk is it Anyway?*, London, October 2006. United Kingdom Better Regulation Commission, *Public Risk: The Next Frontier for Better Regulation*, London, January 2008. For a pan European approach see: EC Commission, *White Paper on European Governance*, COM(2001) 428 final.

²⁴ C. Hood, H. Rothstein, R. Baldwin, 20–21.

risk, risk analysis, social response, and socio-economic effects”, it is obvious that social factors and interests play a significant role as features of regulatory regimes.²⁵ For example, risk regulatory concept in the United States is characterized by a strong participation of interest groups, while European risk policy has been developing as highly paternalistic, in favour of consumers.

Institutions and legal culture are also affecting risk governance concepts. The function of law in risk regulation is not solely to establish rules ordering or prohibiting certain activities; legal order also consists of institutions and practices. Legal culture, which also refers to ideas, values, aspirations and mentalities,²⁶ has been affecting risk governance. When the law introduces a concept of risk, the legal culture determines its environment. This contrast in cultures and institutional settings on risk governance may again be illustrated by comparing the institutional settings in the US and EU.²⁷ It is often said that there is a culture of adversarial legalism in the United States.²⁸ It appears that the accent is put on *ex post* mechanisms: judicial reviews are frequent, and courts as institutions play a major role in litigation. On the other side, Europeans are considered to be more concerned with risks and more in favour of *ex ante* approach.²⁹ There are differences in the decision-making process as well, and some of them would be addressed further.

Regulating risks is central to the role of a modern government. From a legal perspective, the function of law in regulating risks is primarily centred on two interwoven issues: how to minimise risk and its consequences and how to regulate the administrative power in regulating risks to society, including the judicial review of administrative decisions. The law has been constituting and limiting public administration through the establishment of competences of a regulator, limiting regulatory discretion and regulating the decision-making procedures.

The subject matter of the regulation of the former is risk. Central task of a modern Economic Law as Regulatory Law is to prevent the

²⁵ R. E. Kasperson *et al.*, The Social Amplification of Risk: A Conceptual Framework, *Risk Analysis* 8 (2) /1988, 177.

²⁶ D. Nelken, “Using the Concept of Legal Culture”, *Australian Journal of Legal Philosophy* 29/2004, 1, at p.1.

²⁷ Most obvious example is food safety regulation. With respect to this see: M. A. Echols, “Food Safety Regulation in the European Union and the United States: different cultures, different laws”, *Columbia Journal of European Law* 4/1998, 525; A. Alemanno, *Trade in Food – Regulatory and Judicial Approaches in the EC and the WTO*, Cameron May, London 2008.

²⁸ R. Kagan, *Adversarial Legalism: The American Way of Law*, Harvard University Press, Cambridge MA 2003.

²⁹ This applies to Continental Europe. The UK administrative law seems to be dominated by the idea of negotiation and informal agreements. C. Harlow, R. Rawlings, *Law and Administration*, Cambridge University Press, Cambridge 2009.

anomalies of the market mechanism, ensure its stable functioning and protect market participants from the unwanted effects. In terms of risk regulation, market relationships in a modern economy are more complex than at the beginnings of capitalism, as well as the rules regulating them. The production process has become more complex, and so are the goods as the output of this process and the production standards. But the role of law in risk policy is not only about standard-setting, it includes the relationship among different parts of the regulatory system. There is often a mismatch between technical, scientific and policy analyses of risk and the legal institutions and procedures through which the responsibility for risk is allocated.³⁰

To regulate risk, first, the risk should be identified. Risks, notably technological, are assessable only through scientific analysis, and not by direct observation.³¹ In assessing whether the risk exists and how it should be treated, the law should determine risk assessment and management methodologies, and set parameters of a 'good decision making'.³² In risk regulation there are no universally acceptable options, risk levels are often flexible and the policy choices are not irreversible. Hence, the risk regulatory process assumes an evolving strategy, through which the law itself evolves, the process which is known in theory as 'proceduralisation of regulation'.³³ As the technical nature of the regulated areas is increasing and requires a specific knowledge, the law should also facilitate collaboration between regulators and professionals in the lawmaking process and risk evaluation. This would contribute to better understanding of the issues at stake and facilitate compliance with the rules. The distinction between purely technical assessment of risks by the experts and actions undertaken by decision-makers is increasingly being questioned.³⁴ The law must acknowledge the importance of science in risk analysis and decision-making, but also has to set parameters framing the recourse to science in administrative decision-making.

As risk prevention and reduction is the goal of regulators, regulation of risks is inevitably interlinked with regulation of administrative power and the establishment of foundations for a judicial review. The law

³⁰ G. C. Hazard, "The Role of the Legal System in Response to Public Risk", in: E. J. Burger (ed), *Risk*, University of Michigan Press, Ann Arbor 1993, 229, at. p. 236.

³¹ C. Hood, H. Rothstein, R. Baldwin, 4.

³² For example, stipulating which factors would be taken into account, prescribing that the decisions should be based on a comparative risk analysis, the precautionary principle, cost/benefit analysis etc.

³³ J. Black, "Proceduralizing Regulation: Part I", *Oxford Journal of Legal Studies*, Vol. 20, 4/2000, 597.

³⁴ C. Noiville, N. De Sadeleer, "La gestion des risques écologiques et sanitaires à l'épreuve des chiffres – Le droit entre enjeux scientifique et politiques", *Revue du droit de l'Union européenne* 2/2001, 406.

sets standards for the accountability of administrative decision-makers. In defining the role and power of public administration, and establishing the standards of accountability, risk governance concepts should be in line with pre-existing institutional frameworks.

Defining the competence of regulators and referring to specific tasks and procedures that have to be followed with regard to risk identification, management and risk communication, the law attempts to limit administrative discretion. Judicial scrutiny of agency's risk assessment usually occurs when a court is reviewing an agency's regulation or decision for which the assessment was done. Often the general administrative procedure rules specify the conditions for setting aside agency's action. Of these, the court most often refer to agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law" and when the court determines that the agency undertook the action "without observance of procedure required by law."³⁵ In judging the agency's scientific risk assessment the courts in general lack the risk analysis expertise, and law often fails to set specific criteria for the courts in evaluating risk assessment. This is why courts, notably in the US (but also increasingly in the EU) often defer to the agency's expertise.³⁶ One of the reasons is the blurring of the line between science and policy, when the court cannot separate science from policy decision which is imbedded into the risk assessment. This opens a paradox of (de)stabilisatory function of science which will briefly be discussed in relation to the preventative paradigm.

4. REGULATION AS A PARADIGM OF REGULATORY CAPITALISM

The market alone cannot properly address the problem of risk. An extremely liberal concept of the market, essentially based on a hypothesis of a perfect and competitive market, obviously does not always function in the best and the most effective way. Therefore it is necessary to identify and correct negative effects of market failures, which is often interpreted as an interference of the state in certain activities of private parties.³⁷ Excessive interference of the state has been restrained and intervention of the state was suppressed and displaced.³⁸ 'Deregulation' movement is an elusive concept, as its essence is the process of reducing state

³⁵ The standard prescribed in the United States Administrative Procedure Act of 1949 (5 U.S.C. Sec 706(2)2(A)).

³⁶ R. A. Merrill, "Science in the Regulatory Process", *Law and Contemporary Problems* 66/2003, 1.

³⁷ B. Mitnick, *The Political Economy of Regulation*, New York 1980, 2, 7.

³⁸ P. Genschel, B. Zangl, "Die Zerfaserung von Staatlichkeit und die Zentralität des Staates", *Aus Politik un Zeitgeschichte* 20 21/2007, 10.

control over an industry or activity to make it structurally more responsive to market forces.³⁹ Essentially, deregulation of the market strengthened regulatory role of the state⁴⁰ and created a paradox that the role of state is limited, but it has actually been augmented.⁴¹

The process of regulation of a modern economy does not represent self-denial of the role of the state, but the state's attempt to discover the most suitable means of influencing the market and participants to achieve socially acceptable goals.⁴² Therefore, the concept of 'Regulation' itself is one of the paradigms. For a long time, the notion of 'regulation' was used as a synonym for 'legislation' (French *réglementation*, German *Regelung*),⁴³ as legal rule or the activity of legislating. That distinction between a narrow concept of regulation as legal or at least legally sanctioned rule-making and a broader concept of regulation has led to all sorts of conceptual misrecognitions and confusions.⁴⁴ The concept of regulation itself is a scientific paradigm, which was adopted in social sciences later than in natural sciences. On the basis of the notion of 'regulation' in natural sciences,⁴⁵ the essence of market regulation is to maintain an equilibrium, as well as to construct and promote such equilibrium.⁴⁶ Regulation implies the possibility of balancing a unity of heterogeneous elements, the possibility to ensure a harmony of interests, from individual to collective.⁴⁷ As such, regulation is the process of systematic, legitimate, influence on subjects and events, through a combination of ordering devices and mechanisms,⁴⁸ a purposive attempt to influence and con-

³⁹ R. Baldwin, C. McCrudden (eds), *Regulation and Public Law*, Weidenfeld and Nicholson, London 1987, 24.

⁴⁰ R. Cranston, "Regulation and Deregulation: General Issues", *University of New South Wales Law Journal* 5/1982, 1.

⁴¹ G. Majone, "The Rise of Statutory Regulation in Europe", in: G. Majone (ed), *Regulating Europe*, Routledge, London 1996, 47, at p. 54.

⁴² T. Daintith, "Regulation", *International Encyclopedia of Comparative Law*, Vol. XVII, Martinus Nijhoff, 1997, Leiden Ch. X.

⁴³ However, in the broad sense *régulation* (French), *Regulierung* (German).

⁴⁴ N. Walker, "Epilogue: On Regulating the Regulation of Regulation", in: F. Cafaggi, *Reframing Self Regulation in European Private Law*, Kluwer Law International, 2006, 347.

⁴⁵ For an overwhelming overview of the concept of regulation in natural sciences see: A. Lichnerowicz *et al.*, *L'idée de régulation dans les sciences*, Maloine Doin, Paris 1977.

⁴⁶ M. A. Frison Roche, "Le droit de la régulation", *Recueil Dalloz*, Paris 2001, 601, at p. 613.

⁴⁷ J. Chevalier, "De quelques usages du concept de régulation" in M. Maille (ed), *La régulation entre droit et politique*, L'Harmattan, Paris 1995, 71, at p. 87.

⁴⁸ In light of the approach adopted by C. Parker, J. Braithwaite, "Regulation", in: P. Cane, M. Tushnet (eds), *The Oxford Handbook of Legal Studies*, Oxford University Press, Oxford 2003, 119, at p. 119.

trol economic and social activity.⁴⁹ Actions of the modern regulatory State, which nowadays guarantees the welfare of the society,⁵⁰ rather than imposes interventionist measures, are based on those rules which aim to ensure the balance between private interests of individual market parties and their associations and those in charge of safeguarding the general interest. Opposed to control, the primary role of the modern state is to oversee and ‘regulate’ the market.⁵¹

In the ‘regulatory state’, legal rules do not only have imperative character, but to a certain extent the character of incentives directing the behaviour in a socially accountable way. As traffic signs regulate road traffic with a wide range of signs of prohibition or of informative nature, not every sign has the character of a rule that triggers sanction.⁵² The role of law is not only to order or ban, but to create incentives, to direct, and harmonise interests of the stakeholders. This balancing of partial interests and the general interest to preserve the order of capitalism is in the essence of ‘regulatory capitalism’.⁵³

The strategy of risk regulation in the era of regulatory capitalism must be tailored in line with the public interest, in creating optimal environment from the standpoint of the regulated and the beneficiaries of risk regulation. Regulatory process is therefore linked to various broad strategies, including rules of a different kind and an array of adjudicative processes and institutional arrangements, characterised by ‘nodal’ role of the regulatory state and public administration. The linkage of process to strategy is inevitably close, and therefore it would be difficult to claim legitimacy for the risk regulation process if the overall strategy is not legitimate.⁵⁴ The process of scientific risk assessment is marked by numerous technical and normative weaknesses, hence requiring that public partici-

⁴⁹ B. Morgan, K. Yeung, *An Introduction to Law and Regulation*, Cambridge University Press, Cambridge 2007, at p. 1.

⁵⁰ G. F. Schuppert, “Der moderne Staat als Gewährleistungsstaat”, in: E. Schröter (ed): *Empirische Policy und Verwaltungsforschung*, Opladen 2001, 399.

⁵¹ Using Osborne and Gaebler’s famous metaphor “steering, but not rowing”, Majone described the modern state as “regulatory state”. G. Majone, “The Rise of the Regulatory State in Western Europe”, *West European Politics* 17/1994, 77; On the concept ‘regulatory state’ see also J. Chevallier, “L’État régulateur”, *Revue française d’administration publique* 111/2004, 473.

⁵² For an excellent overview of controversies of the use of legal rules in regulatory policy: J. Black, “Which Arrow: Rule Type and Regulatory Policy”, in: D. J. Galligan (ed), *A Reader on Administrative Law*, Oxford University Press, Oxford 1996, 166–167.

⁵³ D. Levi Faur, “The global diffusion of regulatory capitalism”, *Annals of the American Academy of Political and Social Science* 598/2005, 12; J. Braithwaite, *Regulatory Capitalism How it works, ideas for making it work better*, Edward Elgar, Cheltenham 2008.

⁵⁴ R. Baldwin, *Rules and Government*, Oxford University Press, Oxford 1995, 291.

pation in the regulatory process discipline the use of these technocratic tools to ensure the fulfilment of legitimate interests of citizens. A risk society “can remain a democratic one only by remaining conscious of democratic values and by searching for institutional measures that will promote those values in social decision-making.”⁵⁵ Designing an appropriate institutional division and balance between regulators, politicians, courts, regulated and the public is one of the most important challenges of regulatory capitalism.

5. TWO PARADIGMS OF ADMINISTRATIVE CONSTITUTIONALISM IN TECHNOLOGICAL RISK REGULATION

The abandonment of an illusion of a completely liberal market, especially in the context of the existing financial crisis, opens a wide sphere of balancing of individual and joint interests and changes in a role of the executive function, which represents a basis of mechanism of social regulation in a regulatory state. The executive branch of government and public administration represent intermediaries between a goal of the legal norm and its implementation, while judiciary function is essentially *ex post* regulation.⁵⁶

Due to increased complexity of a post-industrial society, there is a tendency to farm off regulatory functions to independent regulatory agencies, for various reasons.⁵⁷ The increase in a number of agencies and policy makers and their powers brought ‘risk bureaucracies’ themselves at the heart of a concern. Being entrusted with the mission to assess, prevent and manage risks, the administrative apparatus may enact implementing legislation and has wider adjudicative powers. As far as the executive function acts in line with its statutory powers, taking an action in line with applicable rules formally discharges the regulator from responsibility. But in a risk society, marked by uncertainty, the regulator is tempted to fill in regulatory gaps and to adopt a more flexible approach. Hence, the role of public administration in regulating risk, which definitely dominates the area of decision making, is inherently paradoxical and risk regulatory concepts reflect that fact.

⁵⁵ D. J. Fiorino, “Environmental Risk and Democratic Process”, *Columbia Journal of Environmental Law* 14/1989, 501, at p. 523.

⁵⁶ In regulating the markets, the main difference between a judge and a regulator is that the judge intervenes *ex post*, while regulator predominantly *ex ante*. B. Arrunaba, V. Andonova, “Market Institutions and Judicial Rulemaking”, in: C. Menard, M. M. Shirley (eds): *Handbook of New Institutional Economics*, Springer, Berlin Heidelberg 2005, 229.

⁵⁷ M. Thatcher, “Delegation to Independent Regulatory Agencies: Pressures, Functions and Contextual Mediation”, *West European Politics* 25/2002, 125.

Although there is a multitude of models of administrative constitutionalism, which refers to constituting, limiting and holding public administration to account, Fisher has identified two dominating models – the deliberative-constitutive and rational-instrumental model.⁵⁸ On one side, the needs of a complex society are urging for an open process of ongoing, expert-based decision making by non-elected decision makers. The former model conceptualises public administration as a body which exercises a flexible discretion in solving multifaceted problems. The latter, the rational-instrumental model, conceptualises public administration as an ‘agent’ of the legislative branch, an ‘instrument’, constrained as much as possible and entrusted to perform the predetermined tasks with as little discretion as possible.⁵⁹

Neither model offers perfect public administration. Criticisms of risk regulatory concepts are essentially criticisms of the models and legitimacy of public administration. Whatever the context, the law should provide the framework for public administration in three main ways: by defining the competence of institutions; by placing limits on the discretion of decision makers; and by defining the procedures a decision maker must follow.⁶⁰ The deliberative-constitutive model is based on a wide, albeit not unfettered discretion. In a world of uncertainty, the decision making about risk is highly uncertain and thus more substantive and constitutive role for public administration is needed. In contrast, the rational-instrumental model could be based on legislative provision setting out how discretion should be exercised.⁶¹ Risk and expertise are kept under control by limiting the role of the regulator to the application of the facts in a process regulated by the rigour of risk assessment and other operations. However, what is considered a reasonable exercise of discretion varies significantly from country to country. The discretion often involves a choice among various options based on scientific data and/or social values. That is why the issue of risk decision making has often been depicted as being the choice between science on one side, and democracy and ethical values on the other side. But both paradigms simultaneously exist, and this distinction is false. It is the law which is called to authoritatively define the role of science and the conditions for risk-decision making.

⁵⁸ E. Fisher, (2007), 26–47.

⁵⁹ The most obvious expression of the rational instrumental theory is the Weberian model of bureaucracy. M. Weber, *From Max Weber: Essays in Sociology*, Routledge, London 1991, chapter 7.

⁶⁰ E. Fisher, ‘Risk Regulatory Concepts and the Law’ in OECD, *Risk and Regulatory Policy – Improving the Governance of Risk*, OECD, Paris 2010, 45, at 66–69.

⁶¹ An illustrative example found in the US is a detailed legislative provision in para. 655(b)(5) of the US Occupational Safety and Health Act.

6. A PUBLIC-PRIVATE PARTNERSHIP AND TRANSNATIONAL GOVERNANCE OF RISKS IN A GLOBALISED RISK SOCIETY

The issue of public-private collaboration in risk management is one that is increasingly gaining the importance. Public or private, the role of regulation is to enable co-existence of legitimate interests of participants and the market in its totality.⁶² Narrower concepts of regulation centre on state's attempts to influence socially valuable behaviour by establishing and enforcing legal rules. In that sense, 'regulation' is a modality or type of participation of the state in institutional operations and alternative to other modalities.⁶³ However, a social essence of the concept of 'regulation' is its social nature: it belongs to all market factors, not only to the state. Therefore, regulation is a *divided function*.⁶⁴

This broader concept of regulation sets the agenda for a research into new methods of delegated governance in regulating risks. Based on a social 'concert' of regulators,⁶⁵ the modern, responsible and reflexive law, should not accept the *status quo* represented by conventional forms of command-and-control regulation, but go further in search for better solutions, identification of surrogate regulators and tools of a new governance. It should aim to leverage the private sector and encourage the internalisation of the regulatory function and compliance.⁶⁶

That process of 'social interactions' is complicated because it assumes multiple manifestations of the immediate regulatory activities of state, para-statal and private institutions.⁶⁷ The 'new public management' in implementation and enforcement is based on interactions between market institutions, non-governmental organisations and organisations established to protect the private interest, under the coordinative role of the administrative apparatus.⁶⁸

⁶² M. A. Frison Roche, "Définition du droit de la régulation économique", in: M. A. Frison Roche, *Les régulations économiques légitimité et efficacité*, Vol. 1, Presses de Sciences Po et Dalloz, Paris 2004, 7.

⁶³ A. Jemmaud, "Normes juridiques et action" M. Maille (ed.): *La régulation entre droit et politique*, L'Harmattan, Paris 1995, 95, at. p. 97.

⁶⁴ G. Marcou, "Introduction" G. Marcou, F. Moderne, *Droit de la régulation, service public et intégration régionale*, L'Harmattan, Paris 2005, 21.

⁶⁵ M. M. Leitão Marques, A. Casimiro Ferreira, "A concertação económica e social", *Revista Crítica de Ciências Socialis*, 1991, 31.

⁶⁶ C. Coglianese, J. Nash (eds), *Leveraging the Private Sector: Management Based Strategies for Improving Environmental Performance*, Resources for the Future Press, Washington DC 2006; J. Freeman, "The Private Role in Public Governance", *New York University Law Review* 75/2000, 543.

⁶⁷ G. Becker, "A Theory of Social Interactions", *Journal of Political Economy* 82/1974, 1063.

⁶⁸ The literature is considerable. For example: C. Hood, C. Scott, *Bureaucratic Regulation and New Public Management in the UK: Mirror Image Developments?* Lon

The regulatory process infiltrates more and more into private law domain and enhances the role of private actors in the regulatory arena.⁶⁹ ‘Privatisation of regulation’ supports the thesis that risk regulation can not be divided into the ‘public’ and the ‘private’ sphere. In regulating risks to society, modern Economic Law transcends the public-private dualism,⁷⁰ which is commonly associated with liberal political theory.⁷¹ As the role of the state in today’s world is much more concerned with individual utility, new dimension of the action of the state through public administration, as a partner in the regulatory process, has a different logic than that of having a monopoly over the regulatory processes. With the enduring global financial crisis, one may be concerned about advocating institutional solutions other than a traditional central regulatory authority. However, the current economic crisis, attributed by many to a lack of central regulatory vigour, does not diminish the need for the new governance. Completely different, the crisis calls for a proactive regulation. More than ever, the law is facing a challenge of how to alter the incentives of private actors so that they better ensure the public goal of stable and efficient markets.

Returning to the public/private distinction, change in the role of the administrative apparatus, change in the regulatory processes and new techniques of regulation have clearly erased the stereotype of a classic division between administrative and civil law on the national,⁷² as well as

don School of Economics, London 1996; P. Bayne, “Administrative Law and the New Managerialism in Public Administration”, *Australian Law Journal* 62/1988, 1040; C. Harlow, “Back to Basics: Reinventing Administrative Law”, *Public Law* 8/1997, 245; A. Vokßkuhle, “Neue Verwaltungsrechtswissenschaft”, in: W. Hoffman Riem, E. Schmidt Aßmann, A. A. Vokßkuhle (eds), *Grundlagen des Verwaltungsrechts*, Vol I, München 2006, 21.

⁶⁹ F. Cafaggi, “Le rôle des acteurs privés dans le processus de régulation: participation, autorégulation et régulation privée” in *La régulation, nouveaux modes? Nouveaux territoires*, *Revue française d’administration publique* 109/2004, 23.

⁷⁰ D. Truchet, “La distinction du droit public et du droit privé dans le Droit Économique” J. B. Auby, M. Freedland (eds), *The Public Law/Private Law Divide: Une entente assez cordiale?* Panthéon Assas, LGDJ Diffuseur, Paris 2004, 57.

⁷¹ P. Cane, “Public Law and Private Law: A Study of the Analysis and Use of a Legal Concept” in: J. Eekelaar, J. Bell (eds), *Oxford Essays in Jurisprudence*, Third Series, Clarendon Press, Oxford 1987, 57.

⁷² C. Parker, J. Braithwaite, 125 126; D. Oliver, “Pourquoi n’y a t il pas vraiment de distinction entre droit public et droit privé en Angleterre?”, *Revue internationale de droit comparé* 53/2001, 327; F. J. Säcker, “Regulierungsrecht im Spannungsfeld zwischen öffentlicher und privater Rechtsdurchsetzung” M. Ronellenfitsch, R. Schweinsberg, I. Henseler Unger (eds), *Aktuelle Probleme des Eisenbahnrechts*, Verlag Dr. Kovac, Hamburg 2009, 159; H. Woolfe, “Public Law Private Law: Why the Divide? A Personal View”, *Public Law* 86/1986, 220. M. Freedland, “The evolving approach to the Public/Private distinction in English Law”, in: J. B. Auby, M. Freedland (eds), 101.

on international level.⁷³ The idea of internalisation of the regulatory function places greater emphasis on the evolving nature of regulatory strategies and the role of private parties in developing the regulatory framework.⁷⁴ An obvious example is found in the EU, where new modes of regulation, ranging from co-regulation to self-regulation, have emphasised the role of private law in the European multilevel regulatory architecture.⁷⁵

Internalisation of regulatory function at the level of market subjects signifies that the regulatory process is becoming decentralised through a hybrid, heterarchical, relationship, through collaborative governance between public administration, the regulated and the stakeholders.⁷⁶ As already emphasised, the law is calling for the involvement of other regulatory actors by regulating the basis for their involvement.⁷⁷ This new public management leads towards a new governance compromise, which includes a process of ‘negotiating a law’ and the co-existence of various private and public instruments of regulation.⁷⁸

As chains of production and supply are becoming more dispersed in the global economy, with materials and ingredients from various countries with different risks and regulatory systems, risk management was getting more complicated and costly, urging for convergence on common standards and principles of technological risk assessment and management. In transnational risk regulatory networks and international forums the trend towards private market governance and global governance is gaining the importance.⁷⁹ In addition to regulators, the private

⁷³ E. Benvenisti: “The interplay between actors as determinants of the evolution of administrative law in international institutions”, *Law and Contemporary Problems* 68/2003, 319.

⁷⁴ G. Teubner, *Autopoietic Law: A New Approach to Law and Society*, Walter de Gruyter, Berlin 1988; G. Teubner, “Regulatory Law: Chronicle of Death Foretold”, *Social and Legal Studies* 1/1992, 451.

⁷⁵ F. Cafaggi, “New Modes of Regulation in Europe: Critical Rethinking of the Recent European Paths”, in: F. Cafaggi, *Reframing Self Regulation in European Private Law*, Kluwer Law International, 2006, Preface.

⁷⁶ J. Freeman, “Collaborative Governance in the Administrative State” *UCLA Law Review* 45/1997, 1; J. Black, “Decentring Regulation: Understanding the Role of Regulation and Self Regulation in a post Regulatory World”, *Current Legal Problems* 54/2001, 103.

⁷⁷ L. McDonald, “The Rule of Law in the ‘New Regulatory State’”, 33 *Common Law World Review* 33/2004, 33.

⁷⁸ A. Pirovano, *Changement Social et Droit Negocié*, Economica, Paris 1988, 5.

⁷⁹ J. Rugie, “Global markets and global governance – the prospects for convergence”, S. Bernstein, L. Pauly, (eds.) *Global liberalism and political order: Towards a new grand compromise*, NY State University Press, New York 2007, 23–50; D. Vogel, “Private global business regulation”, *Annual Review of Political Science* 11/2008, 261.

sector could be entrusted to oversee private entities. One example is a private standard-setting, which represent an important mechanism of risk management in many spheres of market activities. Many such standards exist nowadays, and many forums have been established to ensure private standard harmonization. Private standards may be developed by individual firms, or even by non-governmental organisations such as consumer associations and associations promoting environmental issues and sustainable consumption. Private standards have often developed as a collective action of large firms sharing common interests, and/or as a response to actions of public regulators.⁸⁰ Regulators may mandate the use of such standards and make them legitimate, for instance through accreditation.

Private standard setting and monitoring as a tool of modern risk regulation has many benefits. Most of all, the private sector may mobilize resources and design standards more dynamically than the public sector, improving the overall efficiency of risk management. However, there are challenges to private standard settings and enforcement, mostly related to their responsibility.⁸¹ The main challenge is whether regulators have enough resources to identify and sanction violations of private standards. This problem points to another concern: a political risk for failure of the risk management system. In the end, it is the government to be blamed for the regulatory failure if the private means of risk regulation fail. Therefore, the delegation of responsibilities to private parties raises questions about transparency and accountability in modern, polycentric, regulatory regimes.⁸² Since the government would be blamed for the failure of a private risk regulatory approach, more attention needs to be given to questions of implementation and accountability. But the power in a regulatory state is now fragmented, spread between public, private and hybrid actors. Hence, the role of traditional public accountability mechanisms characterizing hierarchal regulatory structure are diminishing and being replaced by broader and more complex “accountability networks”.⁸³

⁸⁰ One of the best examples is the HACCP process, which is the main method for assessing and managing food safety risks in agro food processes, a set of pro active actions in the supply chain, aiming in particular to ensure traceability and responsibility of suppliers. On the legislative challenges it poses see in particular: J. Vapnek, “Legislative implementation of the food chain approach”, *Vanderbilt Journal of Transnational Law* 40/2007, 987.

⁸¹ F. Cafaggi, “Responsabilité et gouvernance des régulateurs privés”, *Revue Internationale du Droit Economique* 2005, 111.

⁸² J. Black, “Constructing and Contesting Legitimacy and Accountability in Polycentric Regulatory Regimes”, *Regulation & Governance* 2/2008, 137.

⁸³ C. Scott, “Accountability in the Regulatory State”, *Journal of Law and Society* 27/2000, 38.

7. THE PREVENTATIVE PARADIGM AND (DE)STABILIZATORY FUNCTION OF SCIENCE

In a risk society, the public concern is shifted from remediation of damages to the prediction of risk.⁸⁴ The science has become a tool of rational risk analysis, and, as a rule, precedes policy decisions about measures to prevent or reduce risks. The legal system increasingly recognizes the use of scientific data and evidence as a basis for policy making and formulation of regulatory measures.⁸⁵

The process of risk analysis should therefore be based on scientific expertise which should provide a value-neutral assessment. For this reason it would be necessary to develop several key principles governing the use of science as a basis of policy. Although it is not possible to define the level of risk at the global level due to different social context of each country, science-based principles of risk assessment may enhance its transnational consistency, where social and economic considerations are not shared in national risk management policies.⁸⁶ However, the existing principles of the use of scientific expertise in risk analysis are not coherent, and there is no single set of rules governing the use of science in decision making, although in the area of international trade and environmental law there are examples of rules and principles on scientific risk assessment as a basis for measures in relation to risks to the environment, human, animal and plant life and health.⁸⁷

⁸⁴ N. De Sadeleer, *Environmental Principles: from Political Slogans to Legal Rules*, Oxford University Press, Oxford 2002, 91.

⁸⁵ An example is the EU Treaty which refers to the use of science in formulating internal market measures in Article 14 “*The Commission, in its proposals envisaged in paragraph 1 concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts*”.

⁸⁶ The culture should be sufficiently powerful to generate multiple scientific consensuses across nations. J. Atik, “Science and International Regulatory Convergence”, *Northwestern Journal of International Law and Business* 17/(1996/1997), 736, at p. 738.

⁸⁷ *Agreement on Sanitary and Phytosanitary Measures*, Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, General Agreement on Tariffs and Trade, Annex 1A, April 15, 1994. The *Cartagena Protocol on Biosafety to the Convention on Biological Diversity* which entered into force on September 11, 2003; the *Stockholm Convention on Persistent Organic Pollutants*, entered into force on May 17, 2004. Setting of horizontal risk analysis principles in legislation and practice in the EU are worth to be mentioned. The communication on consumer health and food safety (COM(97) 183 final), as a response to the BSE crisis set up a number principles which are applicable beyond the agro food sector and systematically applied in creation of European (regulatory) agencies and scientific committees, while the Commission’s Communication on the collection and use of expertise of (COM(2002) 713 final) relates to scientific risk assessment.

The choice of the acceptable level of risk is a political decision. However, the politics of safety is afflicted by the problem of uncertainty in defining and characterising risks, the scientific approaches to risk measurement, the perceptions about risk and ultimately the decisional criteria used to manage risks. Scientific progress is a result of a gradual accumulation of knowledge and science can never provide absolute certainty. *Science cannot respond* to all unanswered questions of risk policy because scientific knowledge used in risk assessment is affected by uncertainty.⁸⁸ The limiting factor is not solely the existence of scientific uncertainty, but as well the insufficiency of scientific evidence. Moreover, many of the issues which arise in the course of the interaction between science and society cannot be answered by science.⁸⁹ This makes it difficult to maintain a clear line between scientific and political aspects of decision-making.

The problem of uncertainty requires consent in deciding whether an action is necessary and, if so, which alternatives ought to be considered. Decisions on measures to address risks to health and safety inevitably involve personal social value judgments as to the significance of a particular risk.⁹⁰ The modern regulatory systems are moving towards a more integrated approach to risk analysis that acknowledges the influence of policy choices and the democratization of the process of risk regulation by taking into account non-scientific considerations influencing public perception about risk.⁹¹ As a tool of risk management, science has a high potential to discipline the politics of risk regulation, but there should be a point where social value judgments prevent scientifically evidenced policy choices which might not be considered as acceptable by the society.

From a legal standpoint, the most difficult issues are the separation between scientific advice and decision-making, and the judicial review of science-based risk regulatory measures. The latter issue is an ex post valuation of scientific expertise through control of regulatory powers of the regulators. When scientific data, as the outcome of scientific research, served as a basis for a legislative act or an individual decision, courts (usually made up of non-scientifically trained persons) are asked to determine whether risk regulatory measures pursue legitimate objectives. A fading border line between scientific and policy decisions in regulating

⁸⁸ B. Wynne, Uncertainty and Environmental Learning: Reconciling Science and Policy in the Preventative Paradigm, *Global Environmental Change*, June 1992, 111.

⁸⁹ Issues known as 'trans scientific'. G. Majone, Science and Trans Science in Standard Setting, *Science, Technology & Human Values* 9/1984, 15.

⁹⁰ W. W. Lowrance, *Of Acceptable Risk: Science and the Determination of Safety*, William Kaufmann, Los Altos 1976, 8.

⁹¹ J. A. Tickner, S. Wright, "The Precautionary Principle and Democratising Expertise: a US Perspective", *Science and Public Policy* 30/2003, 213, at p. 217.

risks has made it difficult for judges to determine when they were looking into areas of agency expertise, which essentially falls within the issue of conflicting paradigms of administrative constitutionalism.

Ex ante valuation of scientific expertise in policy decision making is the authorisation to rely on scientific expertise in policy making. To this end, the law sets standards and principles relating to risk analysis and establishes institutional arrangements between scientific expertise and policy-making, which also serve as a basis for judicial review, as referred to above. The judicial approaches differ in terms of valuation of scientific expertise. Approach in the US is known as the ‘frontiers of science doctrine’,⁹² while European risk regulation concept is more based on the ‘precautionary principle.’⁹³

Hence, to address the problem of uncertainty, the law may mandate risk assessment as a prerequisite to the adoption of precautionary measures. As mentioned above, some jurisdictions, such as the US, insist on a ‘sound science’ approach, while the others, such as the EU as the most prominent representative, insist on the necessity for precaution.⁹⁴ That is to say, where there are threats of serious or irreversible damage, the lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent hazards.⁹⁵ As a rule, measures addressing risks should not be maintained without sufficient scientific evidence. However, when the relevant scientific evidence is insufficient, the law may authorize adoption of provisional measures in the course of obtaining the additional information necessary for a more objective assessment

⁹² M. Shapiro, ‘The Frontiers of Science Doctrine: American Experiences with the Judicial Control of Science Based Decision Making’, in: Joerges, Ladeur and Vos (eds), *Integrating Scientific Expertise into Regulatory Decision Making*, Nomos Verlagsgesellschaft, Baden Baden 1997, 325.

⁹³ R. E. Löfstedt, D. Vogel, ‘The Changing Character of Regulation: a Comparison of Europe and the United States’, *Risk Analysis* 21/2001, 399.

⁹⁴ This diverging approaches manifested especially in trade disputes regarding the restriction of imports between the US and the EU before the Appellate Body of the World Trade Organisation (the most prominent ‘Beef Hormones’ case, EC *Measures Concerning Meat and Meat Products, Report of the Appellate Body*, WT/DS26/AB/R & WT/DS48/AB/R, 16 January 1998). Interestingly, the essential element of many American statutes regulating health and environmental risks at the beginning of the second half of the last century was precaution, such as the *Clean Air Act of 1963*, 42 U.S.C. §7401 7671q. The current public opinion of risk regulatory approach in the EU has been commented to resemble the US approach in 1960s–1970s when regulatory agencies sought to gain public trust through pursuing precautionary health and environmental policies. R. E. Löfstedt, D. Vogel, 403–404. On the similarities between judicial approaches to review of risk regulatory measures in the US and EU see: J. B. Wiener, ‘Whose Precaution After All? A Comment on the Comparison and Evolution of Risk Regulatory Systems’, *Duke Journal of Comparative and International Law* 13/2003, 207.

⁹⁵ Based on definition of the precautionary principle in the *Rio Declaration on Environment and Development*, Principle No. 15.

of risk.⁹⁶ If the law allows for a too much leeway to agencies to interpret scientific data, they may be tempted to introduce regulatory measures on the basis of a mere speculation about uncertain risks and try to justify it by referring to their regulatory objectives.⁹⁷ As Shapiro noted, courts will be at their most deferential in cases where an agency is operating ‘at the frontier’, when it has made a policy choice among a range of options left open by scientific uncertainty.⁹⁸

To ensure preventative character of risk regulation and limit the power of administration in the same time, the law also plays a role in setting out the procedures that regulators must follow. In some cases these procedures are minimal, but in other cases they are quite substantive. The procedures may be related to the steps which must be taken in making decisions, the type of information and factors that must be taken into account, the procedures on how a specific body must conduct itself etc. Risk assessment bodies consisting of experts could be institutionally separated from policy-making instances. That is the case in the EU, where a number of European (quasi) regulatory agencies which are contributing to risk regulation in the internal market are aided by various independent scientific committees or expert panels. On the other side, in other OECD countries, particularly in the United States, regulators are predominantly involved both in assessing risks and policy making. As a rule, in these countries risk assessment and policy making are functionally separated, even under the same roof. Otherwise, in addition to public administration often referred to as the ‘fourth branch’ of government, the scientific community made of policymakers is pretending to constitute the ‘fifth branch’.⁹⁹

8. CONCLUSION

In this article the author attempted to identify several paradigms underlying risk regulation in a globalised risk society and pointed to the important socio-legal challenges for risk regulation in a regulatory state,

⁹⁶ See article 5.7. (as an exception to article 2.2.) of the *Agreement on Sanitary and Phytosanitary Measures*.

⁹⁷ For an extensive critique of this phenomenon see S. Breyer, *Breaking the Vicious Circle: Towards Effective Risk Regulation*, Harvard University Press, Cambridge MA 1993.

⁹⁸ M. Shapiro, ‘The Frontiers of Science Doctrine: American Experiences with the Judicial Control of Science Based Decision Making’, in: C. Joerges, Ladeur, E. Vos (eds), *Integrating Scientific Expertise into Regulatory Decision Making*, Nomos Verlagsgesellschaft, Baden Baden 1997, 325, at p. 334–338.

⁹⁹ S. Jasanoff, *The Fifth Branch: Science Advisors as Policymakers*, Harvard University Press, Cambridge MA 1990.

which is becoming increasingly focused on legal and policy issues of risk detection and management.

Regulation is a divided function. Global economy undoubtedly requires new modes of polycentric regulation that encourage the involvement of a private sector while still preserving role of the government. The law must acknowledge that governments and the private sector could negotiate and jointly act in the interest of private parties and the market. The new paradigms of governance, and the need for a proactive regulatory strategy and reflexive regulation in a globalised world, transformed the role of law in regulating risks to society. Law is no longer considered an intrusive element of regulation, in a sense that it only creates limitations. The law is no longer construed in instrumental terms as a tool for enhancing either the scientific or democratic aspects of risk regulation; it authoritatively defines and influences these concepts and creates the conditions for risk regulation.¹⁰⁰ The law should not only be considered a set of rules, but a complex culture which interacts with the operation of any risk regulatory concept, and provides a discourse for challenging decisions about risk.

Regulators as decision-makers are faced with the task of assessing the legitimacy of risk regulatory objectives on the basis of scientific evidence, and the tasks taken to address risks are complicated by the prevalence of scientific uncertainty and divergences of views over acceptable levels of risk. Although science lacks its own normative component, it may be taken as one of the parameters in assessing the validity of risk regulatory measures. Uncertainty is inherent in risk assessment and there seem to be no viable alternatives, so the challenge for law is to deal effectively with science and uncertainty.

In modern democracies, the process of risk analysis and management will be mistrusted if it is not designed in line with principles of good public administration. No matter to which extent the risk assessment and management function is outsourced, public administration will always remain a facilitator in the governance of risk. The democratic process must be disciplined by the introduction of technocratic tools such as science and cost-benefit analysis. And *vice versa*, the use of these technocratic tools must be disciplined by the democratic, deliberative, process.

¹⁰⁰ E. Fisher, (2007), 14 17.