

Book Reviews

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The Reality of Precaution – Comparing Risk Regulation in the US and Europe

by Jonathan Wiener, Michael Rogers, James Hammitt, and Peter Sand (eds).

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The *Reality of Precaution* is a highly innovative book for several reasons. It engages into a comparative analysis of various fields and legal systems, focusing on the precautionary principle (PP). On the basis of a combination of qualitative and quantitative analysis it challenges the substantive and methodological premises that have so far characterized similar endeavors, posing new questions on the scholarly and policy agenda of risk regulation.

The architecture of risk regulation is conceptually too complex to be fully discussed in a single book review. For this reason a particular perspective has been selected through which the major findings are discussed: that of comparative law.

The main focus of the book is on the critique of the flip-flop hypothesis contending that Europe has become more precautionary than US. The critique does not turn into a symmetric counterclaim, i.e. that U.S. is more precautionary than EU; rather it asserts that no clear general patterns of convergence, divergence or flip-flop can be identified in risk-regulation

between the two legal systems across field. In some sectors Europe has adopted stricter standards or implemented more strictly the PP, whereas in other areas the opposite has occurred. The main pattern is that of hybridization whereby features of one regime are integrated into the other and vice versa, also as a consequence of the increasing influence of global regulation. According to several contributions of the book a key factor, which has moderated the substantive impact of PP and increased hybridity, is the better regulation agenda in both US and EU. The conclusions suggest that we have entered the era of post precaution where the influence of better regulation is reshaping the contours of the PP.¹ This influence affects not only the decisions to regulate but also the instruments of regulation and the responsibilities of communities and individuals in assessing and managing risks, as well as in deciding about trade-offs.

The book clearly challenges conventional analysis, based on comparisons of discrete and state centered regulatory systems. It shows that legal systems and regulatory subfields are ever more influenced by interconnectedness, which increases the degree of hybridity borrowing from various sources, both domestic and international. It focuses less on the transformation of regulatory regimes caused by the increasing contribution of private non state-based regulations, which also contribute to the modification of the unit of comparative analysis. Privately led risk regulation regimes tend to be functionally rather than territorially organized and do not fit the state centered approach of conventional comparative law.² They further underline the need to redefine the units of analysis and the methodology to compare different regimes. The discussion here will be focusing on the first dimension, which constitutes one of the many milestones of the book, but references to privately designed risk regulation regimes will be

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1 Jonathan Wiener, "Precaution", in Daniel Bodansky, Jutta Brunnée und Ellen Hey (eds), *The Oxford Handbook of International Environmental Law*, (Oxford: Oxford University Press, 2007), pp. 597 et seq., at p. 554.

2 Fabrizio Cafaggi, "New Foundations of Transnational Private Regulation", 38 *Journal of Law and Society* (2011), pp. 20 et seq.

made to reinforce the paradigm shift advocated by Wiener and his coauthors.

Moreover, it should be said at the outset that the scholarly enterprise of the book is combined with a clear policy agenda. The proposal is to favor regulatory transatlantic dialogue aimed at creating a global policy laboratory, which does not reject but transforms comparative methodology. It is a fascinating perspective to which I fully subscribe, notwithstanding the difficulties posed by existing competition of risk regulation and by the emergence of new players whose approach is yet to be clearly defined (in particular China, India and Brazil).

I. Framework: The Multiple Dimensions of the Precautionary Principle(s).

The analysis in the book is focused on the different applications of the PP in risk regulation in US and EU and on the factors influencing its evolution over the last 40 years.

The main research question distilled from the different contributions, can be summarized in the following way: how do policy makers deal with risk uncertainty and limited knowledge about probability (P), as well as with the magnitude of consequences (L) of risk materialization across fields? The comparative analysis breaks this question down into several variables that affect US and European approaches, in particular the horizontal nature of the principle in EU law, and whether PP should not only influence risk assessment but also risk management.

The definition of PP is based on the relationship between the state of scientific knowledge and the regulatory action/inertia. In EU the principle has been introduced into the Treaty as a horizontal principle (Article 191(2) TFEU).³ However, this common denominator hides a plurality of definitions, which are risk or field specific. There are numerous and not necessarily consistent definitions of PP within and across areas such as product safety, environment, and regulated risks, i.e. hazardous products and processes.⁴ The differences in Europe between environmental and food safety regulations analyzed in the book provide a good illustration of how, even when a principle acquires 'constitutional' status, its implementation may preserve old or generate new differences. These differences are not only the results of diverse balances among (public and private) interests, which affect risk assessment and management, but they also reflect di-

verse risk assessment technologies and regulatory cultures, including the relationship between regulators and regulatees and the influence of the principle of proportionality on shaping that relationship. Differences concerning risk perception in individual fields are extremely important to explain institutional reactions, since many of the regimes have evolved as a consequence of pressure during crisis rather than on the basis of an incremental strategy.⁵

It is often the case that scientific knowledge, unlike technology, is considered an independent variable when setting the standard and defining risk management alternatives. Hence, the interpretation of PP often takes particular knowledge and to some degree uncertainty about scientific evidence as a given and then determines if and which regulatory action should be carried out. Insufficient weight on both sides of the Atlantic is given to the possibility that regulatory instruments can improve risk assessment and increase knowledge over time emphasizing the recursive relationship between science and regulation. This approach is challenged by several contributions to the book which instead suggest that regulatory action might be knowledge enhancing, and thereby, at least, a partly become a dependent variable of the regulatory process: i.e. acquisition of new informa-

3 Article 191 (2) of the Treaty on the Functioning of the European Union, OJ 2010 C 83/49 states: "*Union policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Union. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay*".

4 The core element of the general food law definition of the PP, namely decision making under scientific uncertainty and a margin of appreciation associated with it – already emerged in rulings dating back to 1980, before such concept was included in the EC Treaty. In particular in Case C-174/1982, Criminal proceedings against Sandoz BV [1983] ECR 2445, at para. 16, the court affirmed: "*In so far as there are uncertainties at the present state of scientific research, it is for the MS, in the absence of harmonization, to decide what degree of protection of the health and life of humans they intend to assure, having regard however for the requirements of the free movement of goods within the Community*".

5 Cass Sunstein, *Laws of Fear: Beyond the Precautionary Principle* (Cambridge: Cambridge University Press, 2005), pp. 89 *et seq.* See the ruling of the ECJ in the so called BSE cases, namely Case C-157/96, The Queen v Ministry of Agriculture, Fisheries and Food and Commissioners of Customs & Excise, *ex parte* National Farmers' Union and Others [1998] ECR I-02211, at para. 63 where the Court, evaluating the Commission adoption of emergency measure banning all exports of British beef, found the measure not to be in breach of the principle of proportionality, affirming that "*Where there is uncertainty as to the existence or extent of risks to human health, the institutions may take protective measures without having to wait until the reality and seriousness of those risks become fully apparent*". See also Case C-180/96 *United Kingdom of Great Britain and Northern Ireland v Commission of the European Communities* [1998] ECR I-02265.

tion over the regulatory cycle may (partially) modify regulatory strategies which in turn can produce new knowledge affecting scientific findings. Accordingly, uncertainty becomes partly endogenous to the risk analysis process. The example of hazard analysis and critical control points (HACCP), commonly adopted in the area of food safety, shows that regulatory technologies can reduce uncertainty. Therefore, available *ex ante* scientific knowledge should not be the only factor upon which regulatory action should be based on, but it should become one of the variables to be considered when engaging in regulation.

The PP is meant to introduce standards based on scientific knowledge, even if the corresponding technology for risk management is missing at the time of standard setting. The goal then becomes the development and the subsequent adoption of new technologies for risk management on the basis of risk assessment. A dynamic perspective, which incorporates learning into the operationalization of the PP principle along the regulatory process, can contribute to improve effectiveness.

The institutional and substantive dimensions of precautionary principle

The analysis in the book runs along two dimensions of PP: an institutional and a substantive one. The articulation of PP is made through the combination between the set of institutions and the systems of rules aimed at implementing it. The institutional dimension deals with the institutions involved in the definition and execution of PP. In particular, it defines the relationship between administrative and judicial risk regulation, the role of judicial review and the procedural tools to identify and aggregate preferences of those who can be affected by the emergence of the risk, even when the probability of materialization is small. The substantive dimension is related to the standard setting and its implementation that competent institutions have to engage in, when faced with uncertainty about the probability and the magnitude of risks and their trade-offs.

The distinction between institutional and substantive aspects helps disentangling the comparison

among regimes and countries, addressing both the static and dynamic evolution of risk regulation in EU and US. There is wide recognition throughout the book that the quality of risk regulation is higher in the US, due to the policy learning curve, which is generally associated to the regulatory institutions in place.⁶ This is primarily associated with an institutional evolution, partly driven by the application of impact assessment to risk regulation as a result of the better regulation agenda. Various contributions to the book make clear that higher regulatory quality does not necessarily go together with stricter standards; rather it is measured according to the rule making process and its effectiveness in risk reduction.

But going deeper - is there a clear definition of the institutional dimension of the PP that can be scrutinized comparatively?

From a descriptive perspective, it is not always clear what the PP tells us about the institutional framework of risk regulation: i.e. whether it presupposes one or more than one type of allocation between *ex ante* and *ex post* measures and how they are distributed between the administration, the agencies, and the judiciary leaving aside private regulators. The thesis advanced by the book is that better regulation and in particular regulatory impact assessment has played a significant role in the implementation of PP.

From a normative perspective, it is unclear which allocation of tasks between agencies and judiciary best fit the implementation of PP. Clearly dealing with uncertainty about risks suggests a combination between *ex ante* and *ex post*, where *ex post* operating institutions can 'learn' about the features of the regulated risks and revise the standard setting or the implementation strategy. The analysis of how courts decisions influence, or can potentially affect the regulatory cycle is slightly underdeveloped but in some of the areas, especially in relation to the transnational litigation, the role of the judiciary has been significant.

From an institutional standpoint, this evolutionary pattern, following the learning curve, may be problematic if the *ex post* activity is primarily assigned to the judiciary because it would require a much broader scope for judicial review or at least a different approach from that currently adopted. How should the information gap concerning risk between time of standard setting and time of judicial review affect the role of the Courts? The answer to this question should be placed in the broader framework of the relationship between regulators and Courts in assessing and managing risk regulation.

6 Giandomenico Majone, "Political Institutions and the Principle of Precaution", in Jonathan Wiener, Michael Rogers, James Hammitt, et al. (eds), *The Reality of Precaution - Comparing Risk Regulation in the US and Europe* (Washington: Resource for the Future Press, 2011), pp. 411 et seq., at p. 431.

We are reminded that both the availability and scope of judicial review is different in the US and EU.⁷ However, the analysis seems to be premised on the idea that courts reviewing the regulatory activity act as a watchdog, rather than being part of a regulatory dialogue. Clearly the relationship between agencies and courts would be different if courts were allowed to signal and propose cooperative problem-solving between regulators and regulatees rather than operating within a purely adversarial framework with the regulators. Evidence suggests that cooperative enforcement is used more frequently in the implementation of PP and the regulators are often asked by courts to cooperate with the regulatees to redesign the modes of implementation.⁸

Yet, as it is clear when market based regulation is adopted, *ex post* action can also be based on administrative measures. Symmetrically, the judiciary may intervene *ex ante* using injunction to prohibit or to authorize activities by the regulated entities.⁹ Clearly the *ex ante/ex post* can not be juxtaposed mechanically to administration/adjudication.

The comparative analysis developed by several contributions is based on the assumption that liability may play a different role in US and EU risk regulation. This is clear in the case of tobacco, where litigation has had a very different impact in the two systems. Within the EU the example of HIV contaminated blood shows, on the one hand, the importance of liability as a trigger for subsequent regulation, on the other hand, the different regulatory responses which have emerged among Member States (MSs) from litigation.¹⁰ Some contributors, however, claim that the influence of liability is altogether negligible in risk regulation.¹¹ More empirical research is needed to verify if and how much impact has litigation had on regulatory activities concerning risk regulation between US and EU and within EU among various MS.

Clearly in the area of product liability related to food the two legal systems differ in practice more than in the books. While in the US liability has contributed to a large extent to regulate safety risks, in Europe and in particular within the EU the impact of liability as a risk regulatory device has been rather limited. This is due to multiple factors, including the availability of mass torts and class actions in the US, which are still largely unavailable in Europe. Differences also exist in relation to administrative regulation. It is only with the Food Safety Modernization Act (FSMA) that the US has adapted its framework to the European food safety model defined in 2002 with the establishment

of the EFSA. Yet, even after the enactment of FSMA, the explicit recognition of PP in EU food law constitutes a significant difference between the two legal and institutional frameworks. This, however, is not to say that within food law there are areas where stricter standards are adopted in the US.¹² The institutional

7 Lucas Berkamp and Turner Smith Jr., "Legal and Administrative Systems: Implications for Precautionary Regulation", in Jonathan Wiener, Michael Rogers, James Hammitt, et al. (eds), *The Reality of Precaution - Comparing Risk Regulation in the US and Europe* (Washington: Resource for the Future Press, 2011), pp. 434 et seq., at p. 470. Judicial review in EU has a more limited scope due to a voluntary restraint adopted by courts on their own discretion. A clear example is Case C- 331/88, *The Queen v Minister of Agriculture, Fisheries and Food and Secretary of State for Health*, ex parte: Fedesa and others, [1990] ECR I-04023, at para. 8, where the ECJ was asked to make a preliminary ruling on the validity of national regulations which aimed to implement Directive 88/146/EC prohibiting the use of a number of hormones in livestock. In particular the claimant, Fedesa had held that anxieties of consumers related to the hormones in question lacked any foundation in science, and that as a consequence the principle of legal certainty for traders of hormones was violated. The court declined to make a judgment with regard to scientific evidence stating that: "Even if it were to be held, as the applicants in the main proceedings have argued, that the principle of legal certainty requires any measures adopted by the Community institutions to be founded on a rational and objective basis, judicial review must, having regard to the discretionary power conferred on the Council in the implementation of the common agricultural policy, be limited to examining whether the measures in question is vitiated by a manifest error or misuse of powers, or whether the authority in question has manifestly exceeded the limits of its discretion".

8 See Case T-229/2004, *Kingdom of Sweden v Commission of the European Communities* [2007] ECR II-02437, where the CFI revoked a decision to authorize the pesticide *Paraquat* upon the basis that the Commission had not acted in a sufficiently precautionary manner when issuing the authorization.

9 Fabrizio Cafaggi, "A Coordinated Approach to Regulation and Civil Liability in European Law: Rethinking Institutional Complementarities", in Fabrizio Cafaggi (ed.) *The Institutional Framework of European Private Law*, (Oxford: Oxford University Press, 2006), pp.191 et seq.

10 Simon Whittaker, *Product Liability: English Law, French Law, and European Harmonisation*, (Oxford: Oxford University Press, 2005). Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC, OJ 2003 L 33/30 followed the blood contamination scandals such as HIV-infected blood in France, Germany and Portugal. However, given that the Directive sets minimum standards, it does not prevent MS from maintaining or introducing more stringent national protective measures, for instance relating to requirements for voluntary and unpaid blood donations.

11 For example Berkamp and Smith Jr., "Legal and Administrative Systems", *supra*, note 7, at p. 475 state: "we do not see a clear indication, in either the US or the EU legal or administrative system, of any actual significant impact on the degree of precaution in the resulting risk regulation".

12 George Gray, Michael Rogers and Jonathan Wiener, "Beef Hormones, and Mad Cows", in Jonathan Wiener, Michael Rogers, James Hammitt, et al. (eds), *The Reality of Precaution - Comparing Risk Regulation in the US and Europe* (Washington: Resource for the Future Press, 2011), pp. 65 et seq., at p. 68 et seq.; Alberto Alemanno, "How to Get Out of the Transatlantic Regulatory Deadlock over Genetically Modified Organisms?", in David Vogel and Johan Swinnen (eds), *Transatlantic Regulatory Cooperation* (Cheltenham: Edward Elgar Publishing Ltd., 2011) pp. 200 et seq.

framework in food safety differs also in relation to certifiers, fully recognized in the US as primary actors, still playing a residual role in the legal framework in Europe. Thence, from an institutional perspective the implementation of the PP has taken different routes, leading to different responses from the industry and the other relevant actors.

II. The Challenges of Risk Regulatory Regimes to Comparative Law

"We do not reject comparisons. We seek better comparisons" (J. Wiener)

The structure of the book is comparative in multiple senses. It is comparative because the main question is whether the EU has become more precautionary than US. Here, we are in the world of comparison among legal systems. It is also comparative in relation to the different risk regulatory regimes face. Qualitative analysis is meant to provide information for the country-based comparison but it can also be used to engage into cross-sectoral comparison within, rather than between, systems. Each case study could be read horizontally within US or EU, in order to compare risk regulation approaches within one legal system across different sectors. If read in this way one could argue that we cannot really speak of the PP, but we should be discussing about precautionary principles (plural!) given the specificity of risks interdependencies that arise in different fields. This

is true in the EU, despite the 'codification' of the principle in the Treaty, as well as in the US, where a horizontal clause is missing. In both dimensions, countries and sectors, the comparison carried in the book is diachronic because it concerns forty years of risk regulation.

The US is considered as a single unit of comparison, but full recognition is given to the differences in regulatory and judicial approaches among the individual States in relation to the PP. If more relevance were given to liability differences would be even more significant. Similarly, the EU is considered as a single unit for the purpose of comparison with the US, although, throughout the book, there is full awareness of the different regulatory cultures developed within the different European states in relation to the PP. In the EU the separation between risk assessment (for agencies) and risk management (for the Commission) is hardly seen at the MS level where the different steps of risk regulation are generally carried by the same institution. Given that often the implementation of risk regulation and its enforcement is left to MSs, it is only by looking at what State agencies and national courts do, that a fully fledged comparative analysis can be carried on.¹³ This is especially true if adjudication via civil liability is factored into the analysis.¹⁴ European legal systems of civil liability have only been partially harmonized and divergences persist in relation to both substantive and procedural terms. Collective actions and aggregate litigation is only the most cited examples. To a certain extent this is also true for the US, given that tort both in the field of product safety and environmental regulation still largely fall under State common laws. But the degree of divergence is much higher in the EU. Notwithstanding these limitations the description conducted at the EU level still reveals significant information for the comparative analysis.

At a more conceptual level the contributions highlight the shortcomings of the conventional comparative legal analysis. The inadequacy of a science of comparative law based on state-centric units of analysis has long been emphasized, underlining the need to integrate transnational law into comparative analysis.¹⁵ After 12 years the challenge posed by Mathias Reinmann is still there. The important progress made to integrate the transnational sphere into more traditional comparison among national legal systems has not yet provided a definitive answer to the search for a new comparative metric, which can affect global policy making.¹⁶ A one size fits all model to integrate

13 See Case C-6/1999, Association Greenpeace France and Others v Ministère de l'Agriculture et de la Pêche and Others [2000] ECR I-1651, at para. 44, where in relation to a question of a French Court regarding whether the MS is bound to follow the decision of the Commission regarding the authorization of GMO product, or it does still retain some discretion, the ECJ found that some discretion still remained, with the MS stating that "*Observance of the precautionary principle is reflected in the right of any MS provisionally to restrict or prohibit the use or sale on its territory of a product which has received consent where it has justifiable reasons to consider that it constitutes a risk to human health or the environment*".

14 Berkamp and Smith Jr., "Legal and Administrative Systems" *supra*, note 7, at p. 474.

15 M. Reinmann, "Beyond National Systems: A Comparative Law for the International Age", 75 *Tulane Law Review* (2001), pp. 1103 *et seq.*

16 Ralf Michaels and Nils Jansen, "Private Law Beyond the State? Europeanization, Globalization, Privatization", 54 *American Journal of Comparative Law* (2006), pp. 843 *et seq.*, Ralf Michaels, "Comparative Law by Numbers? Legal Origins Thesis, Doing Business Reports, and the Silence of Traditional Comparative Law", 57 *American Journal of Comparative Law* (2009), pp. 765 *et seq.*

the transnational sphere cannot work. The problems differ between international and transnational private law. Given that transnational risk regulation is a combination of both, one needs to distinguish the two and then coordinate them with national or regional systems. Several questions remain on the table. In particular, how should transnational risk regulation be conceptualized? How should we describe the impact of transnational risk regulation on national institutional frameworks? How do different risk perception systems by communities affect the comparison? Should transnational risk regulation regimes be considered independently or even as autonomous legal orders to be compared with nation states? Or, should they be considered as part of a supranational legal order that constrains the standard setting process of national legal systems? More specifically, how should the comparison be structured when no hierarchy between the transnational and the domestic level exists so that states and private actors can choose 'if' and 'how much' they integrate the transnational with the domestic spheres?

The challenge goes beyond adding the vertical perspective to the horizontal one. Geometry helps but it is not conclusive. As mentioned, transnational private law concerning risk regulation does not necessarily coincide with the traditional models of international law of risk regulation. Many of the transnational regimes might be organized around markets, industries and/or commons, which might not have a treaty basis.

Hence, the core comparative question is how functional risk-regulation regimes, organized around communities and interest groups, interplay with the more traditional territorial ones. Legal systems tend to become multilevel, intertwined and their comparison has to include functional in addition to territorial variables. The pattern of systems' conflicts and systems' coordination pose new challenges for comparative law especially if it adopts the dynamic perspective of the reality of precaution.

These aspects are even more accentuated in the field of risk regulation. The collective dimension of risks and the necessary interdependence of the regulatory responses impose new forms of regimes' coordination within risk regulation. Risks in the area of food or that of environment follow patterns associated to trade and consumption, which are changing over time and across communities. Several contributions suggest that risk regulatory regimes are expanding their reach beyond national boundaries and their

comparison requires, abandoning the state-centered features around which the more recent debate on the law matter and legal origins has developed.¹⁷ The change of unit of analysis, or at least the differentiation of units for the purpose of comparison, should become the standard feature of comparative law and certainly for comparative risk regulation. For example, risk perception might differ within states to the same extent or even more widely than across states depending on the social status or the religious beliefs.

The case studies show how globalization is contributing to hybridization rather than convergence over a single regulatory model. The focus of the book is on a particular aspect of hybridization related to diffusion of ideas, in particular instruments and techniques for risk regulation. The claim is that globalization of legal rules and, to a much more limited extent that of institutions does not eliminate the role of comparative law. On the contrary, its function becomes even more relevant in transnational regimes where the institutional framework is composed by both common rules and institutions and specific, local ones.

Regulatory policies and solutions are discussed in the selected case studies. Often these policies confront each other within the framework of transnational and international regulation. This implies that:

- a) There is a common set of rules which even if only covering part of the regimes, influences its overall outlook
- b) Often there are new transnational bodies ranging from international organizations to associations, from regulatory networks to informal but stable *fora* aimed at exchanging views and information about regulatory practices¹⁸

The analysis in the case studies focuses on convergences and divergences between EU and US, examining if and how legal transplants have occurred. The contributions make clear that the conventional account of legal transplants might not be adequate. While there is borrowing, the transfer may be driven at times by

17 Jonathan Wiener, "The Real Pattern of Precaution", in Jonathan Wiener, Michael Rogers, James Hammitt, et al. (eds), *The Reality of Precaution - Comparing Risk Regulation in the US and Europe* (Washington: Resource for the Future Press, 2011), pp. 552 et seq., at p. 553

18 As general examples in this regard one can mention the ISEAL Alliance or the Global Harmonization Initiative with regard to food safety standards; furthermore WTO Workshop on Regulatory Practices provides for such a forum (http://www.wto.org/english/tratop_e/serv_e/workshop_apr11_e/workshop_apr11_e.htm).

the lender, at times by the borrower, depending on the nature of the risk and the way interconnectedness operates. But in the majority of cases new regulatory practices rather than simple borrowing emerge.

Less attention is devoted to judicial transplants and how the state judiciaries have contributed to the dissemination of the PP across legal fields. The diffusion of the PP has often taken place also through judicial use of the PP in areas different from those originally affected, before being incorporated into regulatory instruments. This is conventionally acknowledged from environment to food safety but it has also happened in the opposite direction where judicial applications of the PP in food have been 'transplanted' into the environment. Clearly cross-sectoral diffusion of the principle is favored by the existence of a horizontal clause in the case of the EU but it has occurred in the US as well. Such a principle invites not only legislatures but also judiciaries to engage into cross-sectoral applications. Comparative analysis on judicial transplants within sector and across countries and between sectors within countries would shed more light on the evolutionary process.

III. An Agenda for Future Research in Comparative Risk Regulation

As it is often the case complex architectures trigger wider research agendas. Rather than providing conclusive answers they offer conceptual challenges to be further explored both theoretically and empirically. This is certainly the case for the Reality of precaution impressive book.

The book invites to explore the modes of hybridization of new regulatory regimes focusing on risk regulation. Each seems to be the result of specific factors and features, hard to reconcile in a coherent and consistent uniform paradigm. Culture, politics, trade protectionism, risk perception all contribute to differentiate the regimes and to define the specificity of the implementation of the PP.¹⁹

The contributions in the book show that the PP encompasses both an institutional and a substantive

dimension. In a two by two matrix which correlates *ex ante* and *ex post* with both administrative law and civil liability the results differ according to each sub field concerned with risk regulation.

It is clear that no legal system adopts an approach where the *ex ante* coincides with administrative regulation and *ex post* with judicial intervention. Judicial *ex ante* risk regulation is managed with the use of injunctions, which can either prohibit or permit, subject to specific conditions, a risk generating activity. There is symmetry between judicial injunctions, including both prohibitory and permissive ones, as well as administrative orders, which can ban or authorize/license the product/activity of the regulated entity. Judicial *ex post* risk regulation deploys damages awards to induce risk management and control. The unanswered question is whether and how courts and agencies complement each other by using different remedies or addressing different types of risks.²⁰

Symmetrically, administrative regulation uses both *ex ante* (injunctive type remedy) and *ex post* instruments like fines or other pecuniary remedies.²¹ Responsive and market based regulation have increased the number of instruments to be used by administrative agencies to a broader extent than judicial remedies. Within the latter there is probably a much more creative use of judicial power in the US than in Europe. Particularly, US courts have often engaged in the creation of innovative remedies. The future research analysis should try to explore more systematically which combination between *ex ante* and *ex post* is deployed by administrative risk regulation and which is deployed by judicial risk regulation when complementing injunction and damages.

Both legal institutions (agencies and courts) have responded to risk regulation by differentiating and adapting to the specific features of risks. Legal responses to risk regulation have become more risks specific. Deeper efforts for comparative analysis should look at inter-sectoral comparison acknowledging risk specificity.

Administrative law has been progressively diversified in continental law, due to the increasing institutional differentiation which has brought about the creation of subfields with their own principles concerning risk-regulation. Macro-areas like product safety and environmental protection address risk regulation differently and even within those areas micro fields with their own logic have developed. They are responsive to the specificity of risk, the communities involved, and to the different structure of industries and NGOs.

19 Sunstein, *Laws of Fear*, *supra*, note 5.

20 Cafaggi, "A Coordinated Approach to Regulation", *supra*, note 9.

21 Richard Stewart, "Instrument Choice", in Daniel Bodansky, Jutta Brunnée und Ellen Hey (eds), *The Oxford Handbook of International Environmental Law*, (Oxford: Oxford University Press, 2007), pp. 147 *et seq.*

Civil liability has gone through a similar process of internal differentiation, with different degrees, in each MS. The research question, in need for empirical responses is: to what extent can the civil liability system be conceived as a form of risk regulation and how they complement administrative and private regulation?

To the extent to which the answer to the 'if' question is affirmative, the (following) 'how' question has to be addressed: how have domestic and international regimes deployed tort laws as a risk regulatory device to implement or complement the PP? Civil liability at domestic level is differently organized across legal systems. Even continental codified regimes which are conceptually built around a few general rules have been subject to a process of differentiation whereby judges specify the meaning of liability, causation and remedies in relation to the specific risk distinguishing between product safety and environmental standards. Hence, we observe the development of subfields like product liability, and within product liability specificities concerning drugs and food still exist. Similarly, we observe the development of the subfield of environmental civil liability and within that subfield important differences exist depending on the type of environmental harm addressed.

How should the combination between institutional and substantive dimensions be incorporated into the comparative analysis of PP? While it is clear that risk regulation is the outcome of the relationship between rules and institutions, a complex comparative metric in risk regulation has not yet been developed. In particular, the analysis often looks at regulatory action, rather than at its effects. A metric to compare effectiveness across regimes is needed. Comparing a ban to a license might not tell the full story about effectiveness of risk regulation and the impact of PP. What appears to be a more stringent remedy can be less effective depending on the degree of compliance. Furthermore, it might be the case that identical standards bring about different results, due to the different weight of agencies and courts in each legal system or sector, and the scope of judicial review. Here, it is the institutional framework rather than the substantive one that needs a more precise comparative metric. It would be interesting to engage into a separate, yet coordinated analysis of the legal and political institutions, agencies and courts, involved in risk regulation and to verify their impact on the standards and rules. This comparative metric is not only theoretically relevant but it might have relevant policy implications especially for transnational regimes.

A growing area of interest is certainly that of regulatory impact assessment (RIA) and its potential influence on judicial and administrative risk regulation both *ex ante* and *ex post*. The application of RIA to risk regulation has increased participation of civil society in both risk assessment and risk management. But how this participation is changing the methods of evaluation and the selection of priorities in policy agendas concerned with risk regulation is unclear. So is the use of RIA by the judiciaries while exercising judicial review and defining liability standards. If the intuition of the book about the influence of better regulation on the PP is correct, comparative risk management and comparative risk assessment technologies will be strongly affected by RIA.

In the US cost-benefit analysis characterizes both regulatory action by agencies and, to a limited extent, adjudication in the field of tort law, especially that of product liability. However, the methodologies deployed by agencies are rather different from those used by the judiciaries. Furthermore, lack of institutional coordination can bring about serious policy shortcomings. While we certainly recognize the importance of cost-benefit analysis for risk regulation, more information is needed to coordinate the different institutions involved within and between subfields when applying the PP.

In Europe, while RIA is entering the regulatory scene, it is still nearly absent in adjudication, giving rise to even broader methodological differences in assessing the risk and defining the instruments by agencies and courts in relation to the US.

A comparative analysis, focusing on the role of impact assessment in risk regulation while looking at agencies and courts in the EU and the US, could shed more light on the factors driving to differences and contributing to the global comparative policy laboratory proposed by Jonathan Wiener and his co-authors. The focus on regulatory change and drivers of legal innovation could provide useful integration to the most innovative accounts on the evolution of regulatory capitalisms in the new comparative law agenda.²²

22 David Levi-Faur, "Varieties of Regulatory Capitalism: Getting the Most Out of the Comparative Method", 19 (3) *Governance* (2006), pp. 367 et seq.; Curtis Milhaupt and Katharina Pistor, *Law & Capitalism: What Corporate Crises Reveal about Legal Systems and Economic Development around the World* (Chicago: University of Chicago Press, 2008); John Braithwaite, *Regulatory Capitalism: How It Works, Ideas for Making It Work Better* (Cheltenham: Edward Elgar Publishing Ltd., 2008).