The Risk of Risk Analysis

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I. My personal experience with risk regulation

My own risk regulation story is somewhat uncanny. When I embarked upon my career as a barrister at the Brussels bar, I had no idea at all that risk assessment and risk management might one day become one of the key issues I would have to deal with. I mostly worked in the end of the 80s and early 90s on the implementation process in Belgium and in other Member States of a swathe of environmental directives, ranging from water pollution to bird protection. Scientific uncertainty was not the first priority at that time, though I was already aware that the evolution of ecosystems is somewhat embedded in lingering uncertainties. I had to carve out the proper legal provisions at national level in order to flesh out the secondary EU law obligations. This was a tedious work, given that Belgium had launched the process of federalisation in the early 80s.

I began to write my PhD in 1995, tracing the evolution of various environmental principles from their origins as vague political slogans reflecting fears concerning environmental hazards through to their embodiment in enforceable laws. In so doing, I realised that several risk issues had become increasingly important since the early 1980s. This has been due in part to a fundamental change in the type and scale of risk posed by industry. Issues such as global warming, acidification of oceans, the spread of endocrine disruptors and persistent organic pollutants typify the new kinds of risk: potentially catastrophic consequences may ensue, yet there is no scientific agreement concerning their precise cause, duration and other concerns. I reached the conclusion that environmental law has always responded to the risks posed by industrial society but that the new generation of risks calls for a new set of environmental principles. My thesis sought to demonstrate how three of the most important principles of environmental law had grown out of this new age of ecological risk: the polluter pays principle, the preventive principle and the precautionary principle.

After publishing my doctoral thesis in 1999 in French, I immediately wrote a new version in English, which was published in 2002.[1] As part of this process, I had the opportunity to participate in a number of meetings on both sides of the Atlantic where I became much more aware of the risk dimension to environmental policy. In addition, I discovered the complexity of food safety law, which was quickly turning into a legal discipline in its own right. Thanks to a Marie Curie Chair at Oslo University on risk management and later on a Jean Monnet Chair on trade and the environment at St Louis University in Brussels, I was able to become much more knowledgeable regarding the interactions between risk

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[1] *Environmental Principles. From Political Slogans to Legal Rules* (Oxford University Press 2002).

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assessment and risk management. I have also provided legal advice in relation to some of the key EU legislation dealing with risks, including REACH.

In teaching EU institutional law in Brussels, I focus on various arcane institutional issues, ranging from agencies to comitology. When so doing, I offer students a variety of examples of conflict between the EU institutions or between the institutions and various Member States regarding, for instance, GMOs and endocrine disruptors.

II. How to define risk regulation research?

Given that I focused on the adoption and the judicial review of both preventive and precautionary measures in the environmental field (air and water pollution, nature conservation, biodiversity, industrial hazards, chemical substances, pesticides, etc.) from an international, EU and comparative law perspective, I never had the chance to adumbrate all issues that are likely to be contemplated in the field of risk regulation research. As a matter of course, lawyers who are drafting or taking part in the drafting of risk regulations should become acquainted with an interdisciplinary approach, in particular with respect to the scientific, societal and economic dimensions of the risks to be regulated. However, time shortage and budgetary constraints preclude such an interdisciplinary approach, at least at university level. Therefore the interdisciplinary dimension should become a key part of such researches. That being said, one should become aware of the hurdles to overcome. Lawyers practising EU law are sometimes at pains to understand their colleagues practising domestic law. It comes thus as no surprise that toxicologists are somewhat afraid of legal issues and that some lawyers consider toxicology as a trivial matter.

Though much has been written about the precautionary principle, the manner in which it can be implemented is still dogged by controversy. It has been put forward as the best as well as the worst of principles. Moreover, its legal status is still embroiled with controversies. Lately, the French presidential candidate François Fillon has been calling into question the constitutional status of precaution. Account must be taken of the fact that several issues related to the implementation of the precautionary principle still need to be tackled. Of course, the key issue is to seek an equitable path that would preserve the useful effect of the precautionary principle without paralysing innovation.

Firstly, critics of the principle often set precaution and scientific knowledge against one another. However, it can be argued that the precautionary principle and the principles of scientific rigour are not antithetical, but rather mutually reinforcing. Indeed, one of the central features associated with the precautionary principle is the continuous re-evaluation of scientific evidence. By way of illustration, all decisions taken in a context of uncertainty should regularly be revised in the light of new information. The question then arises how to reconcile the risk assessment analysis typically used by regulatory agencies and the tendency of political authorities to break free of these procedures in the name of the precautionary principle. Traditional risk assessment procedures focus only on a small sub-set of the totality of issues of concern in the wider debate. The selected issues are more readily quantifiable because they are more amenable to measurement under an individual favoured metric (such as human mortality or monetary value). A number of risks thus lie outside the conceptual framework of

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formal risk regulation. Synergistic or additive effects of different compounds are not assessed under current regulatory appraisal, each substance being taken in isolation on a case-by-case basis. The potential benefits of a technological risk which might be offset against any adverse effects are excluded from the scope of present regulatory risk assessment.

By narrowly defining the scientific basis for health or environmental decision-making in terms of quantitative assessment, the classical risk assessment methodology required by international organisations can limit the ability of national authorities to take precautionary measures. These limitations of the risk assessment approach have become even more obvious in the face of new environmental challenges such as endocrine disrupting substances and POPs. Scientific proof of cause-effect relationships between these classes of chemicals and adverse effects on human health and the environment may take several years or decades to establish and may never be fully demonstrated owing to limitations in experimental design and the complexity of natural ecosystems. Therefore, research in social science should focus on the wider scope that could be adopted during the scientific appraisal in order to enhance regulatory decisions that are both "precautionary" and "scientifically sound".

Secondly, regulatory authorities are often presented with a more or less finished product by risk assessors, in the form of a risk recommendation that leaves them very little margin in choosing an alternative. As a result, normative decisions are completely determined by the scope of the assessment. Thus, to give more leeway to the decision-maker, risk assessment must be conceived in such a way that it serves to inform decision-makers and allow them to select the right regulatory action rather than leave decisions to assessors. In this connection, researchers could focus on the ways in which EU case law developments could be flesh out. On this matter, the General Court of the EU has in fact held that:

> "it is for the Community institutions to determine the level of protection which they deem appropriate for society. It is by reference to that level of protection that they must then, while dealing with the first component of the risk assessment, determine the level of the risk – i.e. the critical probability threshold for adverse effects on human health and for the seriousness of those effects – which in their judgement is no longer acceptable for society and above which it is necessary, in the interests of protecting human health, to take preventive measures in spite of any existing scientific uncertainty. Therefore, determining the level of risk deemed unacceptable involves the Community institutions in defining the political objectives to be pursued under the powers conferred on them by the Treaty".[2]

Thirdly, the question also arises whether the public authorities should carry out a classical cost-benefit analysis (CBA) before taking any precautionary action, let alone preventive action. However, the requirement to carry out a CBA might be inappropriate for the following reasons. First, CBA does not address the issue of defining what "costs" are "economically acceptable", and for whom. In addition, it will never be accurate as long as economic analysis remains incapable of correctly internalising all externalities in a context of uncertainty. From an economic point of view, there are clearly no simple or comprehensive rules for integrating risk and uncertainty into decision-making. Indeed,

[2] Case T-13/99, *Pfizer*, para. 151.

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the uncertainty inherent in precaution increases the possibility that ecological interests could systematically be compromised compared to competing interests since, as recalled above, the gravity of suspected damage can only be known in an approximate manner. In addition to the irreversible, we must acknowledge the problem of the irreparable. Hence, the precautionary principle contradicts the postulates of an insurance-based society, which presupposes that one can assign a price to everything. For these reasons, balancing the disadvantages of a precautionary measure against the advantages it is meant to secure cannot be limited to carrying out a classical cost-benefit analysis. Everything cannot, always, be considered from an economic perspective. Environmental goods such as endangered species or landscapes are not commodities; their value can only be appreciated collectively. Where risks are deemed unacceptable, they must be prevented absolutely and must not be subject to a CBA.

Accordingly, researchers could focus on the manner in which CBA could be broadened to take into account long-term non-economic advantages for society as a whole.

III. The future of risk regulation

Last, but not least, what is the future of risk regulation? Considering the space dedicated within CETA to the right to regulate with the aim of achieving legitimate public interests (Articles 8.9 and 24.3), risk regulation issues are likely to be subject to much debate over the coming years.

That being said, one has to face hard facts. It is when the legal bases for EU action are at their firmest—where the legal principles underlying this branch of law are enunciated by the EU Courts and several national supreme courts when ruling on hard cases – and when the values are most clearly proclaimed in both the TEU and TFEU that legislative output in environmental protection matters slows down, in accordance with the principle of subsidiarity. Environmental law appears to be the sacrificial victim to recent political developments – Better Regulation, Smart Regulation, etc – under which, according to the logic of deregulation, the law was called upon to climb down from its pedestal in order to engage with market requirements. Brexit is likely to exacerbate that trend, though the numerous treaties to which the UK is already party would place certain constraints on the Government if it sought to water down environmental legislation or to repeal it.[3]

However, deregulatory trends are likely to infringe several Treaty obligations. Pursuant to Article 3(3) TEU, Article 191(2) TFEU, and Article 37 EUCFR, EU policies shall aim at attaining a high level of environmental protection. In accordance with Articles 168(1) and 169(1) TFEU as well as Articles 35 and 37, EUCFR, public health and consumer protection policies reiterate this qualitative requirement. Moreover, with respect to measures related to the establishment and the functioning of the internal market, Article 114(3) TFEU lays down a similar obligation. By the same token, in *Tatar v Romania*, the ECtHR stressed that the precautionary principle could be seen as a basis for the obligation to attain a high level of environmental protection.[4]

[3] P Oliver, "Environment after Brexit: Further Thoughts", Morkton Chamber, 28 November 2016.

[4] *Tatar v Romania*, 27 January 2009, para. 120.

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Be it for workers, patients, consumers, or the environment, the requirement to attain a "high level of protection" has barely attracted any attention and has been the object of only a few commentaries in the academic literature. These obligations have often been classed in the category of declarations of intent. They are considered at best as policy principles devoid of any binding force, or as a guarantee of legitimacy which is automatically placed on draft regulations, directives, and decisions. Nonetheless, these obligations to attain a high level of protection have to be taken into consideration by EU institutions as well as by Member States. Since they are binding on the EU institutions, environmental and health measures may be subject to review in the light of these requirements.[5]

[5] Case C-341/95 *Safety Hi-Tech SRL* [1998] ECR I-4355, para. 53; Cases C-14/06 & 295/06 *Parliament and Denmark v Commission* [2008] ECR I-1649, paras. 74 and 75.

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