NanoEthics (2008) 2:61–71
DOI 10.1007/s11569-008-0029-8

ORIGINAL PAPER

Risk Regulation, EU Law and Emerging Technologies: Smother or Smooth?

Geert van Calster

Received: 8 January 2008 / Accepted: 8 January 2008 / Published online: 13 February 2008

Abstract Risk analysis as a regulatory driver has now become firmly entrenched in public health and environmental protection. Risk analysis at any level essentially has to accommodate two gut feelings of the constituency: whether society should be risk-prone or risk averse, and whether government and its institutions can be trusted to make the necessary decisions with a high or a low degree of discretion. The precautionary principle (or rejection thereof) arguably is the ultimate reflection of the promotion of risk to a societal value. There is no doubt that especially amongst the representatives of the Member States (as opposed to the officials at the European Commission), public (pre)caution with respect to the long-term environmental and public health implications of gene technology influenced the reluctance to allow marketing of GM foods and feeds until a strict regulatory regime had been rolled out. Industry would argue that the delay in regulation, as well as the eventual regime was of such a nature as to stifle the technology. This contribution reviews a number of features of standard EU risk analysis decisions, so as to assess its current propensity towards smothering rather than smoothing the introduction of new technology. The current development of a regulatory framework for nanotechnology serves as a case study.

Keywords Emerging technologies · Law · Nanotechnology · Regulation · Risk analysis

Introduction

Risk analysis entered the greater political stage amongst others during the 2000 US Presidential elections campaign, during which President Bush quipped, "If my opponent had been there at the moon launch, it would have been a "risky rocket scheme." If he'd been there when Edison was testing the light bulb, it would have been a "risky anti-candle scheme."[1]

Risk analysis as a regulatory driver has now become firmly entrenched in public health and environmental protection. Over and above having to respond to the physically and socio-politically complex nature of environmental problems ([4], p. 117), and the intricate nature and ever-evolving knowledge of human health concerns, risk analysis at any level essentially has to accommodate two gut feelings of the constituency: whether society should be risk-prone or risk averse, and whether government and its institutions can be trusted to make the necessary

G. van Calster (✉)
Collegium Falconis,
Tiensestraat 41,
3000 Leuven, Belgium
e-mail: gavc@law.kuleuven.be

[1] George Bush speech to Republican National Convention, 3 August 2000.

decisions with a high or a low degree of discretion. The precautionary principle (or rejection thereof) arguably is the ultimate reflection of the promotion of risk to a societal value. From humble origins, 'risk', and 'risk management' have been propelled to the forefront of public health and environmental regulation, not just at the national level but in international fora, too.[2]

The European Union (EU)'s regime on the marketing of genetically modified organisms (GMOs) is a notorious recent application of risk analysis and its close alliance with societal preferences. There is no doubt that especially amongst the representatives of the Member States (as opposed to the officials at the European Commission), public (pre)caution with respect to the long-term environmental and public health implications of gene technology influenced the reluctance to allow marketing of GM foods and feeds until a strict regulatory regime had been rolled out. Industry would argue that the delay in regulation, as well as the eventual regime was of such a nature as to stifle the technology.

This contribution will review a number of features of standard EU risk analysis decisions, so as to assess its current[3] propensity towards smothering rather than smoothing the introduction of new technology. The current development of a regulatory framework for nanotechnology will serve as a case study.

Risk Regulation in the European Union

The current regulatory direction of the EU and its Member States is in large part down to three distinct well-documented developments with a large degree of causality (see e.g. [15], p. 14 ff.): regulatory failures in the Member States, a preference for risk aversion with the public, and an increase in the EU's regulatory powers, especially with the introduction of the Single European Act (1986).

Regulatory failures include of course the UK's BSE crisis, as well as the Belgian dioxin crisis, both food-related and hence speaking directly to people's fears. Lessons learned from both events were instrumental in the subsequent creation of the European Food Safety Authority—EFSA.

The link between these failures and the apparent current *risk aversion* among EU citizens would seem undeniable and is indeed illustrated[4] by the rise in public support for the various green parties throughout Europe, especially in the very aftermath of the aforementioned crises.[5]

Finally, the expansion of the EU's regulatory power (i.e. via the introduction of qualified majority voting in Council, as opposed to unanimity, for the regulatory issues concerned) is in large part a reaction to the internal market impact of diverging regulatory policies in the Member States. The economic imperative of enhancing market integration remains a strong driver for regulatory integration in the EU.

Benzene and the Risk Assessment Revolution

The decision of the United States Supreme Court in *Benzene*[6] is widely seen as having heralded the introduction of risk assessment as the default standard for risk analysis by US regulators. Prior to *Benzene*, the Occupational Safety and Health Administration (OSHA) had adopted a policy in line with which the permissible exposure limit (PEL) was set with respect to carcinogens,

> at that level which had been demonstrated to be safe or at the lowest "feasible" level if no exposures had been shown to be safe. OSHA interpreted "feasible" to mean that a workplace standard must not seriously cripple a regulated industry, but it could impose substantial costs and result in the shutdown of marginal operators. Thus, because OSHA regarded benzene as a carcinogen, its own policy demanded that the

[2] See the World Trade Organisation's Agreement on Sanitary and Phytosanitary Standards–SPS, and the amply analysed decisions of the Panel and the Appellate Body in the *EU Hormones* case: WT/DS26/AB/R (16 January 1998).

[3] Arguably precisely because of their close links to society's risk aversion or fondness, risk management patterns are not static and may certainly change over time. Literature has mapped risk management patterns in the USA during the 1960s and 1970s, when the USA led the world in environmental and public health proactiveness, often even in a way which cannot be called but precautionary. See e.g. [15], p. 4 ff.

[4] Ibidem.

[5] Similarly, Chernobyl heavily influenced the not altogether rosy picture painted in [1].

[6] Industrial Union Department, AFL-CIO v. American Petroleum Inst., 448 U.S. 607 (1980; Benzene).

> existing 10/25/50 ppm standard be revised to the lowest feasible level unless some safe exposure level were demonstrated. ([6], p. 124).

'Feasibility' as a criterion is evidently not the most verifiable, neither are the parameters which OSHA added in order to enhance predictability. When it was challenged in court, OSHA was essentially rebuked for not having a risk assessment attitude vis-a-vis the standard (which was based on a general carcinogen policy, which enforced an across-the-board exposure limit based on benzene being a carcinogenic, rather than limits based on the assessment of risk for specific exposure levels), and for not having performed a proper economic assessment of the costs of the standard (and its alternatives; [6], p. 126). However, it is impossible to ascertain the precise justification of the Supreme Court in its rebuke of the standard, because the 5/4 majority issued three opinions (ibidem). Justice Rehnquist, later Chief Justice, while siding with the majority, argued that the substantive requirement for health standards contained in Section 6(b)(5) of the Act[7] in fact amounts to an unconstitutional delegation of legislative power, which Congress, not a regulatory authority, should enact. With reference to inter alia Locke's *Second Treatise of Civil Government*, the late Rehnquist argued that "the very essence of legislative authority under our system (is the making of) the hard choices, and not the filling in of the blanks."[8] The unconstitutionality argument was not further entertained in the judgment and the majority opinion, as the OSHA standard had already been found illegal on different grounds. That the significant risk theory decided the case rather than the constitutional arguments on the delegation of power, in the author's view amounts to an important piece of legal history, at least with respect to risk management. Indeed arguably the Rehnquist view on the limits to regulatory power outside of Congress, leaving the making of what he called the hard choices up to elected representatives, edges towards the predominant view in the EU and its Member States, that risk management as the third and crucial step in risk analysis, after risk identification and risk assessment and prior to risk communication, in essence is and ought to be a political decision.

Notwithstanding *Benzene* being weak precedent (not just because of the slim majority but also because of the absence of a solid majority opinion), the Court's finding that OSHA needed to demonstrate 'significant risk' before it could act ([6], p. 126; [4], p. 105) led to risk assessment becoming the standard for regulatory agencies. One particular important instruction given after *Benzene*, was the US Congress commissioning the National Research Council—NRC,

> To assess the merits of separating the analytic functions of developing risks assessments from the regulatory functions of making policy decisions
>
> To consider the feasibility of designating a single organisation to do risks assessments for all regulatory agencies
>
> To consider the feasibility of developing uniform risk assessment guidelines for use by all regulatory agencies.[9]

The ensuing *Risk assessment in the Federal Government: Managing the process*, more generally known as the Red Book, holds ten recommendations. The NRC itself acknowledged that risk assessment itself cannot be made completely free of policy considerations,[10] but nevertheless recommended that regulatory agencies take steps to establish and maintain a clear conceptual distinction between assessment of risks and the consideration of risk management alternatives. By that it meant that

> the scientific findings and policy judgments embodied in risks assessments should be explicitly distinguished from the political, economic, and technical considerations that influence the design and choice of regulatory strategies.[11]

[7] "In promulgating standards dealing with toxic materials (...), shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life."

[8] *Benzene*, note 6 above, at 687.

[9] Congressional directives to the NRC, as quoted in *Risk assessment in the Federal Government: Managing the process*, Washington, National Academy Press, National Academy of Sciences, 1983, p. 2.

[10] Ibidem, p. 151.

[11] Ibidem.

The report described the ultimate aim of risk management as being

> to evaluate trade-offs between health consequences and other effects of specific regulatory actions; this evaluation includes the application of value judgments to reach a policy decision.[12–13]

It goes on to warn against extra-agency separation of risk management decisions, arguing that direct communication with the risk assessors is desirable to ensure that the regulatory decision-maker understands the relative quality of the available scientific evidence, the degree of uncertainty implicit in the final risk assessment, and the sensitivity of the results to the assumptions that have been necessary to produce the assessment. Such separation could also impair the risk manager's ability to obtain assessments that are timely and in a useful form. (…) Because drawbacks are likely to be most pronounced in the case of extra-agency separation, the Committee does not believe that it is appropriate to remove the risk assessment function and place it in an organization completely separated from the regulatory agencies (…).[14]

On balance the Red Book does not, in this author's view, display a stubborn or 'highly objective' ([4], p. 110] understanding of risk assessment per se. Indeed the report points quite clearly to the assumptions and uncertainties which are inherent even in risk assessment insulated from societal input. It is precisely the reporters' concern that the ultimate act of risk management, with its non-scientific input, has a proper and complete view of the risk assessment stage (including all its inadequacies) that prompts them to advocate intra-agency decision-making. Clearly in the following decades, the size, shape and form of input from civil society have changed to such an extent that even well intentioned intra-agency input processes fall short of the requirements of participatory democracy. This has prompted the NRC effectively to update its recommendations, through what it now calls 'risk characterisation' [9].

Risk Assessment in the EU

European Institutions have only fairly recently started to consider the conceptual approach to risk analysis as carried out at the EU level. Three developments have arguably led to the current systemic approach to risk analysis at the EU: some high profile risk management failures at the national level, and the seemingly wanting interaction between the national and the EU level; the governance crisis at the EU level (to a large part unrelated to risk considerations); and the increasing recourse made by the EU to the precautionary principle.

National Risk Management Failures and Their Backlash at the EU Level

Generally, regulatory failures often drive regulatory developments. Little regulatory law is inspired by a purely academic risk analysis exercise. Quite literally, from the ashes of disaster grow the roses (whether or not thorny) of regulatory success. However the two most often cited drivers of the reform of the EU's risk analysis approach, the 1996 BSE crisis in the UK, and the 1999 dioxin contamination scandal in Belgium, have earned a somewhat higher gloss in the regulatory history in the EU, because they had a dramatic impact on the institutional arrangements at the EU level. In particular, the BSE and dioxin crises led to a considerable overhaul of the food law sector,[15] including a now more general recourse to regulatory agencies. The European Food Safety Authority—

[12] Ibidem.

[13] Consequently this would in the author's view not exclude consideration of e.g. environmental issues (stricto sensu, e.g. biodiversity). Hence while the USA may perhaps view 'scientific risk' as narrowly focused, risk assessment as understood by the Red Book can include a lot more than strictly defined laboratory risk (compare with [7]). Consequently rather than a conceptual change, US risk analysis may only require a change in practical approach, for it to respond to more 'modern' approaches to risk.

[14] Congressional directives to the NRC, note 9 above, pp. 152–153.

[15] While not mentioned by name in the EU Commission's early 2000 White Paper on food safety [COM (1999), p. 719], the mistakes made in the run-up to the *BSE* and *Dioxin* crises heavily inspired the integrated food chain safety approach of the White Paper and of the legislation that resulted from it: Regulation 178/2002 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: OJ [2002] L31/1.

EFSA was the first of a new 'breed' of regulatory agencies at the EU level, with a much more guarded autonomy and, arguably, the climax of the EU's belief in a more or less strict separation (institutionally speaking) between risk assessment[16] and risk management in particular, making EFSA the key player in risk assessment, and risk management and risk communication the domain of the European Commission together with the national authorities ([14], p. 154; [8], p. 194 ff.).

Tellingly, in its White Paper on food safety,[17] the Commission defines 'legislation and control' as the two components of risk management, and suggests that the inclusion of risk management in the mandate of what is now the EFSA would raise three 'very serious' issues:

> Firstly, there is a serious concern that a transfer of regulatory powers to an independent Authority could lead to an unwarranted dilution of democratic accountability. The current decision-making process provides a high degree of accountability and transparency, which could be difficult to replicate in a decentralised structure.
>
> Secondly, the control function must be at the heart of the Commission's risk management process if it is to act effectively on behalf of the consumer, notably in ensuring that recommendations for action arising from control are properly followed up. The Commission must retain both regulation and control if it is to discharge the responsibilities placed upon it under the Treaties.
>
> Thirdly, an Authority with regulatory power could not be created under the current institutional arrangements of the European Union, and would require modification of the existing provisions of the EC Treaty.[18]

Arguably, the first argument of the European Commission for keeping exclusive control of risk management, democratic accountability, is somewhat curious. The European Commission itself of course is not elected, neither are there any plans for changing this, and the very accountability problems at the Commission led to the current governance debate (more on that below). It has been suggested ([8], p. 195] that the failure to grant the EFSA risk management powers, is simply down to Commission and Member States reluctance to sign away regulatory power.

The creation of the EFSA, following national crises, undoubtedly has strengthened the risk management /risk assessment distinction at the EU level.

Governance and the Impact on Regulation

The European Commission suggested its own concept of governance in its April 2001 White Paper on European Governance, in which the term "European governance" refers to "rules, processes and behaviour that affect the way in which powers are exercised at [the] European level, particularly as regards openness, participation, accountability, effectiveness and coherence."[19] The governance White Paper was a reaction to the public backlash caused by, among others, misadministration at the top of the Commission and a general malaise in its accounting procedures. In many ways the initiatives following the White Paper are meant to reconnect a sceptic European public with the EU institutions. Of interest here are not so much the important considerations in the White Paper with respect to the review of regulatory instruments (including thoughts on the traditional theme of command and control viz new

[16] Article 3(10) of Regulation 178/2002 (note 15 above): 'risk analysis' means 'a process consisting of three interconnected components: risk assessment, risk management and risk communication'. Article 3(11): 'Risk assessment' means 'a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation'. Article 3(12): 'Risk management' means the process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options'.

[17] Note 15 above, p.14 ff.

[18] The latter element refers to the *Meroni* doctrine of the European Court of Justice, joined cases 9 and 10/56, *Meroni e Co, Industrie Metallurgiche, SpA v High Authority*. In contrast to the United States, the European Court of Justice (ECJ) has held, in a long line of case-law, that agencies cannot in principle be entrusted with powers that go beyond those for which they do not require discretionary assessment.

[19] *European Commission, European Governance—A White Paper*, COM (2001), p. 428.

regulatory instruments: see [13]) but rather the Commission's thoughts on expert advice.

The Commission highlights the increasing reliance, in the development of EU regulatory law, on expert advice, and the consequential need, given the focus of the White Paper, on public trust in that advice,[20] especially since it notes

> It is often unclear who is actually deciding—experts or those with political authority. At the same time, a better-informed public increasingly questions the content and independence of the expert advice that is given. These issues become more acute whenever the Union is required to apply the precautionary principle and play its role in risk assessment and risk management.

The Commission further referred to the new EFSA, which was being proposed at the time, and it announced the publication of guidelines on the collection and use of expert opinion. It duly published these in December 2002,[21] along with its 'Science and society action plan'.[22] Heterogeneity was one of the parameters put forward by the Commission, including a specific reference to ensuring (properly managed) input by 'maverick' scientists to challenge mainstream ideas.[23] The latter was a particular problem e.g. during the BSE crisis, when the relevant committees provided for self-interested bargaining, rather than the subjection of expert evidence to good argument, given that the relevant committees tended to be dominated by British experts, who inevitably had the most experience in the field, but, perhaps equally inevitably, brought with them the expectations of the Government which had most to lose ([5], pp. 86–87).

The Impact of the Precautionary Principle

The precautionary principle is of course quoted as the one distinguishing feature between the EU (and its Member States) and others. In this author's experience, the principle is best pondered by contrasting it with the prevention principle.

Principle 2 of the Rio Declaration:[24]

> States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental and developmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction.

Principle 15 of the Rio Declaration:

> In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

The prevention principle (principle of preventive action) obliges the authorities to take action at the earliest possible stage, if at all possible prior to any damage occurring, to prevent known risks from being realised. There is no undisputed definition of the precautionary principle. It is generally defined in a negative sense, in that according to the principle, States must not defer regulatory action even if there is no conclusive scientific proof between a given (in) action and damage to human health and/or the environment. The two principles at issue differ as follows.

As for the *content* of the principles, the classic method of distinguishing between them is by describing them in terms of risk analysis. The principle of preventive action deals with known risks; the link between certain activities or occurrences and environmental damage occurring, is certain, and States are obliged to prevent the damage from occurring. The precautionary principle by contrast deals with *uncertain* risks. For the activities concerned, there is

[20] White Paper on Governance, note 19 above, p. 19.

[21] Communication from the Commission on the collection and use of expertise by the Commission: principles and guidelines (improving the knowledge base for better politics), COM (2002), p. 713.

[22] COM (2001), p. 714.

[23] Note 21 above, p. 16.

[24] *Rio Declaration on Environment and Development*, UN doc A/CONF.151/26 (Vol.1), available via http://www.un.org/documents/ga/conf151/aconf15126–1annex1.htm.

no watertight proof that a given human activity causes damage; indeed there may in some cases not even be a proof of damage. Evidently, this distinction works as a core introduction to the precautionary principle, but does not carry much further than that. Indeed fully known risks are extraordinarily rare.

Importantly, the *legal weight* of both principles also differs. The prevention principle, in its international context, is part of public international law. It is an application of *sic utere tuo ut alienum non laedas*, which is a natural limit to the sovereignty principle as set out above, and explicitly recognised for instance in the *Trail Smelter* arbitrage.[25] The legal nature of the precautionary principle, on the other hand, is disputed. A number of Treaties include the principle, and it is certainly a general principle within certain regional context, such as in particular the European Union.[26] But it is arguably too early to refer to the principle as being part of public international law.

Early 2000, the Commission adopted a Communication on the precautionary principle, which was designed in particular to ease tensions with the USA[27] and which arguably may be called the highest-profile exercise so far to try and translate the principle into specific guidelines.

Importantly, the Communication was initially sponsored in particular by the trade directorate-general at the European Commission. Sir (now Lord) Brittan, the then trade Commissioner, launched the Communication as a handbook for the use of the principle in EU risk analysis, with a view to reassuring the Union's trade partners that recourse to the principle was not haphazard, unpredictable, and therefore, arguably, a violation of international trade agreements, but rather well thought-through and systematic.

The Commission insists in this document that the precautionary principle in its European context is a justified part of risk management. The latter, the Commission insists, is not a purely scientific exercise but to a considerable degree a policy process. The communication details that any measures taken on the basis of the principle have to be proportionate vis-a-vis the level of environmental protection sought; that they must not be discriminatory in their application (in particular vis-a-vis the trading partners of the EC), that they have to be consistent with any measures which have already been taken; (consistency); that they have to be based on technical analysis and, where possible, economic cost and benefit analysis; and that they have to be subject to constant monitoring and evaluation, including potential review (in particular with a view to integrating potential new scientific developments).

Even where the international community has agreed to a definition, such as in the Rio Declaration, the principle is often softened by reference to cost-effectiveness etc. See e.g. Principle 15, recalled above:

> In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

The reference to a State's capabilities mainly refers to another principle, included below, namely the principle of common but differentiated responsibilities. It is of course also a reflection of the very notion of sustainable development, as set out above, namely the three-pillar approach, implying that state-of-the-art environmental regulation cannot be achieved at all cost, and in particular not when the State involved has no economic cloud to back it up.

The reference to cost-effectiveness implies a notion of environmental standards generally known (especially in the EU) as 'BATNEEC': Best Available Techniques Not Entailing Excessive Costs, and potentially massively curtails the impact of the precautionary principle on developing countries. However it is in a rather developed country that effectiveness was coupled with opposition to the precautionary principle. In the USA, the 'no regrets doctrine' was developed by the Bush (Sr) Administration—and taken up by the subsequent Clinton administration—in response to early European action to combat climate change. Bush Sr argued that in the face of uncertainty, rather than taking precautionary action which often implies a high degree of uncertainty, the US should only advocate taking measures which it would never come to regret. This would include for instance energy savings measures which, if climate

[25] US v Canada, 3 RIAA (1941) 1907.

[26] See for a particularly lucid overview [3].

[27] COM (2000), p. 1.

change were proven a fad (or uninfluenced by human behaviour) would have had the certain, cost-effective benefit of saving energy and, which if climate change were proven true and man-influenced, would have been at least a partial response to the phenomenon.

That the precautionary principle should meet with more opposition than the prevention principle cannot in fact be blamed on the failure of the international community to define the former unequivocally. In particular, whilst the prevention principle is undisputed in its definition and legally binding character, it is actually flouted on a daily basis: Indeed every and any industrial activity causes pollution, and evidently not all of that pollution is prevented or even mitigated, neither does every pollution caused by one State on the territory of another lead to action in the courts. Obviously a *modus operandi* has been reached through which, depending on the circumstances, an acceptable level of pollution is defined in international treaties, in regional law (e.g. EU law) or indeed by implicit arrangement.

In summary, there is plenty of uncertainty in the prevention principle, too, however this has not hampered its development as a binding principle of international environmental law. Consequently, while the precautionary principle may usefully be quoted as a focal point for the divide between in particular the United States and the European Union, in reality the dichotomy between the USA and the EU in terms of risk analysis, goes further than that, and certainly deeper than the belief as to whether the precautionary principle is a binding principle of international law.

In particular the EU and its Member States view risk analysis as a linear process, in which the various steps of a risk analysis process (see above: risk identification, risk assessment, risk management, and risk communication), are neatly divided. Importantly, the EU assigns the responsibility and the main lead in each of these steps to different professional groupings. Whilst the steps of risk identification and certainly that of risk assessment are a responsibility of scientists, the step of risk management is very firmly seen as a *political* step, in which elected politicians on both the national scene and the European scene, take the lead. This preponderant role of politicians in risk management makes the process prone, so its critics say, to being susceptible to scaremongers, and to recourse to the precautionary principle.

Hence it is more likely that the general outlook on life and risk is determinant for the regulatory approach of these States, than their belief as to whether the precautionary principle as part of the law of sustainable development is legally binding or not.

EU Risk Analysis and Nanotechnologies: Are They Being Stifled?

How does all of the above relate to the debate on the future of nanotechnology?

The Biotech Experience

First of all, there is a tempting analogy with biotechnology regulation. This has not escaped the attention of many commentators. From an emerging technology point of view, biotech regulation in the EU has certainly failed. Regardless of whether one wishes to push the technology or not, the process leading to the current biotechnology regulation was flawed and lessons need to be learned. One obvious feature of the process at the EU level was the vivid headlines that emerged in the EU's popular press (with the UK's tabloids taking the lead) and the emergence of the notorious Frankenfood headline. Whether these headlines encouraged rather than fed on politicians' mistrust in the technology is not clear to the author, neither is it relevant for the purpose of this contribution. What is clear is that on the waves of popular mistrust of biotechnology, a large number of Member States stalled marketing approval for GM foods and feeds, leading the regulatory process into a comitology loop and regulatory uncertainty of a prolonged nature. Indeed it is important to point out that the current regulatory regime for approval of marketing GM technology in the EU still rests upon the precautionary principle, given the absence of certainty with respect to the long-term impact of the technology on human health and the environment. The rollout of biotechnology in the EU has been smothered, not *because of* the precautionary principle, but rather as a result of that principle being employed by national governments in a tussle over regulatory priority with the Commission. That is exactly why the EU were condemned by a World Trade Organisation Panel under the terms of the Agreement on Sanitary and Phytosanitary Agreement—SPS: it rebuked the

EU for the 'undue delay'[28] in its SPS measures caused by the national de facto moratoria on the technology.[29]

It's the Uncertainty, Stupid

Arguably, regulatory uncertainty and delays at the EU or any other level smothers new technologies, rather than the lax or stringent content of that eventual regulatory regime. The intervention of the precautionary principle in this view, to the extent it impacts on the content of the regime, is hence not necessarily a technology killer. The exception to that evidently are those instances where the principle is being called upon completely to prohibit a given technology, whether or not until certainty has been established. Such application of the principle takes it to its most extreme form, which may not be advocated by many but does lead to mistrust of the principle in a large section of the scientific community. Indeed the exercises are popular in which scientists are asked to name long-existing and crucial technologies which would not have made it beyond the idea stage, were the precautionary principle (in its technology killer format) to have been around at the time of their invention.[30]

It is also noteworthy that even though this author argues that the rigour of a regulatory regime is less damaging to new technologies than prolonged uncertainty, extensive regulatory requirements may have a disproportionate impact on small and medium-sized companies, which typically have less critical mass (both in terms of finance and in terms of staff) to deal with extensive testing and compliance requirements. This is a particular concern, for instance, should REACH, the new chemicals regime of the EU, be rolled out for nanotechnology [2].

Current Challenges and Dangers for Nanotechnologies

The signs are that the EU is treading cautiously in developing the regulatory framework for nanotechnology. Neither the Commission nor indeed the European Parliament, let alone the Member States, are contemplating a moratorium on the technologies, or similar kinds of drastic action. Rather, in its various action plans [10] (which typically do not reflect on the regulation of the technology as the main priority, rather on the roll-out and research and development), the Commission has emphasised the need for a comprehensive risk assessment exercise, starting with a thorough review of current risk assessment methodologies, and their suitability to nanotechnologies.

Considerable work has been done in this area by the EU's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) which identified large gaps of information and hence reads like a giant in-tray. Some of these are meant to be addressed by funding under the seventh European Union framework program for research and development, and funding mechanisms throughout the world are providing similar incentives.[31]

However some formidable challenges remain.

Firstly, of particular importance in assessing the risk management of nanotechnology is its 'converging technology' nature. A good example of this nature lies within the electronics sector. 'Nanoelectronics' is based on the synergy between electrical engineering, material science, physics, chemistry and biology—the results of such synergy are labelled 'converging technologies'. The first three disciplines employ a 'top-down' approach to achieve nanometre dimensions: increasingly precise manufacturing and finishing of materials. The other sciences use a 'bottom-up' approach in which macrostructures are built from individual atoms and molecules. The expectation is that these two opposite approaches will converge in the field of nanoelectronics where expertise from all disciplines is brought together. Cross fertilization between top-down and bottom-up approaches will

[28] This is a technical term in the Agreement, obliging the WTO Members to 'undertake and complete' procedures leading to sanitary and Phytosanitary measures without undue delay.

[29] Reports of WTO Panel in "European Communities—Measures affecting the approval and marketing of biotech products", DS291, DS292 and DS293.

[30] Electricity, X-rays, sonar and the like being popular choices: see e.g. Starr, S., *Science, risk and the price of precaution*, quoted in [12], p. 25 (footnote 58).

[31] Scientific Committee on Emerging and Newly Identified Health Risks—SCENIHR, modified opinion (after public consultation) on the appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies, SCENIHR/002/05.

hopefully give birth to novel information communication technologies (ICT) and generic technologies for enhanced environment and human health monitoring. From an application point of view, this would seem extraordinarily promising. From a risk management viewpoint it is extraordinarily challenging. Not only does the management of the risks posed by the various scientific disciplines require these various disciplines to 'speak' to one another as to the potential hazards of the application. Each of them also poses specific challenges from the ethical angle, and advances perceived in one discipline may moreover lead to increased risks in another (see also [11]). The challenge of risk analysis in general has left the sphere of individual responsibility, and has been projected into the collective sphere, as technological advance and specialisation means that individual scientists can hardly foresee the consequences of their discoveries for related fields ([16], p. 6), as indeed vividly illustrated by nanotechnologies.

Further, paradoxically, in the author's view, one is faced with quite a challenge when it comes to engaging public opinion in the regulatory debate on nanotechnologies. As noted above, Member States' agendas in the biotechnology debate were to a large extent if not driven by, then at least accompanied with screaming headlines in the European media. Subsequent attempts, in particular in the United Kingdom, to engage the public proactively through vast road shows, even if they yielded result (which in itself is uncertain), evidently cannot be repeated for every new technology that emerges. At the moment the European debate is strangely free from controversy, which this author at least watches with anxiety. Arguably, the involvement of public interest groups in the regulatory debate is a measure of general interest in the issue. Using that yardstick, things are not looking to good in the EU. Interest groups in the USA have been far more involved in the regulatory debate, making it more adversary and leading to a more participatory form of rule making from the start.[32]

In the EU, whilst there is no contemplated effort to avoid the debate, let alone sabotage it, public discussions are being held at a much more mundane pace. Theoretically, as has indeed been suggested by the European Commission, it would seem advisable to await the outcome of risk assessment prior to designing the regulatory answers to any identified risks. However this author would rather have the public discover nanotechnology soon, rather than waiting for an incident or cultural event (such as a novel, or a film) à la Frankenfood which would capture the public's imagination for the wrong reasons.

The negotiation of REACH did, albeit very lately, provoke lobbying of a number of NGOs with a view to introducing nano-specific provisions in the Regulation.[33] Whilst ultimately unsuccessful, this attempt did raise the profile of nano-regulation, albeit for the moment to specialists and EU-anoraks only.

Conclusion

This contribution has *inter alia* reviewed the *Benzene* judgment of the US Supreme Court, and has recalled the late Chief Justice Rehnquist's view on the absence of authority of the courts in 'making the hard choices', also with respect to risk analysis. Rehnquist's view was not carried though in the final decision, however arguably lies conceptually very close to the mainstream European Union view on risk management in particular. Namely that this step in risk analysis ought to be the domain of elected politicians rather than regulatory agencies or indeed the courts.

With the current view among public opinion in the EU largely risk averse, the EU has a propensity to be cautious, ultra-cautious or indeed precautious vis-a-vis new technologies. Depending on one's view, that does indeed tend to smother the latter before they have an opportunity to come to fruition. However in the particular case of nanotechnologies, there are no signs of any propensity in the EU to walk the extreme

[32] With a healthy dose of discussion among NGOs themselves, including with respect to the *pros* and *cons* of extensive proactive involvement in particular of NGO *Environmental Defense*: see the Environmental Defense/DuPont nano partnership: http://www.environmentaldefense.org/documents/5989_Nano%20Risk%20Framework-final%20draft-26feb07-pdf.pdf.

[33] Friends of the Earth Europe (2006), *REACH and nanotechnology—briefing*, 5 October, Brussels: FoE Europe, p.1, and proposed Amendments 87, 115, 158, 160, 217, 228, 325 and 333, accepted by the Environment Committee (European Parliament (2006), *Recommendation for Second Reading*, 13 October, Amendments 24, 56, 79, 87, 161 and 165) but not by the Parliament in plenary.

precautionary path which some advocate. Rather, the EU are currently sponsoring an impressive data gathering exercise in which traditional methods of risk identification and risk assessment are challenged by the nano qualities of the materials and applications under research. Public opinion, whipped up by media frenzy of, as yet unrealised, nano 'darkness', may still act as a dark horse in the risk analysis process. Hence timely and complete participation of the public is of huge importance, if one is to avoid a repetition of the regulatory sclerosis faced by biotechnology.

Acknowledgement Many thanks to an anonymous reviewer for comments on an earlier draft.

References

1. Beck U (1986) Risikogesellschaft. Auf dem Weg in eine andere Moderne. Suhrkamp, Frankfurt
2. Bowman D, van Calster G (2007) Reflecting on REACH: Global implications of the European union's chemicals regulation. Nanotechnology Law and Business 4(3):375–384
3. Fisher E (2002) Precaution, precaution everywhere: developing a 'common understanding' of the precautionary principle in the European community. Maastrich J Eur Comp Law 9:7–28
4. Fisher E (2006) Risk and environmental law: a beginner's guide. In: Environmental law for sustainability. Hart, Oxford, pp 97–125
5. Lee M (2005) EU environmental law—challenges, change and decision-making. Hart, Oxford
6. Linet M, Bailey P (1981) Benzene, leukemia, and the supreme court. J Public Health Policy 2(2):116–135
7. Marden E (2003) Risk and regulation: US regulatory policy on genetically modified food and agriculture. Boston Coll Law Rev 44:733–787
8. O'Rourke R (2005) European food law. Sweet & Maxwell, London
9. Stern P, Fineberg H (eds) (1996) Understanding risk: informing decisions in a democratic society. National Academy Press, Washington
10. Oud M (2007) A European perspective. In: HodgeGA, BowmanDM, LudlowK (eds) New global frontiers in regulation: the age of nanotechnology. Edward Elgar, Cheltenham
11. Sunstein C (1996) Health–health tradeoffs. The University of Chicago Law Review, Chicago, p 1533
12. Sunstein C (2005) Laws of rear. Cambridge University Press, Cambridge
13. Van Calster G (2006) Governance structures for nanotechnology regulation in the EU. Environmental Law Report, pp 10953–10957
14. Van der Meulen B, Van der Velde (2004) Food safety law in the European Union. Wageningen Academic, Wageningen
15. Vogel D (2003) The politics of risk regulation in Europe and the United States. Yearbook of European Environmental Law 3:1–43
16. Von Schomberg R (2007) From the ethics of technology towards an ethics of knowledge policy and knowledge assessment, working document, January 2007, Publication series of the Governance and Ethics Unit at DG Research, European Commission