

**Regulation, Regulators, and the  
Crisis of Law and Government**

## The Risk Versus Hazard Debate:

Reconciling Inconsistencies in Health  
and Safety Regulation within the UK  
and across the EU

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## Executive Summary

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- It is evident that inconsistencies exist across the European Union (EU) in relation to the regulation of certain substances and/or activities. These inconsistencies arise due to member state variations in the approach of classifying what is a risk versus what is a hazard. EU policymakers face a challenge to consolidate the varying approaches that can result in certain products and/or activities categorized as a risk in one member state and banned as a hazard in another state. These challenges have given rise to the debate surrounding risk versus hazard classification approaches, which stakeholders from academia, regulatory bodies, law, policy, and industry can provide some key insights into, and generate recommendations for the resolution of existing inconsistencies.
- There is general consensus that there needs to be renewed consideration of European-wide risk regulation to ensure that decisions are being made based on the best available science, and that ultimately any legislation passed is more scientific and risk based.
- Successful implementation of a risk-based approach to regulation is dependent on a balance between socially acceptable levels of risk and benefit trade-offs on the one hand, and the socio-economic impacts of regulating or banning substances and/or activities on the other. A shift towards risk-based regulation must be able to communicate from an evidence-based position that avoiding the risk altogether may increase exposure to other risks; however, social trust is needed if this concept is to become established.
- The role of the courts should be to define what is meant by risk and hazard classifications. In this regard, the courts are responsible for making delicate value judgments of risk in relation to probability, tolerability, risk/benefit trade-offs, and social acceptance of harm. They must avoid defining risk in absolute and unreasonable terms, and judge when to intervene to uphold their value judgments.
- Successful consistent implementation of a risk assessment approach requires more productive efforts at proactive communication. Effective communication can help promote the public trust needed for a European-wide risk-based approach, and research initiatives must get underway to ensure this is carried out appropriately.
- Social intolerance of exposure to risks can also be addressed through initiatives in education, leadership, and media reform. These considerations can lead to public acceptance and support of policies made based on the best available evidence. Steps towards this type of an approach have been seen and continue to be seen in the UK.

# The Risk versus Hazard Debate:

## Reconciling Inconsistencies in Health and Safety Regulation within the UK and across the EU

### Introduction

On 12 October 2011, the Centre for Socio-Legal Studies of the University of Oxford, in partnership with the Foundation for Law, Justice and Society and the British Safety Council, convened a panel discussion entitled 'Risk Versus Hazard: Hypocrisy in Policy'. The panel was moderated by Professor Denis Galligan and comprised Professor Ragnar Löfstedt, director of the Kings Centre for Risk Management at Kings College London; Mark Tyler, leading UK health and safety lawyer and partner at Shook Hardy & Bacon; Lynda Armstrong, chair of the British Safety Council; and Dave Bench, chief scientist of the Health and Safety Executive (HSE).

The purpose of the panel was to shed light on the apparent inconsistency in the classification of products and activities as risks versus hazards across the European Union member states. Classification as a risk as opposed to a hazard has several implications for regulation, particularly across borders when the same product or activity is labelled as a risk in one country, but a hazard in another member state. Inconsistency in regulation has come under considerable scrutiny, with the debate founded on whether regulations should be based on a hazard or risk assessment, and how such classifications may be applied consistently across the European Union.

### The Risk versus Hazard Debate

Since the early 1970s with the formation of environmental and health and safety regulatory agencies in many European states, there has been growing debate about how best to regulate substances (such as chemicals including metals, food additives and preservatives) and human activities as risks or hazards. The key component of this debate is whether regulatory decision-making can and should be based on hazard classification alone, foregoing risk assessment.

From an economics perspective, decision-making on the basis of hazard classification alone largely neglects impact assessment (the process that prepares evidence for political decision-makers regarding the advantages and disadvantages of possible policy options by assessing their potential impact)<sup>1</sup> and in doing so often results in poor regulatory policymaking.<sup>2</sup> This raises the question as to why strictly hazard-based classifications are still being made, and the extent to which confusion between the terms 'risk' and 'hazard' may play a role.

### Defining 'Risk' and 'Hazard'

In order to understand the nuances of this debate it is necessary to make the technical distinction between the terms 'risk' and 'hazard'. A hazard classification refers to the potential for a substance to cause harm, while a risk assessment refers to the combination of the likelihood of, and the severity of, a substance's potential harm.<sup>3</sup> Despite this clear distinction in how a substance or activity may be approached in terms of regulation, it is evident that confusion still exists amongst policymakers regarding the meaning of the two terms. Distinction between risk and hazard is particularly blurry outside of the United States (where the majority of empirical risk and hazard research is conducted). The implication for this confusion for Europe in particular is the potential intentional or unintentional misappropriation of the terms in regards to product and/or activity classification and subsequent regulation.<sup>4</sup>

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1. More on impact assessment at [http://ec.europa.eu/governance/impact/index\\_en.htm](http://ec.europa.eu/governance/impact/index_en.htm)

2. Löfstedt, R. (2011) 'Risk Versus Hazard; EU Requires a Fundamental Rethink of Risk Policy'. *Chemical Week*. Available at: [http://www.chemweek.com/chem\\_ideas/Guest-Author/37786.html](http://www.chemweek.com/chem_ideas/Guest-Author/37786.html)

3. HSE Code of Practice accompanying the Management of Health and Safety at Work Regulations.

4. Löfstedt, R. (2011) 'Risk Versus Hazard; EU Requires a Fundamental Rethink of Risk Policy'. *Chemical Week*. Available at: [http://www.chemweek.com/chem\\_ideas/Guest-Author/37786.html](http://www.chemweek.com/chem_ideas/Guest-Author/37786.html)

### Policy Challenges

Confusion between the terms 'risk' and 'hazard' can lead to arbitrary decision-making on hazard classifications and risk assessments for a substance or an activity, and, consequently, inconsistent regulations across EU member states and regulatory bodies. Examples include the European foods regulatory bodies favouring the use of risk assessment while other sectors may prefer hazard classifications and the United Kingdom's adoption of a more risk-based approach than Sweden, which favours impact assessment.<sup>5</sup> Furthermore, it is alleged that member states in the European Union may arbitrarily choose risk versus hazard classifications of products and/or activities when it is politically suitable.

The primary question arising from this debate is how to prevent confusion between what is meant by *risk* and *hazard* and to ensure that the regulations coming out of the UK and European Union are not made based on arbitrary hazard or risk classifications, but are rather made as a result of an evidence-based approach. In order to address these questions, one must consider how Europeans regulate risks. Do some nations and/or regulated sectors prefer hazard classifications over risk assessments? What are the differences in risk versus hazard classification across borders and regulatory sectors?

Additionally, in regards to addressing European-wide consistency, one must consider the role of the courts. The following questions arise in relation to the role of the courts: how do the courts define risk? Have risk and hazard been conflated by the courts? Should the courts even be involved in the science of risk? If not, who or what body is held accountable for any negative outcomes resulting from inappropriate categorization and the regulation that results?

This policy brief will examine these questions in turn from the perspectives of the panellists from the 12 October panel discussion. The ultimate purpose of this brief is to offer recommendations towards a

consistent European-wide approach towards evidence-based regulation.

### Risk- and Hazard-Based Approaches to Regulation

Whether or not to steer regulation towards a risk- or hazard-based approach has been in debate across the European Union member states and across regulatory regimes. In a paper titled 'Risk versus Hazard – How to Regulate in the 21st Century',<sup>6</sup> Professor Ragnar Löfstedt describes the 'rather long and at times acrimonious discussion' of the merits of risk assessments for regulatory purposes, with particular regard to chemical substances. The lack of any consensus over use of risk assessments and hazard classifications may be due in part to the cultural and historical differences between member states. Löfstedt explains that Austrians, for example, are much more comfortable using hazard assessments than risk assessments when it comes to regulating genetically modified foods than the Spanish. Similarly, the Swedes are more comfortable calling for bans for chemicals based on hazard assessments than, for example, the British.

In addition to culturally motivated toleration of risk, a lack of consensus across EU member states may also be attributed to the belief that the terms are interchangeable, or confusion over the exact meaning of the terms in question. At the panel discussion in Oxford, Dave Bench explained:

*We [the regulators] seem to have become confused about the difference between risk and hazard. We have become lazy in our usage of terminology and often use one word when what we really mean is the other. Muddled thinking can lead to believing, mistakenly, that the only way to reduce risk is to reduce or remove the hazard, when we can manage or reduce risk by leaving the hazard unchanged but controlling or reducing its exposure.*

5. Ibid.

6. Löfstedt, R. (2011) 'Risk versus Hazard – How to Regulate in the 21st Century', *European Journal of Risk Regulation* 2: 149-68.

Despite this potential for confusion, attempts to reach consistent European-wide regulations have been made in certain sectors, such as the directly applicable European regulation that came into force in June 2011 for pesticides. This introduces the concept of 'hazard triggers', whereby any company wishing to put a substance on the market has to pass hazard tests before going through some degree of risk assessment, although the definitions of these hazard triggers requires some refinement yet.

Bench explained that, without further clarity in the definition of hazard triggers, regulators may feel impelled to take products off the market, and that research into risk trade-offs is necessary to avoid an unintended increase of risk in an unforeseen arena or manner. In the United Kingdom, the Health and Safety Executive (HSE) tested this measure by producing its own impact assessment of hazard triggers for specific substances to evaluate the potential consequences, citing levels of uncertainty. It was found that the HSE in the UK favours a risk-based approach as opposed to dealing with hazard trigger requirements, indicating the need for more defined and sensible European-wide legislation proposals.

Lynda Armstrong described how the British Safety Council (BSC) plays their part in helping to prevent an excessively cautious approach to risk, whether in the workplace or in society more generally. This is done through audits, which help leaders to understand the hazards they face and how to proportionately manage the risks of injury and ill health in their respective workplaces. Audits fulfill the important role of providing the means of assessing the effectiveness of the systems that are in place and identifying where improvements can be made, and as such, must be carried out by experts who recognize that less regulation is appropriate where hazards and risks are low.

Evidence produced from audits may not be enough to ensure public support for less regulation if such a finding is reached. While it is necessary to consider the best available evidence to understand the socio-

economic impacts of regulating or banning substances and/or activities, in the event that evidence supports a risk-based approach (as appears to be the case in pesticides regulation) then any shifts in regulation must still take into account societal expectations. While immense leaps in technology and innovations have resulted in societal benefits, there exists varying tolerability for the accompanying risks.<sup>7</sup> Successful shifts in regulation demand consideration of the societal expectations regarding risk and benefit trade-offs, and steps to increase social tolerability of risk should be taken when necessary, based on the best available evidence. Recommendations on how to do so are discussed throughout the remainder of this policy brief.

### *Motivations and Consequences of a Hazard-Based Approach to Regulation*

The previous section has described the decision-making from which derives a risk- or hazard-based approach to regulation. While such decisions can be shown to derive from the best available evidence, it does not necessarily follow that they will be accepted by special interest groups or the public at large. Ragnar Löfstedt argued that some EU member states arbitrarily choose risk or hazard classifications of products and/or activities according to political expediency, to avoid imposing unpopular regulation: 'Currently, multiple actors at different member state and European levels are pushing their own views and opinions of how regulations should be formed, resulting in the passing of bans/directives and regulations that are at times hazard based and at other times risk based'.

Dave Bench confirmed that, in Europe, this has resulted in a tendency to adopt hazard-based regulation, since this is easier for politicians to sell to a general public not necessarily well versed in the subtle nuances of the debate.

Löfstedt further went on to explain that this approach can exclude 'real world' information about

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7. Beck, U. (1992) *Risk Society*. London: Sage Publications.

the real likelihood of harm, and could lead to the banning of a wide array of substances, ranging from petrol to cars, even to computers. One of the main problems with hazard classifications is that they are only one initial component of the risk analysis, and policymakers can take the decision to ban certain chemicals and metals on the assumption or idea that they may be hazardous without testing whether this is actually the case.

Löfstedt explained that many officials in the European Commission are concerned about this too, recognizing that a hazard-based approach takes away the scientific rigour of risk assessments. They also allow regulations to be de facto based on the cultural norms and histories of certain member states. Risk assessments, on the other hand, examine the weight of evidence as to whether a hazard actually exists, and often provide a quantitative indication of the probability of various outcomes, including a characterization of the severity of the possible consequences.

### **The Move Towards a Risk-Based Approach**

It is evident from the debate that the panellists agreed that an evidence-based approach for the regulation of risk is the most appropriate way forward for Europe-wide health and safety regulation. The current regulatory environment applies risk- and hazard-based approaches inconsistently across the European Union. Consistent application of evidence-based decision-making, following the appropriate peer review, can result in consistent application of risk versus hazard approaches to regulation. Ragnar Löfstedt stated, 'What is needed is a fundamental rethink of European risk policy to ensure that, as we go forward, it is based on the best available science'.

Dave Bench supported the development of European-wide legislation that is more scientific and risk based, recommending that regulators take measured risks, look for and recognize the hazards in new and novel technologies, and manage the risk where possible. Avoiding the risk altogether is not a solution since it may result in exposure to other unintended risks.

He described how, within the UK, risk assessment and management has been a central approach to health and safety regulation for many years. The UK has a strong regulatory framework built upon principles of risk management that span a wide range of industries. A risk-based approach can be applied just as easily to longstanding industrial processes as to new and emerging technologies. Even if the hazards are not fully known or understood, the risk can still be managed or reduced by control of the level of exposure.

Lynda Armstrong described the British Safety Council's view that, regardless of the type of policy passed, it is essential that such policy and law-making is informed by the relevant knowledge, which, for the UK at least, demonstrates that risk can be managed while many hazardous operations are still enabled to take place.

The move towards a wider risk-based approach requires careful consideration of social tolerability of risk.<sup>8</sup> In order to convince the public to increase their appetite for risk, public trust and confidence in the regulators is essential, which in turn is only possible through a system of checks and balances provided by the courts.<sup>9</sup> Even with perfect implementation of an evidence-based approach and consideration of public perceptions of risk, the courts must be available for when the regulators from time to time make the wrong decision. In addition to the role of courts, there must be increased attention to the role of risk communication in promoting trust and understanding, as well as public and workplace engagement.<sup>10</sup> Both the role of the courts and the role of risk communication towards establishing public trust are examined in turn.

8. Boudier, F. et al. (eds.) (2007) *The Tolerability of Risk: A New Framework for Risk Management*. London: Earthscan.

9. Löfstedt, R. (2005) *Risk Management in Post-Trust Societies*. Basingstoke: Palgrave/Macmillan.

10. Löfstedt, R. (2011) 'Risk versus Hazard – How to Regulate in the 21st Century'. *European Journal of Risk Regulation* 2: 149-68.

### *The Role of the Courts*

In defining the role of the courts, it necessary to determine at the outset what the courts should definitely not become involved in – namely, regulatory decision-making. Dave Bench illustrated this point by describing a time when the UK government took the HSE to judicial review over the way it operated its risk assessment on bystander exposure to pesticides. The judicial review went to the High Court under the allegation that Bench's teams were not operating bystander exposure assessment in accordance with the then relevant piece of European legislation referred to as 'the directive'. Bench expressed incredulity as to 'why on earth the high court would agree to take this judicial review at all'. His reasoning was grounded in the fact that the allegation concerned the technical issue of how a regulator decides to apply a piece of legislation, and traditionally courts would not get involved in regulatory decision-making. Despite this, the court ruled against the HSE's application of the directive, although when the decision was appealed, the regulator's position was supported. The court stated that the regulator's decision-making regarding the application of a particular model (as long as appropriately considered by the regulator as suitable for estimating exposure) is ultimately in the jurisdiction of the regulator. This ruling proved favourable for the HSE and established more generally that it is up to the regulator, not the courts, to decide what is a suitable approach or an appropriate model for relevant regulatory purposes.

Bench described the final ruling as a 'common sense conclusion', although it is not insignificant to note that this was only reached after three years and a cost to the taxpayer of £2 million.

Rather than take on responsibilities of the regulator, the role of the courts should be to define what is meant by risk and hazard classifications. Mark Tyler described the difficulty of finding cases defining risk (besides the modern ones under the Health and Safety at Work Act 1974), but cited *Bolton v Stone*,<sup>11</sup> a

case about a cricket ball being hit out of a ground and hitting someone in a road nearby, which was decided in the UK in 1951. While the judge had thrown the case out, the Court of Appeal disagreed and awarded damages. It then received consideration by the House of Lords, then the highest appellate court, which decided the Court of Appeal had got it wrong. The House of Lords stated that it was not enough to show something may *possibly* cause injury if it happens, such as a ball going over the fence, but that greater probability must be shown. It was stated, 'Life would be almost impossible if one were to attempt to take precautions against every risk that one can foresee'.

Tyler argued that this judgment is very much in accordance with the 'common sense' viewpoint and quite emphatically (though not explicitly) rebuked any notion that the law should be concerned with regulating or assigning liability on the existence of hazards. However, he argued that the approach to risk took a wrong turn some forty-two years later when the Court of Appeal had to address itself to risk, albeit in a different context. This time it was in regard to an appeal against a Health and Safety at Work Act conviction for the Science Museum.<sup>12</sup> The HSE had brought a case under Section 3 of the Health and Safety at Work Act which stated: 'It shall be the duty of every employer to conduct his undertaking in such a way as to ensure, so far as is reasonably practicable, that persons not in his employment who may be affected thereby are not thereby exposed to risks to their health and safety'.

The prosecution set out to prove the Science Museum had exposed members of the public to legionella bacteria at certain times, which proved to be unfounded. The prosecution then changed its case, claiming that they only had to prove that there could have been a danger, and the burden shifted to the defence to show they had done all that was reasonably practicable. The judge allowed the case to continue and the Science Museum was convicted and fined a nominal fee, suggesting the court's genuine

11. [1951] AC 850.

12. *R v Board of Trustees of the Science Museum* [1993] 3 All ER 853.

attitude towards the case. Tyler explained how this case echoed the precautionary principle in that it applied weakly to the possibility of harm, and pointed out the difficulty of reconciling this case with the principles widely accepted in the risk community, that a risk is not the same as a hazard.

Tyler explained how courts have repeatedly stated that the policy goal of preventing accidents in the UK statutory regime justifies a zero tolerance approach to risk at work. Looking at this in terms of compensation claims, a social judgment can be inferred that injured people should receive compensation, irrespective of considerations of foreseeable probability prior to the event. However, this has a huge practical significance to people who are charged with risk management duties if one cannot distinguish between risk and hazard.

This 'possibility of danger' definition of risk is cited in virtually every large-scale health and safety prosecution, but only recently have the higher courts begun to reassess its implications and try to modify how risk should be assessed.

Tyler continued by describing legal inconsistencies across sectors, illustrated by *Dugmore v Swansea NHS Trust*,<sup>13</sup> a case under the chemicals regulations known as COSHH. The claimant of the COSHH regulations succeeded, and the employer's duty was defined as, to 'ensure that exposure to a substance hazardous to health is either prevented or, where this is not reasonably practicable, adequately controlled'. The courts here found that a case for uncontrolled exposure was enough for liability. Tyler provided this example and others to show that there is no coherent theory of risk in health and safety law, let alone wider law.

Tyler also provided an example of a case alleging lack of risk foresight. The outcome of *R v Porter*<sup>14</sup> can be summed up in the following: 'What is important is that the risk which the prosecution must prove should

be real as opposed to fanciful or hypothetical... There is no obligation under the statute to alleviate those risks which are merely fanciful'.

This case and others illustrate that prosecution should not be undertaken for a risk that would reasonably be considered to be fanciful and/or trivial. In conclusion, Tyler stated,

*I say with reservations about how long it may take us to get there that we appear to be heading back to the golden age when the courts saw their role as being to treat risk not as an absolute concept but one which involves value judgments – often very delicate ones – of foreseeability, tolerability, risk/benefit, and social acceptance of harm. These are value judgments the Court should not duck, or else we have to accept a hazard-based system of liability in many criminal and civil cases.*

As described in this section, it is the role of the courts to militate against the defining of risk in absolute and unreasonable terms. The courts' role is not to get involved in regulatory decision-making, but rather provide a backstop for society when value judgments related to risk are grossly unheeded. The knowledge that legal mechanisms are in place for public interest can help support social acceptance of potentially increasing risk tolerance. This infrastructure, as well as the role of communication discussed next, can aid a policy shift towards evidence-based decision-making.

### **The Role of Risk Communication**

The role of communication in moving towards a risk-based approach was discussed by all participants during the discussion. Ragnar Löfstedt explained that efforts towards improving the risk communication capacity and competencies of regulators in Europe was a necessary step in engaging with the public and other relevant stakeholders to bring about relevant shifts in regulatory policies. It was agreed across the panel that regulators must make more productive efforts at proactive communication concerning the trade-offs between risks and benefits to prevent public confusion.

13. [2003] 1 All ER 333.

14. [2008] EWCA Crim 1271.

Dave Bench also advocated increased communication and partnership between regulators and policymakers so that potential regulatory requirements legislation is discussed thoroughly prior to being passed. This type of relationship building could prove mutually beneficial in terms of increased understanding and compliance. Lynda Armstrong added that any changes in the regulatory framework must involve and secure the support of the businesses that it is designed to protect and regulate. To be effective, all business leaders need to have a deep understanding of the risks facing their respective businesses and demonstrate their commitment by playing a role in helping to educate their workforce in managing relevant risks safely.

Also discussed was the need for research initiatives to analyse how risk versus hazard classifications are being understood by the public, so that the role of risk communication may be appropriately considered. The mapping of lay cognitive processes is the first step in illustrating interpretations of risks and hazards for the purpose of developing evidence-based communications.<sup>15</sup> Cognitive processes must also be mapped to ensure that the communications are being interpreted as intended. Without the necessary testing, risk communications may result in confusion, and unintentional and adverse outcomes.<sup>16</sup> Baruch Fischhoff, leading scholar in the field of risk communication, states, 'One should no more release untested communications than untested pharmaceuticals'.<sup>17</sup>

### **Additional Recommendations** **Education**

Ragnar Löfstedt recommended increased education initiatives for stakeholders and the public on the exact nature of risk assessment, as well as improved scientific competency of the European Parliament.

The view that competencies must be improved was supported by Lynda Armstrong, who identified the promotion of leadership encouraging far greater workforce involvement as the best means to achieve this. She described the British Safety Council's future plans to build competencies and promote appropriate risk aversion for member organizations and their relevant employees. She described education efforts for young people to help develop an understanding of health and safety risks and an appreciation of the behaviours that should be adopted in readiness for the beginning of their working lives. The benefits are believed to be twofold; firstly, a better understanding of working safely will discourage inappropriate risk aversion; and secondly, these young people will prove crucial in eventually developing knowledge and using it wisely concerning hazard and risk.

### **Leadership**

Lynda Armstrong argued that it must be one of the top priorities of leaders to understand the risks of their businesses, communicate those risks to staff, and promote best practice. She went on to ponder rhetorically how many leaders could provide evidence and identify the top five risks faced in their organization. In order to rank leading risks to business, leaders must first understand the range of risks their businesses face. The challenge then becomes how to adapt risk frameworks for practitioners.

### **Media**

In order to achieve a European-wide risk-based approach, Ragnar Löfstedt argued that more consistent European-wide media guidelines were needed to counter inaccurate reporting. Lynda Armstrong also reflected upon amplified risk reporting and stated,

*The British Safety Council, like other organizations, recognizes that many of the headline-grabbing stories concerning health and safety gone mad are, frankly, mythical creations of over-eager journalists. But these stories cannot be quickly dismissed and discounted. They have greatly influenced the public perception of*

15. Morgan, G. et al. (2002) *Risk Communication: A Mental Models Approach*. Cambridge: Cambridge University Press.

16. Fischhoff, B. and A. Bostrom (2002) *Risk Perception and Communication*. Oxford: Oxford University Press.

17. Fischhoff, B. (2007) 'Risk perception and communication'. In: S. Ayers et al. (ed) *Cambridge Handbook of Psychology, Health and Medicine*, p. 190. Cambridge: Cambridge University Press.

*health and safety, more so possibly than what can be the catastrophic consequences of neglectful or harmful health and safety management practices.*

She went on to explain how major catastrophes that hit the headlines should, and do, have an impact on regulation. She cited the Buncefield explosion of December 2005 and explained that the consequent actions taken by the industry, the government, and the regulator to learn lessons should be recognized and appreciated. She described the government's response to Buncefield to 'set goals that the Major Incident Investigation Board believed needed to be achieved to prevent another Buncefield-type incident from occurring'.

### Conclusion

It was evident from the panel discussion that there exists an inconsistency across the European Union in risk versus hazard classifications of products and activities, which results in wide discrepancies in policy across member states and between regulatory agencies within member states. The wide range of expert perspectives expressed during the panel discussion make evident the unanimous support for a risk-based approach to health and safety regulation in the UK and the EU. The principal finding from the analysis was the need for renewed consideration of how Europe as a unified entity approaches the implementation of risk-based regulation, and that this approach must be peer reviewed and evidence based.

While the evidence cited in support of risk-based regulation is available to regulators, hazard classifications are still prevalent. This may be due to the political pressures on regulators to protect society at all costs. But such an approach can result in the misallocation of resources and create unintended risks. Many hazards are the result of scientific and technological innovations, and it is possible to enjoy the benefits that come from societal progress provided that the consequential hazards are recognized and the risks are managed. However, in order for this concept to become established, public trust must be addressed.

The role of courts and the role of risk communication are primary drivers behind establishing public trust to ensure that special interest groups and the public at large react favourably to any shifts in regulation towards a European-wide risk-based approach. Social intolerance of exposure to risks can also be addressed through initiatives in education, workplace leadership, and media reporting. Regulatory agencies may also consider increased measures in regard to transparency, although transparency is by no means a panacea for public trust.<sup>18</sup> Consideration of these recommendations can lead to the acceptance and support of policy made based on the best available evidence.

It is important to note that the nature of regulation in Europe has in fact been shifting in the direction of evidence-based policymaking.<sup>19</sup> Since the debate described in this policy brief, a review of health and safety regulations in the UK was published by Ragnar Löfstedt in November 2011.<sup>20</sup> All twenty-six evidence-based recommendations proposed were accepted by the UK government shortly after.<sup>21</sup> This evidence-based review promotes a risk-based approach, and the UK government's acceptance suggests a significant policy step in the direction promoted by the panellists. The review also calls for increased engagement with Europe to ensure consistent policy implementation, further supporting a European-wide harmonization.

18. Chakraborty, S. and R. Löfstedt (forthcoming) 'Transparency Initiative by the FDA's Center for Drug Evaluation and Research (CDER): Two Pilot Studies of Public Perceptions', *European Journal of Risk Regulation*.

19. Löfstedt, R. et al. (2011) 'The Changing Nature of Communication and Regulation of Risk in Europe', *Journal of Risk Research* 14(4): 409-429.

20. Löfstedt, R. (2011). 'Reclaiming health and safety for all: An independent review of health and safety legislation'. London: The Stationery Office. Available at <http://www.dwp.gov.uk/docs/löfstedt-report.pdf>.

21. Department for Work and Pensions (2011) 'The Government Response to the Löfstedt Report'. Available at <http://www.dwp.gov.uk/docs/löfstedt-report-response.pdf>.





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## Regulation, Regulators, and the Crisis of Law and Government

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