SUMMARY OF DISCUSSIONS ON RISK AND REGULATION AT THE MEETING OF THE GROUP ON REGULATORY POLICY, 1-2 DECEMBER 2008¹

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INTRODUCTION

- 1. This paper summarises the discussions on *Regulatory reform and the management of risks* held by the Group on Regulatory Policy during its December 2008 meeting. Risk management approaches have become pervasive in recent years in policy fields ranging from food safety to the supervision of financial markets. The summary examines how these approaches have contributed to better policy-making, and how they could be strengthened in order to address important policy challenges that have been underscored by recent crises: the need to strike a balance between efficient market regulation and the protection of public and citizen welfare; the problems posed by risks which transcend sectors and borders; the pitfalls of reactive regulation.
- 2. The meeting brought together practitioners, academics and government officials from a wide array of policy areas. In the context of the financial crisis, an entire session was devoted to risk management in the context of financial sector regulation. It provided insights into the challenges of risk regulation in a dynamic global environment that are relevant well beyond that specific industry. Participants also presented a diversity of national and regional perspectives over risk regulation issues. They placed particular emphasis on identifying best practices in risk-based regulatory practices, examining to what extent these could be transposed in different countries and sectors, and discussing the usefulness of general guidelines in this regard.
- 3. The scope and quality of the exchanges showed the relevance of the Group on Regulatory Policy for discussing multidisciplinary issues such as risk regulation. The discussions proved particularly suited for examining the complex interfaces between good governance principles, regulatory challenges and communication issues. In this regard, the discussions highlighted areas where the OECD could contribute to a better understanding of risk regulation challenges and improve international dialogue and cooperation on risk issues.
- 4. The discussions addressed in particular the following questions:
 - What are the policy tools and support needed to promote risk-based approaches? To which extent have these tools been adopted in various sectors?
 - What are the benefits of a whole of government approach to risk management?
 - What are the relevant common elements to consider in terms of risk assessment, management and communication? What is their relevance for developing specific sectoral approaches?
 - How to manage risk while fostering competition and remaining neutral in terms of market openness?
 - How can risk-based approaches contribute to successful regulatory management, compliance and enforcement strategies?
 - How to address the implications in terms of capacity building as well as facilitating access to information for supervisory authorities?
 - What is the potential for incorporating useful guidance in current instruments for guiding regulatory practice, drawing on risk-based approaches?
 - How to develop effective risk communication strategies?

- 5. The following sections deal with each of these questions in turn. The first section addresses issues pertaining to the regulation of risks to society, which we will call "risk regulation". The second section is more specifically about the use of risk concepts by regulators in managing their own objectives, which we will call "risk-based regulation". Box 1 provides further clarification on the risk and regulation terminology.
- 6. The meeting delivered three important policy messages to policy-makers. First, increased international cooperation on risk assessment and management is needed, including in the form of guidance on general principles. Second, regulators in the financial sector but also in other sectors will have to pay more attention to background risks and systemic risk in the future. Third, the existence of a gap between the level of risk that is targeted by policy-makers and the level that is achievable through regulation is inevitable. This risk gap has to be explicitly recognised and managed. These appear as major issues for future analysis and discussion at the OECD.

Box 1. The risk and regulation terminology

Examples drawn from a variety of sectors (food safety, environmental protection, financial regulation, occupational health and safety) show that "risk-based regulation" is a box that different institutions fill with very different contents.

According to professor Julia Black, at least four meanings coexist.

First, regulation of risks to society, which has a long history and extended scope in areas such as environmental protection or health and safety regulations: here risks are identified, their level is assessed, a decision is taken as to how much risk reduction is needed, and a piece of legislation is introduced accordingly.

Second, a loose collection of approaches which regulators adopt and express in terms of risk, including their own management system.

Third, in banking and insurance in particular, regulators rely on the risk models that firms use internally to set their capital requirements.

Fourth, in a broader regulatory context, it means a systematised decision-making frameworks and procedures that prioritise regulatory activities and deploy supervisory resources – in particular those of inspection and enforcement – based on an assessment of the risks that firms pose to the regulator's objectives.

In addition, as emphasised by Dr Liz Fisher, risk regulatory concepts have been pushed forward in public governance through four different developments, which only adds to the confusion.

First, as part of public management reform, where financial management principles have been introduced within public administration. This has been essentially a technical – not a legal – development, which can be exemplified by the Orange book of the UK Treasury.

Second, as an element of re-characterisation of the regulatory subject matter. Environmental protection, for instance, has become the management of environmental risks. The same applies to safety at work, to the management of financial markets. This re-characterisation is the consequence of the introduction of new tools of risk assessment and management in fields of regulation – a change that occurred about thirty years ago, and took different forms in different sectors.

Third, as a tool of legal enforcement and criminal justice.

And fourth, as part of the general debate about the role of the State, *i.e.* as a rationale for State intervention, or lack thereof, or even as an overarching principle of public action.

This means that terminological clarification is necessary at the onset of any reflection on risk and regulation. Discussions at the GRP revolved around the first and the last of the four meanings above, namely the regulation of risks to society (first section of the paper) and the management of their own risks by regulators (second section).

RISK GOVERNANCE

- 7. It has become common to say that handling risks is central to the role of governments nowadays, and even that governing is in effect about managing risks. The use of concepts such as risk, hazard, security, risk analysis, risk assessment, risk management and communication, risk/risk analysis, risk-based approaches, risk transfers and the precautionary principle has become widespread. From a legal perspective, these concepts have been introduced mainly because they regulate administrative power essentially in three ways:
 - They define the competence of administrators by reference to specific tasks with regard to identified risks:
 - They limit administrative discretion by creating procedures that have to be followed;
 - They are being put in place with the purpose of enhancing the accountability and the rationality
 of administrative decisions, primarily by setting standards against which decision-makers are
 accountable.
- 8. Participants in the meeting held a lively debate regarding the relevance and usefulness of risk governance guidelines. Critics underlined the context-dependent nature of risk, and the danger that general guidelines might hamper the ability of regulators and decision-makers to adapt to specific circumstances. Proponents insisted on the need for and potential benefits of better harmonisation of risk regulation practices across sectors and countries.
- 9. In the light of the legal analysis of risk governance concepts, this debate can be recasted as one about the optimal degree of regulation of administrative power: too much restriction would unnecessarily burden decision-making with complex and costly procedures and limit its ability to effectively deal with public issues; too little would open the door to arbitrary, inconsistent and inefficient decisions.
- 10. The question then becomes: Which aspects of risk governance could usefully be addressed through general principles? And on which aspects should contextual and, when necessary, discretionary decision-making prevail?

The potential scope for risk governance principles

- 11. Mr. Delogu, from the Health and Consumer Directorate General of the European Commission, indicated that notwithstanding their legal and jurisdictional differences, countries can share a number of key principles governing the use of scientific knowledge as basis of policy, the separation between scientific advice and decision-making, transparency, and the open exchange of information with stakeholders.
- 12. Such principles underlie the three-pillar approach to risk governance that the European Union has adopted, and applies to a wide range of risk issues. The approach, which is also common in other OECD countries, distinguishes risk assessment, risk management and risk communication. Risk assessment covers the scientific aspects of identification and characterisation of hazards, evaluation of the probability of certain events and of exposure to these events, and characterisation of risk. Risk management covers the identification and assessment of the policy options to face risk, and the choice of the best option from a societal standpoint. Risk communication consists of a dialogue with stakeholders and society at large, and intervenes at both of the previous stages. In particular, it helps checking the consistency of messages delivered by risk assessors and managers, who operate in separate and autonomous spheres.

- 13. Risk assessments quantify the potential loss related to an adverse event. They can also inform cost-effectiveness or cost-benefit analyses about the benefits of risk reduction, for instance through "league tables" of the costs of life-years saved through different policy measures. Risk assessments can also help make tradeoffs when reducing a risk induces an increase in another risk (*e.g.* replacing large cars by small cars and its consequences for environmental and accident costs).
- 14. Based on this information, the choice of the acceptable level of risk is political. Science does not have anything to say on this matter, but can help ensure the consistency of decisions. Although it is not possible to define a level of risk that is appropriate globally because societal demands differ, science-based principles of risk assessment enhance consistency across national jurisdictions. Based on his experience at the US Office of Management and Budget, Dr. John Graham emphasised the scientific, value-neutral nature of risk assessment, and deemed it wrong to assume that risk assessments are "anti-regulation". For instance, risk assessments have led to new regulations or tightening of existing regulations in a number of cases in recent years in the United States, including foods labels for trans-fat content, fuel-saving mileage rules for SUVs, restrictions on air pollution from diesel engines and coal plants, and reductions in worker exposures to hexavalent chromium.

The need for a contextual approach

- 15. On the other hand, the study of law highlights the need for a critical and contextual approach to risk governance concepts and the danger of excessive generalisations. Legal culture, in particular, affects the way in which these concepts operate. Law is not only a set of rules; it also consists of institutions, practices, ideals. Concepts of risk that are introduced in law are therefore going to interact with this culture. In the United States, for instance, there is a culture of adversarial legalism, where judicial reviews are frequent and courts play a major role in litigation. This is not the case in European countries. There are also new legal cultures appearing, such as that of the World Trade Organisation.
- 16. Therefore, the use of risk governance concepts should account for differences in legal culture. When defining the competence of public administration, limiting discretion and holding decision-makers to account, risk governance concepts need to be placed in the context of pre-existing constitutional and institutional frameworks.
- 17. The contrast between the US and the EU institutional settings on risk governance is a case in point.
- 18. There is no unique and comprehensive instrument defining the approach to risk analysis in the EU, in particular no overarching set of rules and principles. However, several documents include horizontal risk analysis principles which have been taken on board in specific instruments, over time:
 - The EU Treaty itself refers to scientific data and evidence as a basis for policy and regulatory measures. In particular, Article 95 relative to competence for internal market states: "The Commission, in its proposals envisaged in paragraph 1 [internal market measures] concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts." (Article 95(3)). Interestingly, however, the European Court of Justice has put little emphasis on this aspect of the article in its decisions.

- The communication on consumer health and food safety (1997) elaborated after the BSE crisis includes a definition of risk analysis, assessment, management, and communication. It establishes a number of principles which are relevant beyond the area of food safety, and are systematically applied in the EU: separation between scientific advice and regulatory decisions (risk assessment bodies are hence institutionally separated from management instances a feature that is not common in other OECD countries); the constitution and operation of scientific committees or panels in charge of risk assessment should guarantee their excellence, independence, and transparency (in particular, the work of the committees is documented and publicly available, members are independent experts selected upon calls for tender, and remunerated according to a system of indemnities).
- The communication on the collection and use of expertise (2002) applies in particular to risk issues.
- Certain guidelines and principles have been translated into legally binding instruments, such as the EU food law (2002) or the Commission decision establishing scientific committees in the field of consumer safety, public health and the environment (*i.e.* in non-food areas, elaborated in 2004 and revised in 2008). The food law, in particular, established EFSA as an independent authority in charge of assessing risks in the food chain.
- 19. Rules of procedure, working practices and methodological guidelines derived from these documents reflect the same principles, with practical adaptations to specific needs. This has led to the creation of sectoral agencies and scientific committees in charge of assessing risks and providing advice to decision-makers: the European Food Safety Agency (EFSA), the European Medicines Agency (EMEA), the European Environment Agency, the European Centre for Disease Prevention and Control (ECDC), the European Chemicals Agency (ECHA), the Scientific Committees Emerging and Newly Identified Health Risks (SCENIHR), on Consumer Products (SCCP), on Health and Environmental Risks (SCHER) and on Occupational Exposure Limits (SCOEL).
- 20. It is interesting to note that the role of these agencies differs from that of their counterparts in the United States: the US Centers for Disease Control and Prevention, the Environmental Protection Agency or the Food and Drug Administration are involved both in assessing and in managing risks, even though in all cases, the two activities are functionally separated.
- 21. In the United States, regulators have a mandatory duty to respond in writing to comments by stakeholders regarding risk assessments. Such legal obligations would be difficult to transpose to the EU, where risk assessors are independent and separate from regulators.
- 22. The need to account for such national specificities should therefore be borne in mind as a caveat when considering principles of governance in the areas of risk assessment and management.

Risk assessment guidelines

Why guidelines?

- 23. Risks are identified through clinical case reports, epidemiology, controlled experiments, theory and mechanistic studies, fault-tree analysis and large-scale computer models. Why are guidelines needed? Risk assessments, for instance in environmental health, have to deal with a number of issues for which there is no "objective" solution:
 - Extrapolate from one species to another, where different species used in experiment can give different results.

- Extrapolate from high doses to low doses, with different statistical models.
- Synthesise the results of different studies, which might have divergent conclusions, *e.g.* through meta-studies.
- Integrate uncertainties, for instance when experts disagree.
- Combine hard data (e.g. experimental) and subjective probabilities (e.g. carcinogenic effects at very low doses) through simulation.
- Deal with variability (e.g. the existence of populations with high susceptibility).
- Deal with equity issues, and quantifying risk equity as well as risk efficiency (*e.g.* when particular groups of the population are more exposed than the average).
- Define under which conditions an event starts being considered as "adverse".
- 24. Without guidelines, risk assessors are likely to deal with these issues in variable (from agency to agency) and inconsistent (from one case to the other) ways. Arbitrary variation in analytic practices undermines the credibility of agencies and can spur political backlash from stakeholders.
- 25. The global nature of risks creates the need for increased convergence between risk management procedures internationally. Collaboration and convergence on risk issues have been advanced in a number of fora, including the European Commission's recent initiatives:
 - The Transatlantic Risk Assessment Dialogue between the EU, the USA and Canada was launched in July 2008 to promote better understanding of the respective systems and to establish a framework for convergence on methodological aspects and some substantive risk issues, such as emerging risks.
 - The International Risk Assessment Conference started in 2008 aims at encouraging international dialogue on risk assessment in order to move towards more consistent approaches. It operates through the exchange of information and the launching of common projects regarding particular risks or methodological issues.

Scope and content

- 26. Risk assessment procedures have to conform to certain quality criteria. They have to rely on transparent data and models, and be conditional on the possibility to replicate the results. They have to be peer reviewed by specialists. They have to provide the opportunity for stakeholders to comment and mandate regulators to respond explicitly to those comments. They have to mandate risk assessors to respond to regulators' requests for information.
- 27. Risk assessment guidelines therefore have to cover the following points:
 - the scope, methods and transparency of risk assessments;
 - procedures for peer review of risk assessments (e.g. U.S. OMB's Peer Review Bulletin);
 - different risk-management frameworks and how risk assessments are helpful (*e.g.* "negligible-risk" versus "cost-benefit" frameworks);

- procedures whereby stakeholders can seek correction of erroneous or misleading information in risk assessments (e.g., U.S. OMB's Information Quality Guidelines).
- 28. Critics emphasise certain limitations of risk assessment, and call for their careful use and adaptation to the context:
 - Risk assessments do not take scientific uncertainty into account. The scientific evaluation of a hazard and its potential consequences is subject to technical, methodological, and epistemological sources of uncertainty. When using risk assessments, we therefore need to have a sophisticated understanding of these various forms of uncertainty.
 - Risk assessments also ignore important factors that cannot be assessed quantitatively, or issues of distribution and equity.
- 29. In summary, according to Dr. Graham, "risk assessment and cost-benefit analysis provide a range within which decisions are compatible with evidence". Where exactly to place the decision within that range, and how to integrate scientific uncertainties, remains a matter of policy choice. However, the framework created by sound risk assessment facilitates international cooperation over decisions which affect the global community.

Risk regulation and good regulation

30. The Chair, Mr. Frédéric Jenny, stressed the difference between setting a general framework for risk assessment and establishing rules of risk management decision-making: "risk management enjoys, by nature, more degrees of freedom than risk assessment". Still, risk management decisions are submitted in many countries (*e.g.* EU member countries) to principles of better regulation, which imply in particular that any measure be evaluated both before and after being applied. Three illustrations from very different areas of risk management further demonstrate the relevance of good regulation principles in risk management.

The management of food safety crises by the UK government

Mr. Tim Heyman, from the United Kingdom's Risk and Regulation Advisory Council, discussed how risk management can improve the effectiveness of regulation, by referring to the example of the Foot and Mouth Disease outbreaks. In 2001, the UK government reacted to the Foot and Mouth Disease epidemic by deciding to slaughter millions of animals. This led to billions of pounds of public cost and huge damage to the UK's image abroad. In 2007, the government managed concurrent outbreaks of FMD, avian flu and blue tongue by not responding to the media storm, letting experts (in particular the chief veterinary officer) talk, and trusting the farmer industry to decide what to do. There was very little economic damage and little interest shown by the public – despite attempts from the media to escalate the issue. The government managed to transfer some of its responsibility, based its decisions on sound evidence, used appropriate processes to apply and present them. The episode showed that principles of good regulation provide an appropriate framework for risk regulation: proportionality, accountability, consistency, transparency, targeting.

The OECD guidance for effective and efficient financial regulation

- 32. The Directorate for Financial and Enterprise Affairs presented the OECD guidance for effective and efficient financial regulation to the Group (DAF/CMF/2008/18). The guidance emphasizes the importance of a sound policy framework for effective and efficient regulation. Although the guidance does not explicitly refer to risk governance concepts, there is a large degree of similarity between its principles and those of the three-pillar risk governance approach:
 - Understanding the financial landscape and its expected evolution: Policy-makers and regulators should describe what the financial system ought to look like and what should be its outcomes, and understand how the system works (transparency, data collection, sound analysis of risks in the financial system). Particular emphasis should be placed on macroeconomic and international linkages.
 - The policy objectives that have been elaborated for the financial system: They need to be clearly
 articulated, and rooted in sound market failure analysis and assessment of socio-economic needs.
 These objectives provide the benchmark for assessing the effectiveness of financial regulation,
 and provide an accountability framework for financial regulators.
 - An examination of the range of policy instruments that are available to government: In particular, to understand the interactions between these instruments, *e.g.* between deposit insurance schemes and financial regulations. This is key, in particular, to understanding moral hazard issues that may arise as a result of government interventions.
 - Institutions in place to implement these instruments: Institutions have a large impact on the success and efficiency of regulatory interventions in the financial sector.
 - Governments need to make a comprehensive review of the system of regulations for the financial sector at least every 5 years.

Australia's best practice for policy development

- 33. Mr. Gary Banks, chairman of Australia's "Productivity Commission" exposed the principles of best practice for policy development that the Commission put forward in response to recurrent problems of regulatory complexity, inconsistency and failure:
 - Understand the policy problem or issue
 - Specify the policy rationale and objectives
 - Outline policy options
 - Assess their efficacy and relative costs and benefits
 - Develop an implementation strategy
 - Monitor outcomes and adjust policy if appropriate.

34. Mr. Banks underlined the compatibility (and actual similarity) of these precepts with risk assessment and management principles. Indeed, Australia's regulatory impact assessments (documented through a Regulation Impact Statement) integrate elements of risk assessment and characterisation when relevant.

Public/private complementarity in risk management

- 35. In addition to reflections on the relevance and scope of general principles of risk governance, the GRP discussions identified the issue of public/private complementarity over risk management as one that, in Mr. Jeroen Nijland's words, might gain in importance in the near future. Professor Spencer Henson's presentation provided important insights in this regard.
- 36. Private standards have emerged as a key mechanism of risk management in a variety of markets. The example of food safety standards in European, and gradually global, agro-food value chains highlights the reasons and consequences of this development. The standards can regulate primarily food safety aspects, or sometimes other aspects with ramifications into safety. For any of the attributes that standards regulate, participants in the supply chain and consumers seek to ensure that a minimum level is observed. Up to that level, standards help managing risk and prevent competition based on safety features. Beyond that level, they are a differentiation tool.
- 37. Private standards have been tightly related to the actions of public regulators regulatory requirements have actually triggered and shaped the development of private standards. Risk-based procedures such as HACCP² have played a key role in this, by requiring pro-active actions from the various elements of the supply chain. So has also the trend in regulation towards an integrated approach of the supply chain, in particular with the aim of ensuring traceability (farm to fork, etc.), and the evolution in liability regimes putting responsibility on suppliers. The UK Food Safety Act, in particular, led food retailers first to create their own standards and engage systematic inspections of their retailers, and later to agree on common standards that could be certified by a third party, and to create the first industry-wide food safety standard in Europe: the British Retail Consortium standard. In other cases, the weaknesses of regulation have triggered the reaction of private firms with large brand capital, or the collective action of multiple firms with common interests. In countries such as Canada, it is not the retail sector but the farming industry that has played the lead role in the emergence of private standards.
- 38. After having induced the creation of private standards, public regulation now seems to increasingly rely on them. Sometimes, governments mandate the use of such standards (*e.g.* in the safety area in Europe), but more often they are voluntary and pushed forward by major economic actors, such as retail firms. The UK Food Standards Agency sets the frequency of inspection of farms on a number of indicators, one being whether the farm is certified by a private food safety standard. Governments' action is also key in creating a framework for the legitimacy of private standards, for instance through accreditation systems.
- 39. These standards are evolving very rapidly. Until recently, the idea that consumers were obsessed about food safety was the driving force behind private standards, with the objective of actually enhancing the level of safety within agro-food value chains. As value chains were becoming more dispersed globally, with ingredients coming from different countries with diverse risks and regulatory systems, risk management was getting more complicated and costly, making the case for having such standards ever stronger. The trend towards private market governance, with some private entities controlling what other private entities do, also contributed.

Hazard Analysis and Critical Control Point (HACCP) is the principal method for assessing and managing food safety risks in agro-food processes.

- 40. There is now a plethora of such standards, some developed by individual firms, some by coalitions of private firms national or international, or even by entities outside the agro-food industry (e.g. NGOs promoting sustainable production and consumption). Through the Global Food Safety Initiative, the private European standards are being benchmarked against one another, and private standard equivalents are being created. These processes of harmonisation are similar to those taking place internationally in the public sphere.
- 41. Advocates for private standards emphasise that new resources are brought into risk management and argue that private standards are designed in a more dynamic manner and enforced more efficiently than public ones, and therefore contribute to the efficiency of risk management. They characterize standards as information transmission mechanisms regarding products, production and supply conditions. Standards therefore reduce the cost of acquiring information, push information down the supply chain, and improve overall efficiency.
- 42. Critics highlight the lack of transparency of processes and accountability of actors involved in standard setting and enforcement, and question their actual impact on societal risk management since the risks that they manage in effect are private. They argue in favour of a better control of the standards. In international fora such as the WTO, the emergence of private standards has become a very controversial issue, with questions about their impact on trade, on competition, the dominant role of major players in agro-food systems, the consequences for consumer protection. Some representatives have expressed concerns that the SPS agreement might not be sufficient if in practice trade is increasingly governed by private standards. The issue of whether private standards fall under the WTO's jurisdiction is still in debate. This raises interesting questions regarding the future role of the WTO in international food safety regulation, and more broadly on the respective roles of the public and private sectors in food safety.

RISK-BASED REGULATION: PRACTICES AND CHALLENGES

- 43. The concept of risk-based regulation designates systematised decision-making frameworks and procedures that prioritise regulatory activities and deploy supervisory resources, in particular those of inspection and enforcement, based on an assessment of the risks that firms pose to a regulator's objectives.
- 44. The key question for the regulator is the margin of risk that the authority is ready to tolerate beyond the official objective, and the source of that increased risk.
- 45. The organisation therefore needs to first determine its risk tolerance, which is different from the risk that society is ready to tolerate and varies from one sector to the other. In food hygiene procedures, the implicit objective is to achieve zero failure. In financial services, some failures are tolerable. In health and safety and environmental protection, the idea is to bring failure down to the lowest achievable (or reasonably practicable) level. Second, the regulator needs to identify the risks to the achievement of its objectives, and this can be a complex task if the organisation has a range of legislative instruments that it has to implement rather than a set of clear statutory objectives. To assess the risks, it then needs to assign scores and rankings. Ultimately, resource allocation has to relate to these scores.
- 46. Risk-based regulation poses a number of methodological issues. One is the relative role of objective measures, such as size of plant, volume of production, amount of emission and the like, versus subjective measures such as the inherent risk of the business, the quality of management and controls, etc. Objective measures often are assessed by the regulated firms themselves, whereas the subjective indicators rely on the exercise of judgement by inspectors, which induce specific challenges.
- 47. Another issue is linked with impact and probability. Depending on their respective weights, the organisation directs its resources towards the prevention of high frequency-low impact events or rather of low probability-high impact ones. Usually, impact is predominant, showing a particular aversion for large events (or, more precisely, non-compliance of large entities). Some regulators are more interested by the nature than the scale of the harm. Since supervision resources are limited, the relative weighing of probability and impact leads to a bias in enforcement, and to a category of forgotten offenders who have fallen off the regulators' radar screen.
- 48. Finally, there is also the question of the "bulge", *i.e.* the large numbers of regulated entities which pose very low risks individually, but together make a large contribution to the regulator's aggregate risk. Strategies towards these go from random inspections to a segmentation of the population based on the likely outcomes of inspections.

Experiences of risk-based approaches to regulation

49. In the context of the financial crisis, the GRP devoted particular attention to risk management in the context of financial sector regulation. Rolf Alter, Chief of Staff of the Secretary-General, identified three questions that need to be urgently addressed by the international community: Where and how to regulate better? How to link up national regulatory systems? Which institutional structures have demonstrated effectiveness in coping with systemic risk? According to Rolf Alter, "there is a considerable need for better understanding of regulatory challenges and linkages between national regulatory systems" in this area.

- 50. The AMF has published since 2007 an annual analysis of changes occurring in the financial system, with a view to establishing a list of risk priorities in relation to its different objectives. According to its Secretary-General Mr. Gérard Rameix, the Authority sees this annual publication as a tool of communication with its various publics, in particular for collecting their views on the ranking of risks. It launched the analysis with the aim of improving its regulatory activity, and in particular of better dealing with the tension between two of its foremost goals: protecting investors and supporting the financial system's health.
- 51. In the AMF model, risk is computed by combining the impact of an event, derived through a top-down analysis (market trends, activity statistics), and its probability, estimated in a bottom-up fashion (firm- and activity-specific information). Although this has been done in a more analytical than mathematical way, it has proved very useful. Indeed, the straightforward methodology of a risk-based approach provides the basis for substantial progress in regulatory policies by systematically identifying problem areas.
- 52. For instance, it enabled the AMF to differentiate its consideration of individual investor risks and of wholesale market risks although the two are connected through the systemic risk. The main risk identified for the retail market was a lack of understanding among individual investors of certain products, which were getting increasingly complex. Along with the ability of retailers to make use of sophisticated methods of asset management, the AMF deemed it necessary to improve the financial knowledge of consumers. This opened a field of investigation for the AMF regarding the type of information provided to consumers, the quality of advertising, etc. The efforts of the FSA in this regard were very significant. The risks that were given priority on the wholesale market were related to governance and to acquisition of equity. In France, it is possible to acquire equity in a way that is camouflaged, so that costs of takeovers are underestimated.
- 53. Three years ago, the French Parliament asked the AMF to produce an annual report to assess the credit rating agencies as a source of risk while the agencies are not submitted to financial regulations. In a report published in 2006, the AMF showed that the turnover of the agencies was changing, a significant share of it now coming from the rating of structured products, which they were co-producing with financial institutions. This was considered as a source of concern.
- 54. Transparency issues on wholesale markets, information and knowledge of retail consumers, the role of rating agencies: these risk factors have proved relevant in the light of the financial crisis.
- 55. Mr. Lyndon Nelson, from the Financial Services Authority, explained to the GRP that FSA's decision to engage into risk-based regulation made explicit what had been implicit in particular the fact that limited resources had to be allocated to almost unlimited claims. The FSA's remit can give an idea of the tradeoffs that have to be made: 30,000 institutions, 175,000 individuals across a range of financial services, with a number of international players, overseen by 11 regulatory bodies. This first decision was entirely different from the following step, which consisted in determining the organisation's risk tolerance.
- 56. The principles of risk-based regulation at the FSA are: to achieve the industry standard, to show positive appetite and accountability, and to be universal, integrated, objective, consistent, action-focused, transparent, and dynamic.
- 57. The risk-based approach reflects the preferences of the organisation's management, in particular in terms of risk appetite. It uses 27 different models of risk-based model, which all integrate different sources of information (general intelligence, regulatory returns, macroeconomic analysis), identify the importance of that information, to assess the risk, prioritise it and if needed, take action. The most important element of the approach is clearly the technology, which enables it to deliver a combination of complex models in a simple, easy-to-use form.

- 58. The consequences of introducing a risk-based approach are:
 - a concept of risk that is shared across the organisation –bringing risk-based decision-making to individual processes
 - an agreed system of measuring risks across a defined risk universe
 - a clear articulation about the action that is to be taken and by whom once risk thresholds have been breached:
- 59. The risk-based approach has also provided FSA, in Mr. Nelson's words, with "a measure of performance". The current crisis seems to indicate that the incentives that risk-based regulation had created were not appropriately placed. In response, the FSA has already made adjustments in its level of risk appetite regarding both banking and insurance industries. The aim is still to reward those firms that manage their risks well. The requirements are to be transparent, consistent and pro-active. The industry has generally achieved a high standard of risk management, and demands high standards from its own regulators.
- Mr. Laszlo Balogh former Managing Director between 2000 and 2005 at the Hungarian FSA, recalled the establishment of the integrated financial supervisory authority in year 2000. Since year 2000 the supervisor in Hungary has been integrated (banking, insurance, pension funds, capial markets). The role of financial regulators is to set limits to financial institutions' risk taking in order to ensure the safety of other participants. He presented in the historical context some experience and features of the Authority's risk-based model introduced at the early times, based on large sets of data reported routinely by financial institutions. Out of this data, simple and integrated indicators were constructed to measure and signal growing risks. When certain indicators or a group of indicators reached a threshold value, the model 'ringed'. On quarterly basis, the calibrated IT system produced some 'automatic' evaluations of firms through the indicators (for smaller firms, using less data and simplified methods). Calculated results are assessed against qualitative analysis of the firms and their situation. The risk indication was rather an alarm for the supervisory authority indicating that a thorough qualitative assessment is also warranted. Certain key institutions were subject to stress-testing to simulate extreme conditions.
- 61. When both quantitative and judgement-based assessment indicated unusual situations, a number of further steps could be launched: a dialogue was engaged with the bank in order to fully understand the situation, targeted on-site inspections were launched, immediate supervisory action could take place, certain targeted corrective measures had been requested from the firm, and in some cases, firms were put under strict monitoring.
- 62. As from 2002, after 2 years of operation of this IT-supported supervisory indicator system, the HFSA had developed a risk profile for each of the major supervised firms, and could, when conducting a comprehensive examination of a bank or other financial institution (including on-site visits), concentrate its supervisory resources on these specific areas identified through the risk profile. The system had to be calibrated regularly to account for the dynamism of risks.
- 63. In conclusion Mr. Balogh said that regulation and supervision should set limits to excessive and harmful risk taking, however it should not jeopardise innovation in the sector. No financial regulation may function without risk assessment and risk monitoring. Markets and products are evolving, consequently risk profile and risk factors are changing: the regulator has to keep pace with these developments. Markets, risks and regulation in the financial sector are by nature dynamic. The supervisory agency is compelled to be dynamic as well.

The risk gap: regulators as risk monitors

- 64. "Background risks" are a key issue in financial regulations, where they can seriously affect the firms themselves, and therefore the risks that they pose to regulators.
- 65. Beyond the financial sector, participants coined the term "risk gap" to designate the difference between the targets set out in laws and regulations and the levels of risk that regulators can actually achieve to implement. Regulators know that compliance with laws and regulations cannot be fully enforced. Risk-based regulation makes that knowledge explicit, and measures the error margin in risk regulation.
- 66. The Greek Delegate, Ms Efi Stefanopoulos, indicated that the fires that devastated the country's forests in summer 2007 and killed 40 people were a tragic illustration of such a risk gap: "the regulatory framework was in place, based on a determined level of risk acceptance, but inadequate application and enforcement of the regulation had not been accounted for". For instance, 13 authorities (local, regional, state, Ministry of Culture if archaeological sites were near) were involved in preventative clean-up of forests. A risk-based approach would have helped identifying and assessing the inadequacies of risk regulation.
- 67. The role of financial regulators is to set limits to financial institutions' risk-taking in order to ensure the safety of others. The risks consist of: credit risks, market risks, liquidity risks, operational risks (legal, IT, reputational, human and criminal), and external disaster risks. Some of these firm-level risks are correlated: an exceptional market downturn, for instance, would affect simultaneously many firms. An extreme case of background risk is the systemic risk, *i.e.* the threat that a single failure would pose the entire financial infrastructure, with considerable negative spill-overs for the economy and society at large.
- 68. Prudential rules were initially meant to minimize the risks related to the establishment and operation of a financial institution: rules regarding capital and ownership, requirements regarding the personal integrity and professionalism of managers, and requirements of proportionality between the bank's own-funds and the risks it is exposed to. These rules have been complemented with internal rules relative to decision-making processes, controls, sharing of responsibilities, and so on.
- 69. However, financial regulators are not supposed to control simply compliance with laws and internal procedures of individual financial institutions, but also to supervise sector developments, detect emerging risks such as those related to new products, and monitor systemic risks.
- 70. In short, financial regulators are in charge on monitoring the actual level of risk to the financial system. Actual risk differs from the level of risk acceptance because of two reasons: first, as stated before, because risk-reducing regulations cannot be perfectly enforced; second, because of the existence of background, and at the extreme, systemic risks.

Lessons learned

- 71. The GRP discussions therefore helped clarify the links between risk regulation and risk-based regulation, and underlined the important if often overlooked role of regulatory agencies as risk monitors. Together with the other major themes developed in this synthesis, risk monitoring by regulators raises a number of critical questions and appears as a promising avenue for future work on risk and regulation:
 - How can the knowledge of regulators regarding the risk gap feed back into risk assessment and management?
 - How can regulators communicate that knowledge without triggering public outcry and political over-reaction?

• Finally, building on the financial system example, should regulators consider more closely background risk factors as additional elements of a risk gap?

These appeared as promising and important avenues for future work on risk and regulation at the OECD.

- 72. The challenges faced by regulators who have started implementing risk-based approaches fall under three categories: methodological, cultural and organisational, legal and political.
 - Methodological challenges: Complexity in terms of routine use; difficulty of collecting the right knowledge and data, rather than using the knowledge at hand; taking into account the interconnected nature of many risks; ensuring consistency and accuracy when relying on subjective assessments can substantially burden the rating process, and making forward-looking assessments.
 - Cultural and organisational challenges: Managing changes necessitated by risk approaches, in
 particular to ensure compliance with and appropriate use of the system internally; creating
 incentives for regulators to cooperate in the handling of inter-connected risks; finding a balance
 between central control and local discretion; making resources follow risks; the FSA, for
 instance, has not yet managed to implement genuine risk-based resourcing (whether measured in
 human skill, technology or cash terms).
 - Legal and political challenges: Regulatory authorities have to abide by a number of legal texts, and seeking to punish and even identify minor violations of these texts is not among their priorities. In many countries, the government has had a historical role in providing protection against both small and large risks. Following a risk-based approach is tantamount to acknowledging that the regulator does not have enough resources to fulfil all its tasks, and that such protection cannot be always provided. Ultimately, this is a political risk for governments.
- 73. The experience of regulators in dealing with these challenges provides a number of lessons for launching, maintaining and managing a risk-based approach:
 - Initial phase: start with risks and not rules; verify that the organisation has the actual power to implement such approaches (*e.g.* it is not constrained by a minimum number of inspections it should achieve); define objectives to be attained through risk-based regulation; beware of other regulatory or governmental policies which may contradict or hinder the adoption of a risk based approach; ensure you know what your goals are it is worth doing, but don't do it for the wrong reasons;
 - Transition phase: acknowledge that designing and implementing a risk based framework will take time; acknowledge that organisational challenges are significant and should not be underestimated; think beyond the risk assessment to how the organisation will respond;
 - Maintenance: keep the framework simple to use and be prepared for the need to make continual adjustments; think in terms of achievability;
 - Management: respond to the need for communication internally and externally; recognise that risk based processes require regulators, and politicians, to take risks.
- 74. There is, finally, the question of how regulators "can look beyond the individual firm" and "integrate external risks in the framework of firm-level assessments". In the context of the financial crisis, this issue will continue to attract the attention of policy makers.