EUROPEAN RISK FORUM – POLICY NOTE 20

EX POST EVALUATION AND THE MANAGEMENT OF RISK: THOUGHTS FROM THE ERF RISK FORUM

2011

EUROPEAN RISK FORUM

The European Risk Forum (ERF) is an expert-led and not-for-profit think tank with the aim of promoting high quality risk assessment and risk management decisions by the EU institutions, and raising the awareness of the risk management issues at EU-level.

In order to achieve this, the Forum applies the expertise of a well-established network of experts to 'horizontal', cross-sectoral issues. In particular, it addresses regulatory decision-making structures, tools and processes, as well as the risks and benefits of new and emerging technologies, of climate change, and of lifestyle choices.

The Forum believes that:

- High quality risk management decisions should take place within a structured framework that emphasises a rigorous and comprehensive understanding of the need for public policy action (risk assessment), and a transparent assessment of the workability, effectiveness, cost, benefits, and legitimacy of different policy options (risk management).

- Risk management decision-making processes should ensure that outcomes are capable of meeting agreed social objectives in a proportionate manner;

- Risk management decisions should minimise negative, unintended consequences (such as new, unintended risks, economic losses, reduced personal freedoms, or restrictions on consumer choice);

- The way in which risk management decisions are made should be structured, consistent, non-discriminatory, predictable, open, transparent, evidence-based, legitimate, accountable, and, over time, subject to review.

Achieving these goals is, the Forum believes, likely to require extensive use of evidence (especially science); rigorous definition of policy objectives; clear and comprehensive description and assessment of problems and their underlying causes; realistic understanding of the costs and benefits of policy options; and, extensive consultation.

The Forum works with all of the EU's institutions to promote ideas and debate. Original research is produced and is made widely available to opinion-formers and policy-makers at EU-level. As an expert group, the Forum brings together multiple sources of evidence (such as the experience of practioners and policy-makers; non-EU good practices; and academic research) to assess issues and to identify new ideas. Indeed, direct engagement with opinion-formers and policy-makers, using an extensive programme of conferences, lunches, and roundtables, is a feature of the Forum's work.

The ERF is supported principally by the private sector. The ERF does not seek to promote any specific set of values, ideologies, or interests. Instead it considers high quality risk assessment and risk management decisions as being in the public interest. An advisory group of leading academics supports the ERF's work.

Rue de la Loi 227, B – 1040 Brussels, Belgium
Telephone + 32 2 613 28 28 Facsimile + 32 2 613 28 29
www.riskforum.eu email: info@riskforum.eu

EXECUTIVE SUMMARY

The European Risk Forum (ERF) is an expert-led and not-for-profit think tank with the aim of promoting high quality risk assessment and risk management decisions by the EU institutions, and raising the awareness of risk management issues at EU-level. Since 2008, the ERF has promoted the adoption, by the EU's institutions, of rigorous and systematic ex post evaluation of regulatory decisions. With the publication of the Communication on 'Smart Regulation' in 2010, the European Commission formally adopted this important process as part of its approach to making and implementing laws.

In view of this, the ERF held a meeting in March 2011 of invited guests and expert speakers to consider ex post evaluation of risk management decisions and to identify conclusions and recommendations relevant for the development of an effective ex post evaluation process at EU-level. The meeting was held under the Chatham House Rule. Invited guests included senior officials from the European Commission, United Nations, OECD, Swiss Government, and US Government; senior lawyers from leading law firms; representatives of EU and of US-based companies; and, senior managers from the veterinary medicine, metals and mining, food and drink, personal care, household cleaning products, cosmetics, luxury goods, pharmaceuticals, performance materials, crop protection, medical devices, detergents, chemicals, business service and biotechnology sectors.

Invited experts and other meeting participants, together with ERF experts, identified a number of recommendations that, if implemented fully, could help strengthen and improve the ex post evaluation of risk management measures by the EU's institutions. Specifically:

- Improve the initial quality of risk management measures prior to implementation through the development of specific ex ante assessment guidance.

- Strengthen the role of the European Commission's Impact Assessment Board by requiring it to ensure that, for all risk management proposals there are measurable outcomes, quantified metrics of costs and benefits, and a clear link between problem definition and risk management option.

- Establish monitoring and early warning mechanisms for existing and new risk management rules.

- Make widespread use of high quality scientific assessments to evaluate the relevance and effectiveness of risk management measures.

- Ensure the extensive involvement of affected parties during the process of ex post evaluation.

- Develop a comprehensive understanding of 'horizontal' (multi-sectoral) unintended consequences of risk management rules, and develop guidance for regulators.

- Prevent regulators from introducing replacement risk management measures until ex post evaluations have been undertaken.

Rue de la Loi 227, B – 1040 Brussels, Belgium
Telephone + 32 2 613 28 28 Facsimile + 32 2 613 28 29
www.riskforum.eu email: info@riskforum.eu

1. BACKGROUND

The European Risk Forum (ERF) is an expert-led and not-for-profit think tank with the aim of promoting high quality risk assessment and risk management decisions by the EU institutions, and raising the awareness of risk management issues at EU-level. In order to achieve this, the ERF applies the expertise of a well-established network of experts to 'horizontal', cross-sectoral issues. In particular, it addresses regulatory decision-making structures, tools and processes, as well as the risks and benefits of new and emerging technologies, of climate change, and of lifestyle choices.

Achieving high quality risk management decisions is, the ERF believes, likely to require extensive use of evidence (especially science); rigorous definition of policy objectives; clear and comprehensive description and assessment of problems and of their underlying causes; realistic understanding of the costs and benefits of policy options; and, extensive consultation.

Since 2008, the ERF has promoted the adoption, by the EU's institutions, of rigorous and systematic ex post evaluation of regulatory decisions. With the publication of the Communication on 'Smart Regulation' in 2010, the European Commission formally adopted this important process as part of its approach to making and implementing laws.

In view of this, the ERF held a meeting in March 2011 of invited guests and expert speakers to consider ex post evaluation of regulatory decisions and to identify conclusions and recommendations relevant for the development of an effective ex post evaluation process at EU-level. The meeting was held under the Chatham House Rule. Invited guests included senior officials from the European Commission, United Nations, and US Government; senior lawyers from leading law firms; representatives of EU and of US-based companies; and, senior managers from the veterinary medicine, metals and mining, food and drink, personal care, household cleaning products, cosmetics, luxury goods, pharmaceuticals, performance materials, crop protection, medical devices, detergents, chemicals, business service and biotechnology sectors.

Two expert panels examined different aspects of the ex post evaluation of regulatory decisions. One panel, made up of senior officials from the OECD, European Commission, and Swiss Government, along with a senior representative of US companies and ERF experts, considered developments in the use of ex post evaluation processes in the EU and elsewhere, and highlighted new ideas for the evaluation of risk management decisions. Recommendations for ex post evaluation processes at EU-level were also debated.

The second panel examined some of the unintended consequences of risk management regulation in the EU. The panel, made up of senior managers from the crop protection, chemicals, food and drink, and biotechnology industries, used "real world" experiences to highlight horizontal themes that have emerged from risk management decisions. Ideas for the development of EU-level ex post evaluation processes, and how they might improve the effectiveness of risk management decisions, were examined as well.

This ERF Background Note summarises some of the issues raised by guests, speakers, and ERF experts at the meeting held in March 2011. It is not an exhaustive record of the debates. It provides ideas for the development of ex post evaluation at EU-level.

2. EX POST EVALUATION AND THE POLICY CYCLE

Experts from the OECD, European Commission, Swiss Government, and European Risk Forum commented on the purpose of ex post evaluation of regulatory outcomes, the role it plays in the "policy cycle", its benefits for legislators and regulators, and the rationale for its increased use by governments throughout the OECD area. Specifically, they highlighted a number of issues, including:

- Ex post evaluation is a regulatory process management tool that assesses systematically the outcomes of regulatory decisions after implementation. Used well, it examines the relevance, effectiveness, and impacts of regulatory decisions. At its most successful, it identifies expected outcomes, unintended consequences, reasons for failure, and causes of success.

- The progressive introduction of ex post evaluation of regulatory decisions by an increasing number of governments throughout the OECD area forms part of the wider "regulatory performance agenda" being pursued by regulators. It strengthens the "evidence-based" approach to policy-making and complements other regulatory process management tools, such as consultation, simplification, impact assessment, access to documents, and evidential standards.

- Systematic and rigorous ex post analysis enhances the quality of regulatory decisions and the processes used to make them. It improves the quality of future regulatory decisions by providing policy-makers and decision-makers with evidence of "real world" effects, unintended consequences, design failings, and compliance weaknesses. It facilitates the reform of existing regulations, identifying outcomes where costs exceed benefits, highlighting areas for improvement and the causes of success or failure, and providing legitimacy for regulatory reform. Ex post analyses also improve the effectiveness of "ex ante" analyses and processes, as well as enhancing accountability and transparency, and reducing the risk of regulatory failure.

- In most OECD countries, however, there is relatively little tradition or expertise in systematic ex post evaluation of regulatory decisions. High quality ex post evaluations are, moreover, difficult to undertake: obtaining credible evidence is expensive; and, identifying the distinctive impact of regulatory factors on real-world situations is challenging because of the time lag between implementation and evaluation, combined with the impact of other, non-regulatory events.

- Despite these difficulties, substantial progress has been made in some OECD member countries. Taking account of this, it is possible to identify a small number of "success factors" for the effective use of ex post evaluation tools to assess the outcomes of regulatory decisions. These include high level political support (such as the Commission's 2010 Communication and the recent Executive Order from President Obama in the USA); clear analysis of expected outcomes and metrics in ex ante assessments; sunset clauses to force regulators to undertake reviews; systematic review of existing rules after extensive consultation; dedicated policies, tools and institutions to oversee and undertake implementation; and clear, flexible guidelines for analyses.

3. EX POST EVALUATION AND THE MANAGEMENT OF RISK

The ex post evaluation of risk management measures was discussed by ERF and industry experts. They made a number of observations:

- Risk management is a core role of all modern governments, including the EU's institutions. It embraces the prevention, reduction, or re-allocation of a wide range of risks, including those potentially posed by technologies. Risk management measures typically involve a combination of primary laws (defining objectives and the level of risk acceptance) and complex, case-by-case implementation processes, such as comitology or the "New Approach" at EU-level.

- Effective management of risk ensures an acceptable trade-off between protection of citizens and the environment from harms on the one hand, and the promotion of innovation, investment, and entrepreneurship on the other. Achieving this balance is often difficult at EU-level because of the shift in policy goals from risk reduction to social aspiration; the reduced influence of science and increased impact of social concern and precaution on decision-making; and, the politicisation of implementation processes. All of these factors lead, in too many cases, to costs exceeding benefits of risk management measures, in part because of the emergence of negative unintended consequences.

- Indeed, poor quality risk management measures can undermine incentives to innovate, without creating compensating public benefits. This occurs because risk management decisions affect public attitudes and levels of acceptance of risk, as well as the time, cost, and certainty of developing new or improved products. In many cases, risk management decisions also reduce the availability of established technologies, because of the impact of regulatory-induced "defensive R&D" decisions on the de-listing of existing substances by suppliers.

- In view of the EU's strategic focus on the promotion of innovation, so as to raise living standards and meet other social challenges, combined with the increasing evidence of negative unintended consequences of existing policy actions, there is an urgent need to undertake high quality, systematic ex post analysis of a wide range of risk management measures.

- When this is undertaken, regulators and assessors need to focus on six issues: they must ensure that the initial need to regulate was justified and that the scientific basis for this was correct; second, they must ensure that the original proposal, and its attendant ex ante analyses, identified and quantified costs, benefits, and success measures fully; third, they should estimate the expected costs and benefits delivered by the measure, as well as highlighting any unintended consequences; fourth, they should assess the original ex ante assessment process and consider its completeness and accuracy; fifth, the causes of any successes or failings must by highlighted; and, finally, the need for any revisions to the measure must be considered.

4. UNDERSTANDING THE CONSEQUENCES OF REGULATORY DECISIONS

High quality, systematic ex post analysis provides policy-makers with the opportunity to understand the consequences of regulatory decisions. In turn, this provides a basis for the revision of existing legislation as well as identifying wider 'horizontal' lessons. Used well, this enables policy-makers to improve the design of new legislation and to avoid repeating mistakes. Experts from a range of industries examined these issues, using information from case studies to highlight some of the unintended consequences of existing risk management rules:

- In the Crop Protection sector, the progressive introduction of new health and environmental standards since 1993 has triggered the removal of more than two-thirds of active substances, predominantly because of the cost of mandatory defensive R&D. At the same time, these additional risk management requirements have increased substantially the cost of developing new, replacement molecules, creating barriers to innovation and reducing numbers of new products. (New risk management requirements, agreed in 2009, will worsen the situation, establishing additional precautionary and hazard-based requirements and seeking mandatory substitution for some types of substance.) Taken together, these regulatory factors have triggered a substantial lack of products for minor uses (leading to lower yields for some crops) and reduced the ability of farmers to combat "drug resistance" and disease in major arable crops. Over time, this is likely to erode agricultural productivity, increasing reliance on imports and worsening carbon emissions.

- Evidence from other sectors provides complementary, horizontal evidence of these types of regulatory impact. In the Animal Health industry, for instance, new safety and environmental standards and tests, applied progressively since 1990, have severely reduced the availability of existing substances, primarily for reasons of cost, whilst at the same time increasing the capitalised costs of investing in new products. This has triggered reduced investment in new products in the EU, greater use of older technologies, and a significant lack of availability of medicines to treat minor species and diseases.

- In response to concerns about the use of new technologies in the Food and Drink industry, the EU introduced the Novel Foods rules. These require mandatory pre-market approval, supported by complex safety testing, for the use of certain technologies. Unlike other OECD countries, the EU's implementation processes, and testing requirements, impose substantial delays and additional costs, on prospective new products, without any evidence of higher standards of safety or protection. The same new product required 31 months for regulatory approval in the EU, compared to 3 months in the USA, for instance. As a result, relatively little use has been made in the EU of certain new food technologies, limiting the innovative capacity of the Food and Drink sector. In effect, EU regulation has distorted technology choices in a global industry, making it more difficult for EU-based companies to develop some new segments for the European market and hence to increase value added and productivity. This produces a 'drag' on improvements in overall EU living standards, because of the overall importance of the Food and Drink industry to the EU's economy.

- In the Chemicals industry, business groups have invested in ex post analyses in order to monitor the impact of the new REACH legislation. Evidence from a tracking study of a representative panel of companies shows how the initial phases of REACH, focused on registration and testing of higher volume products, have created substantial costs without any evidence of major benefits for human health. A significant number of companies reported losses, including de-listing of uses of substances because of the costs of mandatory testing. Other companies had experienced stigmatisation of materials because of listing requirements for authorisation. Losses of existing substances and stigmatisation are likely to pose problems for innovation in all parts of the chemicals value chain over time. Alongside this, companies have spent hundreds of millions of Euros to comply with registration and testing requirements. The justification of these costs remains unproven. The tracking study, combined with other evidence, shows that, as yet, no single, major new hazard has been identified.

- The regulatory landscape facing users of modern biotechnology in the EU illustrates many of the unintended consequences of risk management rules for the dissemination of new, enabling technologies. In the EU, unlike most other OECD countries, users of biotechnology must adapt to technology-specific risk management laws, combined with the impact of a formal Precautionary Principal and highly politicised technical regulatory decision-making processes. Taken as a whole, this approach to managing risk amplifies social concern and stigmatises new technology, creating incentives for downstream users and investors to use older, less productive ideas. Many of the wider consequences of this approach are now becoming apparent. In the agricultural sector, for instance, the lack of use of modern biotechnology, combined with obstacles to trade in bio-crops, reduces food security for the poultry and pork industries, lowers overall productivity, and requires feed-stock for the future "bio-economy" to be imported.

- A number of 'horizontal' lessons are highlighted by these examples. First, the application of new safety or environmental standards to uses of existing products will, unless carefully designed, trigger major losses of substances. Businesses will not defend substances, even if they are safe, when the costs of mandatory defensive R&D exceed capitalised contribution margins. Second, increasing safety and environmental requirements for new products is likely to distort investment in innovation. Higher capitalised costs of new product development reduce the number of projects supported, focus efforts of large markets (to the exclusion of smaller ones), and favour older, proven technologies over new ones. If the EU's regulatory-induced costs are higher than those incurred elsewhere, then higher development costs will trigger delocalisation of investment. Third, regulatory factors can distort technology choices, favouring older, well-established approaches rather than newer platform technologies. Over time, this limits the capacity of economies to up-grade. Four, poorly-designed, well-intentioned risk management rules can trigger risk-risk outcomes, such as a lack of availability of medicines for animals or increased crop disease. Finally, all good risk management regulation should provide good, quantified evidence that benefits justify costs. Unless this is done openly and explicitly then resources are wasted and, because of the "health-health" trade-offs that emerge, morbidity and mortality may increase rather than be reduced.

5. RECOMMENDATIONS

Experts and other meeting participants, together with ERF experts, identified a number of recommendations that, if implemented fully, could help strengthen and improve the ex post evaluation of risk management measures by the EU's institutions. Specifically:

- **Improve the initial quality of risk management measures prior to implementation through the development of specific guidance for the ex ante assessment of such proposals.** Guidance should require the "problem definition" to be based solely on high quality science, supported by peer review of relevant risk assessments. It should ensure that all proposed risk management rules have tangible, measurable objectives. The use of cost effectiveness tools should be encouraged strongly along with the quantification of costs and benefits. Finally, regulators should be required to seek the least onerous risk management option, to ensure that options target the causes of the problem directly, to select only those options based on proven effectiveness and workability, to act proportionately, and to consider unintended consequences.

- **Strengthen the role of the European Commission's Impact Assessment Board** by requiring it to ensure that, for all risk management proposals there are measurable outcomes, quantified metrics of costs and benefits, and a clear link between problem definition and risk management option. Through these reviews, the IAB should verify that effective ex post analysis is feasible.

- **Establish monitoring and early warning mechanisms for existing and new risk management rules** to ensure that potential regulatory failures, unintended consequences, and implementation problems are identified.

- **Make widespread use of high quality scientific assessments to evaluate the relevance and effectiveness of risk management measures.** This should be supported by the introduction of wider evidential and process standards for the use of scientific evidence in decision-making.

- **Ensure the extensive involvement of affected parties during the process of ex post evaluation,** using surveys, formal consultation exercises and other relevant methods.

- **Develop a comprehensive understanding of 'horizontal' (multi-sectoral) unintended consequences of risk management rules, and develop guidance for regulators.** Issues of concern include impacts on innovation, dissemination of new technologies, the loss of existing technologies, demand stigmatisation, and risk-risk.

- **Prevent regulators from introducing replacement risk management measures until ex post evaluations have been undertaken.**

2011

This Background Note was written by Richard Meads, the European Risk Forum's rapporteur, with help from members of the Forum. However, the views and opinions expressed in this paper do not necessarily state or reflect those of the European Risk Forum.

Rue de la Loi 227, B – 1040 Brussels, Belgium
Telephone + 32 2 613 28 28 Facsimile + 32 2 613 28 29
www.riskforum.eu email: info@riskforum.eu