



EUROPEAN RISK FORUM – COMMUNICATION 12

**THE INNOVATION PRINCIPLE – LETTER TO THE PRESIDENTS OF THE
EUROPEAN COMMISSION, THE EUROPE COUNCIL, AND THE EUROPEAN
PARLIAMENT**

October 2013

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 practitioners 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.

EXECUTIVE SUMMARY

Innovation is the single most important driver of societal prosperity and is indispensable for sustainable development and economic growth. Without innovation European industry will lose competitive advantage and attractiveness for investment and steadily fall behind other economies.

Prosperity concerns the life of everybody and is a common good. To achieve it, investors, managers, and entrepreneurs need to be innovative and take business risks. Governments can play an important role by supporting a business environment that encourages innovation. In Europe, such “enabling conditions” are mainly shaped and guaranteed through EU policies.

Innovation has been and remains a high priority for the EU, however the focus has generally been more on funding than the regulatory environment. Nevertheless, over the past two decades, the EU institutions have put in place important and far-reaching risk assessment and risk management functions.

In too many instances, however, the necessary balance of precaution and proportion is increasingly being replaced by a simple reliance on the precautionary principle and the avoidance of technological risk.

In advance of the October 2013 European Council on innovation, twelve of the largest investors in innovation in the EU, supported by the European Risk Forum, have written to the Presidents of the European Commission, European Council and European Parliament both to draw attention to these concerns and to propose a constructive way forward.

The letter proposes the formal adoption of an **Innovation Principle** in European risk management and regulatory practice. The principle is simple – that whenever precautionary legislation is under consideration, the impact on innovation should also be taken into full account in the policy and legislative process. It seeks to balance a reliance on hazard based regulatory approaches, geared to removing or avoiding unknown risks, with encouragement of innovation as an equally important objective for the EU.

This communication from the European Risk Forum contains a copy of the letter from the CEOs, a set of seven key recommendations, and further explanation of the Innovation Principle.

The Innovation Principle
"Stimulating Economic Recovery"

Open Letter to Mr. José Manuel Barroso
President of the European Commission
Rue de la Loi 200
1049 Brussels

Mr. Herman Van Rompuy
President of the European Council
Rue de la Loi 175
1048 Brussels

Mr. Martin Schulz
President of the European Parliament
Rue Wiertz 60
1047 Brussels

9 October 2013

Dear Presidents,

As major investors in European innovation, we welcome the focus of European leaders on innovation as the key to sustainable economic recovery and future European prosperity. Together our companies invest more than €21 billion every year in research and development and would like to see Europe continue as a leader in global innovation.

For this reason, we are deeply concerned by the negative impact of recent developments in risk management and regulatory policy on the innovation environment in Europe. Innovation is by definition a risk taking activity. These risks need to be recognised, assessed and managed but they cannot be avoided, if society is to overcome important challenges such as food, water and energy security and sustainability.

Europe has consistently sought a balanced approach to risk management through a rigorous science based approach and careful balancing of the principles of precaution and proportion in relevant regulation. Whereas precaution calls for the avoidance of risk, proportion allows the benefits of risk taking to be weighed against the possible consequences on the basis of the best available evidence.

Our concern is that the necessary balance of precaution and proportion is increasingly being replaced by a simple reliance on the precautionary principle and the avoidance of technological risk. We see numerous practical examples across a range of technologies, from engineering to chemicals and agriculture to medical sciences. The potential for all these technologies to advance social and economic welfare is undisputed but is being put at risk by an increasing preference for risk avoidance and the loss of scientific methodology from the regulatory process.

We are writing in advance of the October 2013 European Council on innovation, both to draw attention to these concerns and to propose a constructive way forward. In this spirit, we would like to propose the formal adoption of an **Innovation Principle** in European risk management and regulatory practice. The principle is simple – that whenever precautionary legislation is under consideration, the impact on innovation should also be taken into full account in the policy and legislative process.

To help advance discussion we are pleased to attach a set of seven key recommendations. We see these very much as initial proposals and our intention is to add support to the many productive ideas already put forward by the High Level Group on Innovation Policy Management and other expert bodies.

The stakes are high and we believe that a shift of emphasis is urgently needed. The **Innovation Principle** can help to restore the balance of European regulatory policy in favour of continued investment in European innovation and we look for positive outcomes from the forthcoming European Council. We will, of course, be very pleased to contribute our expertise and experience in whatever form would be most useful and appropriate to achieve this objective.

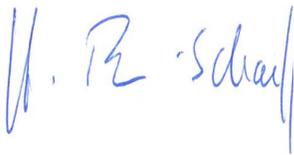
Yours sincerely,



Dr. Marijn Dekkers
Chairman of the Board of Management
Bayer AG



Kurt Bock
Chairman of the Board of
Executive Directors
BASF SE



Dr. Helga Rubsamen
Chief Executive Officer
Curis GmbH



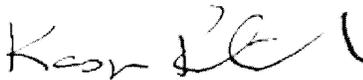
Andrew Liveris
President, Chairman and
Chief Executive Officer
The Dow Chemical Company



Robert Hansen
Chief Executive Officer
Dow Corning Corporation



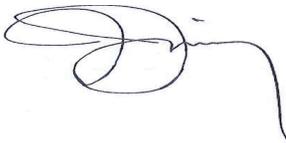
Antonio Galindez
President and Chief Executive Officer
Dow AgroSciences LLC



Kasper Rorsted
Chief Executive Officer
Henkel AG & Company



Harry van Dorenmalen
Chairman
IBM Europe



Joseph Jimenez
Chief Executive Officer
Novartis AG



Frans van Houten
President and Chief Executive
Royal Philips



Jean-Pierre Clamadieu
Chief Executive Officer
Solvay S.A.

Michael Mack
Chief Executive Officer
Syngenta AG



The Innovation Principle

“Stimulating Economic Recovery”

Key Recommendations

1. Establish a formal regulatory policy framework to support innovation in Europe based on the principles of:
 - science based risk assessment and management
 - balance and proportionality together with precaution
 - reduction of regulatory burdens in line with the conclusions of the May 2013 *Competitiveness Council*
 - full inclusion of relevant expertise
 - transparency of information and evaluation processes
 - protection of commercially confidential information
2. Initiate an in-depth review of the effectiveness or otherwise of existing regulatory processes in supporting innovation
3. Amend the Commission’s Impact Assessment guidelines to require formal evaluation of the impact on innovation and new technology development of new or amended legislation, regulation or administrative decisions
4. Revise the Commission’s Impact Assessment guidelines to include specific methodologies for:
 - evaluation of the complex costs and benefits of advanced technological development
 - assessment of the impact of proposed regulation on product development economics and product de-selection
 - determination and presentation of the uncertainties and risks associated with proposed or likely alternative courses of action
5. Develop formal regulatory process management standards for the use of science in legislative and regulatory decision-making and establish clear accountability within the European Commission for the development, use and continuous improvement of such standards

6. Require the obligatory ex-post evaluation of the effectiveness of risk management legislation, regulation or administrative decisions in addressing the issue originally identified as causing concern and provide for the amendment/reversal of such measures where:
 - new evidence becomes available to demonstrate an acceptable balance of risks
 - ex-post evaluation demonstrates no material impact on the issue originally identified as giving rise to concern

7. Provide a formal power for the Chief Scientist of the European Commission to review the use of scientific evidence in risk management legislation, regulation or administrative decision and to require further scientific assessment where appropriate

The Innovation Principle
“Stimulating Economic Recovery”

Innovation Principle Q&A

Questions	Answers
What do you mean with innovation?	Innovation is the process of translating discoveries and ideas into technologies, processes, products and services and bringing these to market so that they can benefit society. As such, it is vital for consumers, citizens and companies of all types and investors in all sectors.
Why is innovation so important?	Innovation is the single most important driver of societal prosperity and is indispensable for sustainable development and economic growth. Without innovation European industry will lose competitive advantage and attractiveness for investment and steadily fall behind other economies.
Why do you address innovation at the EU level?	Prosperity concerns the life of everybody and is a common good. To achieve it, investors, managers, and entrepreneurs need to be innovative and take business risks. Governments can play an important role by supporting a business environment that encourages innovation. In Europe, such “enabling conditions” are mainly shaped and guaranteed through EU policies.
Why is the Innovation Principle necessary?	Innovation has been and remains a high priority for the EU, however the focus has generally been more on funding than the regulatory environment. Nevertheless, over the past two decades, the EU institutions have put in place important and far-reaching risk assessment and risk management functions. The Innovation Principle proposes to continue this development by establishing a new and positive policy-making framework in support of innovation. It seeks to balance a reliance on hazard based regulatory approaches, geared to removing or avoiding unknown risks, with encouragement of innovation as an equally important objective for the EU.
Why so much emphasis on risk? Should safety not be the main objective?	Safety and security are essential elements of prosperity. Nonetheless, without risk we would not have progress in areas such as transport, telecommunications or medicine. There is no innovation without risk and these risks need to be accepted, understood and managed if society is to reap the benefits & Europe is to be technologically competitive.

Is the Innovation Principle intended to undermine or attack the Precautionary Principle?	No. The Precautionary Principle is important and there for a purpose. The Innovation Principle is intended to create a positive framework for European innovation, providing a way to balance precaution and innovation for wider social benefit. Without such a balance, innovation and progress will suffer, with no demonstrable benefit for human health or the environment.
Isn't this just another case of industry lobbying for innovation, without regard for human or environmental safety?	The Innovation Principle is intended to support social progress and economic prosperity through encouraging innovation. Seen in this way, it's in everyone's benefit. Where there is real danger and unacceptable risk, precautionary considerations should be uppermost. The Innovation Principle does not set out to support innovation irrespective of its impact on health or the environment. It seeks to support an evidence-based approach, relying on scientific excellence, which is accountable, proportionate, balanced and reviewable.
Who is behind the Innovation Principle?	The Innovation Principle was conceived and developed by members of the European Risk Forum.
What is the European Risk Forum?	The European Risk Forum (ERF) is an expert-led, not-for-profit think tank, which promotes high-quality risk assessment and risk management decisions by the EU institutions and raises awareness of risk management issues at the EU level. The ERF pursues a strict cross-sectoral ("horizontal") approach in its promotion of good principle and practices for risk governance, and does not advocate for any individual industry or product. Further information on the ERF is available on its web site: http://www.riskforum.eu/ .
Why is the Innovation Principle not more specific?	The ERF letter to the three EU Presidents, which was signed by twelve CEOs of leading innovative companies from a range of different industrial sectors, aims to initiate a process of support and encouragement for innovation. The letter and attached recommendations mark the start of a process, and not the end of one. It will take time, effort and vision to establish the Innovation Principle as a European policy framework, and stakeholders, experts and policy makers are encouraged to contribute to this process.
Writing a letter to Presidents of the EU institutions is a good start, but won't the Innovation Principle just be forgotten after the Summit?	Yes indeed. The Innovation Principle letter to the three EU Presidents alone will not of itself accomplish the objective. The ERF and its member organizations are committed to build on this initiative, and include other stakeholder, to give the Innovation Principle the momentum it needs to have a positive impact on EU policy making.
Which companies signed the letter?	The CEOs of the following companies have signed the letter: BASF, Bayer AG, Curis, The Dow Chemical Company, Dow AgroSciences, Dow Corning, Henkel, IBM, Novartis, Philips,

	Solvay and Syngenta. Other leading innovative companies from a range of industrial sectors have also indicated their support for the initiative and an interest to participate in the ongoing process of establishing it as a corner stone of EU policy.
Why didn't more company CEOs sign the letter.	With limited time before the EU Council's Innovation Summit, which will start on 24 October, it was important to move forward with this initial strong body of support for the Innovation Principle, before the summit. With this impressive start, the ERF is confident that other companies and sectors will contribute to the ongoing process of establishing the Innovation Principle in EU Policy.
Which industrial sectors are represented by the CEOs who signed the letter to the three EU Presidents?	CEOs representing the chemicals, pharmaceuticals, nutrition, materials, consumer products, electronics, biotechnology, crop protection and agricultural sciences sectors signed the letter.
How can I learn more about this initiative? How can I signal my interest to participate?	The European Risk Forum is coordinating the initiative. You can contact the ERF Secretary General, Dirk Hudig, at dirk.hudig@fipra.com . It may also be useful to liaise directly with peers at companies already participating in the initiative.