The Problem of Low and Uncertain Risks: Balancing Risks and Benefits

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I. Introduction

Both the Lisbon Treaty and the new Inter-Institutional Agreement strengthen the role of the European Parliament (EP) as co-legislator. At the same time, European Union (EU) officials increasingly recognise the need for broader acceptance of the principles and agreements of the Better (Smart) Regulation strategy, as proposed in an October 2010 Commission Communication.[1] There is a need to make high quality risk management decisions in a more risk averse environment and a changed policy framework. Indeed, principles supporting better regulation have become more widely adopted by all EU institutions, notably with the Impact Assessment Board (IAB) of the European Commission, which now screens all new proposals. Due to the broad diffusion of these principles, risk assessment techniques have become more widely understood. This trend is particularly salient in four areas of application: (1) the on-going debate between regulating by hazard and regulating by risk; (2) a better understanding of the nature of risk/risk trade-offs, (3) use of benefit/risk assessment, and (4) the Commission Communication regarding the precautionary principle[2].

II. Importance of risk assessment

1. Hazard and risk

The regulation of substances on a hazard-based method is, by itself, both restrictive and problematic. This method does not consider the probability of risk occurring, only the presumed realization of the danger of that risk. Indeed, this method does not balance the likelihood of incurring costs against the likelihood of incurring benefits, given a particular action or product. There are dangerous substances such as chemical intermediates which never lead to exposure risks. Further, while numerous substances are meant to have a salutatory biological effect, what level of demonstrably dangerous residues is acceptable? The capability of new technologies to discover even minute traces of chemical substances – such as a sugar cube in an Olympic-sized swimming pool – emphasizes the need for nuanced legislative and policy deliberation of the hazard and risk distinction.

2. Risk / Risk trade-offs

Some regulations, such as REACH, the EU's legislation on the regulation of chemicals[3], allow for regulators to substitute substances with others which are determined to be safer. This however, raises the question of whether or not these different substances pose new, unforeseen risks for the public. For example, some environmental groups see genetically modified cotton with insect-repellent properties as more desirable than the alternative of using insecticides. However, it is unclear what long-run effects such modified cotton may have on the larger ecosystem and the possibility of this danger may lay outside

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1 European Commission, "Communication from the Commission to the European Parliament, the Council, the European Economics and Social Committee, and the Committee of the Regions: Smart Regulation in the European Union", Brussels: COM 2010 543 Final.

2 Communication from the European Commission on the Precautionary Principle, Brussels: COM 2000/001.

3 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), available on the Internet at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:136:0003:0280:en:PDF> (last accessed on 13 April 2012).

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the scope of current scientific measurement. In this realm of uncertainty, how can science avoid the dangers of politicisation?[4]

3. Benefit / Risk assessment

It is further unclear if current cost-benefit assessment methodologies give enough weight to the benefit side of the calculation. For example, pharmaceuticals may have unwanted side effects, but save lives as well. Presumably, regulators grant approval when the probable outcome of potential benefits outweighs the probable outcome of potential risks. However, the perennial debate asks how the benefits of a life-prolonging drug should be calculated. How can a regulator quantify the benefit received from a prolonged life, or is this even a calculation that a centralized authority can make on behalf of its citizens? Perhaps not, but regulators will do so regardless, given the perceived lack of a suitable substitute action. Regulators, however, may be in a position to better assess some risks, such as determining whether or not there exists "zero risk"[5] in bioactive materials, an evaluation which the general populace may not be capable of rendering.

4. Precautionary principle

The principle of precaution is invoked when, in the face of uncertainty regarding the potential risk of a product or action, regulators exhibit precaution by attempting to counteract the realization of a particular risk. Generally, an insufficiency of scientific evidence or experience causes an uncertainty as to whether the risk is irreversible or proportionate to a given action. The October 2010 Commission Communication (op cit.) on the precautionary principle well explains the correct application of this principle, yet it is not often properly applied.[6] Indeed, the record in the EU is that precaution is a one-way street. Even when the evidence and experience have been accumulated that prove either the ineffectiveness of or lack of a necessity for a given regulation, the precaution is not lifted. One example of such excessive regulation is the EU restriction of the cultivation of pesticide-resistant soya beans despite evidence from decades of crop harvests and millions of hectares of soya beans – with no manifestation of danger to humans or the environment.

III. European Parliament and regulatory risk assessment

Malcolm Harbour, MEP, has suggested that every new legislative proposal be first presented to the European Parliament, giving MEPs a chance to question the risk impact assessment (RIA) accompanying the proposal. Mr Harbour recommends this after reporting that the EP often finds Commission RIAs unsatisfactory, or, indeed, must order their own assessment when the Commission does not provide one[7]. An EP examination of the RIA will make clear what the aims and the means of a particular proposal are, before scrutiny by rapporteurs. With the adoption of this new procedure, one of the roles of the EP could be to inspect the science and analytical method used for the RIA. Another procedural suggestion is for the EP, before an existing piece of legislation is revised, to conduct a retrospective assessment in order to verify whether regulatory objectives have been attained without unintended consequences.

An important recent development is the appointment of the EU Chief Scientific Officer. The President of the European Commission has recently appointed Professor Glover who is attached to the Bureau of European Policy Advisers (BEPA), the Commission think tank that reports to the President.[8]

At present four procedural documents address risks in view of better regulation: (1) Risk Assessment (regulation establishing the EU Food Safety Authority); (2) Impact Assessment Guidelines; (3) Commission Communication on the use of the Precautionary Principle; and (4) Communication for the Use of Science and External Experts. The proposal is that these overlapping documents be unified into a single instrument (a guideline for the EU Institutions)

4 European Risk Forum, "The Precautionary Principle: Application and Way Forward", October 2011.

5 The term "zero risk" is placed within inverted commas because the concept is misleading. See for example: John D. Graham and Jonathan B. Wiener, *Risk Versus Risk: Trade-offs in Protecting Health and the Environment* (Cambridge, MA: Harvard University Press, 1995).

6 European Commission, "Communication from the Commission to the European Parliament, the Council, the European Economics and Social Committee, and the Committee of the Regions", *supra* note 1.

7 House of Lords – European Union Committee, "Impact Assessments in the EU: Room for Improvement? Report with Evidence", 4th Report of Session 2009–2010, 62 *HL Paper* (2010).

8 Paula Columbo, "BEPA: A Fresh Start." 17 November 2011, available on the Internet at <http://ec.europa.eu/bepa/about/fresh-start/index_en.htm> (last accessed on 13 April 2012).

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that would enhance the clarity and legal status of the regulatory process, not only for the institutions, but also for all associated stakeholders.

IV. European Parliament and Member States – Comitology

In the Lisbon Treaty, the provisions on delegated acts in Article 290[9] give for the first time real power to the EP in secondary legislation. The EP can now send observers to meetings, enhancing transparency in the co-legislation process. The EP also has a prime opportunity to become a guardian of the quality of science being used in the administrative decision-making processes. For instance, in a recent case the science used to reach a regulatory decision was not disclosed, purportedly for intellectual property-rights reasons. This should not be permitted in an intellectually scrupulous regulatory regime.

Given the changing nature of comitology in EU decision-making, the following two recommendations should be heeded. Firstly, the EP should consider its new power as an invitation to act as an ombudsman to assure that (1) procedural integrity is maintained, (2) that transparency is assured, and (3) that arguments based on junk science are promptly and accurately discredited. Secondly, the RIA resources of the EP need not be used to duplicate the original work of the Commission. However, the EP could subject the data they receive from the Commission in a more rapid way to peer-review or to carry out limited impact assessments on important amendments.

V. European Parliament and agencies

It is important to bear in mind that the Commission cannot officially delegate its powers to associated EU agencies. The agencies are therefore in principle advisory, and only the Commission makes the final decisions. In reality, however, the agencies can deliver expertise, which the Commission cannot provide and which even more certainly the EP does not have. One example of such an expert-led agency is the European Medicines Agency, which delivers advice that the Commission then adopts. Yet, agencies do not just report to the Commission. In fact, several agencies also report to the EP on their work. These agencies develop the implementing regulations and guidelines in secondary legislation, which is more often than not more voluminous (and in some cases more important) than the primary legislation which was established through the co-decision process. For example, the REACH regulation (op cit.) is some 120 pages, while the annexes and guidelines run to over 1,000 pages.

The EP also has an important role in risk communication. The public needs to be assured that the work of the agencies is of a sufficient scientific standard. The Scientific and Technology Options Assessment (STOA), an agency of the EP which has access to outside experts in cutting-edge technologies, should consider playing a more active role in supporting the agencies in the public domain in order to contain unnecessary scares and panics.

VI. Risk and proportionality

Many of the major risks arising for the environment, such as waste, water quality, and use of manufactured substances, have been addressed by the EU in recent years. There is, however, a danger that an ever more risk-averse society becomes increasingly intolerant of very marginal risks at the expense of healthy innovation and the further exploration of the unknown frontiers of science. These opportunity costs are often hidden from the public eye, and so regulators must be particularly vigilant. This is another, often unmentioned, form of regulatory precaution whose benefits are harder to see. Indeed, there is a trade-off between innovation and growth on the one hand and dealing with uncertainty in a way that effectively manages risk on the other. The EP has an important role in maintaining an acceptable balance so that innovation is not suppressed and the European standard of living and safety is ultimately sustained.

The recent appointment of a Director to oversee the EP capability of impact assessment, is potentially a very important step so that the EP is no longer solely dependent on the impact assessments made by the Commission services. This new capability can be expected in the future to act as a guarantor of quality in the system, by having parliamentary own resources to produce if required a second opinion.

9 Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community, signed at Lisbon, 13 December 2007, available on the Internet at <http://eur-lex.europa.eu/JOHtml.do?uri=OJ:C:2007:306:SOM:EN:HTML> (last accessed 13 April 2012).

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VII. Conclusions and recommendations

1. It is recommended that the EP takes steps to ensure that:
   i. Credible, high quality scientific evidence remains the key knowledge input – STOA should be used to help achieve this.
   ii. All decisions should be properly balanced, recognising complex costs as well as concerns – the new RIA approach should focus on this.
   iii. Innovation and public health goals are pursued together – use of co-decision powers to ensure this occurs.
   iv. Risk management should be based on open, predictable decision-making processes – the operation of comitology should be overseen by the EP, with this as a goal.
2. With the adoption of the EP's examination of the RIA, one of the roles that the EP could have would be to inspect the science and analytical method used for the RIA.
3. Another procedural suggestion is for the EP, before an existing piece of legislation is amended, to conduct a retrospective assessment in order to verify whether regulatory objectives have been attained without unintended consequences.
4. At present four procedural documents address risks in view of better regulation: (1) Risk Assessment (regulation establishing the EU Food Safety Authority); (2) Impact Assessment Guidelines; (3) Commission Communication on the use of the Precautionary Principle; and (4) Communication for the Use of Science and External Experts. The proposal is that these overlapping documents be unified into a single instrument (a guideline for the EU Institutions) that would enhance the clarity and legal status of the regulatory process, not only for the institutions, but also for all associated stakeholders.
5. The EP should consider its new power as an invitation to act as an ombudsman to assure that (1) procedural integrity is maintained, that (2) transparency is assured, and (3) that arguments based on junk science are promptly and accurately discredited.
6. The RIA resources of the EP need not be used to duplicate the original work of the Commission. However, the EP could subject the data they receive from the Commission in a more rapid way to peer-review or to carry out limited impact assessments on important amendments.
7. The EP also has an important role in risk communication. The public needs to be assured that the work of the agencies is of a sufficient scientific standard. The Scientific and Technology Options Assessment (STOA), an agency of the EP which has access to outside experts in cutting-edge technologies, should consider playing a more active role in supporting the agencies in the public domain in order to contain unnecessary scares and panics.

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