Editorial

The European Journal of Risk Regulation closes the year by hosting a special issue devoted to the ongoing reform of the regulation of medical devices in the European Union. It builds upon an international conference titled 'Revising Medical Devices Regulation – The Legal Challenges', organized at Tilburg University, in co-operation with the EJRR. Both the event and this special issue were led by Professor Leigh Hancher, assisted by Maria Eva Földes, from Tilburg University's TILEC (Tilburg Law and Economics Center).

In line with the research approach privileged by our Journal, this symposium brought together policymakers from several European institutions and supervisory bodies, academics, lawyers as well as health professionals and industry representatives. The main achievement of both the conference and the symposium is to offer an opportunity for scientific reflection upon a theme typically overlooked by both legal and policy scholars. Indeed, as denounced by the editors of this special issue, the law of medical devices largely remains a Cinderella discipline within EU risk regulation, being overshadowed by the regulatory regime for pharmaceutical products.

Therefore, the three articles that were selected through a competitive procedure provide a unique opportunity to gain a deeper and critical understanding not only of the current reform but also of this often-neglected area of regulatory law.

In addition to the Symposium, this issue contains three original articles. The first one, co-authored by Martijn Groenleer and Simone Gabbi, offers an original analysis of the role that EU agencies, notably a risk regulation agency such as EFSA, play in the international sphere. By blending political science, international relations and legal theory, the authors test whether EFSA has played an active role as a 'policy entrepreneur', making use of the opportunities offered by the EU food law policy within which it acts, in order to gain influence vis-à-vis other food actors. In particular, they illustrate how the Authority's drivers behind its international emergence are functional (i.e. to discharge its scientific duty EFSA needs to have access to the best information available) on the one side, and strategic (i.e. to impose its scientific authority at the global level) on the other. They predict that in the light of the above motivations the international involvement of EFSA will grow even further in parallel to its domestic growth. Indeed, it emerges that overall, despite the limited scope of action allowed by its legal framework, EFSA has – through time – been imposing itself on the international scene.

The second article, by Lukas Bergkamp and Lawrence Kogan provides a timely assessment of the ongoing negotiations of the Transatlantic Trade and Investment Partnership (TTIP) by focusing on its horizontal chapter and the impact that it might have on risk regulation on both sides of the Atlantic and beyond. They criticize both the EU and US delegations for failing to address their differences on scientific policymaking, and in particular the use to be made of the precautionary principle.

The last article discusses in turn one of the most controversial, yet often disregarded, aspects of gambling regulation: gambling by minors. While most jurisdictions attempt to eradicate minors' access to gambling by making it illegal, they often merely impose strict age-verification procedures that largely fail to achieve their declared objective. By focusing on the UK experience, the author elaborates a set of recommendations aimed at enhancing the gambling regimes vis-à-vis minors.

As usual, our correspondents keep us abreast of the latest developments in different risk regulation policies by covering issues such as the regulation of trans fats in the EU (at the time of writing the US FDA has announced its intention to ban them), that of clinical trials, GM-animals, lifestyle risks, and the newly-released Diagnostic and Statistical Manual of Mental Disorders.

Moreover, at the time the EU Commission is consulting upon its draft Evaluation Policy Guidelines, Lorna Schrefler, Giacomo Luchetta and Felice Simonelli share their experience in carrying out two Cumulative Cost Assessments (CCAs) on behalf of the EU Commission. As explained by our authors, a CCA is not a new technique to assess *ex post* outcomes of a regulation, but a set of existing tools that provide a policy appraisal 'by focusing on all policies having an impact on one class of addressees, rather than focusing on all addresses of one policy' as it is generally the case.

Several annotations of important and recent risk-related rulings from the EU Courts and the US Supreme Court complete the issue.

Finally, before wishing you happy holidays, let me thank the growing community of reviewers for their contributions during 2013. We publish their names below in sign of appreciation. It has been another great year for the EJRR!

I wish you happy holidays and a pleasant reading!

Alberto Alemanno