



EUROPEAN RISK FORUM – POLICY NOTE 29

DRAWING LESSONS FROM CROSS-SECTORAL AND INTERNATIONAL EXPERIENCES WITH REGULATORY CONVERGENCE TO ADVANCE THE TTIP AGENDA

– THOUGHTS FROM THE RISK FORUM

April 2014

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. One of the overall objectives of the ERF is the promotion of regulatory convergence in general, and between the EU and the USA in particular. To tackle continuing technical and regulatory barriers to trade, and to exploit fully the economic potential of the US and EU markets, a Transatlantic Trade and Investment Partnership (TTIP) has been proposed by the US-EU High Level Working Group on Jobs and Growth.

Regulatory co-operation is one of the most important pillars of the future Transatlantic Trade and Investment Partnership (TTIP). Throughout the OECD area, cross-border regulatory co-operation takes many forms.

In view of this, the ERF held a meeting in April 2014 of invited guests and expert speakers to draw lessons from cross-sectoral and international experiences with regulatory convergence to support the TTIP negotiations. The meeting was held under the Chatham House Rule. Invited guests included senior officials from the European Commission, the United States Government; and the OECD; academics and legal experts; senior representatives from industry associations and international standards organisations; and, senior managers from the automotive, chemicals, energy, biotechnology, crop protection, veterinary medicine, plastics, oil and gas, food and drink, personal care, detergent, metals, mining, toy, and pharmaceutical sectors.

Experts and other meeting participants, together with ERF experts, identified a small number of recommendations that, if included in the final TTIP agreement, could help strengthen regulatory convergence and reduce barriers to trade and investment. Specifically:

- Require regulatory governance, and relevant processes, standards, and requirements, in the EU and the USA to recognise explicitly the need to take account of impacts of proposed measures on the TTIP and its wider goals;
- Seek mutual recognition of existing technical standards based on the concept of “equivalence of regulatory outcome”;
- Establish a new approach to developing future technical standards;
- Embed the principles of “better regulation” in the TTIP agreement;
- Develop a common scientific and risk assessment framework to support decisions to manage potential harms posed by technologies and lifestyle choices;
- Focus on developing a framework encompassing science and evidentiary quality, risk assessment, and processes for using science in decision-making;
- Work jointly to develop a list of good practices for the use of science in decision-making, based on existing EU and US experience; and, adapt existing policies and processes for the use of science in decision-making based on the “levelling up” concept.

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. The promotion of regulatory convergence in general, and between the EU and the USA in particular is one of the overall objectives of the ERF. Over time, we have supported a number of initiatives covering issues such as regulatory process management, impact assessment, cost effectiveness analysis, risk assessment practices and standards, information quality standards, use of science in decision-making, the use of precaution, and the management of potential harms posed by new technologies.

To tackle continuing technical and regulatory barriers to trade, and to exploit fully the economic potential of the US and EU markets, a Transatlantic Trade and Investment Partnership (TTIP) has been proposed by the US-EU High Level Working Group on Jobs and Growth. Leaders on both sides of the Atlantic have expressed support. It is hoped that the TTIP negotiations will achieve a number of goals, including establishing rules and disciplines that address challenges to the global trading system, reducing costs associated with regulatory difference, and delivering greater comparability of regulations and standards.

Regulatory co-operation is one of the most important pillars of TTIP. Throughout the OECD area, cross-border regulatory co-operation takes many forms. Formal mechanisms range from common laws (developed through supra-national institutions such as the EU) to bilateral agreements reached through binding treaties. Softer approaches encompass looser frameworks between governments (such as the regulatory co-operation agreement between the USA and Canada); sectoral agreements achieved through networks of regulators, such as the Basel Accords for banking; soft laws, including mutual recognition and the use of international standards for product safety and performance; and informal agreements between regulators to share information, as occurs between EU and US competition regulators.

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A panel of experts examined experiences with international regulatory convergence from a range of perspectives. The panel included senior officials from the European Commission, a legal and public policy expert, the OECD, senior managers from a range of different sectors, and a leading academic. Recommendations for issues to be considered in the negotiations were also debated.

This ERF Policy Note summarises some of the issues raised by guests, speakers, and ERF experts at the meeting held in April 2014. It is not an exhaustive record of the debates. It provides ideas for the development of the TTIP negotiations.

2. DISCUSSIONS

Experts from the European Commission, US Government, OECD academia, and companies, along with invited guests and ERF experts commented on the following:

- Nature of Agreement
- Obstacles
- Policy Innovation
- Regulatory Convergence

2.1. NATURE OF AGREEMENT

- Current trade talks (the Transatlantic Trade and Investment Partnership – TTIP) are a once-in-a-lifetime opportunity to build a solid basis for regulatory co-operation, despite the institutional differences between the two sides. Differences in regulation have become one of the major drivers of trade frictions between the EU and the USA. Reducing these could help deliver a ground-breaking trade agreement, reducing market barriers, strengthening incentives to innovate and generating major economic benefits for citizens on both sides of the Atlantic.
- Negotiators should focus on delivering an agreement of substance encompassing tangible reductions in existing frictions in economically and politically important sectors and the establishment of procedures to avoid the emergence of new barriers. A substantial agreement will deliver change in major sectors, such as autos, agriculture, chemicals, IT and Finance. It will provide evidence of a new political will, and attendant procedures and institutions, to resolve future regulatory differences. Finally, there will be mechanisms for ensuring greater and earlier transparency in the development of new rules on both sides of the Atlantic.
- A substantial TTIP agreement has the potential to reduce healthcare costs and to expand access to medicines in the USA and the EU, without sacrificing scientific or regulatory standards. These are genuine benefits for citizens, particularly when societies are ageing and government spending is under pressure. Freer trade and the removal of unnecessary duplications during manufacturing product development can generate significant social gains, alongside greater prosperity.
- Over time, mutual recognition of regulatory standards should be the basis for trade between the EU and the USA, and this should be recognised in any agreement. However, this will not be achieved until there is acceptance by policy-makers, that existing frameworks of risk regulations deliver a similar level of protection for citizens and the environment on both sides of the Atlantic – the concept of “equivalence of outcome”.
- TTIP could further strengthen incentives to innovate by developing common rules for the protection of intellectual property.
- If TTIP is to be successful, then any agreement must be ambitious. In the event that negotiators focus primarily on easily resolvable issues, energy will be diverted away from more important matters and an opportunity for change will be lost. A lack of ambition may also undermine commitment from politicians and business leaders.

2.2. OBSTACLES

- Within the EU, there is opposition to reductions in trade barriers. Opponents claim that reforms will undermine protections of consumers and the environment, whilst also threatening lifestyles. There will be, it is asserted, a race to the bottom, implying that US safety standards are lower than those prevailing in Europe. These concerns need to be challenged, so as to ensure that public debates are properly balanced. It needs to be emphasised, for example, that the US approach to regulating risks delivers a comparable level of protection to that enjoyed by Europeans. When considering public discourse surrounding TTIP, policy-makers should also remember that, in liberal democracies, only elected governments represent the public interest and that the interests of the vast majority of citizens will be served best by a substantial agreement which promotes greater prosperity.
- There is opposition to TTIP within both major US political parties. Parts of the Democratic Party are always sceptical about the value of trade agreements, and a number of leaders have constituency-specific concerns. A more complex problem is the opposition to freer trade within parts of the Republican Party. It is clear that, to overcome these obstacles and to achieve a positive vote, a bi-partisan approach will be needed, supported by the business community along with moderate Republicans and Democrats. This will only happen if the TTIP agreement is substantial, offering supporters something worth fighting for. Potential support for TTIP in the USA is expected to increase after the mid-term elections.
- One potential obstacle to progress is bureaucratic resistance within regulatory communities in the EU and USA. As creators of many of the barriers to freer trade, officials may be reluctant to remove them. Only political support and commitment can overcome such resistance. Preferably, political leaders should demand across-the-board mutual recognition as an underlying principle of trade between the EU and USA, forcing regulators to justify any deviation rationally and with supporting evidence
- Looking at the longer term, it is important to develop mechanisms for avoiding the emergence of new barriers. In part this will depend upon the values of regulators converging in a number of key areas, most notably the role, and limits, of government as a manager of risk; the level, and nature, of social acceptance of risk; the consequences for prosperity, freedom, and choice of risk aversion; and the importance of participation, transparency, sound evidence, and impact assessment for good decision-making. To achieve this will require the development of trust between regulators and the pulling together of robust evidence to support greater convergence of values.
- There are major institutional and legal differences between the way in which the USA and the EU make laws and implement them. These cannot be harmonised. This provides a context within which negotiations must take place. A successful outcome depends on developing mutual trust, empowering regulators, respecting differences in legal and institutional frameworks, and recognising the economic and social drivers of reform.
- TTIP will encompass a mix of horizontal and sectoral measures. Changes of this type and of the scale necessary to deliver results will, inevitably, provoke opposition to change. A challenge facing EU and US policymakers is to build support for reform. The concerns of opponents should be understood and worries about loss of sovereignty or protection (from risks) should be assuaged. As part of the process of developing a

successful agreement, it is important to communicate to stakeholders that TTIP is not designed to de-regulate or to lower standards of consumer or environmental protection.

2.3. POLICY INNOVATION

- One possible model for moving negotiations forward, and hence delivering an ambitious agreement, is to adopt the EU's "New Approach" as a way of establishing the principle of mutual recognition. When managing a wide range of safety risks in many product areas, the EU sets out essential requirements in primary laws, leaving voluntary (standard-setting) bodies to determine how these might be satisfied and conformity assured. These standards are voluntary, but conformity with them provides 'prima facie' evidence of legal compliance. This approach to managing risk separates political and technical decision-making.
- In the automotive sector, a material reduction in existing regulatory-induced barriers to trade is the goal of auto companies on both sides of the Atlantic. A further objective is that any agreement should not lead to any automatic increase or reduction in safety or environment standards in the EU or in the USA. To achieve these goals, the auto industry is developing a new regulatory concept. This is known as "equivalence of regulatory outcome", and involves considering a vehicle as a whole, when considering safety and environmental standards, rather than individual parts or components. For this innovative approach to succeed, mutual trust and respect is needed. Each side has to accept the social choices of the other and avoid negative judgements. Success depends on recognising the equivalence of the overall aims of safety and environmental rules, and accepting that EU and US citizens demand similar levels of protection. Progress will not be possible if negotiators focus, instead, on the specific, and often different, technical choices that each group has made to achieve similar goals.
- In parts of the pharmaceutical sector, progress is being made to remove duplication of regulatory requirements that raise costs for producers without creating additional safety benefits. A recent initiative by generics companies on both sides of the Atlantic to develop new guidance for assessing the safety, quality, and efficacy of biosimilar products illustrates this. Within this initiative, all parties are seeking a common technical approach including, if possible, the reduction of duplicate clinical trials. These changes do not remove the right of the EU or the USA to refuse to authorise a product: sovereignty is unaffected. If it is successful this exercise in regulatory co-operation will create incentives for innovation, reduce the costs of healthcare, and widen access to medicines.
- Work undertaken by the OECD to try and harmonise safety requirements in the crop protection sector provides an additional model which TTIP negotiators can draw on to reduce trade frictions. Recent initiatives have focused on technical areas, including toxicological test guidelines and maximum residue limits. Taken together, these global activities provide the beginning of a framework for the development of a common approach to risk assessment based on internationally-accepted science and realistic exposure scenarios. A shared approach to understanding the risks posed by crop protection products will help increase the quality of regulatory decisions on both sides of the Atlantic.
- Mutual recognition of national safety and environmental standards occurs every day in the aeronautical sector. Planes are certified safe by national authorities and enter

other markets continuously. Such trust is not confined to the aviation industry. In the auto sector, the trade agreement between Australia and New Zealand allows vehicles approved for use in one country to be sold and used in the other.

- New approaches to old problems will only succeed if they are supported by politicians and business. Companies need to articulate why change is needed and to explain the benefits for citizens. Politicians have to accept that there is overall equivalence in the safety and environmental standards sought by people on both sides of the Atlantic.

2.4. REGULATORY CONVERGENCE

- An aim of TTIP is to strengthen regulatory convergence, as well reducing trade barriers. The concept of convergence is underpinned by a set of building blocks, specifically a common acceptance of the OECD's regulatory principles; greater co-operation between regulators; development of a Transatlantic 'reflex' in regulatory processes; and, better stakeholder consultation and participation.
- Formal mandates for regulators in the EU and the USA should be revised, so as to prevent laws, rules, and guidelines being based solely on domestic concerns. One possibility would be to require regulators to consider the impacts on their own economy of a measure that could affect international trade or investment decisions, thereby combining international and domestic impacts. Moreover, regulators should be given the legal authority to share information with other regulators and to accept their interpretations, where this is appropriate.
- One way of making the TTIP agreement substantial could be to embed 'better regulation' principles within it. This could help trigger the development of common regulatory processes, as well as defining and agreeing good practices. It would strengthen support for 'better regulation' on both sides of the Atlantic, helping, over time, to reduce the likelihood of new trade frictions.
- Regulatory differences could be reduced, in the future, if trading partners are consulted prior to the development of specific legislative or regulatory proposals.
- Horizontal risk governance policy at EU-level has not developed in a coherent or systematic way. Hazard-only methods of managing harms have emerged over the last ten years, without extensive consideration of the potential of such an approach for trade friction. Other potential negative impacts, such as the loss of technologies or erosion of incentives to innovate, have also been overlooked. These issues need to be considered, and a formal risk governance policy developed. TTIP can act to spur on this process.
- The EU's processes for implementing secondary legislation remain, in many respects, inconsistent and inadequate. More transparency and public participation is needed. Legally-binding due process standards are lacking. And, the scope of regulatory process standards needs to be expanded to include rules which implement laws. Improvements in this phase of the policy-cycle, based on OECD best practices, would make regulatory convergence with the USA easier. Adoption by the EU of a high quality Law of Administrative Procedures would help overcome these weaknesses, raising standards of governance at EU-level, reducing regulatory uncertainty and cost, and making international regulatory convergence easier.

- Substantial progress towards regulatory convergence can be achieved by focusing on the achievement of a common approach to science, scientific evidence, and risk assessment as part of the TTIP agreement. A common scientific approach needs to be developed to understanding hazards and risk, to building shared scientific methodologies, to assessment of risks, and to interpreting scientific evidence and findings. Scientists on both sides of the Atlantic should, moreover, be brought together to examine specific issues.

3. RECOMMENDATIONS

Experts and other meeting participants, together with ERF experts, identified a small number of recommendations that, if included in the final TTIP agreement, could help strengthen regulatory convergence and reduce barriers to trade and investment. Specifically:

- **Require regulatory governance, and relevant processes, standards, and requirements, in the EU and the USA to recognise explicitly the need to take account of impacts of proposed measures on the TTIP and its wider goals.** This should be overseen by the Secretariat-General in the European Commission and OIRA in the US government. It should encompass, for instance, formal consultation procedures and recognition of impacts in IAs. Where appropriate the mandates of regulators should be revised to formally take account of impact of regulation on major trading partners.
- **Seek mutual recognition of existing technical standards based on the concept of equivalence of regulatory outcome.** It should be assumed that existing frameworks of risk regulations deliver a similar level of protection for citizens and the environment on both sides of the Atlantic – the concept of “equivalence of outcome”.
- **Establish a new approach to developing future technical standards,** avoiding the creation of new EU or US-specific requirements and based on the principal of mutual recognition; or the equivalence of outcomes
- **Embed the principles of “better regulation” in the TTIP agreement.** Good practices should be defined and agreed, based on the OECD guidelines and recommendations.
- **Develop a common scientific and risk assessment framework to support decisions to manage potential harms posed by technologies and lifestyle choices.** Over time this should cover issues such as information quality, data requirements, interpretation of studies and data, assessments of risk and use of “real world” approaches, peer review of risk assessments, and risk communication¹.
- **Focus on developing a framework encompassing science and evidentiary quality, risk assessment, and processes for using science in decision-making.** The scope of the framework can be expanded in due course to include issues such as risk communication and risk governance.

¹ This approach should be separate from the Global Risk Assessment Dialogue. The TTIP approach should seek to move rapidly focusing on bringing together existing standards and processes rather than focusing on a common lexicon et al. The dialogue has made little progress since it was set up in 2008.

- **Work jointly to develop a list of good practices for the use of science in decision-making, based on existing EU and US experience.** This should contribute to the development of a “common scientific space”.
- **Adapt existing policies and processes for the use of science in decision-making based on the “levelling up” concept.** Both parties should aim to ensure that the best practice becomes the norm on both sides of the Atlantic.

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This Policy Note was written by Richard Meads, the European Risk Forum’s Rapporteur. However, the views and opinions expressed in this paper do not necessarily reflect or state those of the European Risk Forum or its members.

European Risk Forum

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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.

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