EUROPEAN RISK FORUM – POLICY NOTE 25

THE TRANSATLANTIC TRADE AND INVESTMENT PARTNERSHIP AND REGULATORY CONVERGENCE

– THOUGHTS FROM THE RISK FORUM

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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. Decision-makers on both sides of the Atlantic have expressed support.

In view of this, the ERF held a meeting in November 2013 of invited guests and expert speakers to consider the state of play of the TTIP negotiations and to debate ways forward. The meeting was held under the Chatham House Rule. Invited guests included senior officials from the European Commission, the United States Government; United Nations, academics, European Parliament, US and EU industry associations senior lawyers from leading law firms; representatives of EU and of US-based companies; 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.

Meeting participants, together with ERF experts, identified a number of ideas for inclusion in the final TTIP agreement, including the development of a shared approach to science, evidentiary quality, and risk assessment ("a common scientific space").

Specifically, leading to the following recommendations for regulatory convergence:

- Adopt a set of common, guiding principles for regulatory decision-making, specifically transparency, participation, and accountability;
- Set up a new Regulatory Co-operation Council to oversee the implementation of TTIP based on senior officials from the main US and EU regulatory bodies;
- Establish a formal mechanism for joint review of future regulations which could have a significant impact of Trans-Atlantic trade and investment;
- 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;
- Develop a common scientific and risk assessment framework to support decisions to manage potential harms posed by technologies and lifestyle choices;
- Set up a major exchange programme between agency and regulatory officials;
- Seek mutual recognition of existing technical standards; and,
- Establish a new approach to developing future technical standards.

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.

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. 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, data 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. Decision-makers 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.

Indeed, regulatory co-operation is one of the most important pillars of the future Transatlantic Trade and Investment Partnership (TTIP). The ERF believes that the ultimate objective should be an extension of the concepts underlying the EU Single Market to include its main trading partners, the USA. Achieving regulatory co-operation will require trust among all parties with a view to overcoming institutional and cultural differences.

In view of this, the ERF held a meeting in November 2013 of invited guests and expert speakers to consider the state of play of the TTIP negotiations and to debate ways forward.

The meeting was held under the Chatham House Rule. Invited guests included senior officials from the European Commission, the United States Government; United Nations, academics, European Parliament, US and EU industry associations senior lawyers from leading law firms; representatives of EU and of US-based companies; 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.

A panel of experts examined different aspects of the TTIP process, including regulatory equivalence; evidence-based decision-making; mutual recognition; technical standards; and regulatory institutions, principles, and cultures. The panel included senior officials from the

European Commission, the United States government, senior representatives of EU and US business associations and a leading academic. Recommendations for issues to be considered in the negotiations were also debated.

This ERF Background Note summarises some of the issues raised by guests, speakers, and ERF experts at the meeting held in November 2013. It is not an exhaustive record of the debates. It provides ideas and recommendations for the development of the TTIP agreement.

2. DISCUSSIONS

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

- Overall Approach (section 2.1.);
- Regulatory Convergence – Principles (2.2.);
- Management of Risk (2.3.);
- Policies, Institutions and Legal Framework (2.4.); and
- Technical Standards (2.5.).

2.1. OVERALL APPROACH

- Regulatory convergence between the EU and the USA offers an opportunity to achieve major economic pay-offs. The creation of a single Trans-Atlantic regulatory space would strengthen incentives for investment and innovation by the private sector, delivering economic growth and increased employment. For policy-makers on both sides of the Atlantic, the challenge is built on a shared recognition of the problems posed by existing non-tariff barriers to trade and to find ways to deliver a new, Trans-Atlantic regulatory environment over the long-term. Instead of the traditional approach to trade negotiations, focusing on "give and take", a new culture is needed which focuses on developing a shared, 'horizontal' approach to promoting innovation whilst also protecting citizens and the environment.

- In the past, much of the public debate surrounding Trans-Atlantic trade focused on controversial issues (such as GMOs or hormones in beef or BSE), overlooking the countless problem-free decisions made on a daily basis, and creating an aura of pessimism. This has hampered progress towards developing new regulatory processes and institutions, which could prevent the emergence of future non-tariff barriers to trade. However, there is now a shared political will to achieve a new relationship, further strengthening trade and investment, creating economic gains in a period of slow-down, and building stronger, geo-political bonds between the EU and the USA.

- Indeed, it is important for opinion-formers on both sides of the Atlantic to recognise that the goals of the TTIP negotiations are achievable. It will, however, take time to achieve these goals because it depends on building trust between communities of regulators, a process that began in the 1990s. Within this context, TTIP can be seen by EU and US regulators as providing them with ways to do their jobs better, enhancing regulatory efficiency and effectiveness, and protecting citizens and the

environment from harmful technologies without damaging investment. It also removes duplication of effort, reducing government expenditure.

- Conceptually, non-tariff barriers to trade can result from a wide range of different types of decisions by public officials, including standards, conformity assessments, technical (or scientific) guidelines, secondary legislation, adjudications, and rule-making. One problem that needs to be considered by negotiators is that too many of these **decisions are politicised at EU-level**, most notably rule-making and adjudications and, increasingly, technical and scientific guidelines. Political involvement in implementation decisions also occurs in the USA, a notable example being the rejection by the Head of the FDA of the recommendation to approve a "morning after pill", but this less is rare. If the TTIP is going to succeed then the issue of politicisation of implementation decisions must be confronted. Ideally, the political input in policy-making should be confined to drawing up of legislation, leaving implementation to be based on legally enforceable due process standards. Adoption by the EU institutions of a high quality Law of Administrative Procedures would limit politicisation of implementation decisions, encouraging investment and innovation, improving governance, and eroding non-tariff barriers to trade.

- Negotiations within the TTIP framework should focus on significant issues not minor items. They should, moreover, separate sectoral from horizontal issues. Sectoral agreements are annexes with a dynamic dimension whereas the primary agreement should focus on higher-level horizontal issues, particularly a framework to encourage regulatory co-operation.

2.2. REGULATORY CONVERGENCE – PRINCIPLES

- The TTIP process has to **accept institutional differences**: it cannot expect to restrict the political choices of the US Congress or of the European Council and Parliament. Instead it should focus on the responsibilities of the executive functions of governments (and their agencies), namely the implementation of primary laws through adjudications, rule-making, standards, guidelines, and other similar processes.

- Negotiators should seek to reduce the current and future costs for business that are the result of unnecessary divergences between EU and US regulatory requirements. In part, this will be achieved if regulatory decision-making processes are strengthened. A number of initiatives could, if adopted, contribute to this. They include basing sanitary and phyto-sanitary (SPS) rules solely on **high quality, widely-accepted science**; establishing a common evidentiary base for regulators that make risk management decisions; accepting political choices about the social acceptance of risk; and, making regulatory processes more transparent hence ensuring higher standards of participation and reducing the likelihood of poor quality rules. Sector-level initiatives should accompany these 'horizontal' initiatives.

- One way of enhancing regulatory coherence between the EU and the USA is for regulators on both sides of the Atlantic to adopt a set of guiding principles that should, if implemented fully, reduce unnecessary divergences. The principles are:
  - **Transparency** (regulators on both areas and stakeholders should have full access to decision-making processes and supporting evidence);
  - **Participation** (decisions should be informed by better consultation, including public hearings, and enhanced co-operation between agencies); and,

- **Accountability** (implementation of laws through rule-making should meet globally-accepted standards of good administration).

- It is important, for long-term success, to embed these principles and the importance of Trans-Atlantic regulatory convergence into the culture of regulators in the EU and USA. Regulators should, moreover, be encouraged to learn from each other.

2.3. MANAGEMENT OF RISK

- Regulatory frameworks that protect citizens and the environment from harms in this new Trans-Atlantic economic area should be based on four basic assumptions:
  - That consumers require the same degree of protection and safety in the USA and the EU;
  - That the best way to protect citizens and the environment is to base risk management decisions on the **best available science, world-class risk assessment, and open regulatory processes**;
  - That the regulatory competencies, capacities and processes of the USA and EU are equivalent and meet the **OECD's standards for regulatory governance**; and,
  - That technical standards, including those set out directly in legislation, should be equivalent.

- The EU and the USA share a common scientific heritage built on excellence and a **deep respect for the "scientific method"**. Both recognise the power of high quality scientific evidence to identify potential harms, to assess risks, to develop effective risk management measures, and to improve governance. Both are fully aware of the threats to good governance if science is politicised or if low quality evidence is used to inform decisions. Evidence-based decisions, derived form the best available scientific evidence, build trust, enhance legitimacy, and reduce the risk of regulatory failure. Indeed, the EU and the USA both accept the role of widely-accepted science in providing the basis for global trade: it forms the bedrock on which the WTO agreements are based.

- One way in which the goals of the TTIP can be advanced is by the establishment of a **common scientific and risk assessment framework for the EU and the USA**. Such an approach makes the mutual recognition of standards easier and lessens the risk of unintentional trade frictions. It can build on the existing US requirements set out in OMB guidance and on recent initiatives by DG SANCO and the independent scientific committees to develop new rules of procedure.

2.4. POLICIES, INSTITUTIONS, AND LEGAL FRAMEWORK

- An objective of the TTIP negotiations should be to set up a **formal mechanism**, involving regulators from both sides of the Atlantic, **to review future regulations** that could have a significant impact on Trans-Atlantic trade, innovation of investment. If this is agreed, it would be a genuine innovation in the regulatory process. It would create new, more demanding requirements, including the quality of scientific evidence, which must be met in order to justify the need for policy action and the nature of the proposed measure. It would, for instance, establish better evidentiary standards needed to trigger risk management measures. Over time, this would have a dramatic impact on regulatory quality, helping to improve the framing of regulatory issues and

sharpening the focus on the "problem definition" phase of the decision-making process.

- A new institutional framework is needed to make sure that the TTIP is effective. One way of achieving this would be by creating a **formal Regulatory Co-operation Council, possibly made up of the heads of EU and US regulatory agencies or equivalents** (probably OIRA in the USA and the Sec-Gen in the EU). This new body would have **oversight of implementation**; examine proposals for greater convergence; prompt new initiatives; support international standardisation; and examine amendments to sectoral annexes. Political oversight issues would also need to be resolved.

- Inter-actions between regulators should be subject to political oversight on both sides of the Atlantic. This should form part of a related process designed to enhance overall standards of transparency in decision-making.

- The EU and the USA could consider making the TTIP provisions mandatory, strengthening powers of oversight bodies and enhancing regulatory quality.

- A well-designed TTIP, focused on enhancing regulatory process standards, could strengthen governance of rule-making at EU-level. It would also help reinforce science as the principal knowledge input for risk management decisions.

- To help meet TTIP's ambitious regulatory convergence goals, the EU institutions need to adopt a **EU Law of Administrative Procedures**. Properly designed, and meeting global best practice standards, this would embed the principles of good administration and provide EU citizens and businesses with legally-binding due process standards. It would establish a legal framework for rule-making which is similar to the approach in the USA, as well as improving the quality of regulatory decisions and limiting Trans-Atlantic divergences. Regulatory convergence would be further enhanced if the EU and US adopt the core principles of transparency, participation, and accountability.

2.5. TECHNICAL STANDARDS

- The TTIP discussions should stimulate a significant examination of how technical, safety or performance standards, and associated conformity assessments, are developed and implemented. It will, thus, act as a process of **sharing good practice**, ideally seeking a new way forward. A problem facing negotiators is that standardisation 'models' in the EU and the US have different origins. In the EU, the process is based on the "new approach", where public standardisation bodies provide detailed rules to deliver the general requirements of general, framework laws. The US approach is different: standards are set principally by the private sector. A way needs to be found to overcome this difference.

- Within the TTIP process there is scope for establishing a **better approach to developing technical standards**. In the USA, the Administrative Procedures Act requires US agencies to assess international standards when proposing a new US standard. A TTIP agreement could provide a requirement for such reviews to include existing EU standards. Moreover, there is no obvious barrier preventing the EU from adopting an existing US standard, rather than developing an EU-specific one. Such an approach would, if adopted, make it easier for smaller companies to treat the EU and the USA as a single market, reducing barriers to innovation and trade.

- The TTIP negotiations could consider establishing **shared market surveillance mechanisms**, so as to ensure products meet mutually agreed standards. This would strengthen confidence of citizens in the capacity of TTIP to ensure high standards of protection.

3. RECOMMENDATIONS

Experts and other meeting participants, together with ERF experts, identified a number of recommendations that, if included in the final TTIP agreement, could help strengthen regulatory convergence and improve the quality of decision-making. Specifically:

- **Adopt a set of common, guiding principles for regulatory decision-making**, specifically transparency, participation, and accountability;
- **Set up a new Regulatory Co-operation Council to oversee the implementation of TTIP based on senior officials from the main regulatory bodies in the USA and the EU**, probably OIRA and the Secretariat-General;
- **Establish a formal mechanism for joint review of future regulations which could have a significant impact of Trans-Atlantic trade and investment**, embedding a higher evidentiary standard for government action;
- **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.** This should be overseen by the Secretariat-General in the European Commission and OIRA in the US government, using the new Regulatory Co-operation Council It should encompass, for instance, formal consultation procedures and recognition of impacts in IAs.
- **Develop a common scientific and risk assessment framework to support decisions to manage potential harms posed by technologies and lifestyle choices.** It should cover issues such as information quality, interpretation of studies and data, assessments of risk and use of "real world" approaches, peer review of risk assessments, and risk communication[1]
- **Set up a major exchange programme between agency and regulatory officials,** as part of the TTIP, modelled on the France/Germany Elysee Treaty, which has led to the exchange of people and ideas for many decades;
- **Seek mutual recognition of existing technical standards,** including compliance certifications and verifications, unless there are substantive, evidence-based reasons why standards are not equivalent;
- **Establish a new approach to developing future technical standards**, avoiding the creation of new EU or US-specific requirements;

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[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.

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); and

- 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 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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