EUROPEAN RISK FORUM – POLICY NOTE 27

THE TRANSATLANTIC TRADE AND INVESTMENT PARTNERSHIP AND REGULATORY CONVERGENCE

– "A COMMON SCIENTIFIC SPACE"

March 2014

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EXECUTIVE SUMMARY

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 Transatlantic Trade and Investment Partnership (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.

Initially, the framework should focus on three issues: science and the quality of evidence; risk assessment; and procedures, including governance

Based on the objectives of the TTIP, the European Risk Forum (ERF) believes that the following recommendations will help promote the development of a shared approach to the use of scientific evidence to manage risk, reducing potential non-tariff barriers to trade, and strengthening incentives to innovate. Specifically:

- **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, interpretation of studies and data, assessments of risk and use of "real world" approaches, peer review of risk assessments, and risk communication.
- **Focus initially 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.
- **Work jointly to develop a list of good practices, based on existing EU and US experience.** A starting point for this exercise is provided by the ERF's initial list of possible best practices (these are included in Section 3.2.).
- **Adapt existing policies and processes 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.

1. BACKGROUND

The evolution of trade relations within the world's largest trading bloc over the past 50 years has seen the steady of erosion of physical and economic barriers to trade such as tariffs and quotas. In recent times, action has been also taken to tackle more complex obstacles. With the establishment of the Transatlantic Economic Partnership in 1998, for instance, senior official and politicians from the EU and the USA have worked together to develop ways to improve transatlantic trade and investment relationships, including addressing technical barriers to trade.

As a result of these and other initiatives, many of the main remaining impediments to the free flow of goods and services are regulatory.

To tackle these and other similar differences, 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, and negotiations have commenced.

It is hoped that the TTIP 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.

One of the overall objectives of the European Risk Forum (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, information quality standards, use of science in decision-making, the use of precaution, and the management of potential harms posed by new technologies.

The ERF aims to support the TTIP initiative by providing EU and US officials with specific ideas for inclusion in any agreement and by raising awareness of additional issues that need to be considered in the negotiations or both.

In this paper, the ERF focuses on the development of a common scientific and risk assessment framework as an objective of the TTIP, as part of the process of promoting regulatory convergence, limiting trade frictions, and reducing barriers to innovation.

2. TTIP AND REGULATORY FRAMEWORKS FOR RISK MANAGEMENT

Public risk management is one of the fundamental ways in which governments solve problems and meet the expectations of citizens. It is most readily associated with government actions to protect people at work and to protect citizens and the environment from harms posed by technologies and lifestyle choices.

If it is successful, TTIP will facilitate the development of a new economic area. Within this geographic region, the regulatory frameworks that protect citizens and the environment should, the ERF believes, be based on four assumptions:

- **That the regulatory competencies, capacities and processes of the USA and EU are equivalent and meet the OECD's standards for regulatory governance**, ensuring high quality decision-making that manages risks, without triggering major, negative unintended consequences.

- **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,** minimising politicisation of the assessment of harms, maximising compliance with WTO standards, and limiting the scope for unforeseen and unnecessary trade frictions.

- **That consumers require the same degree of protection and safety in the USA and the EU.** Therefore in principle if a product is safe to sell and consume in the EU it should also be safe in the USA, and vice versa, creating a simple basis for the mutual recognition of regulatory decisions[1]. This would increase margins on traded goods and reduce the capitalized cost of the investment needed to develop new, innovative products for both markets.

- **That technical standards, including those set out directly in legislation, should be equivalent**. If the EU and the USA dos not set standards, others will. The benefits of the EU and the USA becoming the 'de facto' standard-setters for the world are potentially enormous. There would be major economic gains in global trade, as well as large economies of scale.

One way in which these assumptions can influence operational risk management decisions is through the development and adoption of a common scientific and risk assessment framework ("a common scientific space").

3. TTIP AND "A COMMON SCIENTIFIC SPACE"

3.1. OVERALL APPROACH

In managing risks to human health, public safety, and the environment, scientific evidence has been the key knowledge input for decision-making, in the USA and the EU, throughout the "regulatory cycle". Used well, science provides effective ways of identifying potential risks, protecting citizens, stimulating innovation, and using resources wisely. It also enables governments to base actions on evidence derived from transparent, rational processes, enhancing accountability, trust, and effectiveness.

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

[1] As a result of controversial decisions made in the past, there may be some perceived exceptions such as GMOs, but these should be set aside initially. The initial aim should be to agree the principle.

guidance[2] and on recent initiatives by DG SANCO and the independent scientific committees to develop new rules of procedure[3].

Initially, the framework should focus on three issues:

- Science and the Quality of Evidence;
- Risk Assessment; and
- Procedures and Governance.

Working jointly, regulators should develop a framework using the best practices from the USA and the European Union. At all times, the aim should be to "level up" existing policies and processes, such that the best and most demanding existing standard becomes the new shared approach.

3.2. GOOD PRACTICES – INITIAL IDEAS

Looking at initiatives undertaken in the USA, the European Union and other OECD member countries, it is possible to identify a number of good practices for improving access to the best available science, enhancing risk assessment, whilst also for strengthening public confidence in the objectivity of risk analysis processes and their findings[4].

Some of these practices have already been adopted by the EU or the USA or both. The challenge is, the ERF believes, to use these ideas as a starting point for assessing the approach used by regulators on both sides of the Atlantic to science and evidence, risk assessment, and procedures for overseeing scientific advice.

Specific good practice ideas include:

Science and the Quality of Evidence

- Rigorous standards for scientific quality are in place. These have a presumption favouring peer reviewed data and results, a definition of scientific quality, and require sufficient transparency to facilitate reproducibility. They also require studies, information, and data to be based on widely accepted and objective practices (the "scientific method");

- The utility of studies, data, and findings is assessed solely on the basis of transparent quality standards;

Risk Assessment

- There are transparent standards for risk analysis which include requirements to use the best reasonably obtainable scientific data, and to provide a characterisation of risks that is both qualitative and quantitative.

- Assessment of risks meets best international standards; is based on the best data, scientific knowledge, and methodology available at the time of the preparation of an opinion; and is quantified if practical;

[2] US Executive Order 13609 'Promoting International Regulatory Co-operation' (2012)

[3] DG SANCO 'Rules of Procedure of the Scientific Committees on Consumer Safety, Health and Environmental Risks, and Emerging and Newly Identified Health Risks' (2013)

[4] These comments also take account of discussions held at meetings of the ERF Risk Forum between 2007 and 2013.

- Specific criteria for critically evaluating data and scientific information are clearly explained. The application of these criteria is documented and explained;

- When assessing the likelihood of harm, risk assessors ensure that, wherever possible and appropriate, "real world" experience, including normal handling and use, informs the development of exposure scenarios;

- Uncertainties, limitations, and assumptions, as well as their relative importance and their influence on the results of the assessment are identified, analysed and documented.

- Risk assessors strive to involve or consult the most qualified experts, and to take account of a wide range of views;

- Advice is not influenced by any consideration other than scientific assessment of risks, and that this principle implies in particular the independence from any external economic or political interests, but also from bias related to political, economic, social, philosophical, ethical or any other non-scientific considerations; and,

- Issues of social acceptance of risk do not form part of a risk assessment, and risk management statements are avoided.

- Findings and conclusions of risk assessments are consistent with the available data and knowledge.

Procedure and Governance

- Policies for collection, use, and provision of scientific advice make it clear that the dominant criterion for choosing data, studies and expertise should always be that of 'excellence'. 'Independence' is, in contrast, assured through open processes and institutional checks and balances.

- Within the overall policy framework, 'independence' remains an important goal but is defined on the basis of the objectivity of advice, expertise and advisers. When officials assess scientific advice, two threats to objectivity are considered: bias and conflict-of-interest. Bias is defined as relating to views stated or positions taken that are largely intellectually motivated or that arise from close identification or association of an individual with a particular point of view or the positions or perspectives of a particular group. Tests of conflict-of-interest focus on the financial interests of advisers.

- Advisers are excluded if they have a direct financial interest or if knowledge gained could create competitive advantage or if their biases are likely to prevent them acting objectively. This is deemed to occur if an advisor is totally committed to a particular point of view and unwilling or reasonably perceived to be unwilling to consider other perspectives or relevant evidence to the contrary.

- It is a formal requirement that all risk assessments must be peer reviewed, ensuring good science, more trust, and less likelihood of undue influence. For 'influential' risk assessments, additional scrutiny is required[5]. Such reviews are characterised by

[5] This involves an independent review of the evidence and findings of important risk assessments. Public notice and comment processes are used to highlight areas of concern but an independent reviewer or panel undertakes the review. The importance of independent peer review, as a mechanism for assuring the scientific quality of risk assessments, has been fully recognized in the USA. Requirements for federal agencies are set out in US OMB 'Final Information Quality

scientific and process integrity that maximises excellence and transparency, whilst providing opportunities for public comment.

- Policies and guidance recognises the importance of basing all advice on the best available science, including that funded by the private sector. Indeed, it is accepted that because of the particular knowledge and experience of the private sector, an industrial perspective may, in many situations, be vital to achieving an informed, comprehensive, and authoritative understanding and analysis.

- Regulatory process standards, including information quality requirements, are applied to scientific and technical guidelines, including those drawn up by agencies.

- Risk assessments used to inform public risk management fall within the scope of a legal framework for rule-making. This provides citizens and businesses with legally-binding due process standards, and embeds the principles of good administration into the law.

4. RECOMMENDATIONS

Based on the objectives of the TTIP, the ERF believes that the adoption by the EU and the USA of the following recommendations will help to promote the development of a shared approach to the use of scientific evidence to manage risk, reducing potential non-tariff barriers to trade, and strengthening incentives to innovate. Specifically:

- **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, interpretation of studies and data, assessments of risk and use of "real world" approaches, peer review of risk assessments, and risk communication[6].

- **Focus initially 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.

- **Work jointly to develop a list of good practices, based on existing EU and US experience.** A starting point for this exercise is provided by the ERF's initial list of possible best practices.

- **Adapt existing policies and processes 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.

Bulletin for Peer Review' (2004). The guidance set out in the bulletin aims to increase the quality and credibility of scientific information generated across the US federal government.

[6] 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

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); 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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