The ERF Study

Better Regulation and the Public Management of Risk

The Importance of Regulatory Design for Jobs, Growth and Competitiveness

European Risk Forum

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Foreword

This study focuses on regulatory quality and the importance of having clear and well-designed regulatory instruments for the effective management of risk. Illustrated by case studies, this study shows the importance of clarity and consistency in regulatory design to achieving intended policy objectives. Finally, this study illustrates how excessively complex legislation leads to additional administrative burdens.

The European Risk Forum (ERF) is a specialised think tank, which for more than 10 years has been committed to making timely policy-orientated publications available to policymakers and opinion-formers. The aim is:

- to contribute to the general debate about the best way to manage (at EU-level) risks to human health, public safety, and the environment posed by technologies, economic activity, and lifestyle choices;
- to raise awareness amongst opinion-formers and policymakers regarding risk and the use of science in regulation;
- to promote the development, adoption, and use by the EU's institutions of modern policies, processes, and structures needed to ensure high quality risk assessment and risk management decisions at EU-level.

Alongside its publications, the ERF contributes to consultation processes undertaken by EU institutions and Member States.

ERF publications usually make specific and practical policy recommendations. I hope this study provides a fruitful basis for reflection and discussion amongst all stakeholders who aim to better understand the influence of the regulatory framework on job creation, competitiveness, and growth in the European Union.

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Secretary General
European Risk Forum
Brussels, March 2015

Introduction

The notion of "risk regulation" defines the body of law intended to reduce the likelihood of harm to individuals and society, and protect health, safety, security, and the environment from a variety of risks. Risks may be natural, industrial or technological, voluntary or involuntary, linked to life-style choices, or others. The role of risk regulation in preserving high standards of living and protection levels is undisputed.

Risk regulation deliberately seeks to impact individual and societal behaviour. As risk regulation directly affects the choices made by individuals and business, it can have an effect on technology and product availability, as well as R&D and innovation investment patterns through value chains and across countries. Ultimately, therefore, it can have an effect on jobs and economic growth. Ensuring high quality risk regulatory decisions is crucial.

This study investigates a specific aspect of regulatory quality: the importance of clarity in structuring and designing regulatory instruments aimed at managing risks.

Using a case study approach, this study highlights the impact that clear legal drafting and consistency between the defined problem, the set objectives, and the envisaged policy options have upon regulatory design and effect.

This study also illustrates how excessively general and vague, and excessively complex and verbose legislation tends to create additional burdens because of the need for further legal and administrative explanation.

In the context of this study, regulatory design is defined as the process in which the basic provisions enshrined in a legal act are conceived and formally drafted. Regulatory design hence includes legal and technical definitions as well as the setting of targets and deadlines.

This study's conclusion is that the quality of risk regulation depends largely on the design stage of public policy formulation when terms are defined, objectives and targets are set, and legal requirements are formulated.

Executive Summary

Recommendations

Committed to further promoting the quality of risk management at the EU level, the ERF has identified a series of recommendations particularly addressing the regulatory design stage.

Chapter 1: Risk Regulation

The first chapter of this study examines the process and nature of high-quality regulation, including definitions of quality legislation, policy process, and tools employed by the EU to achieve quality legislation.

The chapter examines the EU Better Regulation Strategy in context, the OECD definition of "good regulation", and the policy cycle to define the core principles and elements of high-quality regulation, including clarity of drafting, and consistency between the defined problem, the set objectives, and the envisaged policy options.

Governance arrangements and core principles of regulatory quality are reviewed, and tools of the policy cycle are examined, including Roadmaps, Impact Assessments (IAs), the Regulatory Fitness and Performance Programme (REFIT), ex post evaluation, and stakeholder engagement.

Public risk management regulation is then examined. Public risk management frequently unfolds through a complex, multi-stage approach involving primary laws that set out societal goals and define levels of risk acceptance, along with technical, implementing tools that include guidelines and standards – which can be labelled "Technical Regulatory Decision-Making Processes" (TRDMPs). TRDMPs are defined and considered in this context. Over the years, the European Risk Forum (ERF) has produced several recommendations for improving TRDMPs; these recommendations are summarised in this chapter.

Finally, Regulatory Impact Analysis (RIA) is considered. RIA is arguably the single most important regulatory tool to improve regulatory quality. If deployed well and consistently, it helps address key questions at all stages of the policy cycle.

Thus the first chapter intends to draw a clear picture of the nature and process of quality legislation as it applies to public risk management regulation.

Chapter 2: Case Study of the EU 20-20-20 Climate and Energy Package

In the second chapter, insights are drawn from a case study that illustrates the potential repercussions of sub-optimal regulatory design.

The overall objective of the EU 20-20-20 Climate and Energy Package is clear: preventing global warming from exceeding 2 °C. The wording of the Package specifies that this should be achieved in a sustainable, secure, and cost-competitive way. In particular, the Package specifies that pursuit of the climate change objective of reducing emissions should simultaneously support growth, preserve the integrity of the internal market, and help the development of low-carbon technology. However, several elements in the legislation are unclear, which has led to confusion and additional burden.

It is evident that contradictory political objectives influenced the design phase of the Package. As a result, while the Package's early objective of fighting global warming has been well framed, its overall design presents a number of flaws. This chapter assesses the extent to which the targets related to (i) a 20% reduction of GHG (Green House Gas) emissions and to (ii) a 20% increased use of energy from renewable sources are consistent with the criteria for Better Regulation. The chapter's analysis focuses on the Package as a good example of a case when a Better Regulation Strategy (BRS) approach could have resulted in a different outcome and higher-quality regulation.

Chapter 3: Case Study of Risk Assessment and Risk Management of Chemicals in the EU

In this chapter, insights are drawn from the second of two case studies that illustrate the potential repercussions of sub-optimal regulatory design.

Using the REACH Regulation on Registration, Evaluation, Authorisation and Restriction of chemicals, and some of the related processes such as the Community Rolling Action Plan (CORAP), and Risk Management Options Analysis (RMOAs), this chapter examines some of the EU's primary approaches to assessing and managing risks related to substances as defined in REACH. These approaches are briefly explained and a number of issues related to them are considered in detail, including concern over REACH´s negative impact on innovation.

The REACH Regulation is reviewed through the lens of the Better Regulation Strategy (BRS), as this chapter assesses the extent to which the targets are consistent with the criteria for Better Regulation. This chapter's analysis focuses on REACH as a good example of a case when a BRS approach could have resulted in a different outcome and higher-quality regulation.

Chapter 4: Conclusions

In the last chapter, conclusions are drawn based upon this study's examination of the elements of quality legislation, as well as an examination of two case studies that illustrate how excessively general and vague, and excessively complex and verbose legislation tends to create additional burdens because of the need for further legal and administrative explanation.

The Conclusions section of this chapter suggests that the chances of ensuring high quality risk regulation are increased through focus on the regulatory design stage because much of the potential effectiveness and efficiency of risk management measures is determined during the very initial stages of policy formulation.

Recommendations

Committed to further promoting the quality of risk management at the EU level, the ERF has identified a series of recommendations particularly addressing the regulatory design stage. Specifically:

Recommendation 1 – Develop the organisational and procedural features of new, formal "horizontal" risk regulation governance at EU level.

The new governance should encompass all three EU institutions and the EU bodies involved in risk assessment, management, and communication. It should include explicit arrangements for the collection and use of evidence based on independence, excellence, and the "scientific method"; for the provision of scientific advice close to the centre of decision-making; and for the explicit correlation between the Better Regulation Strategy (BRS), the promotion of innovation, and the achievements of the Europe2020 targets.

Recommendation 2 – Adopt a formal innovation principle in EU risk management and regulatory practice.

This would require the EU's institutions to fully assess and address the impact on innovation whenever they consider new policy or regulatory proposals. Bans and restrictions based solely on hazard characteristics are disproportionately precautionary and contrary to the evidence-based rationale because they do not generate any proof of the likelihood of harm. Application of a formal innovation principle would raise awareness of the link between regulation and innovation; it would signal to global investors the commitment of the EU to promote innovation, which would improve business confidence; it would align regulatory policy with other, economic goals, enhancing coherence; and it would ensure greater balance in regulatory decision-making, helping decision-makers become more aware of the trade-offs needed to protect citizens from harms whilst also supporting innovation.

Recommendation 3 – Introduce a EU Law of Administrative Procedure (EU LAP) setting out the key principles of good administration (transparency and consistency, public participation, public record, and accountability), and establishing clear, legally binding procedural standards.

The EU LAP would help address the complexity of public risk management and control the growing role and potential discretion that the "administrative state" enjoys as a result. If designed well, it would consolidate the procedural requirements and standards for administrative and regulatory processes. This would grant more predictability, legal certainty, effectiveness, and hence legitimacy to EU decision-making.

Recommendation 4 – Require the European Parliament and the Council of Ministers to apply the same rigour in legal drafting and impact assessment quality standards as the European Commission when co-legislating risk management interventions.

The new Inter-Institutional Agreement on Better Law-Making that is about to be re-negotiated should require Parliament and the Council to proceed to the necessary organisational and procedural adjustments and to deploy adequate resources to at a minimum match the Commission's regulatory standards.

Recommendation 5 – Enhance the overall quality of the Impact Assessments carried out on risk management measures through upgraded guidelines.

The European Commission should revisit its Impact Assessment (IA) guidelines specifically to cover risk regulation. The upgrade should aim at achieving better definitions of the nature and scale of the problem and the potential scenarios for its development, based on scientific risk assessment; better investigation of the workability and proportionality of the envisaged policy options, by using scientific evidence to distinguish between threats of harm and perceptions of risk; more structured identification of possible unintended consequences, countervailing risks and ancillary benefits; and more systematic and robust quantification of outcomes (specifically, the quantified estimates of harms and potential benefits on expected outcomes should reflect real world exposures rather than worst-case or theoretical scenarios).

Recommendation 6 – Complement and reinforce the scrutiny of the Impact Assessment quality through a strengthened Impact Assessment Board and an enhanced transparency.

The quality oversight function at EU level should be reinforced by leveraging multiple scrutiny channels. The mandate of the Impact Assessment Board (IAB) should be revised to ensure greater focus on the linkages between better regulation, innovation, and the Europe2020 targets. The membership of the IAB should be expanded to include top scientists with specific responsibility for assessing the quality of scientific evidence used to justify policy action and for reviewing all risk management decisions. In addition, draft Impact Assessment should be published for notice and comment by all interested parties.

Recommendation 7 – Strengthen the quality of legal drafting of new risk management measures.

This is likely to be achieved by consolidating and centrally publishing all rules and guidance on drafting and interpretation, by involving lawyer-linguists more systematically at an earlier stage, by reducing the fragmentation of the translation process, and by considering the establishment of dedicated drafting units composed of legal drafting specialists working in their mother tongue.

Recommendation 8 – Initiate a comprehensive review of existing risk management interventions that examines critically the use of hazard and substitution to manage harms.

Such a review should be part of the "evaluate first principle" that inspires the European Commission, and it should be applied to the Regulatory Fitness and Performance Programme (REFIT). Specifically, the review should consider the arguments used to support hazard-only management of harms, the weaknesses of the hazard-only approach, and the claimed inadequacies of the risk-based approach. It should also consider the organisational and procedural arrangements currently in place, as well as the tools deployed.

Recommendation 9 – Require all substitution decisions to be based on a case-by-case comparative risk assessment.

Acknowledging that in practice such decisions involve trade-offs between different types of hazard will help improve the quality of decision-making by making risk-risk trade-offs explicit.

Recommendation 10 – Avoid recourse to hazard-based approaches in ongoing and new policy proposals.

The EU institutions should consider introducing a moratorium on designing their risk management measures on the basis of hazard characterisation exclusively, until supporting findings for such an approach have been produced by the review of current interventions that are purely hazard-based.

Recommendation 11 – Require risk assessments to be subject to peer review if they are to be used to support major legislative or regulatory decisions.

Chapter 1: Risk Regulation

1. The EU Better Regulation Strategy in context

Regulation has become the principal tool used to organise society and the economy. Actions to ensure the quality of regulatory interventions draw heavily from principles and good practices promoted by the Organisation for Economic Cooperation and Development (OECD). In its latest Recommendation on Regulatory Policy and Governance (2012), the OECD sets out the current thinking on how to effectively implement organisational and procedural regulatory arrangements to promote economic prosperity, enhance welfare, and pursue public interest.[1]

Figure 1 – Structuring regulatory reform: The 2012 OECD Recommendation

By their very nature, reforms aimed at improving regulatory quality are composite. Three constitutive components should work as equally important pillars supporting the entire reform endeavour:

- **Core principles of regulatory quality** – These answer the question "WHAT should the reform achieve?", providing a definition of what constitutes good regulatory quality. The principles set out by the so-called Mandelkern Report of 2001 remain valid.[2] The report is at the foundation of the whole EU thinking on better regulation. It defines regulatory quality according to the following terms:

[1] OECD, About Regulatory Policy. Available at: http://www.oecd.org/gov/regulatory-policy/about-us.htm Accessed 10/12/2014

[2] Mandelkern Group on Better Regulation, Final Report, 13 November 2001. Available at: http://ec.europa.eu/smart-regulation/better_regulation/documents/mandelkern_report.pdf 10/12/2014

- It must be proven that the intervention is necessary and taken at a level as close as possible to the citizen (necessity and subsidiarity).

- The regulatory intervention must strike an appropriate and justified balance between its costs and benefits (proportionality).

- The intervention should be prepared through as wide a public participation as possible; it should be readily accessible and comprehensible to the public, and it should be possible to easily identify regulatory responsibilities throughout the decision-making process (transparency, accessibility and accountability).

- Regulation should be simple to understand, comply with, and enforce (simplicity).

Box 1 – The OECD definition of "good regulation"

According to the OECD, "good regulation" should:[3]

- serve clearly identified policy goals, and be effective in achieving those goals;
- have a sound legal and empirical basis;
- produce benefits that justify costs, considering the distribution of effects across society, and taking economic, environmental, and social effects into account;
- minimise costs and market distortions;
- promote innovation through market incentives and goal-based approaches;
- be clear, simple, and practical for users;
- be consistent with other regulations and policies; and
- be compatible as far as possible with competition, trade, and investment-facilitating principles at domestic and international levels.

- **Governance arrangements** – These answer the question "WHO should do what to ensure regulatory quality, and at which stage?". These arrangements are of an organisational nature. They build on the "softer" dimension of political commitment for a whole-of-government approach, and normally refer to the design of:

  - The steering dimension: leadership at the centre of the government should be translated into strategic vision to ensure coherence, buy-in, and constant refinement of the reform initiatives over time as well as across policy departments.

[3] OECD, OECD Guiding Principles for Regulatory Quality and Performance, 2005, Paris.

- The coordination dimension: horizontal and vertical arrangements should be in place to maximise policy integration and avoid siloed decision-making.

- The oversight dimension: the quality of regulatory outputs should be ensured through a plurality of channels and (institutional) actors, at various stages of the process.

- **Procedural mechanisms and tools** – These answer the question: "HOW can regulatory quality be achieved?" Under this category feature regulatory tools such as legal drafting; ex ante and ex post regulatory impact analysis; scientific risk assessment; administrative simplification (including digitalisation of procedures); legislative simplification; and public consultation (in its double facets of data collection and stakeholder engagement).

These three components not only depend on one another, they mutually reinforce each other. Their introduction and functioning is not to be considered as a one-off endeavour but as something to be continuously refined. They must be there not only to face regulatory crises but also to ensure a systematic and routine process of multiple checks and constant improvements.

In the EU, efforts to improve the quality of regulation have been made consistently since at least the end of the 1990s. Initiatives were clearly catalysed by the then "Lisbon Strategy" in conjunction with the White Paper on European Governance reforms; the 2002 EU's Better Regulation agenda encompassed several lines of action and was codified in an Inter-institutional Agreement on Better Law-making in 2003. [4] The agenda has been progressively refined from 2005 onwards under the imperative of facilitating the creation of growth and jobs.[5]

Currently, these reform efforts have been regrouped in a structured approach under the so-called Better Regulation Strategy (BRS). This is an umbrella label that consolidates initiatives by the European Commission and, increasingly, the European Parliament and the Council of European Union, on a number of fronts.

[4] Official Journal of the European Union, IIA on Better law-making, 31 December 2003, p. 1. Available at: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32003Q1231%2801%29&from=EN 13/12/2014

[5] Commission of the European Communities, Communication from the Commission to the Council and the European Parliament – Better Regulation for Growth and Jobs in the European Union, Brussels, 16 March 2005, COM(2005) 97. Available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2005:0097:FIN:EN:PDF 13/12/2014

Box 2 – Tackling the policy cycle: EU Better Regulation

The European Commission Better Regulation Strategy[6] (BRS) seeks to improve the quality of administrative and policy decisions taken before, during, and after the EU takes action. The idea of policy cycle informs the tools deployed, with a view to base decision-making on the most comprehensive and reliable evidence available. Broadly speaking, the strategy thus encompasses:

- **Roadmaps**, which are initial descriptions and analysis of the initiatives planned by the Commission. They are published for notice and comments.
- **Impact Assessments (IAs),** which build upon the Roadmaps on the principle of proportionate analysis to eventually become fully-fledged ex ante appraisals of the economic, social, and environmental impacts. IAs should inform decision-makers on the type and magnitude of the problem and the range of policy options likely to address it in an effective and proportionate manner. The need for public and indeed EU action should be at the core of the analysis.
- **Regulatory Fitness and Performance Programme (REFIT)**, which structures the (sectoral) screening of the EU acquis with a view to make it simpler and less burdensome. This also includes repeals of existing legislation and withdrawals of proposals pending in legislative procedure.
- **Ex post evaluation,** whose scope the Commission intends to extend to also cover legislative and regulatory interventions on a more systematic basis. Such retrospective analyses consider the relevance, effectiveness, and efficiency of ongoing measures and should "close the cycle" in compliance with the so-called "evaluating first" principle.
- **Stakeholder engagement** informs all the steps and tools. General principles and minimum standards for consultation regulate the way the Commission interacts with stakeholders and private citizens.

The European Parliament also attaches increasing importance to BRS and evidence-based decision-making. It recently created a Parliament's Research Service (DG EPRS), which includes the European Added Value Unit (EAVA) and the Science and Technology Options Assessment (STOA). The aim is to significantly enhance the coherence and depth of what is offered to MEPs in their daily work. The EP is also strengthening its capacities to inform the agenda-setting and post-implementation phases.

[6] European Commission, Smart Regulation. Available at: http://ec.europa.eu/smart-regulation/index_en.htm 10/12/2014

The BRS meets many of the above-mentioned reform elements. The three "governance arrangements", for instance, appear to be broadly addressed:

- Statements by the President of the European Commission, European Parliament's reports, and Council conclusions over the past decades have testified to the political commitment given to the cause. Since November 2014, the First Vice-President of the European Commission has been responsible for the BR portfolio. This is a promising development towards further strengthening the steering function of the reform.
- Clusters of Commissioners at the political level, and inter-Directorate General (DG) steering groups supported by inter-service consultations at operational level, work to ensure coordination. Greater collaboration is also emerging between the Commission and the Parliament in designing the annual work programmes of the EU. At a more strategic level, the Council works on a longer-term horizon, with close cooperation between subsequent EU Presidencies. The so-called European Semester contributes to maintaining coordination and focus in achieving the Europe2020 targets.
- With regard to regulatory initiatives, the oversight function at the EU level is exercised by a number of actors. They intervene with different prerogatives and roles at various levels and stages of the process. Among them feature for instance the evaluation (RIA) units in the Commission DGs; the Impact Assessment Board (IAB); as well as the EP EAVA unit. Forms of transparency play a further important role, for instance through the publication of the IAB opinions.

2. Ensuring high quality risk regulation

Regulatory reform at the EU level serves two purposes. It is a way to soften the "democratic deficit", as it helps improve the accountability and openness of the system and widens participation. Additionally, it increases the effectiveness and efficiency of the system by reducing regulatory failure through better-substantiated decision-making. Either way, BRS helps to legitimise and instil confidence in EU decision-making and the institutional actors involved, at a time of rooted euro-scepticism and general distrust in public authorities.

An area where the EU has increasingly been called upon by the public to intervene and assert credible authority is protection from risks. The notion of "risk regulation" defines the body of law intended to reduce harm to individuals and society and protect health, safety, security, and the environment from a variety of risks – be they of an industrial or technological nature, natural, linked to life-style choices, voluntary, or involuntary. The role of risk regulation in preserving high standards of living and protection levels is undisputed.

At the same time, because by its very nature it deliberately seeks to change individual and societal behaviour, risk regulation is the type of regulation that can most directly affect choices, and hence technology and product availability, R&D and innovation investment patterns through value chains and across countries, and thus jobs and economic growth. For this reason, ensuring high quality risk regulatory decisions is crucial.

Public risk management frequently unfolds through a complex, multi-stage approach involving framework primary laws that set out societal goals and define levels of risk acceptance, along with technical, implementing tools that include guidelines and standards – which can be labelled "Technical Regulatory Decision-Making Processes" (TRDMPs). These are used by governments to make large numbers of complex case-by-case decisions efficiently and to adapt rapidly and flexibly to technological progress.

At the EU level, this latter dimension covers a wide range of risks, industries, processes, substances, and products. It primarily takes the shape of delegated and implementing acts.[7]

Other forms of EU TRDMPs include 'positive' lists for food additives, food packaging materials, and crop protection products; emission limits; pre-market approval processes for pharmaceuticals, new chemical substances, and genetically modified foodstuffs; and hazard classification of chemical substances.

TRDMPs generate a significant impact upon the behaviour of citizens, consumers, and businesses; upon innovation and inclusive economic growth; and upon sustainability and the environment. This notwithstanding, TRDMPs have not yet been fully and systematically brought under the umbrella of the EU Better Regulation principles and instruments.

Over the years, the European Risk Forum (ERF) has produced several recommendations on improving TRDMPs.

[7] Delegated acts are legal measures in which the EU legislator delegates the power to adopt acts amending non-essential elements of a legislative act to the Commission. This delegation of power has strict limits: only the Commission can be authorised to adopt delegated acts, and the legislator sets the conditions under which this delegation may be implemented (Art. 290 TFEU). Moreover, the Commission is authorised to adopt implementing acts when European measures require uniform implementation in the Member States. The modalities for the legislator's monitoring of the Commission's implementing powers are adopted by the ordinary legislative procedure (Art.291 TFEU).

Box 3 – ERF recommendations for improved Technical Regulatory Decision-making Processes (TRDMP)

Among the main recommendations issued by the European Risk Forum (ERF), the following address the elaboration at the EU level of risk management implementing decisions:[8]

- **EU Law of Administrative Procedure (EU LAP):** The introduction of a well-designed EU LAP enshrining the four key principles of good administration (transparency and consistency, public participation, public record, and accountability) and providing binding standards for administrative due process would consolidate practices, minimise administrative discretion, and provide legal certainty and predictability.
- **Risk assessment and Impact Assessment**: The integration of risk assessment outputs into the IA process should be improved. Detailed guidelines should be introduced for quantifying estimates of potential harm, reflecting real world exposures rather than theoretical and / or worst-case scenarios.
- **Excellence and independence of scientific advice**: The quality of studies, information, and data to be used in scientific assessments supporting risk management decisions should be defined through mandatory standards based on "scientific method" practices. Access to all sources of expertise should be equally ensured. Independence should be defined as a function of scientific objectivity (as opposed to "bias"), alongside conflict-of-interest tests.
- **Transparency**: Ensuring higher degrees of transparency is critical to meeting the principles of legitimate expectations. To that end, the so-called "comitology" process (currently part of delegated and implementing acts) should upgrade its rules of procedures in relation to the public communication of the existence of documents; of the calendar, agendas and minutes of meetings; of the sources and evidence used (or not used) in decisions, and the reasons thereof.

On the other hand, high quality risk regulation depends also on what is being decided upstream, at the stage of the design of public policy interventions. It is this dimension that this study focuses upon.

[8] See http://www.riskforum.eu/themes--library.html for detailed publications and details. A consolidated sample of the recommendations is presented in ERF, ERF Action Plan for Improved Risk Management in the EU, November 2012. Available at http://www.riskforum.eu/uploads/2/5/7/1/25710097/erf_-_actionplan_12-2.pdf 10/12/2014

3. Regulatory design as a pre-condition for managing risks well

This paper investigates a specific aspect of regulatory quality – the importance of clarity in structuring and formulating policy interventions and, more precisely, in designing regulatory instruments aimed at managing risks.

In the context of this paper, regulatory design is defined as the process in which the basic provisions enshrined in a legal act are conceived and formally drafted. Regulatory design hence includes legal and technical definitions as well as the setting of targets and deadlines. It should be noted that the design exercise unfolds over various stages of the legislative and regulatory process, involving all EU institutions and including both technical and political actors.

In particular, this study highlights the relevance that clear legal drafting and the consistency between the defined problem, the set objectives, and the envisaged policy options have upon regulatory design.

Box 4 – The contribution of legal drafting and Impact Assessment (IA) to regulatory quality

Legal drafting is widely considered to be an integral part of the regulatory reform toolkit. It is concerned with the technical quality of a legal act and includes the act's readability and comprehensibility; i.e. whether it is clear, expressed in a simple and precise ("plain") language; whether due attention is paid to internal and external legal and semantic consistency; and, in the EU context, whether consideration is given to the multilingual nature of the regulatory regime.

The very style of legislation – i.e. the way legal acts express a given message – clearly matters. Linguists and sociologists understand laws as "coded in language", thereby stressing the cultural and symbolic relevance that these texts have in informing and shaping individual and societal behaviour.

There is at least anecdotal evidence in economic and comparative literature suggesting that poorly drafted legislation does not merely irritate end-users; it also causes deficient implementation, lowers compliance rates, and complicates enforcement. While admittedly little is known about the way in which the form or style of legal acts affects regulatory outcomes, it is commonly acknowledged that both excessively general and vague, and excessively complex and verbose texts tend to create additional burden because of the need for further legal and administrative explanation, often creating unaccountable discretion when interpreting them.

Regulatory Impact Assessment (RIA) is arguably the single most important regulatory tool to improve regulatory quality. If deployed well and consistently, it helps address key questions at all stages of the policy cycle. As such, it features centrally also in the EU Better Regulation Strategy.[9] In particular, key features of the RIA analytical mechanics include:

- **The comprehensive and detailed definition of the problem:** It is often said that no analysis can compensate for a poor definition of a problem. Therefore, this is a fundamental step in the RIA process, especially when it comes to establishing cause-effect relationships. Understanding the root factors triggering undesired behaviour and conditions and their magnitude over time is a prerequisite for getting both objectives and options right.
- **The idea of setting ambitious but workable objectives:** Risk management measures can only be effective if they mirror efforts to achieve policy objectives that are clear, realistic, and measurable. Failure to do so may hamper implementation efforts, and may make it difficult to track implementation progress, correct implementation patterns, and to assess final achievement.

In the following, insights are drawn from two sectoral case studies – the EU 2020 Climate and Energy Package and the REACH Regulation on chemicals – to illustrate the potential repercussions of sub-optimal regulatory design.[10]

[9] European Commission, Impact Assessment. Available at: http://ec.europa.eu/smart-regulation/impact/index_en.htm 14/12/2014

[10] The paper combines desk review and an original first-hand fact-finding approach. It draws from various sources including official documents, evaluation and statistics; academic literature; stakeholder's position papers and analyses; as well as media reports.

Chapter 2: Case Study of the EU 20-20-20 Climate and Energy Package

1. Introduction

The average global temperature has increased by about 0.8°Celsius since 1880.[11] According to projections, it will increase even more by 2100. Much of the scientific community concludes that a large part of the warming is due to the emission of greenhouse gases (GHGs) and their concentration in the atmosphere, as well as to human activities such as deforestation. In assessing the impact of climate change, the majority of the scientific community asserts there is a correlation between global warming and extraordinary natural events such as floods, forest fires, the melting of glaciers, and rising sea levels. Moreover, scientific evidence illustrates that the risk of natural alterations would increase significantly if global warming exceeded 2°C,[12] thus creating unforeseeable consequences.

The EU has made significant efforts to fight against climate change at both international and Member State (MS) levels. At the international level, climate change policy originated with global negotiations following the Rio Summit in 1992. Subsequently, the Kyoto Protocol to the United Nations Framework Convention on Climate Change (UNFCCC), concluded in 1997, committed its parties by setting internationally binding emission reduction targets. The Kyoto Protocol was based on the assumption that, following 150 years of industrial activities, developed countries are mainly responsible for the current concentration of GHG emissions in the atmosphere. As such, it poses a heavier burden on developed countries, in adherence with the notion of 'common but differentiated responsibilities'.[13] Under Kyoto, the MSs of the EU committed to cut their collective emissions to 8% below 1990 levels by the years 2008-2012.[14]

From a regulatory perspective, despite the fact that international negotiations about global warming had started much earlier, effective actions at EU level were taken only in 2008, and suddenly pushed environmental issues from a marginal position to the heart of the EU's agenda. However, a number of factors explain this reshaping of policy priorities.

[11] Michael Carlowicz, Global Temperatures, Nasa - Earth Observatory. Available at: http://earthobservatory.nasa.gov/Features/WorldOfChange/decadaltemp.php 16/12/2014

[12] Tina Ohliger, Climate Change and the Environment - Fact Sheets on the European Union, European Parliament website. Available at: http://www.europarl.europa.eu/aboutparliament/en/displayFtu.html?ftuId=FTU_5.4.3.html 16/12/2014

[13] United Nations Framework Convention on Climate Change, Kyoto Protocol. Available at: http://unfccc.int/kyoto_protocol/items/2830.php 16/12/2014

[14] European Commission, EU Action on Climate. Available at http://ec.europa.eu/clima/policies/brief/eu/index_en.htm 16/12/2014 At that time, 15 countries were EU Member States. Those states that obtained EU membership in 2004 also agreed to Kyoto reduction targets of 6% or 8% (5% in Croatia's case).

Faced with the failure to ratify the Lisbon Treaty, the continued financial crisis, and growing Euroscepticism, a new and genuine political commitment was needed. In this regard, the fight against climate change was viewed as a policy objective through which the EU could both regain citizens' consensus and interest in the European project as such, and portray itself as an internationally responsible actor in the realm of foreign policy leadership.[15] As Barroso put it, "'The work of the European Union is sometimes seen as rather technical. As cut off from daily concerns. Interesting to specialists, but not relevant to people's daily lives. The action we are discussing today proves this theory wrong. The struggle against climate change and the quest for secure, sustainable, and competitive energy touches on every European, every day... This package represents an opportunity for Europe to show itself at its best. Tackling an issue of fundamental long-term importance. Using the EU's continental scale to best effect."[16]

The EU was keen to implement commitments much more ambitious than those agreed under the Kyoto Protocol. In April 2009, the EU adopted the Climate and Energy Package, which set three binding targets to be reached by 2020 (the so-called "20-20-20 targets"): (i) a 20% reduction in EU GHGs compared to 1990 levels, a level which will be increased to 30% on condition that other developed countries make similar efforts; (ii) a 20% increase of energy consumption produced from renewable resources, and (iii) a 20% reduction in primary energy use through improved energy efficiency. [17]

Against this background, the overall objective of the Package is pretty clear: preventing global warming from exceeding 2°C. The wording of the Package also specifies how this should be achieved: that is, in a sustainable, secure, and cost competitive way. In particular, the pursuit of the climate change objective should simultaneously support growth, preserve the integrity of the internal market, and help the development of low-carbon technology.

However, when the 20-20-20 targets were adopted, climate change concerns represented a priority policy within a larger EU strategy, while the more traditional goals of security of supplies received minor attention.[18] This political circumstance might have influenced the design phase of the Package and undermined the EU's efforts to improve the quality of its regulations.

[15] Dieter Helm, EU Climate-Change Policy – A Critique, Smith School Working Paper Series, University of Oxford, October 2009, pp. 2-3. Available at: http://www.endseurope.com/docs/90904a.pdf 17/12/2014

[16] Jose Manuel Durao Barroso, 20 20 by 2020: Europe's climate change opportunity, European Commission – Press Release, Brussels, 23 January 2008. Available at: http://europa.eu/rapid/press-release_SPEECH-08-34_en.htm 12/01/2014

[17] European Commission, The 2020 Climate and Energy Package. Available at: http://ec.europa.eu/clima/policies/package/index_en.htm 17/12/2014

[18] Clementine d'Oultremont, Re-designing the European Climate and Energy Policies post-2020, European Policy Brief – Egmont Institute, No.29 – March 2014, p.1. Available at http://www.egmontinstitute.be/wp-content/uploads/2014/03/EPB29-corr.pdf 17/12/2014

This analysis focuses on the Package because it represents a good example where a Better Regulation approach could have resulted in a different outcome: although it is also evident that primarily political reasons have influenced its design phase. As a result, while the Package's early objective of fighting global warming has been well framed, its design presents a number of flaws. The next section aims to assess the extent to which the targets related to (i) a 20% reduction of GHGs emissions and to (ii) a 20% increased use of energy from renewable sources have been framed consistently with the criteria for Better Regulation, as detailed in the Introduction.

2. Reduction of GHGs emissions

As mentioned, when the Climate and Energy Package was approved, concerns over climate change prevailed over the other policy objectives of ensuring the security and affordability of energy supplies.[19]

Specifically, under the Package, the EU unilaterally committed to a 20% cut of GHGs, as compared to 1990 levels, by 2020, as agreed at the European Council in March 2007, which, among other things, also called for a 60% to 80% reduction by developed countries of global GHGs by 2050 compared to 1990 levels. [20]

Designed with the intention of facilitating an international post-Kyoto policy framework, the 20% target for GHGs is not solely internally focused. Rather, the EU offered to increase this cut to 30% by 2020, "provided that other developed countries commit themselves to comparable emission reductions and economically more advanced developing countries contribute adequately according to their responsibilities and respective capabilities".[21]

This international dimension raises the most important aspect of the 20% target. As it emerges from the Impact Assessment (IA), the EU's unilateral decision to set the 20% binding target for cutting emissions (as well as 30%) is based on the assumption that developed and developing countries will embark on similar efforts:

[19] ibidem

[20] Council of the European Union, Presidency Conclusions, Brussels, 8/9 March 2007, p.12. Available at: http://register.consilium.europa.eu/doc/srv?l=EN&f=ST%207224%202007%20REV%201 17/12/2014

[21] Official Journal of the European Union, Directive 2009/29/EC of the European Parliament and of the Council of 23 April 2009 amending Directive 2003/87/EC so as to improve and extend the greenhouse gas emission allowance trading scheme of the Community, June 2009, p.1. Available at: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009L0029&from=EN

"Achieving the 2°C objective is economically and technically feasible. This will require developed countries to continue to take the lead in cutting their greenhouse gas emissions and efforts by developing countries to significantly reduce the growth of their emissions before 2020… until such an ambitious international agreement is concluded, the Commission proposed that the EU should already take on a firm independent commitment to achieve at least a 20 % reduction of GHG emissions by 2020".[22]

As such, the wording of the IA seems to reflect the conviction of the EU that a level playing field will emerge sooner or later. In reality, the IA does also consider a situation in which third country competitors would not be faced with similar impacts and that, as a result, the international competitive position of EU energy-intensive sectors would be undermined. However, to address this risk the IA merely proposes that flanking measures could be considered. From a linguistic point of view, such general and vague phrasing contributes to creating ambiguities related to the conception of policy interventions and the design of regulatory instruments. Overall such a lack of clarity regarding how to address a serious risk - such as that an internationally level playing field to fight climate change will not occur - not only undermines the EU's efforts to improve the quality of its regulation, but also poses the additional challenge that the EU's unilateral effort alone might jeopardise the competitiveness of its industries in the global market.

In particular, as Europe's energy-intensive industrial sector warned, the unilateral burden imposed on it vis-à-vis other European and international competitors, is disproportionate. As a consequence, evidence suggests that manufacturing and value chains of products to be placed in the EU market are being moved outside the EU.[23]

In addition to this, in the legislation little attention is paid to the idea that in order to avoid negative consequences on the EU's competitiveness arising from unilateral decisions, the EU should also be able to address the risks related to the combined effect of both a continued economic crisis and the lack of a global level playing field.

This poses a question regarding the extent to which the EU has fully considered the future outcome of international agreements when deciding on the most appropriate level of ambition for itself, or whether political pressure and convenience have instead prevailed.

Interestingly, the EU recognises the importance of the level playing field, but mainly in relation to a possible increase to a 30% GHGs cut, which, as reported, will be implemented on the condition that other developed countries make comparable efforts. This is because,

[22] Commission of the European Communities, Annex to the Impact Assessment. Document accompanying the Package of implementation measures for the EU's objectives on climate change and renewable energy for 2020, SEC(2008), 27 February, p.16. Available at: http://ec.europa.eu/clima/policies/package/docs/climate_package_ia_annex_en.pdf 18/12/2014

[23] Cembureau, Energy Intensive Industries: Why Setting CO2 Targets to 2050 is Unrealistic. Available at: http://www.cembureau.be/newsroom/article/energy-intensive-industries-why-setting-co2-targets-2050-unrealistic 16/12/2014

in reality, the European Commission itself believes that 20% is not an adequate target to contribute significantly to the fight against global warming[24]:

"To stay below 2°C, global emissions need to peak before 2020…Developed countries must take the lead and cut their collective emissions by 30% of 1990 levels by 2020".[25]

While admitting that 30% would be a more appropriate target, the EU 'only' commits to an unsatisfactory 20% target. Therefore, this raises the question of the appropriateness of the 20% binding target designed by the European Commission and suggests that political considerations – such as the ambition to be an example-setter and gain global leadership in the fight against climate change – have influenced the EU's commitment.

Along with the appropriateness of the 20% target, there is the issue of the concrete contribution that the EU's commitment can make to the fight against global warming. Despite recent global developments, the EU is the only region of the world that has taken concrete steps to implement its energy and climate policies.[26] Although the EU has cut its CO2 emissions, global emissions have increased by 36% since 2000. If GHG emissions keep rising at this rate for the next two decades, the internationally agreed target of limiting global warming to below 2°C is unlikely to be achieved[27], possibly producing unintended consequences. For example, rather than demonstrating an effective foreign policy role, the EU could instead create the image of an ineffective participant that imposes policies detrimental to industrial competitiveness.

Overall, the lack of a level playing field and the decision to set the GHGs cut at 20% - rather than a more adequate 30% - undermines the coherence of the design on which the Climate and Energy Package is based since it is not clear the extent to which achieving a 20% cut in GHGs emissions could contribute to preventing global warming or maintaining the EU's competitiveness.[28]

[24] Helm, EU Climate-Change Policy – A Critique, pp. 5-6

[25] European Commission, Climate change: Commission sets out proposals for global pact on climate change at Copenhagen, Press release – IP/09/141, Brussels, 28 January 2009. Available at: http://europa.eu/rapid/press-release_IP-09-141_en.htm?locale=FR 18/12/2014

[26] d'Oultremont, Re-designing the European Climate and Energy Policies post-2020, p.1
On insufficient progress towards a global climate agreement see: BusinessEurope, A competitive EU Energy and climate policy – BusinessEurope recommendations for a 2030 framework for Energy and climate policies, June 2013, p.9. Available at: http://www.bdi.eu/download_content/KlimaUndUmwelt/20130618_FINAL_Brocure_2030_energy_and_climate_LOW_RESOLUTION.pdf 16/12/2014

[27] Gregor Erbach, Reform of the EU carbon market. From backloading to the market stability reserve, European Parliamentary Research Service, October 2014, p.2. Available at: http://www.europarl.europa.eu/RegData/etudes/BRIE/2014/538951/EPRS_BRI%282014%29538951_REV1_EN.pdf 17/12/2014

[28] Helm, EU Climate-Change Policy – A Critique, pp.5-6

In this light, rather than following the criteria for Better Regulations (e.g. setting realistic and measurable objectives), political considerations seem to have influenced the design phase of the Package. For example, it could be argued that, given the impossibility of agreeing on the energy liberalisation agenda (e.g. unbundling), France, Germany, and the UK decided to promote instead a deliberately ambitious climate agenda on which they could find common ground. France had nuclear power, Germany had an influential Green Party and questions related to coalition formation, and the UK had its ambition to promote itself as an international leader.[29]

In the light of similar political reasons, such as the need of an appealing policy to re-connect with voters, the next section will examine the ambiguities and unintended consequences arising from the target related to the promotion of renewable energy, as established in the Package.

3. Increased use of energy from renewable sources

As part of the Climate and Energy Package, the Renewable Energy Sources (RES) Directive[30] aims to ensure that 20% of total EU energy consumption is produced from renewable energy sources by 2020, and it includes provisions for promoting renewable energy sources in the electricity, biofuels[31], and heating and cooling sectors.[32] The target should be reached through mandatory national targets based on 2005 levels, which vary between MSs, from 10% for Malta to 49% for Sweden.[33]

Contextually, a 20% energy efficiency target aims to achieve a 20% saving of primary energy consumption in the EU. In keeping with the motto "doing more with less", the target implies a decreased utilisation of energy while preserving an equivalent pace of economic development.

As a reflection of the scope of this case study, this section will mainly focus on the 20% target set in the RES Directive.

29 Helm, EU Climate-Change Policy – A Critique, p.5

30 Official Journal of the European Union, Directive 2009/28/EC of the European Parliament and of the Council of 23 April 2009 on the promotion of the use of energy from renewable sources and amending and subsequently repealing Directives 2001/77/EC and 2003/30/EC, June 2009. Available at: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009L0028&from=EN 18/12/2014

31 The Directive also requires MS to achieve a 10% minimum target for the share of biofuel consumption in the transport sector by 2020.

32 European Commission, Energy. Available at: http://ec.europa.eu/clima/policies/international/summit_2014/energy/index_en.htm 17/12/2014

33 McKenna Long & Aldridge, Climate change-what is Europe doing to reach the '20-20-20 targets'?. Available at: https://www.mckennalong.com/publications-advisories-2494.html 16/12/2014

As stated in the introduction, a clear drafting refers to the readability and comprehensibility of a legal act (i.e. whether it is clear, expressed in a simple and precise manner in 'plain' language). In particular, the clarity of the legal drafting is necessary to avoid uncertainties and ensure effective and proportionate interventions. In this respect, it can be argued that the RES Directive presents ambiguity regarding the very definition of "renewable". Article 2 of the Directive on Definitions is limited to detailing the meaning of "energy from renewable sources" as "energy from renewable non-fossil sources, namely wind, solar, aerothermal, geothermal, hydrothermal and ocean energy, hydropower, biomass, landfill gas, sewage treatment plant gas and biogases".[34]

However, the text of the Directive provides no clear definition of the term 'renewable'. Indeed, the concept itself is a relative one and open to different interpretations. According to one possible approach, the extraction of energy from a renewable energy source should not decrease its future availability. However, this definition is problematic as, on the one hand it excludes a number of energy sources which policy-makers clearly intended to include – such as biomass and biogas – and, on the other, some types of nuclear reactors might almost qualify. An alternative approach would be to define renewable as 'low carbon'. However, in principle the switch from coal to gas – which 'lowers' carbon emissions – might qualify as low carbon, as might nuclear.[35]

This ambiguity in the definition of a key term produces flexibility, which is politically convenient, but it might also cause future uncertainties for investors. Yet, if the key objective of the European Commission is to cut GHG emissions - as is clear from the design of the RES Directive - then the most appropriate definition is the 'low-carbon' one, which also includes nuclear.[36]

To achieve regulatory quality it is also important that unintended consequences potentially resulting from the regulation are fully considered and tools to address them are specified. In this respect, when setting the target of increasing the use of energy from renewable sources, the regulator seems to have paid little attention to unintended consequences such as fragmentation of the internal energy market, prolonged high costs for renewables, and lack of expected technology development.

With respect to the fragmentation of the internal energy market, the Package leaves remarkable choice to MSs on how to implement their targets. The Package does not appear to consider that if MSs have to promote renewables at a national level, this may cause barriers to cross-border activities and implementation of unilateral domestic

[34] Official Journal of the European Union, Directive 2009/28/EC of the European Parliament and of the Council of 23 April 2009 on the promotion of the use of energy from renewable sources and amending and subsequently repealing Directives 2001/77/EC and 2003/30/EC, p.27

[35] Helm, EU Climate-Change Policy – A Critique, pp. 12-13

[36] Helm, EU Climate-Change Policy – A Critique, pp. 13

decarbonisation strategies, which could ultimately contribute to the fragmentation of the internal energy market.[37]

Article 3 of the RES Directive does outline the measures through which each MS is expected to achieve its renewable targets by adding the cooperative element that should permeate the internal energy market: "In order to reach the targets…Member States may, inter alia, apply the following measures: (a) support schemes; (b) measures of cooperation between different Member States and with third countries for achieving their national overall targets…"[38]

However, the RES Directive makes equal reference to the national competence of the energy policy by stating, "Member States shall have the right to decide… to which extent they support energy from renewable sources which is produced in a different Member State"[39]. Additionally, the RES Directive reiterates the national character of the "renewable energy potential" as well as the specificity of the energy mix of MSs by stating that:

"It is necessary to translate the Community 20 % target into individual targets for each Member State, with due regard to a fair and adequate allocation taking account of Member States' different starting points and potentials, including the existing level of energy from renewable sources and the energy mix".[40]

Box 5 – EU policy on renewables vs. unilateral national measures

Numerous policy instruments and support schemes for renewable energy across the 28 Member States have been introduced unilaterally, augmenting the risk of an uncoordinated fragmentation of the internal energy market.

For example, the unilateral launch of Germany's energy transition policy (i.e. the Energiewende) following the Fukushima nuclear accident has been criticised for a lack of coordination and a disregard of negative impacts on neighbouring countries. Similarly, the UK electricity market reform – including a carbon floor price – puts government rather

[37] Gina Hanrahan, A new wave of European climate and Energy policy. Towards a 2030 framework. The Institute of International and European Affairs, p.9. Available at: http://www.iiea.com/ftp/environmentnexus%20papers/new-wave_european_climate-policy_energy-iiea_gina_hanrahan.pdf 16/12/2014

[38] Official Journal of the European Union, Directive 2009/28/EC of the European Parliament and of the Council of 23 April 2009 on the promotion of the use of energy from renewable sources and amending and subsequently repealing Directives 2001/77/EC and 2003/30/EC, p.28

[39] ibidem

[40] Official Journal of the European Union, Directive 2009/28/EC of the European Parliament and of the Council of 23 April 2009 on the promotion of the use of energy from renewable sources and amending and subsequently repealing Directives 2001/77/EC and 2003/30/EC, p.18

than the market at the core of energy policy. In this respect, energy analysts such as Keay predict a "fundamental clash between liberalisation and decarbonisation agendas across the EU", and argue that the UK approach is "effectively subordinating liberalisation to environmental concerns, accepting a considerable degree of government intervention and a reduction in the role of market forces..."[41]

These tensions between the re-nationalisation of energy policy and the need to protect the integrity of the internal energy market stem from an initial design flaw in the EU Treaties which "deliberately restricts free investment flows that would not conform to each country's list of acceptable energy mix technologies".[42]

From this perspective, it can be argued that, in outlining the design of the RES Directive and the policy options at the disposal of the MSs to reach their objectives, the European Commission has paid little attention to the unintended consequences associated with leaving MSs to decide for themselves how to achieve the target for renewables.

In other words, the design of the RES Directive fails to recognise that the option left to MSs to introduce a variety of mechanisms at national level augments the risk of fragmentation and divergence in the European energy market[43]. Such a fragmentation potentially contributes to a situation in which energy prices differ heavily across the EU, or may pose a burden on neighbouring countries as they might be exposed to increased and unforeseen demand.

It is not surprising that while the renewable and emissions targets are likely to be reached, the unintended consequence of this achievement is that progress is irregular across MSs and some of them have failed to meet interim targets. Thus, a number of MSs will have to increase their efforts to achieve the renewable target by 2020[44]. For instance, Ireland is one of the MSs with a gap to close on both climate and renewable targets.[45]

41 Malcolm Keay, UK electricity market reform and the EU, Oxford: Oxford Institute for Energy Studies, March 2013. Available at: http://www.oxfordenergy.org/2013/03/uk-electricity-market-reform-and-the-eu/ 18/12/2014. Quoted by Hanrahan, A new wave of European climate and Energy policy. Towards a 2030 framework, p.9

42 Keay, UK electricity market reform and the EU.
See also: Albert Bressand, The changed geopolitics of Energy and climate and the challenge for Europe. A geopolitical and European perspective on the triple agenda of competition, Energy secuirty and sustainability, CIEP Paper, April 2012. Available at: http://www.clingendaelenergy.com/inc/upload/files/The_changed_geopolitics_of_energy_and_climate_bressand.pdf 17/12/2014

43 OGP, OGP response to the Green Paper 'A 2030 framework for climate and Energy policies'. 25 June 2013, p.9. Available at: http://www.gasnaturally.eu/uploads/Modules/Publications/ogp_response_to_2030_green_paper_-_june_2013.pdf 18/12/2014

44 European Commission, Renewable Energy progress report, MEMO, Brussels, 27 March 2013 Available at: http://europa.eu/rapid/press-release_MEMO-13-277_en.htm 17/12/2014

45 Hanrahan, A new wave of European climate and Energy policy. Towards a 2030 framework, p.6

Another problematic aspect of the promotion of renewables in the EU is related to cost. In fact, the likely achievement of the 20% target has contributed to an increase in energy prices. National support schemes – established to trigger investment in renewables by subsidising electricity production – affect the price of energy for consumers. For example, in 2011, the net support for electricity produced in the EU from renewables amounted to about 37 EUR billion, while the costs of renewable promotion to be borne by the final consumer throughout MSs was about 13 EUR/MWh.[46]

In the policy design of the RES Directive, the European Commission does identify the risks related to the increase of energy prices as a result of the promotion of renewables in the energy mix of MSs. To address this, the European Commission makes the assumption that renewables are new technologies, subject to R&D, and that as deployment expands their costs will go down[47]. In other words, renewables should become more cost-efficient over time.

Yet, despite falling costs of technologies such as on-shore wind and solar, it is likely that most renewable energy sources will be cost competitive only after 2025[48]. There is, in fact, not enough scope for R&D to provide a remarkable contribution to the EU's effort to increase the energy production from renewable sources. Only after 2020 will a reduction of cost due to technology deployment occur[49]. Therefore, given the impossibility of coming up with new technology within the 2020 frame, there is a disincentive to invest in the development of new technologies related to renewable sources, and a parallel incentive to stick to the existing ones. As such, it is not surprising that up to 2020, much of the renewable energy will come from wind, a well-developed technology.[50]

If the Commission's reasoning is looked at the other way round, the lack of the expected incentive to invest in new technology implies that the cost of renewables will continue to be high. As a result, in view of the aim to reach their 2020 renewable energy targets, MSs are likely to increase the share of costly renewable energy in their national energy mixes[51]. In turn, this is expected to put an additional burden on national budgets.

In this light, the 2020 timeframe seems to be a key flaw in the Package as it is too close for renewable technology to be fully developed and contribute to reach the target. As a consequence, the target for renewables will be achieved by the existing technologies available[52]. For example ocean (or marine) energy has a great potential to contribute to

46 BusinessEurope, A competitive EU Energy and climate policy – BusinessEurope recommendations for a 2030 framework for Energy and climate policies, p.7
47 Helm, EU Climate-Change Policy – A Critique, p.13
48 d'Oultremont, Re-designing the European Climate and Energy Policies post-2020, p.4
49 Helm, EU Climate-Change Policy – A Critique, p.13
50 Helm, EU Climate-Change Policy – A Critique, p.7
51 d'Oultremont, Re-designing the European Climate and Energy Policies post-2020, p.4
52 Helm, EU Climate-Change Policy – A Critique, p.7

meet electricity demand, but the "relevant technology is still in its infancy"[53]. Similarly, although designed for reaching the climate target – the Carbon Capture and Storage (CCS) technology has turned out to be too costly and unable to fully unleash its potential contribution to fight climate change within the 2020 timeframe.

Overall, instead of serving the objective set by the Package, the misleading emphasis on CCS and R&D for renewables represents a missed opportunity to tackle global warming.

Another tool through which policy-makers can use to improve regulatory quality is Regulatory Impact Assessment (RIA), a technique to evaluate the likely impacts of regulations. A comprehensive and rigorously conducted RIA includes the notions of unintended consequences and wider costs, and should lead to the identification of interventions that are proven to directly contribute to solving the problem recognised in the design phase.

From this perspective, a number of other factors such as the continued economic recession and the budgetary constraints of MSs have also contributed to exacerbate the reduction of the EU's competitiveness and the increase in energy prices for consumers as a result of striving to achieve the GHG and RES targets.

To address future uncertainties related to "projected GDP growth and changes in industry and energy sectors", the Joint IA did refer to the principle of flexibility as a policy option chosen to give the EU "an opportunity to make adaptations to change significantly less challenging".[54]

However, the RES Directive recalls that, "flexibility measures… remain under Member States' control in order not to affect their ability to reach their national targets".[55]

In general terms, while recognising the flexibility principle to adapt to future uncertainties, the Joint IA and the RES Directive also pay little attention to the risk that a continued economic recession, budget constraints, and change in the energy landscape might create a further disincentive for public and private sectors to invest in the development of research and technological innovations in the field of renewable energy generation. In addition to the economic downturn, changes to the global energy landscape – such as the shale gas revolution in the US and the crisis of the EU European Trading System (ETS) - have

[53] OECD/IEA, World Energy Outlook 2012. Renewable Energy Outlook, 2012, p.230. Available at: http://www.worldenergyoutlook.org/media/weowebsite/2012/WEO2012_Renewables.pdf

[54] Commission of the European Communities, Impact Assessment – Document accompanying the Package of implementation measures for the EU's objectives on climate change and renewable energy for 2020, SEC(2008), Brussels, 23 January 2008. Available at: http://ec.europa.eu/clima/policies/package/docs/sec_2008_85_ia_en.pdf 17/12/2014

[55] Official Journal of the European Union, Directive 2009/28/EC of the European Parliament and of the Council of 23 April 2009 on the promotion of the use of energy from renewable sources and amending and subsequently repealing Directives 2001/77/EC and 2003/30/EC, p.20

contributed to a carbon price much lower than expected by increasing its availability at an affordable price and mitigating the perceived risk that fossil fuels will run out shortly.

Overall, since the implementation of the Climate and Energy Package, some of the incentives for investing in renewables have become less urgent.[56] Again, this possibility seems not to have been fully considered in the design phase.

[56] Georg Zachmann, Elements of Europe's Energy Union, Bruegel, 10 September 2014. Available at: http://www.bruegel.org/publications/publication-detail/publication/846-elements-of-europes-energy-union/ 18/12/2014

Chapter 3: Case study of risk assessment and risk management of chemicals in the EU

1. Introduction

This chapter will examine some of the main approaches of the EU to assessing and managing risks related to substances. The main focus will be on REACH, the Regulation on Registration, Evaluation, Authorisation and Restriction of chemicals, and some of the related processes such as the Community Rolling Action Plan (CORAP) and Risk Management Options Analysis (RMOAs). These approaches will be briefly explained and a number of issues related to them will be considered in more detail with a particular view also on the Better Regulation agenda.

2. How did we end up with REACH?

The objective of REACH was to replace the former legislative framework for chemical substances, which was a patchwork of many different Directives and Regulations that developed over time. This meant REACH tried to combine about 40 pieces of legislation[57] which companies had to adjust to before 1 June 2007. However, some pieces of legislation remained outside the scope of REACH, such as those covering cosmetics, detergents, health and safety of workers handling chemicals[58], and others.

Some points of criticism raised against the previous compilation of legislation included:

- insufficient information about the effects of many chemicals on human health and the environment;
- a slow identification and assessment of risk;

[57] EMEA Power Transmission Distributors Association (EPTDA), Why REACH. Available at: http://www.eptda.org/Industry/Legislation/REACH/Why-REACH 17/12/2014
See also: REACH replaced the: directive defining and laying down the detailed arrangements for the system of specific information relating to dangerous preparations; directive laying down the principles for assessment of risks to man and the environment of substances; directive laying down an Annex containing information required for the technical dossier referred to in Article 12 of the seventh amendment of Council Directive 67/548/EEC (OJ L 294, 30.11.1993, p. 21); Directive concerning the list of Community legislation; regulation laying down the principles for the assessment of risks to man and the environment of existing, European Official Journal, 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 at: http://old.eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2006R1907:20140410:EN:HTML 17/12/2014

[58] EMEA Power Transmission Distributors Association (EPTDA), Why REACH

- the distinction between "existing" and "new" substances, based on a cut-off date of 1981 ("New" being those introduced to the market after 1981 that therefore have to be tested before they are placed on the market. This led to a lack of public information on existing substances making it difficult to assess and control them effectively);
- allocation of responsibilities (public authorities rather than enterprises that manufacture, import, or use the substances were responsible for undertaking risk assessments of substances);
- risk assessment was not focused and effective as substances were assessed comprehensively rather than in a more concern-oriented approach;
- information on uses of substances was difficult to obtain, as was information on the exposure arising from downstream users because overall only manufacturers and importers of substances had to produce information;
- new substances had to be tested starting from volumes of 10kg per year.[59]

REACH attempted to address these points by gathering information on substances through a regulated process, and no longer distinguishing between new and existing substances but by the amount used per year. It also allocated who must provide or evaluate certain data required for the identification of risks.

3. How does REACH work?

As mentioned above, REACH was devised to establish procedures for collecting and assessing information on the properties and interaction of substances with the environment and human health, and its implementation was to be conducted by a newly established European Chemicals Agency (ECHA).

The main steps of the procedures for the categorisation of chemicals are:

- Companies need to go through an elaborate process of compiling dossiers comprising data on the substance, its properties and safe use.
- Companies need to register their substances by submitting the prepared dossiers.
- ECHA may evaluate registrations for their compliance.

[59] European Commission, DG Enterprise and Industry and DG Environment, REACH in brief, February 2007, p.3. Available at: http://www.hse.gov.uk/reach/resources/inbrief.pdf 17/12/2014

- EU Member States evaluate selected substances to clarify initial concerns for human health or for the environment.
- Authorities can ban hazardous substances if their risks are unmanageable. They can also decide to restrict a use or make it subject to a prior authorisation.[60]

4. What has been criticised about REACH and why

Although its aim was to simplify the previous existing legislations, REACH is still one of the most controversial and complex pieces of EU legislation. It has drawn criticism from all sides of the stakeholder spectrum[61]. It comes as no surprise that REACH tops the list of the TOP10 most burdensome legislative acts for SMEs.[62]

REACH´s negative impact on innovation has sparked strong protest from the industry. This stipulation is also supported by the Interim Evaluation on the impact of the REACH Regulation on the innovativeness of the EU chemical industry. A study by the EU Centre for Strategy and Evaluation Services finds that the regulatory burden placed on firms by REACH tends to draw staff and funds away from more innovative work. As a result, 43% of companies think the regulation has had a negative impact on innovation while only 13% reported a positive impact so far.[63]

If the criticism of REACH can be summarised under one heading, the innovation argument gets to the heart of the issue. The following will examine in more detail the main criticisms considered responsible for this innovation deadlock.

[60] European Chemicals Agency, Understanding REACH. Available at: http://echa.europa.eu/web/guest/regulations/reach/understanding-reach 17/12/2014

[62] European Commission, Results of the public consultation on the TOP10 most burdensome legislative acts for SMEs, 7 March 2013, p. 10. Available at: http://ec.europa.eu/enterprise/policies/sme/files/smes/top10report-final_en.pdf 17/12/2014

[63] Centre for Strategy and Evaluation Services, Interim Evaluation: Impact of the REACH Regulation on the innovativeness of the EU chemical industry, 14 June 2012. Available at: http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/review2012/innovation-final-report_en.pdf 17/12/2014

5. The cost of REACH

The cost of REACH is a challenge for SMEs in particular and is widely regarded as being disproportionate. According to a European Parliament study the overall (direct) cost estimates of REACH specified in the 2003 Impact Assessment[64] turned out to be an underestimate by nearly one half compared to what the Commission initially put forward. By 2012 the difference added up to around EUR 1 billion; by 2018 this may go up to EUR 1.5 billion or possibly much more[65]. The main reasons for these high costs are:

- The number of guidance documents, many of them hundreds of pages long, gives an idea of the complexity of REACH implementation and compliance, and the burden which is imposed on businesses, especially smaller ones. Aside from the fact that it is complicated to manage and access this information, the information is not available in all official EU languages, a point of contention for the Stoiber High Level Group on Administrative Burdens.[66]
- The cost of assembling the correct and detailed information that is demanded, requiring input from different parts of the supply chain, which is often very complex, is significant.
- The need to compile the large amounts of assembled information into a single comprehensive but detailed dossier is burdensome.
- The burden of updating the dossiers on a regular basis, which requires ongoing activities beyond the registration date, is heavy.

These require a lot of time, manpower, and knowledge from applicants and often also require external legal and expert advice. The resources to deal with this "flood of information" can only be acquired through increased financial efforts.

[64] European Commission, Extended impact assessment, COM(2003)644, 29 October 2003. Available at: http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/eia-sec-2003_1171_en.pdf 17/12/2014

[65] European Parliament - Directorate general for internal policies, The Consequences of REACH for SMEs, October 2013, p. 8 . Available at: http://www.eesc.europa.eu/resources/docs/the-consequences-of-reach-for-smes.pdf 17/12/2014

[66] High Level Group on Administrative Burdens, Cutting Red Tape in Europe, 24 July 2014, p.23. Available at: http://ec.europa.eu/smart-regulation/refit/admin_burden/docs/08-10web_ce-brocuttingredtape_en.pdf 17/12/2014

6. REACH Authorisation and Blacklisting

"Authorisation" is a process within REACH that aims to properly control Substances of Very High Concern (SVHCs) while gradually replacing them on the EU internal market.[67] The process itself is divided into different steps such as a candidate list, an authorisation list, and the application for authorisation to use a substance that has been placed on the authorisation list.

Substances that are identified as an SVHC can be placed on a Candidate List. Once the substances are on the list, ECHA looks at the substances based on information in the REACH registration dossiers and recommends priority substances to be included in the so-called authorisation list. When included on the authorisation list, a deadline is set after which the use of that substance in the EU is no longer allowed (this is known as the 'sunset date'), unless authorised. Manufacturers and producers can then apply for authorisation to continue using the substance for a limited period of time.[68] The entire process is based on whether a specific substance (sometimes only for specific uses) poses a hazard rather than a risk to human health and the environment, with the aim of motivating or pushing industry to find substitutes to hazardous substances.

According to the interim evaluation of REACH conducted for the European Commission, the "premature deselection of substances ("blacklisting") is a […] major issue". The study states that industry is concerned about the regulatory uncertainty created by the candidate list in part due to the unjustified stigmatisation. Firms cannot be sure if the substances they are working on as substitute substances for those on the "candidate list" are not going to end up on the candidate list themselves.[69]

This has an impact on competitiveness, jobs, growth, and the internal market since there "is strong pressure from downstream users to not use chemicals on the candidate list and even the SIN list"[70]: The SIN list identifies substances which the NGO called Chemsec believes are SVHC. Like the SIN-list there are also other non-official lists that aim to exert pressure on industry and ECHA.

67 European Chemicals Agency, Authorisation. Available at: http://echa.europa.eu/regulations/reach/authorisation 17/12/2014

68 European Chemicals Agency, The Candidate List. Available at: http://echa.europa.eu/regulations/reach/authorisation/the-candidate-list 17/12/2014

69 Centre for Strategy and Evaluation Services, Interim Evaluation: Impact of the REACH Regulation on the innovativeness of the EU chemical industry, p viii.

70 Centre for Strategy and Evaluation Services, Interim Evaluation: Impact of the REACH Regulation on the innovativeness of the EU chemical industry, p.26

Inclusion in candidate list and authorisation list, or science vs. political will

As stated by the competent EU Commissioners, the aim was to have 136 substances on the Candidate List by 2012, and to include all "relevant" SVHCs by 2020. The first commitment has been met. Currently there are 161 substances on the candidate list (December 2014).

However, it could be argued that this objective was achieved against the principle of Better Regulation as it was not stipulated on which scientific ground this numerical target was set.

Bearing in mind the concept of Better Regulation highlighted above, an assessment should be made of how the targeted number of substances for the candidate list was actually determined, and what the concrete objectives were in view of risk reductions. The process of introducing substances to the Candidate List leaves the impression that there was a political drive to expand the Candidate List rather than an approach based on evidence and clear risk management objectives.

7. Case Studies on REACH

Considering the criticism against REACH, this section looks at two cases that help to explain the points of concern. First, this section assesses the "evaluation" of a substance, demonstrating the process options, and then looks at "authorisation" vs. Occupational Exposure Limits (OEL) or other measures, thus exploring available policy options.

8. Process options - Substance Evaluation and RMO

I. Substance Evaluation & CoRAP

Substance Evaluation is conducted by Member States. The process aims to clarify whether the use of the substance poses a risk to human health or the environment. The process may target a specific concern that needs further clarification.

However, not all substances need an in-depth evaluation. ECHA in cooperation with the Member States defines risk-based criteria, and then selects the registered substances that are to be evaluated.[71] The procedure is mainly stipulated in Articles 44 and 45 of REACH.

[71] European Chemicals Agency, Community rolling action plan. Available at: http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan 17/12/2014

Several outcomes are possible as a result of the evaluation. Conclusions range from:

- no further action is required as the risks are sufficiently under control with the measures already in place; to
- a proposal for harmonised classification and labelling for carcinogenic, mutagenic or toxic to reproductions, respiratory sensitizers or other effects; to
- a proposal to identify the substance as a Substance of Very High Concern (SVHC). Once included on the Candidate List, the substance can be prioritised to go through the authorisation process; to
- EU-wide risk management measures such as a proposal to restrict the substance; to
- actions outside the scope of REACH such as a proposal for EU-wide occupational exposure limits, national measures, or voluntary industry actions.[72]

Due to the profound impact that decisions may have on the producers and users of the substance, this is a crucial time for those companies. For downstream users, this process is even more burdensome as they do not receive regular updates on the status quo throughout the process and are not able to provide feedback. The information and opportunity to intervene is only provided to those who register the substances - such as manufacturers or importers. The result of the evaluation, however, can have a profound impact on downstream users too.

II. Risk Management Option (RMO) Analysis

A RMO Analysis is a process that was not formally foreseen in the REACH Regulation, but has now been accepted by all Member States as a process to evaluate options on how to deal with substances appropriately. The first REACH review recommended "drafting a roadmap in the framework of the RMO process to include all relevant, currently known SVHCs in the candidate list by 2020".[73]

[72] European Chemicals Agency, What happens after substance evaluation? Available at: http://echa.europa.eu/what-happens-after-substance-evaluation 17/12/2014

[73] European Commission, Commission Staff Working Document, General Report on REACH, 5 February 2013, p. 72. Available at: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52013SC0025&from=EN 17/12/2014

The roadmap, which was published in December 2013, states that the RMO Analysis contributes to establishing which substances are relevant SVHCs[74]. In addition, it introduces new features such as:

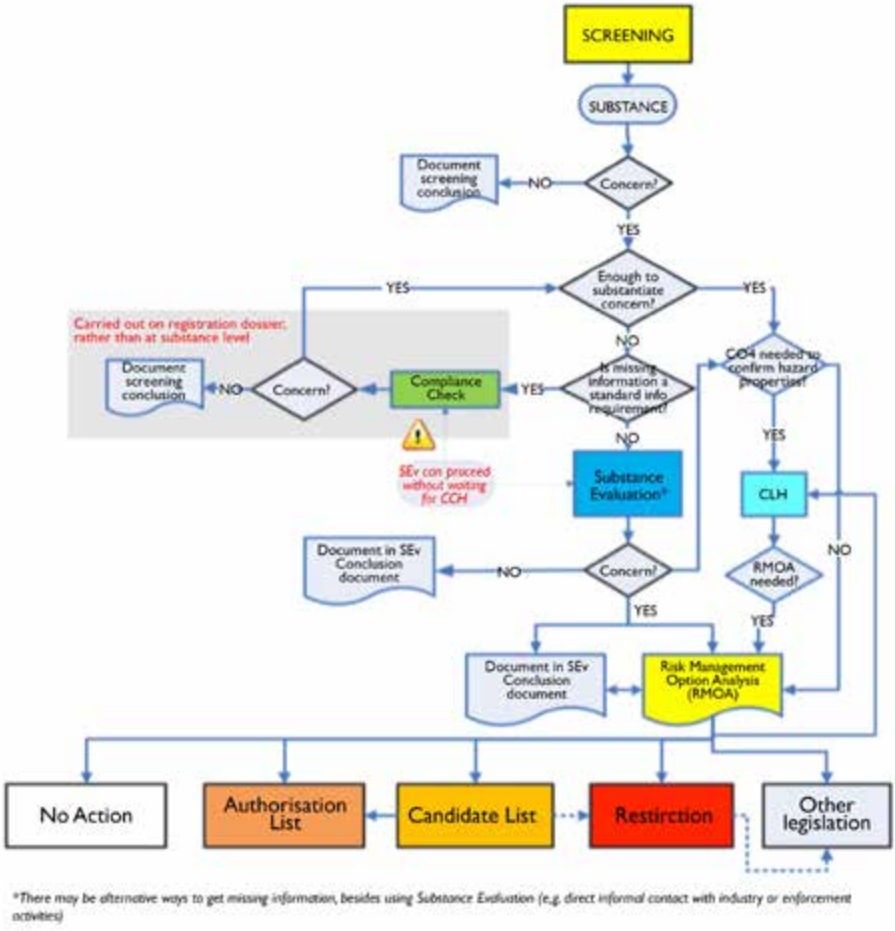
- an annual report which will indicate the planned screening and RMO Analysis activities – the first is expected to be published in March 2015;
- a list of all substances which will be RMO analysed (including indication of the reporting MSCAs);
- a public version of the conclusions of the RMO Analysis;
- the 'Public Activities Coordination Tool' (PACT), available on the ECHA website since September 2014, which will provide substance specific information on the RMO analysed substances, the reporting MSCAs, and the RMO Analysis outcomes.

In relation to the role of the RMO analysis, the roadmap gives priority to substances, with SVHC properties, that are registered for non-intermediate uses.

An RMO Analysis can either be initiated by a Member State independently, in conclusion of a CoRAP substance evaluation, or through the Classification (CLP) process, (See diagram below.)

[74] European Chemicals Agency, SVHC Roadmap to 2020 Implementation Plan, 9 December 2013, p. 6. Available at:http://echa.europa.eu/documents/10162/19126370/svhc_roadmap_implementation_plan_en.pdf 17/12/2014

Figure 1: SVHC Screening in wider context: inter-linkages between the REACH and CLP processes.



Source:

http://echa.europa.eu/documents/10162/19126370/svhc_roadmap_implementation_plan_en.pdf

It is generally agreed (though not legally required) that once a CoRAP evaluation determines the need to take action, an RMO Analysis will automatically be launched to evaluate which risk management option is required and appropriate for the substance, given the economic impact. An RMO Analysis can propose restrictions on the substance, introduce it on the candidate list, apply occupational exposure limits etc. In principle an RMO Analysis can also introduce a substance to the CoRAP list, if the substance has not yet been evaluated.

III. The case of Toluene diisocyanate or tolylidene diisocyanate (TDI)

According to a Substance Evaluation Conclusion document, TDI was selected for substance evaluation through the CoRAP list to clarify risks about:

- respiratory and skin sensitising properties;
- potential carcinogenicity;
- suspected PBT properties;
- wide dispersive use and high aggregate tonnage.

Health effects include development of occupational asthma.

TDI is widely used in flexible polyurethanes to manufacture foams, elastomers, adhesives, and sealants in quantities of 100,000 to 1,000,000 tonnes per annum.

In the case of TDI, Poland - the Member State evaluating the substance - concluded that there was "no need for regulatory follow-up action" as the "hazard and/or exposure was verified to be under appropriate control".[75]

Although the conclusion could have served as a confirmation to industry that their process for treating the substance was adequate, an RMO Analysis was subsequently launched by Germany. BAUA, the German Federal Institute for Occupational Safety and Health, stated that TDI attracted their attention due to its sensitising effect in respiratory passages. This was also one of the three reasons TDI was originally included into the CoRAP list - where Poland concluded that TDI is indeed very toxic by inhalation (vapours), and that it leads to asthma in workers who are occupationally exposed to it. However, Poland concluded that "according to available evidence, when the exposure limits are kept, the risk of respiratory sensitisation is adequately controlled."[76]

[75] Evaluating Member State Competent Authority, Substance Evaluation Conclusion Document for Tolylidene diisocyanate, 12/11/2013, Available at: http://echa.europa.eu/documents/10162/6afcae72-71f1-456b-a591-6d8be9a6f183 17/12/2014

[76] European Chemicals Agency, Substance Evaluation Report - m-tolylidyne diisocyanate, p.i. Available at: http://echa.europa.eu/documents/10162/9801478/corap_sev1_report_247-722-4_pl_en.pdf 17/12/2014

IV. TDI and RMO

BAUA, who carried out the RMO Analysis on TDI, concluded that there is a need for regulatory action at EU level - namely, a restriction of the substance. This includes new data collection for restriction starting in 2016.[77]

In terms of TDI and the various risk assessment or risk management options conducted, there is a strong need for more clarity.

Although an RMO Analysis is essential to the evaluation process to better manage substances according to their actual risk, it is a process that was not formally foreseen in the REACH Regulation but has now been accepted by all Member States. Therefore it is not noted on the ECHA website in the section on REACH regulation but rather separately, in the framework of the new SVHC roadmap implementation plan. In addition, it is also not explicitly named in the REACH Regulation, although the Regulation does refer to "risk management measures". It is therefore difficult for some stakeholders to understand that this part of the process exists and needs to be taken into account when planning for the future.

Although it might be argued that the CoRAP and RMO Analysis evaluate substances from a different angle:

1. considering whether enough information is available, and

2. what risk management process options are best suited to the substance, taking into account socio-economic circumstances;

in fact, they end up assessing duplicate aspects such as the substance's effects on human health and the environment, how it is handled currently, and whether this is adequate or must be improved.

The question remains why the various evaluators and process options often come to different conclusions. An approach in line with better regulation criteria should ensure more clarity and consistency for producers and downstream users. The conclusions of a CoRAP or RMO should provide definite measures, thus preventing individual Member States from introducing further measures.

[77] Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BAuA), Risk Management Option Conclusions Document for Diisocyanates, 29 August 2014, pp. 1-3. Available at: http://www.reach-clp-biozid-helpdesk.de/en/REACH-en/SVHC-Roadmap-en/Downloads_RMOA-Conclusion-en/MDI-Gruppe-en.pdf?__blob=publicationFile&v=2 17/12/2014

9. REACH – Policy options under authorisation

While REACH is one of the most controversial pieces of EU legislation, authorisation seems to have become the most debated part of it.

ECHA summarises the objectives of the REACH Regulation in the following way: "REACH […][was] adopted to improve the protection of human health and the environment from the risks that can be posed by chemicals, while enhancing the competitiveness of the EU chemicals industry. It is also supposed to promote alternative methods for hazard assessment of substances in order to reduce the number of tests on animals."[78]

Even if authorisation can be a measure to achieve these overall objectives, the discrepancies between aspiration and reality can lead to unintended consequences and uncertainties that, under Better Regulation criteria, should have been identified and corrected. Where substitution seems feasible in the near future, the authorisation process may be a good option to provide the necessary time for producers to be able to finalise substitution without economic consequences. However, the Authorisation process should be "ultima ratio" rather than a standard procedure for those substances where substitution is not foreseeable in the near future and substances for which, for instance, risks are related to the workplace only and other community legislation constitutes a better option for management of the risks. This statement is made bearing in mind the potentially enormous socio-economic consequences of the inclusion of a substance in the authorisation list for the respective companies and sectors as well as the potential negative impact on the EU priority of the creation of jobs and growth.

a) Substitution

The authorisation procedure "aims to assure that the risks from Substances of Very High Concern are properly controlled and that these substances are progressively replaced by suitable alternatives while ensuring the good functioning of the EU internal market."[79] This means that substitution is always a preferred option even if the identified risks are well controlled through existing risk management measures, or if the risks and required measures that could effectively be established through a RMO. However the "progressive replacement by suitable alternatives" and "ensuring the good functioning of the EU internal market" would best be achieved where authorisation is used as a "bridging RMO", i.e. as an RMO that is applied when it becomes realistic that the substitution of the substance can be pushed by means of authorisation, and that the substitute is indeed safer.

[78] European Chemicals Agency, REACH. Available at: http://echa.europa.eu/regulations/reach 17/12/2014

[79] European Official Journal, 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), p. 44. Available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:136:0003:0280:en:PDF 12/17/2014

The main concern with the initial approach, particularly when assessing it in view of Better Regulation criteria, is that the measures are not always reasonable in view of the risks that are identified and can be controlled. This is probably largely due to the fact that the regulatory approach is entirely based on the hazard profile of the substance rather than risk management; this can easily lead to decisions that also have a negative impact on jobs, growth, and competitiveness, without achieving any real reduction of risks.

The challenge here is the question of substitution. In other words: Does authorisation lead to substitution in practice, and if so will it at the end also ensure a better level of protection of health and environment at a reasonable cost in comparison to a continued use of a substance subject to authorisation? Substitution is rarely a simple matter of substituting one chemical for another. It can be a costly process involving the consideration of a number of new substances and their full life cycle, as well as changes to production processes.

There have been a number of well-known examples[80] whereby an apparently safer substitute introduced by legislation has led to effects different to those of the substituted substance, but of equivalent concern.

According to ECHA "The purpose is to give industry an incentive to substitute SVHCs with safer chemicals or techniques. Enabling companies to apply for authorisation to use an SVHC - if only for a limited period of time - means that it is not an immediate ban: in the long run it strives for substitution, but in the short-term, companies apply for authorisation to continue using the SVHC."[81]

While there are arguments for this approach, it does not adequately consider the effects of stigmatisation, which in itself has clear negative consequences for the related industries. However there are also examples where there is simply no substitute for a substance, as proven by the continuous exemptions that have been granted by the Rohs Directive.[82]

In addition, there is a planning and investment uncertainty linked to authorisation, in particular for those substances for which substitutes are not available, such as substances that are already used as substitutes for others and that are considered state-of-the-art. A lot of investment cycles exceed the authorised timing given, e.g. investment cycles of 20 years are not uncommon. Having an authorisation for only 12 years is not sufficient

[80] For example see: United States Environmental Protection, EPA Warns Against Use of Refrigerant Substitutes That Pose Fire and Explosion Risk. Available at: Agency http://yosemite.epa.gov/opa/admpress.nsf/0/61416EA839B0618E85257B9B0065AEC0 17/12/2014

[81] Jack De Bruijn, Substitution – safer chemicals, benefits for business, European Chemicals Agency, 22 April 2014. Available at: http://newsletter.echa.europa.eu/home/-/newsletter/entry/2_14_editorial;jsessionid=B2E491CDC3A331410A665B37E201BF06.live1 17/12/2014

[82] Centre for Strategy & Evaluation Services, Interim Evaluation

in those cases, and in the end industry often chooses as a result to invest outside the EU. Furthermore, contracts between companies often stipulate a guarantee of supply exceeding the maximum 12 years that a granted authorisation provides for, which leads to European companies missing out on contracts unless they go – again – outside the EU.

In conclusion, the inclusion of a substance in Annex XIV of REACH could delay (contrary to the objective of REACH) substitution because the focus may be on achieving authorisation, which under many circumstances complies with sound business practice. It is also increasingly likely that for a number of substances subject to authorisation, the end result will not be substitution but relocation of activities outside the EU, particularly when there are no foreseeable substitutes ((as is the case for several metallic compounds), and the longest period (12 years) of authorisation is not sufficient in view of investment cycles. It is important to understand that authorisation is burdensome, costly, and diverts resources from activities that could encourage innovation, job creation, and competitiveness.

b) Intermediates

The European Commission drafted a Roadmap for SVHCs based on the RMO approach; this was published in February 2013. The Roadmap states: "Consistent with the principles of Better Regulation, the RMO identifies the best regulatory option to manage the risk, either in REACH (authorisation, restriction or substance evaluation) or outside of REACH (with another legislation)"[83]. Priority is given to those chemicals that are registered and are not used only as intermediates.

However, the question of when a substance can qualify as an intermediate is another example within the authorisation process to which principles of Better Regulation should be applied. Intermediates' uses are exempt from the provisions of REACH that concern Authorisation (Article 2(8)(b) of REACH). However, there is lack of clarity about what an intermediate use of a substance is, despite the fact that ECHA has issued two guidance documents totalling 100 pages on intermediates[84]. This in itself shows that the regulatory design of REACH is lacking clarity and therefore leaves room for interpretation. In addition, the guidance documents defined fewer substances as intermediates than some stakeholders would have liked. The resulting lack of clarity leads to uncertainty and to additional delays and costs for the affected companies. In addition to the Roadmap

[83] Subsport – Substitution Support Portal, Moving towards safer alternatives, Roadmap on Substances of Very High Concern, February 2013. Available at: http://www.subsport.eu/news/page/4 23/02/2015

[84] European Chemicals Agency, How to assess whether a substance is used as an intermediate under strictly controlled conditions and how to report the information for the intermediate registration in IUCLID, June 2014. Available at: http://echa.europa.eu/documents/10162/13655/pg16_intermediate_registration_en.pdf 17/12/2014 and also see: European Chemicals Agency, Guidance on intermediates, December 2010. Available at: http://echa.europa.eu/documents/10162/13632/intermediates_en.pdf 17/12/2014

published in 2013 to identify relevant SVHCs, the EC also has recently proposed changes to the REACH authorisation process itself that could in some cases make it easier for companies to prepare authorisation applications and increase their chances of gaining approval.

c) OELs

In addition to the above-mentioned issues, there is a controversy with regards to exposure limits.

As mentioned earlier, the Roadmap on SVHCs, which includes RMO Analysis to identify SVHCs, provides the opportunity to look at risks identified and consider which legislation would best manage the risk posed by the SVHC in question. For those substances which are handled at the workplace only and for which risks requiring further risk management are identified for workers only, OELs should be acceptable as the best and most proportionate option rather than having to go through the Authorisation process. This then raises a question of competence. OEL limits are set by the Scientific Committee on OELs (SCOEL) of the European Commission within the framework of the worker safety legislation. On the other hand, there is ECHA, which has a different and often stricter standard for exposure limits expressed through the derived no-effect level (DNEL) values, which are proposed by its Risk Assessment Committee (RAC). These two different measures lead to a lack of consensus between DG Employment of the European Commission and ECHA regarding which exposure limits to work with. This creates confusion for industry and Member States, making it difficult for them to determine which measure to adhere to. A clear decision regarding who can set the standards in the case of an RMO conclusion on OELs would ensure clarity and therefore better regulation.

d) The way forward

In view of the Better Regulation approach, it is difficult to understand why the 2013 review of REACH concluded that "[a]lthough [it] identifies a need for some adjustments to the legislation, the Commission wants to ensure legislative stability and predictability for European businesses and hence at the time proposed no changes to REACH's main terms".

This seems remarkable since the review clearly states that the candidate, and in consequence also the authorisation list, have "unintended consequences" while trying to be a "driver for change". Furthermore the review highlights that "retailers or DUs request greater levels of absence of SVHCs than are foreseen within the Regulation; it generates excessive paper/administrative work; there is uncertainty about which substances may in future appear on the candidate list; and attention to the above matters and other candidate list issues can distract firms from their normal, planned innovative activities."[85] Moreover, there does not seem to be any need on any side to prove that the substance in question is actually posing harm to the environment and human health or that substitution of the substance will actually lead to a better environment or a healthier population... If a substance has a certain hazard profile, this is sufficient for proposing its inclusion on the candidate list, without necessarily taking into account its socio-economic importance and/or whether the substance poses risks. This leads to policy target conflicts as certain substances are recognised as essential to achieve objectives in other policy fields such as energy efficiency or industrial policy, as authorisation has a highly disruptive effect on the value chain and especially SMEs.

It would have been clearly in the spirit of Better Regulation to address these unintended consequences in the official review of REACH. It seems that the EC was not ready to correct the debated parts, though it is now (about a year after publication of the revision report) expected that the EC will propose simplifications to the authorisation process.

As a result of the strong criticism of the authorisation process, the Commission has said that given the problems - real or perceived - encountered with the process, it "would not, in the course of 2014, include any further substances in the authorisation list, in order to focus on its efforts to improve the process as a whole".[86]

The proposed changes by the EC of REACH authorisation process are as follows:

- Type-approval cases:

These are cases where moving to a substitute would require the companies involved to seek re-approval of materials or parts, such as some of those used by the automotive and aerospace sectors, and where type-approval is impossible to gain without the use of substance subject to authorisation. It has been considered that the company applying for authorisation would be allowed to submit simplified versions of the chemical safety report, the socio-economic analysis, and the Analysis of Alternatives (AoA) as part of their authorisation application. In addition, these types of authorisations might qualify for long review periods.[87]

[85] Ibidem

[86] ChemicalWatch, EU Commission sparks controversy with authorisation proposals, 11 November 2014. Available at: http://chemicalwatch.com/21867/eu-commission-sparks-controversy-with-authorisation-proposals 17/12/2014

[87] Ibidem.

- Synergies with worker protection law:

Possible options have yet to be identified; however, the Commission has suggested that in cases where the applicant is seeking authorisation via the adequate control route - for instance of those substances for which the risk is only identified in the workplace - it should be possible to use the relevant occupational exposure limit (OEL) value, instead of the reference derived no-effect level (DNEL) produced by ECHA's Risk Assessment Committee (RAC).[88]

However if this approach is applied there is a need for clarification because there are differences in OELs produced by the Scientific Committee on Occupational Exposure Limits (SCOEL) and DNELs produced by the RAC in ECHA (higher vs. lower). There should be a clear statement in favour of OELs in order to create clarity in the spirit of Better Regulation. Furthermore, this raises the question of whether authorisation in addition to workplace regulation is the appropriate way forward as it remains unclear what additional protection the authorisation route could provide to workers, consumers, or the environment.

- Low-volume uses:

The European Commission is suggesting combining a "notification-style application" for volumes less than 10kg per year per legal entity and an application with additional data for higher - but still considered low - volumes of up to 100kg per year. In both cases, the requirements for the Analysis of Alternatives (AoA) would be significantly reduced to simply giving the total volume used per year and data demonstrating that exposure has been reduced to the lowest level possible. "The Commission also suggests that instead of including information on specific potential alternative substances, the AoA could include a general statement on why substitution of the substance is not possible."[89]

The scope of these changes under consideration is rather narrow. However the fact that the Commission is taking steps to simplify the process is promising. It remains to be seen if they will ever be implemented as suggested, and whether they will in fact bring the simplification foreseen in theory. The proposals have already sparked some controversy from environmental NGOs since they would "aim to make it easier and cheaper to get authorisations…while undermining REACH's goals of protection: the phase-out of substances of very high concern and the promotion of substitution by safer chemicals."[90]

This move by the EC is crucial since the impacts of authorisation are momentous.

88 Ibidem
89 Ibidem.
90 Ibidem

Chapter 4: Conclusions

1. Conclusions

Over the past two decades, the Better Regulation Strategy (BRS) has substantially contributed to improving the way regulatory decisions are taken in the EU decision-making process. The BRS is grounded in well-established principles and encompasses the whole policy-cycle. Nonetheless, specific challenges persist when it comes to ensuring high quality risk management interventions.

This study has addressed the problem of ensuring high quality risk regulation by focusing on the regulatory design stage. It claims that part of the potential effectiveness and efficiency of risk management measures is determined during the very initial stages of policy formulation and that the success of the regulation depends on the way terms are defined, objectives and targets are set, and legal requirements are formulated.

The 2020 Climate and Energy Package case study in Chapter Two illustrates the significant role played by political factors in determining the scope of the EU's commitments to both curb GHGs emissions and increase the use of energy from renewable resources. While this is to a large extent unavoidable – indeed it is part of the internal and the external political game - this should not be a justification for creating excessive ambiguity and providing contracting incentives.

- With respect to the GHGs emission target, by setting a unilateral commitment of a 20% cut – instead of a more adequate 30% – the EU intended to emerge as a responsible actor in the fight against climate change and, at the same time, preserve the EU's competitiveness. However, because of a flawed design, the EU is achieving none of these objectives. For instance, the alternative "flanking measures" that were to be considered in case third country competitors did not buy in have not been fully spelled out, thereby affecting the overall predictability of the required changes.

- With regard to the increase in the use of renewable energy sources by 20%, the lack of the expected technology development by 2020 has kept the cost of producing and using renewable energy high. This has stifled investment in related R&D. Unintended consequences such as the un-coordinated fragmentation of the internal market hamper economies of scale. Meanwhile, the continued economic crisis and the changes in the global energy structure have lessened incentives to invest in renewables and made fossil sources (gas and coal in particular) more attractive. In addition, the ambiguity related to the very definition of "renewable" in the RES Directive may have created uncertainty for investors. Finally, the Package pays little attention to the issue of penalties in case a Member State fails to meet one of the three objectives as well as to the options available to the EU to address

these occurrences. These gaps create uncertainty and undermine the credibility of the EU to enforce its policies.

The REACH Regulation case study in Chapter Three provides insights into a number of critical features of the EU chemical regulatory regime. The REACH Regulation has broadly been presented by decision-makers as an important attempt to protect public safety from the uncontrolled use of potentially harmful substances and products; however, the regulation has several critical design flaws.

- One basic assumption of REACH is that some chemical substances – whether natural or artificially synthesised – are intrinsically hazardous and are therefore unsafe or undesirable. Such a "hazard-based" approach tends to disregard the likelihood of harm (or of unintended consequences), and is not informed by the costs and benefits of individual decisions. The recent SVHC Roadmap has recognised this to a certain degree by including the word "relevant" before SVHCs, as well as including the requirement to conduct Risk Management Option (RMO) Analyses before a substance is added to the Candidate List, in order to ensure the best risk management option is chosen. That said, industry may benefit from a better understanding of the relationship between RMOAs and Substance Evaluation, for example, and a better procedural approach for making use of RMOs before candidate listing is proposed. This would on many occasions provide a better risk management option.

- The designers of REACH have moreover failed to fully account for relevant unintended consequences associated with the authorisation process. The so-called "blacklisting" procedure, for instance, creates uncertainty for firms and triggers potentially unjustified negative public perception (stigmatisation), without taking into consideration that consumers might not even be exposed to several of these substances as they are transformed during processing and do not appear in the end-product. In the worst-case scenario, firms may not be willing to commit to such "defensive R&D"[91] in order to keep their product on the market. Another form of unintended consequence is the emergence of so-called "risk-risk" scenarios, in which attempts at curbing the target risk (e.g. banning a particular chemical) may trigger more harmful countervailing risks (e.g. switching to a less investigated and hence potentially less safe alternative solution). The substitution principle implicit in the REACH design potentially provides fertile ground for such trade-offs.

[91] Defensive Research & Development (R&D) occurs when new safety, quality, or efficacy requirements must be applied to existing products. The costs of testing, registration et al are normally met out of existing research and development budgets, diverting resources away from innovation and towards the 'defence' of existing products.

- As currently designed, moreover, REACH offers little opportunity to evaluators to assess its overall success. Issues such as the proportionality of the organisational and procedural administrative regime introduced by REACH are difficult to gauge if one considers the direct compliance costs imposed on the chemical industry in Europe and the wider impacts on the competitiveness and innovation of the EU on the one hand, and the actual improvement in public health and safety protection on the other. It is remarkable in this respect that the interim review carried out by the European Commission in 2013 failed to note all the consequences of the challenges identified.

- Also, in the case of REACH the legal text itself suffers from drafting and procedural ambiguities, as in the case of the definition of "intermediate" substances and uses, as highlighted in this study. The fact that entire procedures such as the RMO analysis have become routine practices well respected by all stakeholders demonstrates the usefulness of these. However, the process should be better embedded into the REACH documents so as to provide the required clarity and transparency. Otherwise it can become a source of confusion, discretion, and possibly politicisation. Finally, the considerable length of the legal act (some 520 pages) does not appear to meet simplicity and accessibility standards, as promoted by the legal drafting and regulatory quality principles.

The case studies considered in this study have highlighted several critical issues that transcend the specifics of the energy and chemical policy sectors. These "horizontal" issues constitute a source of concern if regulatory quality is to be guaranteed from the earliest stages of policy formulation, and they pose a strong threat to jobs, growth, and competitiveness.

Box 6 – Main cross-sectoral lessons from the case studies

The following "horizontal" issues can be highlighted:

- Ambiguity in drafting key terms and definitions and in formulating legal provisions creates uncertainty and unexpected or countervailing behavioural change.
- Poor definition of policy objectives triggers unclear implementation of the envisaged measures and hinders the potential of post-implementation evaluations.
- Recourse to "hazard-based" approaches takes no account of the likelihood of harm or the benefits of risk-taking, including the controlled use of products with hazardous properties. It also undermines evidence-based and proportionate decision-making, creates potential prejudice to WTO requirements, and is not a guarantee of reduction in harm.
- Recourse to substantial implementing guidelines reduces legal predictability and effectiveness if not accompanied by due administrative process standards. An "EU Administrative State" is emerging, which potentially escapes the principles and good practices enshrined in the Better Regulation Strategy.
- Inadequate consideration of a number of baseline scenarios (for instance global economic trends, markets structure, security of supply) diminishes the scope and effectiveness of the policy options to be deployed.
- Disregard of unintended consequences (such as risk-risk effects) jeopardises efforts to increase protection and achieve effective and proportionate policy outcomes.
- Partial consideration of wider indirect impacts on business strategies under-estimates the impact on innovation, growth, and jobs.

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Production of this report was coordinated by Jan Ahlskog acting as an adviser to the European Risk Forum, with contributions from Lorenzo Allio, Richard Meads, Max Bentinck, Julia von Franz, Domenico Ferrara, Martin Lohr, and with help from members of the Forum. The views and opinions expressed in this paper do not necessarily reflect or state those of the European Risk Forum or its members.

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