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CONFERENCE REPORT

PLANNING ADAPTIVE RISK REGULATION

University College London
7 – 8 January 2016

ÉCOLE POLYTECHNIQUE FÉDÉRALE DE LAUSANNE

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The **EPFL International Risk Governance Center** is a neutral platform for dialogue about opportunities and risks related to science and technologies, with the aim of providing recommendations for their governance.

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Summary

On 7 and 8 January 2016, the International Risk Governance Council (IRGC) organised an international public conference on Planned Adaptive Risk Regulation. The Scientific Committee was composed of professors Granger Morgan (Carnegie Mellon University), Kenneth Oye (Massachusetts Institute of Technology), Arthur Petersen (University College London) and Jonathan Wiener (Duke University). The conference was hosted and co-organised by the Department of Science, Technology, Engineering and Public Policy at University College London (UCL STEaPP).

The conference convened participants from academia, regulatory agencies and industry to discuss experiences, challenges and ways to improve regulation related to new scientific developments, emerging technologies and changing risks. Speakers compared and contrasted past and current cases and potential for planned adaptive regulation in the fields of air quality, pharmaceuticals, fuel economy standards, hydraulic fracturing, flood risk governance, autonomous vehicles, synthetic biology and precision medicine.

The purpose of this conference was to discuss two main questions:

- How can law and regulation keep up with advances in science and technology?

  Regulation of risk in sectors marked by rapid advances in science and technology needs to rely on projections of risks, benefits, safety, efficacy, and acceptable quality, with updates and revisions as new knowledge becomes available. Where context conditions change rapidly, a continuous re-evaluation of risk is often needed. This calls for flexible and adaptive risk regulation. Static or rigid regulation, with just a one-time decision, may lead to gaps in risk management, as well as technological lock-ins, which can be a serious impediment to innovation. Regulatory initiatives to foster innovation while improving the use of pre-market and post-market information are now of increasing interest to regulators, industry and NGOs alike. Some current efforts, such as in pharmaceuticals, are focused on developing more adaptive approaches to the management of risks and uncertainty, through stages of sequential learning and decision making throughout the regulatory process. This conference looked at several case studies (noted above), and sought to identify different mechanisms or types of planned adaptive regulation that could be employed in future cases.

- How can regulated parties cope with flexibility and adaptability in regulatory frameworks?

  In fields of new technologies, it is essential to address potential emerging risks without discouraging healthy risk taking and stifling innovative activities. Adaptive regulation may be needed to keep up with changing science and technology. At the same time, regulatory stability can encourage investment, whereas the prospect of revisions in regulatory and licencing frameworks can engender instability that inhibits investment. Thus, both adaptability and predictability are somehow needed. This calls for not just adaptability, but planned adaptive regulation – planning the adaptive character of regulation in advance. This conference studied and debated different ways to do this, including, for example, by involving the regulated parties in targeted government-sponsored research into emerging risks, which may lead to cutting-edge knowledge becoming available and less surprise about regulatory decision-making, but also requires ways to guarantee the independence and credibility of the research.

This report was written by the IRGC secretariat, with contributions from doctoral students Daniel L Ribeiro[1] and Michael Veale[2], and the organizing committee. It summarizes each session and contains a short introduction to the concept of *Planned Adaptive Regulation* in the appendix. The detailed agenda and slide presentations are available from www.irgc.org.

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Conference Day 1

What Is Planned Adaptive Regulation?

How can regulation keep up with the pace of scientific, technological and societal developments? Taking this 'pacing problem' as the starting point, the first session introduced the purpose, objective and characteristics of Planned Adaptive Risk Regulation.[3] Adaptive approaches aim to address the uncertainty, ambiguity and sometimes controversy that often characterise both scientific and technological developments on which policies and regulation need to rely, and changing context conditions, including those concerning social values and opinions.

Arthur Petersen (UCL) presented a number of important questions that surround the theme of planned adaptive regulation (PAR). PAR is closely connected to the notion of deep uncertainties about risks – when there is not enough evidence to characterize the risks in traditional ways. Some examples relevant to PAR and that will be discussed in the conference are flood risks, autonomous cars, and precision medicine. However, PAR also involves thinking about uncertainty at a deeper methodological level, thus demanding a multifaceted investigation about how to deal with these types of risks. Following Lawrence McCray (MIT), PAR can be regarded as a policy tool that includes in the regulation a plan for a future review and revision, i.e., a reassessment of the knowledge base, leading to a new decision to keep or adjust the regulatory intervention. It also includes a planned targeted research effort to deal with knowledge gaps, which may even *increase* uncertainties, yet will improve our characterisation of them in the process. It suggests an overarching research agenda, touching different disciplines and areas, such as education, political science, and others.

Considerations in the design of adaptive policies

Changing circumstances can undermine how policies remain justified. In his overview talk Granger Morgan (CMU) identified and discussed several strategies that warrant consideration, including:

1) The use of policy experiments to identify promising policy options and "red teams" to identify ways in which proposed regulatory strategies might be gamed by regulated entities before they are implemented, so that problems can be found and corrected while that is still easy to do.

   There is a risk that once a policy is in place, interest and stakeholder groups may develop, reopen political agreements, and this can substantially complicate subsequent revisions. One strategy to deal with this is to try to treat policies as experiments, learn as outcomes evolve, and design the initial policy to allow for adaptation in the face of learning and changed circumstances.

   Manski (2013[4]) makes a case for adopting a diversity of policies (e.g., different plausibly good treatments for different populations). Such diversification strategies, especially if they are well-documented and the consequences are well-monitored, are especially feasible in a federal system such as the US in which 50 different states can serve as laboratories for policy

[3] See Lawrence E. McCray, Kenneth A. Oye and Arthur C. Petersen (2010), "Planned adaptation in risk regulation: An initial survey of US environmental, health, and safety regulation", in *Technological Forecasting & Social Change* 77: 951–959, available from http://www.sciencedirect.com/science/article/pii/S0040162509001942 ; Gary E. Marchant, Braden R. Allenby and Joseph R. Herkert (eds.) (2011), *The Growing Gap Between Emerging Technologies and Legal-Ethical Oversight: The Pacing Problem* (Springer).

[4] C. F. Manski, Public Policy in an Uncertain World , Harvard University Press (2013).

assessment or across the EU in which the possibility exists for 28 different member states to work to achieve the same general objective through the adoption of different strategies.

2) Periodic mandatory regulatory review (including the need to differentiate general rules from specific applications), to make policies work as a 'closed loop', with feedback from implementation to provide corrective adjustments. Perhaps the best example of a mandatory review is the requirement under the US Clean Air Act that the national ambient air quality standards (NAAQS) for all of the major "criteria air pollutants" must be periodically revisited and considered for revision by the US Environmental Protection Agency (EPA). Over the years the implementation of this process has undergone various revisions, but it has always involved a detailed review by EPA staff of all relevant refereed literature, and a subsequent peer review by an independent "Clean Air Science Advisory Committee" (CASAC).
3) The use of sunset rules, to avoid lock-in and ensure that rules become less onerous as knowledge improves. One powerful tool that legislators and agencies can use to assure that regulations and other policies do not become outmoded is to specify a "sunset" date at which a regulation or piece of enabling legislation terminates unless it is revisited and renewed. For example, in the US this strategy has been used to impose a periodic review of tax breaks for a variety of activities such for estate taxes and construction of wind and solar power plants.

   Where it is clear that there are knowledge gaps, the role of sunset clauses and breakpoints becomes important to force reconsideration. A push to conduct research is also needed – and this is often the weaker part of the 'adaptive' systems we see today, even in the already mentioned case of the US EPA dealing with air quality standards.

While there is a strong case to be made that policies should be adaptive and should change as we learn more about physical processes and the behaviour of regulated entities, designing such policies can thus pose a variety of challenges.

Morgan discussed two examples to clarify these points. The first, Carbon Capture and Sequestration, shows how industry can react against adaptive regulation when it is communicated poorly, if industry believes it challenges the stability needed for business planning. The second, the case of metallic out of manufacturing (using 3-D printing), involves the risk of prematurely freezing a regulatory approach. In the earlier technology of casting the metal parts, regulators adopted required the addition of extra metal to address uncertainty. Now that casting is well understood, such 'casting factors' are no longer needed, yet they remain in place. If a similar approach were adopted for metalic additive manufacturing, many of the benefits of this new technology would be obviated.

Adaptive approaches that treat policies as experiments, thus enabling both adaptation and learning by design – via a diverse set of policy approaches – is interesting but will probably be challenging in implementation.

A broader discussion about the institutional separation of researchers acting as 'assessors' and 'reviewers' from those acting as 'decision-makers' is needed to advance the implementation of PAR. The lack of publication of negative results is also an issue that is often raised as slowing the use of scientific progress to improve risk management.

What happens if regulation is not adaptive?

Anne Glover (Aberdeen University) discussed EU regulatory policy, designed to incorporate evidence, as scientific input, at each stage of the policy cycle. Developing regulation at the European level tends to be a linear process involving broad consultation and extensive impact assessment. Evidence from science and technology informs the political and decision process but does not necessarily dictate the

outcome as many other factors are considered. It also often happens that the evidence underpinning the policy is not certain and may be continually evolving, especially in areas of new technology. The challenge then is to develop an evidence-based process where uncertainty can be included in policy formation in a way that does not reduce the confidence of business who may wish to invest in novel technology. To support business investment in new technology, regulation needs to be clearly defined.

Glover urged that the initial definition of indicators for measuring policy achievement and the post-implementation evaluation phase are steps of fundamental importance to the idea of adaptive regulation. One explanatory factor for the challenge of consensus-building during these and other steps is the mismatch between how politicians and scientists accept and welcome uncertainty. Evidence is not value-free, and on its own cannot dictate what to do. Especially when lives are involved, value systems cannot accept a hard calculus of risk, cost and benefit. The interplay and succession of several political institutions in the course of the policy process poses yet another roadblock. If PAR is to become a reality, policymakers and researchers need to be more clear about uncertainty and to guard against the exacerbation of public's perception to some risks by traditional or social media. Biofuels regulation in the EU is a cautionary tale of how the policy cycle might work badly, given the lack of or slow adaptation in the face of unintended consequences. Conversely, a potential successful example is the adaptive pathways approach by the European Medicines Agency (EMA), where approval is granted in stages, and new data is generated throughout the process. This does not change the standards for evaluation of benefits and risks of medicine but facilitates progressive licensing, with full assessment eventually informed by earlier involvement of patients and larger sets of data.

The discussion emphasised that some legal systems and the cultures that support them are more favourable than others to planned adaptation. For example, British traffic laws include the general standard to 'cycle without due care', which can be interpreted over time as culture and technology changes. This is in contrast to the high level of detail included in the US legal system for cycling and traffic safety, which may impose more specific requirements than in the UK.

Adaptive Regulation: An Overview of Past and Current Experiences

This session reviewed examples of current regulations in which planned adaptation is built in, such as in US and EU air quality regulation, or in transportation, and discussed where planned adaptation could be included, such as in hydraulic fracturing. Past successes and failures were discussed to address the challenges of designing and implementing planned adaptive regulation.

Fuel-economy and carbon standards for motor vehicles

As an illustration of planned adaptive regulation, John Graham (Indiana University) explored the forthcoming 2017 "mid-term review" of the US fuel economy standards for 2022–2025, and how those standards may need to be adapted to the new environment of low oil prices, much lower than was anticipated when the 2025 targets were set in 2012.

In 2012 the US federal government established ambitious regulatory targets for average passenger-vehicle fuel economy from 2016 through 2025. Those targets are seen as critical to both national climate and energy-security policies. However, the regulation of fuel-efficiency standards for motor vehicles was also introduced with the goal of offsetting the economic impact of increasing fuel prices on consumers. From 2012 to 2016, there were significant changes in the fuel prices, affecting the initial rationale for the regulatory intervention. The initial cost–benefit justification of the program is at risk. Consequently, the upcoming review of the fuel standards might prove politically difficult. This question

promises to be a prominent example of how policy adaptation requires openness to changing economic conditions and politics.

Scientific and technological change is an idea at the forefront of the current debate on PAR. However economics and politics should also be considered as key changing factors suggesting or even requiring policy adaptation.

Planned adaptation in retrospect: Lessons from exemplary cases and cautionary tales

Under conditions of uncertainty and complexity, the need for adaptive strategies of risk management is manifest. Yet the design and implementation of effective systems of planned adaptation is difficult. The presentation from Kenneth Oye (MIT) looked back at examples of successful and unsuccessful adaptive policy systems.

Exemplary cases include:

- The policies resulting from the 1953 flood disaster in the Netherlands and from the 1995 Kobe earthquake
- EU Transmissible Spongiform Encephalopathies (TSE) Programme to manage and prevent an epidemic of mad cow disease, Bovine Spongiform Encephalopathy (BSE)
- The institutional reforms in the US aviation safety area post 1975, with the US National Transportation Safety Board
- The US National Ambient Air Quality Standards (NAAQs) for fine particulate matter (PM 2.5)
- The recent approach to adaptive licensing of pharmaceuticals, designed to systematically explore uncertainty, thus generating information and feedback into the program. In interesting ways, adaptive licensing represents a sophisticated example of PAR. On the front end, it includes earlier and conditional approval to particular patients, who benefit the most and contribute to evidence development. On the back end, it strengthens observation and modification to labels and licenses. The EMA Adaptive Pathways approach is itself an experiment.

Cautionary tales of unsuccessful past nominally adaptive policy systems include:

- The Thalidomide, Accutane and Vioxx crises
- Lack of early access to HIV/Cancer treatments
- Lack of institutional reform and implementation of PAR by the US NASA after the 1986 Space Shuttle Challenge disaster
- Delay in the translation of research results on harmful effects of transfat into regulatory measures.
- The lack of adaptive regulation around pensions and life expectancy was also raised.

Historically, crisis events have prompted regulatory changes. Sometimes, such changes led to the implementation of PAR systems; other times, the reaction either was restricted to piecemeal modifications, took too long, or simply failed to improve the regulation based on lessons from the crisis.

According to Kenneth Oye, elementary principles for governing emerging risks include:

- Prospectively planned adaptation: as both phenomena being regulated and effects of regulatory policies are not well understood upfront, it is key to understand change with empirical observations. Policies should be proactive and adaptive, engaging with priors on risks and benefits, and updating as understandings of risks and benefits evolve.

- Observing, sensing, and revealing: because parties differ in their interest in harvesting and sharing information needed to evaluate benefits/risks, policies should create incentives and cut disincentives to reveal information needed for risk management (research funding, liability and intellectual property law).
- Credible knowledge assessment: because conflicts of interest, organisational inertia and prior beliefs typically create bias in observation and assessment, policies should provide for credible and legitimate assessment of scientific and technical information under complexity, uncertainty and controversy.

Oye suggested that adaptive policies are influenced by limiting factors:

On the side of industries:

- Industry incumbents prefer existing regulations, which define an environment that has been selective for these existing firms
- Firms dislike policy variability and like predictability
- Firms are concerned that regulatory variability would ratchet up and not down.

On the side of regulators:

- Regulators usually prefer to stick with existing hard-won regulations and standards
- Regulators do not wish to risk de-legitimating rationales for existing policies
- Regulators are concerned that variability will be seen as arbitrary and increase demand for deregulation.

Among the public:

- Limited public capacity and lack of interest in regulatory improvement poses a challenge for public authorities to acknowledge uncertainty, to be seen as possibly shifting targets or changing rationales. Regulators often need clearly defined trigger events to spur reforms that the public will accept.

In the face of these limiting factors, Oye argued, assessing and adapting the role of the US National Academies, think tanks, universities, and some niche oriented firms will be needed to promote interest in more efficient and effective adaptive regulation of risks that would for example overcome the problem of free riding and the neglect of public goods. Good framing and communication will be crucial.

Is adaptive risk regulation possible in a contentious political environment? The case of shale gas regulation in the EU

Hydraulic fracturing for the production of shale gas in Europe ('fracking') is a particularly challenging case for implementing adaptive risk regulation. David Reiner (University of Cambridge) explained that the failure to develop shale gas in Europe is perhaps in part linked to the non-consideration of adaptive strategies. Any planned approach presumes at least some degree of social license to operate that would allow contingent regulation or even stakeholder engagement to be considered. Instead, even pilot projects or exploration wells are rebuffed out of fears that it will have a "camel's nose" effect.

In countries that have banned fracking (or instituted a moratorium), such as France, Germany or Bulgaria, there is little room for flexibility or creative approaches. In the few European countries that have strong government support, notably the UK and Poland, there have been early efforts at regulatory design, which have tried to include elements of compensation and public engagement. The success of both systems has been mixed at best.

Poland has, by far, the highest level of public support for fracking in the EU and has now gone through two rounds of regulation. The second round of regulation has tried to respond to perceived governance failures by offering firms a favourable system, but one which reduces the potential for stakeholder involvement.

In the UK, unyielding government support for the nascent industry has led to minimal willingness to engage the public in a constructive fashion and derisory compensation offers. A 'bad luck' event with the first exploratory well in Lancashire contributed to intensifying the public's risk perception of fracking, which translated into a moratorium and rejection of additional proposed wells.

PAR of fracking in the EU has failed to take hold. A limited number of exploration wells in few European countries with higher levels of political acceptance of fracking has been generating little information necessary to enable learning. Miscommunication about risk and potentials, politicisation of the issue, lack of effective (and authentic) consultation strategies, and of building credibility in government institutions before authorising new activities with new risks may have undermined the potential for what could be (or have been) another relevant experiment of adaptive regulation.

In the US, the states that have declared fracking as a 'new technology' have not done it, and those that have extended existing regulations have tended to engage in it.

Adaptive Management of Natural Hazards

This session looked at flood risk management, water quality standards, hurricanes modeling and insurance and decision making in the face of uncertainty.

Many factors influence the risk and impact of natural hazards. Besides physical factors (e.g., landscape design, climate change), socio-economic factors (e.g., population, assets) are also important. Given that these factors change and feature complex and uncertain behaviour, the design and regulation of infrastructure and spatial developments will have to be flexible enough to be able to deal with such changes.

Major questions to be tackled are: (i) how to deal with surprises in the knowledge base?, and (ii) how to manage stakeholder perceptions and participation in Planned Adaptive Risk Regulation practices?

Adaptiveness in the Dutch Delta Programme

Pieter Bloemen (Staff Delta Commissioner) presented the Dutch Delta Programme and the new (2014) Delta Plan (the nation's second, more than 50 years after the first one), which explicitly includes 'Adaptive Delta Management' as an integral part. The concept that underlies Adaptive Delta Management is the choice of strategies and measures that can give flexibility to respond to new knowledge, by stepping up efforts if necessary or changing strategy.

Adaptiveness requires freedom of movement, tailored agility, and informed alertness:

- Freedom of movement implies that there are options to choose from, both in the short and long term
- Tailored agility demands decision-making processes that target the appropriate scales of action in time and in space. Anticipating predictable trends needs other processes than reacting to unexpected events. And updating nationwide safety standards needs other processes than rescheduling local implementation programmes

- Informed alertness requires both an open attitude to changing conditions and a coherent system for monitoring and evaluating developments.

The Delta Programme on safety against flooding and on fresh water supply has followed this approach in its Adaptive Delta Management, which works as an adaptive management policy tool for flood safety and freshwater supply in the Netherlands. The method connects short-term decisions in the broad physical domain (land use planning, water management, housing, shipping, nature, recreation, etc.) with long-term tasks in the specific domains of safety against flooding and freshwater supply, while working with multiple 'adaptation pathways'. In these 'adaptation pathways', decisions are made based on scenarios that take into account dynamic factors, such as how rapidly climate change develops. Analysis and decisions address which long-term options and intermediate steps must be left open, preparing for future transformations in the system, allowing freedom of movement. Preparations for implementing long-term options (e.g., preparing work on a levee) start as soon as a predefined 'signal standard' is reached, as revealed by the monitoring system in place. Monitoring happens at different levels: each level of the system has been designed for some amount of possible adaptation, but to different degrees. Also, every 12 years a review takes place and standards may be revised. After the Delta decisions are made and are implemented, there is ongoing monitoring of research (including commissioned research), innovation, climate change, socioeconomic conditions and societal preferences.

Of the three core features of the Delta Programme, informed alertness is particularly challenging, given the task of distinguishing noise from signal while monitoring for tipping points.

One must also note that:

- In the Netherlands, the chance of drowning is communicated as a risk metric. The Dutch have the luxury of a homogeneous system where floods are technical issues. This is not always possible in other countries, which often leaves their representatives disillusioned. Some good Dutch examples may not function well in other systems.
- Scale is important. Flood-prone regions are often not wealthy enough to pay for works on their own. Countries that are too large lack the solidarity for small, flood-prone areas. Mid-points in scale – of which the Netherlands as a whole is an example – are important.

Informing adaptive management: Innovations and challenges

As theory and practice make clear, the best response to deeply uncertain conditions is often to pursue strategies that are robust and adaptive. However, policy flexibility and experimentation can often conflict with the need for accountable, objective, and predictable governance. To address these challenges, decision support analytics can help decision-makers lay out well-articulated contingency plans, along with a clear understanding of the limits of these plans. Robert Lempert (RAND) described example applications and discussed institutional and other implementation challenges.

He emphasised the need to distinguish between adaptive plans and the process of making them.

Attributes of adaptive plans are:

- Forward-looking, to identify potential vulnerabilities and responses
- With automatic adjustments, to monitor and respond to vulnerabilities
- Integrated, combining the management of multiple elements in holistic plans.

Attributes of processes of developing plans include:

- Integrative review and learning, to address emerging issues

- Multi-stakeholder deliberation, to promote legitimacy and access to information
- Diversity of approaches, to gain knowledge about most effective approaches
- Decentralised decision making, to improve flexibility and responsiveness.

US EPA follows adaptive decision processes, but the resulting plans are less often adaptive. For instance, the EPA process for setting water quality standards includes the above four characteristics, but in practice the water quality standards do not easily change and while the implementation plans are commonly phrased as adaptive, they often rely mostly on unplanned learning. 'Adaptive' plans rarely stretch beyond branding into practice.

Traditional risk management methods work well when uncertainty is limited, but in conditions of deep uncertainty, uncertainties are often underestimated, competing analyses can contribute to gridlock and misplaced concreteness can blind decision-makers to surprises. Under deeply uncertain conditions, it is often useful to run the analysis 'backwards', from the proposed strategy to the identification of vulnerabilities in the strategy, to the development of adaptation measures to reduce vulnerabilities.

In the case of the Colorado Basin, this approach was used to develop an adaptive management plan. The plan included rule-based adaptive strategies with near-term actions, trends to monitor, and contingency actions, in order to keep indicators within acceptable levels by acting in good time. Such adaptive approaches can be thought of and designed in the context of triple loop learning, connecting and triggering revisions of decisions of different levels (e.g., plans, standards, and statutes). When a plan includes planned learning ("adapt as planned"), it reduces the need for constant revisions, which take place only in predefined circumstances.

However, notwithstanding the usefulness of this analytic decision method, political constraints, legal challenges, and divergent expectations can hinder adaptive learning.

Adapting to scientific information: An insurance perspective

Trevor Maynard (Lloyd's) described how Hurricane Andrew in 1992 led to a number of insurer insolvencies and was like a wake-up call to the insurance industry, paving the way for an influx of new scientific data to the market and a more serious consideration of catastrophe models. Scientific methods proved better than assumptions of claims stationarity and were finally accepted by insurers. Notably although Hurricane Katrina caused widespread wind and flood-related claims payments (USD80bn) there were very few insolvencies due in large part to the capital buffers set up using modelling insights.

New models move away from treating events like hurricanes as stationary processes. Instead, they adopt a near-term view – and even a live forecast – of risk as an alternative to long-term averages. As such, they provide and interesting example for PAR.

Despite this, there was much to learn from Katrina and models came under scrutiny. Notwithstanding, with all the analytical improvements, behavioural elements influence how well or bad forecasting is used. Changing a culture of analysis and forecasting requires overcoming some biases (e.g., herd behaviour, representation bias, availability bias, anchoring, and cognitive dissonance).

The example from adaptive approaches from the insurance industry also underscores the importance of effective monitoring, as well as of high-quality data, and of improved risk communication among all the actors involved. Lloyd's of London now requires formal uncertainty communication in its minimum standards. Amidst this, new risk networks are emerging as fora for linking academia to insurance.

The discussion emphasised that probabilities can be hard to understand, although large probabilities, such as daily rainfall, tend to be understandable to some extent. Yet for tiny uncertainties, even experts misunderstand these. Using the experimental literature to communicate uncertainty should help improve risk communication.

Adaptive Regulation for the Development of Autonomous Cars

Most risks involved in car driving will change with the advent of autonomous cars. Engineers, scientists and car manufacturers have developed technologies that enable personal vehicles to drive fully autonomously, but there are a number of uncertainties that will need to be resolved (including issues of standards and interoperability, safety, public acceptance, cyber security, and liability in case of accident). Risks and their management are being re-evaluated, notably by modelling the driving behaviour or the car, to enable accurate qualitative and quantitative assessment, and by addressing liability concerns that may otherwise slow or even prevent consumer access to advanced autonomous vehicle technology. The revision of vehicle regulation requires strong collaboration between regulators, insurance companies, car manufacturers and software companies, and an incremental approach that will allow adaptation of the regulation to the emerging autonomous vehicle technologies, as well as to the outcome of ex-post regulatory impact assessments that collect and integrate feedback from evidence (accident and incident databases) into planned revisions. The session discussed how new regulatory frameworks can be designed for fully autonomous cars. For example, EU regulation routinely uses ex-post impact assessment. It identifies actual impacts during and after implementation, to enable corrective action to be taken if necessary, and to provide information for improving the design of future interventions.

Authorisation of autonomous vehicles could happen incrementally, promoting autonomous vehicles (AVs) for old, young or disabled people, who do not have access to the benefits that mobility provides. However, regulatory systems have low or negligible capacity at the moment for adaptations, or the high-resolution monitoring systems needed to back them up.

Adaptive approaches to vehicle regulation

Walter Nissler (UNECE) presented the work of the UN World Forum for Harmonization of Vehicle Regulations (WP 29) as the international body that establishes international legal instruments to govern the approval or certification processes for vehicles and their parts and components as a prerequisite to allow their use on public roads. It acts as the secretariat of international conventions, such as the 1958 Agreement on type approval for vehicles, parts and components and the 1998 Agreement establishing Global Technical Regulations for vehicles, parts and components. These UN vehicle regulations deal with safety (general, passive and active), pollution and CO_2 emissions, noise and light signaling. Regulations are mostly performance-based (e.g. maximum allowed acceleration for head and injury of the neck), avoiding design restrictions as much as possible. They are based on the principle of performance orientation, avoiding as much as possible design restrictions. To follow technical progress, they are regularly amended.

The latest technical developments towards the introduction of automated and autonomous vehicles challenge the regulatory system at international level.

Challenges include the adaptation of vehicle construction regulations, introducing new concepts of safety and interoperability; the integration of new technologies and standardization work (ITU, ISO, IEC, IEEE); extending regulation to cover software and updates; data and cybersecurity; and the

continuing consideration of traditional vehicle safety issues. Systemic challenges include mixed traffic versus separation; the adaption of traffic rules (e.g. safety distances), the adaptation of infrastructure; and the revision of concepts of responsibility and liability.

Harmonisation is crucial for a global market. Open questions remain, such as what really needs to be regulated, when regulation is needed and the level of depth into which regulations should go. However, regulators should always seek for enhancement of safety for road users and avoiding unfair competition in the automotive industry.

Adaptive regulation and autonomous cars: Views from the UK regulator

Ian Yarnold (UK Department for Transport) presented the initiatives from the UK Department for Transport (DfT), as an early mover in autonomous vehicle policy. There have been prize funds within the UK for innovation, and a large review in 2015 called *The Pathway to Driverless Cars.* Three main deliverables arose from this project: a code of practice (Spring 2015), the intention to review and amend domestic regulation (Summer 2017), and work preparing international discussions for regulatory change (2018).

Driverless vehicles can legally be tested on public roads in the UK today.

Enabling this has been the 'adaptive interpretation' of regulation in order to allow trials. The *Code of Practice* interprets these much older regulations, some over 150 years old, in a way favourable to tests of autonomous vehicles on UK roads.

Areas where domestic adaptation will be required are in liability; licensing; data security/ownership; road traffic rules. International adaptation will centre more around vehicle standards; cross-border issues and conventions; cyber-security; and over-the-air updates.

Informing regulations for autonomous vehicle technologies

Autonomous vehicles have long been a staple of science fiction and Hollywood. In the coming decades, they may become a staple of our everyday lives, with potentially transformative effects. Managing their risks and maximising their benefits requires carefully designed governance and regulation.

Nidhi Kalra (RAND) presented a calculus of risk and benefit over time in order to open up the debate around AVs and regulatory action. AVs promise greater safety, mobility and efficiency, as well as better land use and reduced congestion. Yet they may also bring economic disruption, increased demand for vehicle miles, sprawl and the decrease of mass transit.

The safety issue is a prerequisite for both the opportunities and challenges: how safe should autonomous vehicles be before they are allowed on the roads, and how do we prove they are safe? While humans can make mistakes, there is a cultural aversion to 'letting machines make mistakes'. Some will insist that for introducing AVs, anything short of totally eliminating risk is a safety compromise. However, waiting for autonomous vehicles to be perfect itself raises safety concerns, because it would mean the needless perpetuation of the well-documented risks posed by human drivers. Kalra proposed that AVs might optimally be introduced when they are just somewhat safer than human drivers (perhaps for use by the least safe human drivers) – or arguably even when the AVs are not yet quite as safe as (safer) human drivers, because this earlier introduction of still-imperfect AVs can enable faster learning to improve AVs (so that AVs more rapidly outperform human drivers) and thereby reduce overall driving risks more steeply.

Technological uncertainty, public acceptance, and a host of other factors make it difficult to develop sound governance around this potentially disruptive technology. Deep uncertainties make it very difficult to develop appropriate regulation, so testing and pilot programs seem key in order to collect

data to help generate knowledge and reduce uncertainty. Then, performance-based regulations will offer possibilities for governing the technology in a forward-looking manner. Adaptive regulation holds opportunities for governing this technology.

Insurance perspective on automated vehicles

Sebastiaan Bongers, Swiss Re, presented an analysis on adoption of AVs over time, and the changing patterns of projected global vehicle risk. Motor vehicle insurance currently accounts for approximately 42% of the total global primary Property & Casualty market and is one of the most important lines of business for insurance companies. Motor insurance is undergoing a transformation as new technologies, such as telematics, give rise to new business models.

Bongers observed that AVs have the potential to significantly reduce the number of automobile accidents. Swiss Re developed several projections to get a better understanding of the important factors influencing auto insurance over the next two decades. In the long run, as AVs are more widely adopted, the amount of risk and therefore the need for personal motorist insurance coverage is anticipated to decrease, while product liability insurance coverage by AV manufacturers may become more important.

However, in the short term insurers anticipate that, globally, the amount of risk will still increase over the next few decades. This is due to slow adoption rate, population growth and emerging markets, and insurance being about theft, damage, etc. – more than just accidents. Even in an extreme demand scenario, where people would rush to buy and drive AVs, risks actually stay stable in the medium term, rather than reduce as we might expect.

Currently, insurers have different approaches to tackling the transition phase. Besides thinking about the liability aspects and policy wordings, insurers will have to build capabilities to assess the automated features in new cars in order to be able to price risks accordingly.

Conference Day 2

Adaptive Risk Governance in Synthetic Biology

In the past five years, the field of synthetic biology has been developing at an extraordinary pace. Exponential declines in the cost of DNA sequencing have led to exponential increases in the quantity and quality of information in genetic databases, while exponential declines in the cost of DNA synthesis and the development of powerful new tools for gene editing such as CRISPR Cas-9 have facilitated the development of industrial, agricultural and environmental applications of synthetic biology. The session discussed:

- Benefits and risks associated with applications of synthetic biology, including synthesis of fuels, flavours and drugs in contained settings, the development and release of genetically modified plants and animals, with applications to agriculture and to modification of wild populations
- Proposed technical measures that may mitigate risks and methods for the evaluation and certification of technical measures
- Policy issues associated with risk regulation including EU reforms and US revisions of the Coordinated Framework for Regulation of Biotechnology.

Regulation is often viewed as the preferred or default option for minimising the risks and uncertainties associated with rapidly emerging technologies such as synthetic biology. The evolving nature and special characteristics of synthetic biology suggest the need for an 'expanded toolkit' beyond regulation to promote adaptive governance and to better tailor appropriate measures to specific situations. This includes not only legal liability regimes, insurance, soft law mechanisms, 'regulation by contract' and standards, but also integrating risk-based issues and gaps with less familiar tools such as technical roadmaps, research consortia agendas, and innovative business models incorporating 'adaptive advantage'.

Introduction

Jim Philp, OECD, introduced the session by reminding that, although there is a consensus about the need for a new regulatory regime for bio-based production, there is very little agreement about what it might look like. The US focuses on the need to streamline the many agencies involved and apply rules for each product application rather than for each production method or technique. The EU has more complex rules for the acceptability of genetic modification for agriculture, but it is not clear to what extent this is an issue in industrial-scale contained use applications.

The introduction to the session asked if standardised tests for biocontainment are suitable for regulatory requirements: is it possible to design laboratory standard tests that would be harmonised across national boundaries and that guarantee an acceptable level of biocontainment, can be readily performed by standard laboratories, can be legalised and will shorten and streamline the regulatory process to enable business and innovation in this field?

Synthetic biology: Governing risks of emerging applications

Kenneth Oye (MIT) discussed how the generalisations on benefits and risks associated with 'synthetic biology' should be replaced by concrete analysis of specific applications. His talk summarised several current and impending applications and standards of synthetic biology with distinctive benefit/risk profiles:

- Synthesis of high-value products (drugs and flavours) in tightly contained settings
- Synthesis of low-value products in semi-contained settings
- GM agricultural crops and livestock
- Gene drives to propagate genetic modifications in wild populations.

He then discussed technical safeguards that may limit potential environmental and security risks (methods of intrinsic containment, including nutrient dependency and codon knockouts, immunisation drives and reversal drives) and flagged regulatory challenges associated with certification of safeguards and management of risks.

In particular, Kenneth Oye noted some of the mismatches, gaps and quirks of the current regulatory system to deal with health, environmental and security issues in a field where technology is increasingly ahead of regulation.

Most current applications of biotechnology use new methods to accomplish conventional ends, such as synthesizing materials or changing the properties of crops. Some emerging applications of biotechnology use new methods to accomplish unconventional ends, such as editing the genes of wild populations, not anticipated when the US and European regulatory frameworks were promulgated. Both conventional and unconventional applications cut across existing jurisdictional boundaries and raise issues that fall beyond the purview of US and EU agencies.

Starting with conventional applications, bacteria, yeast and algae are currently being used to produce high-value drugs, scents and flavors, medium value industrial chemicals, and low-value biofuels. In low-value settings where expensive physical containment may not be economically viable, debate will focus on the effectiveness of biological containment measures in limiting environmental effects associated with inadvertent release. Methods of intrinsic containment have progressed from simple kill switches to advanced work on multiple nutrient dependency strategies to reduce fitness and on engineered genetic codes to limit horizontal gene transfer. There is need for development of protocols for testing and certifying methods of biological containment.

Turning to unconventional applications, gene drives are being developed to suppress invasive species and control vector-borne diseases by driving genetic alternations through wild populations of sexually reproducing plants and animals. The EU debate is just beginning. Within the US, the fit between this novel application and existing lines of jurisdiction is being discussed. FDA has responsibility for evaluating genetically engineered DNA constructs intended to affect animals under provisions for veterinary medicines. USDA could be involved if alterations will affect livestock or crops. EPA has broad responsibility for environmental implications of alterations. State authorities have expressed an interest in evaluating local environmental effects. All Federal and State agencies underscore the need for information on gene drive mechanisms, environmental and security effects, and technical features to limit potential environmental and security effects, including immunization drives and reversal drives. However, no agencies have stepped up to provide funding for such research.

Finally, technical developments in the methods used by biological engineers pose regulatory challenges. Consider three examples. US EPA defines “genetically engineered” organisms as those to which DNA from a different taxonomic genus has been added. With new knowledge of genomics and new genetic engineering technologies, genetic changes with the potential substantially to affect an organism and its ecosystem can be made through deletion, duplication, or even rearrangement of genetic sequences within a given species or genus. Such changes now fall into a regulatory gap. EPA defines “genetically engineered” as an organism produced through deliberate movement of DNA. Directed evolution has become more powerful through the use of new DNA sequencing technologies. Changes made through directed evolution now fall into a regulatory gap. EPA treats instability of genetic constructs as undesirable. Some technical methods of intrinsic containment may deliberately build in instability to degrade the efficiency of constructs in order to localize potential effects. Ironically, regulations designed to protect the environment may preclude application of a potentially significant containment strategies.

Approaches to risk governance under uncertainty could take the following forms:

- 'Permissive': they must allow innovation unless environment, health, security are clearly compromised. After-the-fact reaction must be in place if a crisis materialises, because backlash may limit innovation. Examples include: Post-Fukushima nuclear shutdown, US stasis on gene therapy
- Precautionary: they must limit innovation unless environment, health and security are clearly protected. The diversion of innovation to less regulated areas may heighten risks. Examples include: EU on GMOs, US on stem cell research, German genetic data protection
- ‘Planned adaptive’: they must prepare (fund research to inform priors on benefits and risks), discriminate (foster initial applications with most favourable priors), observe (harvest and process information from initial experience) and adapt (learn from experience and update/correct practices).

Scientific opinions on synthetic biology in the EU

Theo Vermeire (RIVM) introduced the field of synthetic biology as full of exciting possibilities, from adapting crops to thrive in barren lands to growing new organs to save the lives of transplant recipients. As an unexplored scientific territory, synthetic biology also poses potential risks and there is inherent uncertainty regarding these risks. That is why a Working Group under the three non-food Scientific Committees of the European Commission, the Scientific Committee on new and Emerging Health Risks (SCENIHR), the Scientific Committee on Health and Environmental Risks (SCHER) and the Scientific Committee on Consumer Safety (SCCS) recently answered 11 questions on synthetic biology from DG SANTÉ, DG RTD, DG GROW and DG Environment.

Three Opinions were presented. The first Opinion (September 2014) discusses the elements of an operational definition for synthetic biology and its scope. The two Opinions that followed in 2015 focused on risk assessment methodology, safety aspects, specific risks for the environment, knowledge gaps and research priorities.

The presentation also suggested ideas regarding the widely discussed risk governance of an emergent technology like synthetic biology, which is seen as an extension of GM. Emerging technologies increasingly seem to give rise to questions about the safety of their products alongside questions on socio-economic issues, including ethical issues. When fundamental uncertainty exists on the risks and insights in (new) safety aspects are lagging behind the development of new technologies, appropriate legislation cannot be developed timely, public perceptions may be less favourable and innovation may slow down.

When talking to regulators and the public, synthetic biology practitioners tend to emphasise continuity with the past; when talking to prospective funders, they emphasise novelty. Even within scientific communities there are differing opinions. Emergent properties of synthetic biology are expected to create new challenges with regard to the prediction of risk. Built in 'safety locks' are currently not sufficiently reliable, and are not blanket solutions. Different layers and methods of containment should be combined to increase safety. The safe innovation model being developed at RIVM includes the use of 'safe houses' to experiment with different regulations, and risks can be managed early on.

Biotechnology: View from industry

Neil Goldsmith (Evolva) presented the activity of his company, which combines modern biotechnology and traditional fermentation to produce ingredients with supply chain 'issues': "brewers for the 21st century". These approaches offer major benefits in terms of better, healthier ingredients for people around the world, produced in a safer and more affordable manner, with a lower ecological footprint than what has come before. Evolva's ingredients can help individuals reduce the amount of sugar in their food, protect their families from disease-transmitting insects and improve the health and wellbeing of themselves and their pets.

Over the last few decades, society has put in place extensive regulations regarding both biotechnological processes and the products (medicines, food, household goods, fuels, crops) that such processes can impact and improve. These regulations are not just passive, however, but themselves actively shape the flow of how (and which) technologies develop. Whilst crafted with positive intent, such regulations, especially those that emerge as the result of complex political processes, may also have perverse effects. For example, the Convention on Biological Diversity was designed (in part) to promote the sustainable exploitation of biodiversity, but has instead played a part in getting the pharmaceutical industry to adopt alternate technological methods for generating new

medicines, resulting in them largely abandoning biodiversity as a source, in turn reducing (at least in commercial terms) the value of biodiversity.

As new biological technologies continue to come through, it is important to update existing regulatory frameworks. However, such updates must not only seek to reduce risk, they must also seek to capture the benefits of innovation, and to avoid perverse effects. This is becoming ever trickier, given that the rate of technological change is exponentially increasing, whilst the rate of regulatory change is not. As such, the risk that regulations are not adapting, or are adapted poorly, increases.

Neil Goldsmith posited that synthetic biology is thus more of a way of thinking than a product. The contrast is that instead of a top-down approach, synthetic biologists look from bottom-up to create new functionality. Can you regulate a philosophy? Without considering the consumer benefits, there will be a repeat of the folly of the genetically modified (GM) organisms industry. There is increasingly a fusion of biotech and IT in order to develop agile technologies and methods of creation. Neil argued that it is important to encourage self-regulation, given the complexity and speed we see. In parallel to this, academia and industry (where it exists) must be encouraged to be transparent and engage society. Neil Goldsmith argued that products secreted *from* a GM organism are not GM. They are similar to those created *with* a GM product. Already there are 10–15 products based on synthetic biology, soon there may be hundreds or thousands.

Adaptive Risk Governance in Precision Medicine

The term 'precision medicine' is used with reference to two broad areas of application:

- Conventional pharmaceuticals are being used in increasingly discriminating ways, with genotypic and phenotypic information on efficacy, safety and effectiveness of drugs and advanced diagnostic tests on patients, which are used to focus treatments on smaller subgroups of patients
- Unconventional regenerative medicines and somatic gene therapies are developed and administered to genetically defined treatment groups, with some therapies based on modifications of cells extracted from individual patients.

Development, regulation and payment/reimbursement for precision medicines, defined in both senses, pose challenges to conventional methods of governing benefits and risks. The session discussed some of the governance issues associated with precision medicine, including that:

- Conventional methods of governing benefits and risk to very small treatment groups are challenged
- One central element of precision medicine, that is the need to collect and integrate large sets of data, including genetic, health and environment (life-styles), may cause problems of data access and use.

Introduction to the revolution of precision medicine

Gérard Escher (EPFL) posited that precision medicine results from the digital and the genomic revolutions, which announce a new patient-centric and data-intensive medicine. The 'info-nano-bio-cogno' convergence of knowledge is leading to an abundance of data and capacity to extract meaning. Research, clinical trials, informed consent, liability, privacy, and health insurance will be transformed.

But to meet the promises, more data needs to be collected, medical doctors need to be trained and theory and technology must align. The huge cohorts needed for making sense of genomes brings

challenges of data quality, size and privacy in order to make reliable, ethical analysis, alongside challenges of re-skilling doctors to deal with probabilistic counselling and analytical rigour. Without the right balance of individual rights and public health concerns, we risk bypassing the current health infrastructures and regulations. Perhaps we need a Nagoya Protocol for the exchange of human genetic data and resources.

An adaptive regulatory framework for responsible sharing of medical and health-related data and for protecting patient rights is necessary. Countries in Europe and elsewhere are embarking on ambitious policy initiatives and research programmes.

Precision medicine: An overview of changing technologies and regulatory challenges

The presentation from Kenneth Oye (MIT) provided an overview on technical and policy issues associated with the development and regulation of precision medicines, and its various forms (e.g. altering genes, regenerative medicine, germline gene therapies, etc.)

Challenges include:

- Characterisation of degrees of uncertainty over benefits and risks associated with conventional and unconventional precision medicines: how to assess safety and efficacy when the numbers are small and it is even difficult to find enough subjects for random clinical trials
- Cost and governance issues that are associated with ever smaller treatment groups: for rare disorders, prices are climbing, and payers demand more evidence despite weak information. On the other hand, patients would like to have early access to therapies. Patients are exposed to high risk in early use
- Problems with data collection, access and use.

The European Medicine Agency (EMA), US FDA and Japanese PMDA regulatory authorities are innovating to meet these challenges. In particular, EMA is moving towards adaptive pathways for drug licensing, which could also be needed for precision medicine.

Governance debate and policy agenda: The situation in China

Lan Xue, Tsinghua University described the various actors addressing precision medicine and their different motivations: the scientific community is currently driven and/or concerned by data access, government and society are motivated by data privacy and security, committees on ethical, legal and social issues (ELSI) are motivated by ethical issues, and government & industry are driven by economic opportunities.

China is an important player in genomic research and technology, with anticipated application in precision medicine. Initially, genetic test labs were approved at a provincial level. Following negative news publicity, these were all called off from a national standpoint – the reason being that the products were unregistered. Following this, some pilot technologies and institutions were authorised. However, the core trouble here for adaptive regulation is how to coordinate services when different agencies have different agendas and responsibilities.

Genomic research and precision medicine

Jacques Fellay (EPFL) reminded that rules and regulations governing research and clinical activities have historically been very distinct. In today's post-genomic era, every patient – or healthy individual – can be seen as a potential research participant, whose data could contribute to an accelerated pace of scientific discoveries. Open access and citizen science movements are powerful forces that are reshaping the biomedical research enterprise, but their current lack of regulatory content is

problematic when dealing with private health data from the general population. The presentation described the promises and pitfalls of the upcoming confluence between laboratory and clinical genomics, from the perspective of a medical doctor active in human genomic research.

There is a blurred line between clinical care and genomic research. A central goal of precision medicine is to focus, at the individual level, on wellness and progression to disease, rather than disease and progression to death. Currently, genomic medicine looks at rare diseases, limited connections between genes and drugs, genomics of cancer and non-invasive prenatal testing. However, in the future, universal sequencing, sensors, new levels of data and understanding, and clinical access to technology will mean that genomic medicine becomes much more mainstream.

Regulatory challenges of bringing precision medicine to patients

Hans Georg Eichler (European Medicines Agency) described one of the key problems of precision medicine: it is challenging to detect all problems before licensing, or even within decades or generations of their use. This creates a high reputational risk. Post-market studies are a problematic tool and, if they are not delivered, it is difficult or impossible to withdraw the product. Adaptive pathways require us to think over a few points:

- Stop pretending that we know everything at the time of licensing
- Classic medicines do not normally spread like wildfire, we can generally recall them. This may not be possible with precision medicine
- Authorisation can be a graded decision, not binary. Rather than licensing a medication for all, we can determine and limit the treatment-eligible population – starting for example with the population with the biggest unmet need
- We *can* steer use of the product: the reauthorisation of thalidomide is a good example, accompanied by a complex risk management scheme with a patient registry and monitoring system
- Perhaps there are relevant price controls: can we link products to their uncertainty to promote knowledge building?

Concluding Session and Synthesis

The concluding session was a discussion among Arthur Petersen (UCL), Reto Schneider (Swiss Re), Jonathan Wiener (Duke University), Anne Glover (University of Aberdeen), and Jason Blackstock (UCL). This discussion highlighted the following points.

While implementing Planned Adaptive Regulation can be challenging, doing so is often worth the extra effort because PAR represents an effective and efficient approach to regulating old, new and disruptive technologies in the face of uncertainty and evolving circumstances.

PAR is a dynamic approach to regulation. Instead of waiting for certainty, or making a one-time decision, it embraces uncertainty through a plan for the design, monitoring, review and sequential adjustment of policies. PAR incorporates learning from (controlled) implementation, with that learning feeding directly into review and rule-adjustment.

The conference highlighted some of the many **tools and types of PAR currently being used and proposed,** and how the form of PAR may change given the **characteristics of particular risks**. It also raised some **key enabling and confounding dynamics** that may determine the success of any implementation.

(a) **There are many tools and types of PAR.** W*ays to implement* PAR approaches include:

- *Revision processes*: planning for single or periodic reviews of ongoing policies, or mechanisms designed to periodically challenge fundamental regulatory assumptions and criteria
- *Sunset clauses*, or other mechanisms to terminate a policy unless it is reviewed and renewed
- *Learning:* the ability to observe variation and/or conduct experiments, to monitor/collect data, and to modify/improve regulation as one gains experience with the risks and benefits
- Building in *planned rule adjustments,* usually linked to 'signal standards', which are often performance-based
- *Maintaining the option space*: keeping long term avenues open using procedures such as backcasting
- *Fostering adaptive policy systems*, where institutional rules and practices promote adaptation of regulation when new information emerges
- *'Front-end' PAR* through ex ante impact assessment of new or revised policies, as well as through limited release and deployment of technologies (such as adaptive licensing of medicines or performance-based certification of active safety features for automated driving) for the specific subgroups who would benefit most (followed by testing and assessment of wider licensing)
- *'Back-end' PAR*, through ex-post impact assessment (retrospective review) to assess and revise existing regulations, as well as to test and improve the accuracy of ex-ante impact assessments
- *'Red teams'* whose job is to attempt to break or game regulatory systems to help identify problems and aspects in need of revision.

Assessment mechanisms are crucial parts of the PAR toolkit. The impacts of each PAR should be thoroughly assessed – ex-ante and ex-post, or repeatedly – since the amount of risk we are willing to take is strongly reliant on the cost–benefit balance. Failed and successful cases of PAR should be studied in order to improve the assessment of potential losses and benefits of new planned adaptive rules.

Communication and education tools often determine the success of PAR. In the communication sphere, the framing of technologies (e.g. as 'new' or as 'amended'), the extent to which probabilities are understood and related to by audiences, the role of scientists and independent bodies in supporting, structuring and synthesising information are all important. Benefits and costs are often unevenly distributed across actors with different incentives, information and risk tolerance, and communication can unify or polarise these situations. Awareness of cognitive biases may aid communication in this area.

(b) The form of PAR may differ based on the **characteristics of particular risks, benefits and technologies**.

The different *timescales* of costs and benefits create important practical implementation considerations and normative, distributional decisions. The sequential reviews of PAR need to be timed to keep pace with the evolving science and technology of each issue area. For PAR to succeed, the reviews cannot be too seldom or too frequent, and adjusting the timescale itself will require experiments and learning from experience. Even within the same timeframe, different *populations* can experience different levels of impact or risk with different levels of uncertainty. In some cases, the idea of targeting specific subgroups or populations over time was raised – yet the ethics and calculus of this are rarely clear. Different risks also have different *scopes of impact*. At the design phase, policymakers can better minimise unintended consequences by paying attention to the full portfolio of impacts, including the ancillary benefits and countervailing risks. PAR needs to consider a broad array of *types*

of changes, looking beyond scientific and technological developments to include social, economic, demographic and political changes, among others. The conference identified some examples where promising PAR systems were hampered by these broader changing factors. Risk and technologies also bring many *types of uncertainty*. Some knowledge gaps are obvious, while other will appear with time: yet a strong research programme, while possibly even increasing uncertainty, should help us better characterise it. We can learn a lot about some technologies and policies in controlled experiments, while for others we can learn very little. Yet despite these characteristics, it is important to realise that evidence is rarely value-free, and we rarely are able to classify emerging risks well, or understand many of their features.

(c) Finally, PAR cannot be achieved in a vacuum, but is surrounded by both **key enabling and confounding dynamics** which should not go unconsidered.

PAR might be able to improve accountability for policy outcomes, but will be unlikely to achieve this without an *institutional culture of transparency*. In order to detect risks, *foresight and horizon scanning* organisations play a useful role at the forefront of understanding trends. Linked to this, there should be *strong research capacity* to better characterise and clarify remaining uncertainties, with research structures well connected to policy structures. A key question will be *who* conducts and oversees PAR: which institutions in each polity have the authority and responsibility to undertake the research, reviews, and policy revisions. Certain *legal systems* appear more amenable to particular types of PAR than others, especially those where performance outcomes, rather than users' behaviors, are regulated; where rapid adjustment is possible; and where older legislation can be 'adaptively' interpreted. Particular *political systems* are also easier to navigate for PAR – with many examples of PAR at the forefront coming from systems with internal variation as a source of learning. PAR requires credible future commitment, else adaptation may not occur as planned, and a balance between adaptability and the predictabilty sought by investors. *Issues of scale* need careful consideration. Policy variation across subjurisdictions can offer a laboratory for learning – provided that some institutions are actually monitoring this variation and learning from the results. Over-decentralisation can lower capacity for policy experimentation, while over-centralisation can stifle innovation. Similarly, regional risk management needs to strike a balance between resource availability and political solidarity with the affected area. New *boundary organisations* for brokering between evidence and practice seem to support PAR, such as academic networks in the insurance field. *Educational leadership* in risky fields can create an atmosphere of responsibility and self-regulation. New policy-makers should also be trained to use PAR approaches when designing and managing risk. An *inclusive*, *multi-stakeholder* culture helps to better share experience and affirm that PAR can unlock social benefits while being compatible with stability and safety. For this, it is important to investigate and learn how actors have been positioning themselves in ongoing PAR initiatives, and how PAR may affect the political economy of regulation in the future.

A culture change might be necessary: from relying on and aiming at rigid and permanent political agreements, to perceiving and accepting policies as dynamic experiments, contingent on evolving circumstances and advancing understanding. PAR may then be linked to guiding principles for dealing with uncertainty and incorporating learning into policy systems: how to produce decision-relevant knowledge over time, and how to link that knowledge to continual decision-making.

Appendix 1: Conference Programme

Day 1 – Thursday 7 January 2016

Session 1.1: **Introduction**

- Welcome from University College London
  Jason Blackstock, Department of Science, Technology, Engineering and Public Policy (STEaPP), University College London
- Welcome from IRGC
  Philippe Gillet, École Polytechnique Fédérale de Lausanne; IRGC Foundation Board
- Considerations in the design of adaptive policies
  Granger Morgan, Department of Engineering and Public Policy, Carnegie Mellon University; IRGC Scientific & Technical Council (S&TC)
- What is planned adaptive regulation?
  Arthur Petersen, UCL STEaPP; IRGC S&TC
- What happens if regulation is not adaptive?
  Anne Glover, University of Aberdeen, former Chief Scientific Adviser to the President of the European Commission

Session 1.2: **Adaptive Regulation – An overview of past and current experiences**
Facilitation: John Graham, Indiana University

- Fuel-economy/carbon standards for motor vehicles
  John Graham, School of Public and Environmental Affairs, Indiana University; IRGC S&TC
- Planned adaptation in retrospect – Lessons from exemplary cases and cautionary tales
  Kenneth Oye, Program on Emerging Technologies, Massachusetts Institute of Technology; IRGC S&TC
- Adaptive risk regulation and fracking in Europe
  David Reiner, University of Cambridge
- Commentaries: Ragnar Löfstedt, King's Centre for Risk Management, King's College London

Session 1.3: **Adaptive flood risk governance**
Co-organised with: Dutch Delta Programme
Facilitation: Arthur Petersen, University College London

- Introduction
  Arthur Petersen, Department of Science, Technology, Engineering and Public Policy, UCL; IRGC S&TC
- Dutch adaptive delta management
  Pieter Bloemen, Dutch Delta Commissioner
- Informing adaptive management – Innovations and challenges
  Robert Lempert, RAND Corporation
- Adapting to scientific information – An insurance perspective
  Trevor Maynard, Lloyd's

Session 1.4: **Adaptive regulation for the development of autonomous car markets**
Co-organised with: Sustainable Transport Division, World Forum for Harmonization of Vehicle Regulations, United Nations Economic Commission for Europe
Facilitation: Jonathan Wiener, Duke University

- Adaptive approaches to vehicle regulation
  Walter Nissler, Vehicle Regulations and Transport Innovations Section, Transport Division, United Nations Economic Commission for Europe (UNECE)

- Views from the UK regulator
  Ian Yarnold, International Vehicle Standards Division, UK Department for Transport
- Informing regulations for autonomous vehicle technologies
  Nidhi Kalra, RAND Corporation
- Insurance perspectives on automated vehicles
  Sebastiaan Bongers, Swiss Re

Day 2 – Friday 8 January 2016

Session 2.1: **Adaptive risk governance in synthetic biology**
Co-organised with: OECD Working Party on bio-nano-converging technology (WP BNCT)
Facilitation: Kenneth Oye, MIT

- Introduction
  Jim Philp, OECD
- Synthetic biology: Emerging applications and regulatory challenges
  Kenneth Oye; Program on Emerging Technologies, Massachusetts Institute of Technology; IRGC S&TC
- Scientific opinions on synthetic biology in the EU
  Theo Vermeire, Dutch National Institute of Public Health and the Environment and SCENIHR
- Views from industry
  Neil Goldsmith, Evolva
- Commentaries: Richard Kitney, Imperial College London

Session 2.2: **Adaptive risk governance in precision medicine**
Facilitation: Lan Xue, Tsinghua University

- Introduction to the revolution of precision medicine
  Gérard Escher, École Polytechnique Fédérale de Lausanne; IRGC S&TC
- Precision medicine – An overview of changing technologies and regulatory challenges
  Kenneth Oye, Program on Emerging Technologies, Massachusetts Institute of Technology; IRGC S&TC
- Governance debate and policy agenda – The situation in China
  Lan Xue, School of Public Policy and Management, Tsinghua University; IRGC S&TC
- Genomic research and precision medicine
  Jacques Fellay, École Polytechnique Fédérale de Lausanne
- Regulatory challenges of bringing precision medicine to patients
  Hans-Georg Eichler, European Medicines Agency

Session 2.3: **Conclusion – Cross-cutting themes**
Facilitation: Arthur Petersen, UCL

- Reto Schneider, Swiss Re
- Jonathan Wiener, Duke University
- Anne Glover, University of Aberdeen
- Jason Blackstock, University College London

Appendix 2: A Short Introduction to 'Planned Adaptive Regulation'

This short note was written to set the scene before the conference on Planned Adaptive Risk Regulation (PAR) held by the International Risk Governance Council (IRGC) at University College London (UCL) on 7-8 January 2016. Its purpose was to propose a brief literature review about PAR, including main features, examples in practice, and reasons why PAR is desirable or may face challenges in each case.

Introduction: How can law and regulation keep pace with scientific, technological and social change?

Regulation of risk can be difficult in sectors marked by rapid change in science, technology, economic and social conditions. Regulators rely on projections of future outcomes, but also anticipate that actual outcomes may differ and will require rethinking over time as new knowledge becomes available. In fields where context conditions change rapidly, regulation cannot be a one-time final decision; continuous or iterative re-evaluation is needed for policies to keep pace with change. Addressing this 'pacing problem' calls for *adaptive regulation*. Adaptive regulation may also help promote and accommodate innovation, avoiding lock-ins and barriers, through repeated evaluation and revision.

At the same time, adaptive regulation may pose new challenges for regulators, regulated parties and other stakeholders. Periodic re-evaluation and revision might reduce the stability and predictability of rules, which could have the effect of discouraging investment and innovation. Yet some instability is inescapable, because the underlying reason for adaptive regulation is that ongoing changes are occurring in the scientific, technological, economic and social conditions. Given that such change is ongoing, the promise of *planned* adaptive regulation is to handle this change with greater agility and predictability, through planned review and revision, rather than through a purportedly final decision that locks regulation in place and then grows increasingly out of step with the ongoing changes – yielding unintended consequences and rigid rules that inhibit innovation (until high costs or a crisis event force an abrupt and painful overhaul). Thus, *planned* adaptive regulation may be better able to address changing science, technology and conditions, while assuring regulated and affected parties of sufficient foreseeability to guide investment and decisions.

Elements for a definition of Planned Adaptive Regulation

The term 'planned adaptive regulation' refers to the intentional and precursory design of institutions and processes to review and update policies in light of evolving scientific knowledge and changing technological, economic, social and political conditions. It is adaptive, but also planned, so it refers not only to the ability of policies to respond to events and information as they arise, but also to a conscious plan to undertake data collection and repeated review over time. Our use of the term PAR is reserved for cases where:

a) There is a prior commitment, planned early in the policy's design, to subject the policy to periodic re-evaluation and potential revision, and
b) There is a systematic effort or mechanism, planned early in the policy's design, to monitor and synthesise new information for use in the re-evaluations.

References and illustrations

Planned adaptive regulation has been used in various sectors. This section provides some references and illustrations from the literature.

- Air pollution, airplane safety and drug safety (USA)

  "In principle, we want regulatory programs to be based on current realities, as reflected for example in the best knowledge of relevant experts. That would imply that old rules now on the books should be consistent with today's knowledge base, not just what was known when a rule or standard was originally set. ***This paper reports on a survey of US programs, examining how often existing rules are actually updated in light of better knowledge, and identifies five programs that attempt to make policy routinely adaptive. These programs exhibit what we term Planned Adaptation: they both revise rules when relevant new knowledge appears, and take steps to produce such improved knowledge.*** *While Planned Adaptation is rare, it is used in several nationally prominent programs, including air pollution, airplane safety, and drug safety. Planned Adaptation is a policy tool that deserves more attention."*

  Lawrence E. McCray, Kenneth A. Oye and Arthur C. Petersen (2010): "Planned adaptation in risk regulation: An initial survey of US environmental, health, and safety regulation", in *Technological Forecasting & Social Change* Vol 77 (2010) 951–959, available from http://www.sciencedirect.com/science/article/pii/S0040162509001942

- Flood management (The Netherlands)

  "In the Netherlands, dykes and other primary water defence works are assets that are essential to keep the society and economy functioning, by protecting against flooding from sea and rivers due to extreme events. Given that 55% of the country is at risk of flooding, primary water defence works belong to its critical infrastructure. Many factors influence the risk and impact of flooding. Besides physical factors (e.g., landscape design, climate change), also socio-economic factors (e.g., population, assets) are important. Given that these factors change and feature complex and uncertain behaviour in past and future, the design and regulation of this critical infrastructure will have to be flexible enough to be able to deal with such changes. ***'Planned Adaptation' refers to regulatory programmes that plan for future changes in knowledge by producing new knowledge and revising rules at regular intervals.*** *This study describes the emergence of the next generation of Dutch primary water defence infrastructure, which through the stepwise implementation of Planned Adaptation for design and testing of primary water defence works in the mid-1990s has moved beyond the Delta Works approach of 1953 and subsequent unplanned adaptations. This has prepared the ground for the recent introduction of Adaptive Delta Management, which makes an integral part of the new Delta Plan for the Netherlands that was published on 16 September 2014 and which is also analysed in this study."*

  Arthur Petersen and Pieter Bloemen (2015): "Planned Adaptation in Design and Testing of Critical Infrastructure: The Case of Flood Safety in The Netherlands", in Dolan, T and Collins, B, (eds.) ***International Symposium for Next Generation Infrastructure Conference Proceedings: 30 September - 1 October 2014 International Institute of Applied Systems Analysis (IIASA)*** 221 - 225, available from http://discovery.ucl.ac.uk/1469402/

- Pharmaceutical licensing (Europe)

  "The concept of adaptive licensing (AL) has met with considerable interest. Yet some remain skeptical about its feasibility. Others argue that the focus and name of AL should be broadened. Against this background of ongoing debate, ***we examine the environmental changes that will likely make adaptive pathways the preferred approach in the future****. The key drivers include: growing patient demand for timely access to promising therapies, emerging science leading to fragmentation of treatment populations, rising payer influence on product accessibility, and pressure on pharma/investors to ensure sustainability of drug development. We also discuss a number of environmental changes that will enable an adaptive paradigm. A life-span approach to bringing innovation to patients is expected to help address the perceived access vs. evidence trade-off, help de-risk drug development, and lead to better outcomes for patients."*

  Hans-Georg Eichler et al. (2015): "From Adaptive Licensing to Adaptive Pathways: Delivering a Flexible Life-Span Approach to Bring New Drugs to Patients", in *Clinical Pharmacology and Therapeutics*, Vol 97 No 3, March 2015, available from: http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/12/news_detail_002234.jsp&mid=WC0b01ac058004d5c1

- Tools for creating adaptive policies (Canada and India)

  "Experience demonstrates that policies crafted to operate within a certain range of conditions are often faced with unexpected challenges outside of that range. The result is that many policies have unintended impacts and do not accomplish their goals. Adaptive policies are designed to function more effectively in complex, dynamic, and uncertain conditions. Based on over a dozen case studies on public policies relating to agriculture and water resources management in Canada and India, we conclude that there are seven tools policymakers should follow to create adaptive policies. ***Adaptive policies anticipate and plan for the array of conditions that lie ahead: (#1) using integrated and forward-looking analysis; (#2) monitoring key performance indicators to trigger built-in policy adjustments; (#3) undertaking formal policy review and continuous learning; and (#4) using multi-stakeholder deliberation.*** *But not all situations can be anticipated. Unknown unknowns and deep uncertainty will always be part of policymaking. Adaptive policies are able to navigate toward successful outcomes in settings that cannot be anticipated in advance. This can be done by working in concert with certain characteristics of complex adaptive systems and thereby facilitating autonomous actions among stakeholders on the ground. To a degree, adaptive policy tools #3 and #4 can be used toward this purpose, but most directly, such autonomous tools include:* ***(#5) enabling self-organization and social networking; (#6) decentralizing decision-making to the lowest and most effective jurisdictional level; and (#7) promoting variation in policy responses****. This paper elaborates on these seven tools as a pragmatic guide for policymakers who find themselves working in highly complex, dynamic, and uncertain settings."*

  Darren Swanson et al. (2010): "Seven tools for creating adaptive policies" in *Technological Forecasting & Social Change* Volume 77, Issue 6, July 2010, 924–939, available from http://www.sciencedirect.com/science/article/pii/S0040162510000727

- Addressing deep uncertainty using adaptive policies

  *"...policy failures often follow from a failure to take uncertainties into account in making policy, and suggest that taking into account uncertainty can be essential for successful long-term policymaking. It is clear that uncertainty is at the heart of the very nature of long-term policymaking. In long-term policymaking, decision makers must make decisions about the future. The future is impossible to predict. But, that is no reason to throw up one's hands and ignore uncertainty. Quite the opposite. [...] New approaches to policymaking under conditions of deep uncertainty are needed—approaches that protect against and/or prepare for unforeseeable developments. [...]. **A policy that can adapt to changing conditions is well suited to situations involving deep uncertainty. An adaptive policy is aware of the multiplicity of plausible futures that lie ahead, is designed to be changed over time as new information becomes available, and leverages autonomous response to surprise. The adaptive policy approach makes adaptation explicit at the outset of policy formulation. Thus, the inevitable policy changes become part of a larger, recognized process and are not forced to be made repeatedly on an ad-hoc basis.** Under this approach, significant changes in the system would be based on an analytic and deliberative effort that first clarifies system goals, and then identifies policies designed to achieve those goals and ways of modifying those policies as conditions change. Within the adaptive policy framework, individual actors would carry out their activities as they would under normal policy conditions. But policymakers and stakeholders, through monitoring and corrective actions, would try to keep the system headed toward the original goals...."*

  Warren E. Walker et al. (2010): "Addressing deep uncertainty using adaptive policies: Introduction to section 2" in *Technological Forecasting & Social Change* Volume 77, Issue 6, July 2010, 917–92, available from http://www.sciencedirect.com/science/article/pii/S0040162510000715

- Law keeping pace with change

  "The consequence of this growing gap between the pace of technology and law is increasingly outdated and ineffective legal structures, institutions and processes to regulate emerging technologies. The two basic options for addressing this problem are (i) to slow or stop the pace of scientific progress; or (ii) to improve the capacity of the legal system to adapt to rapidly evolving technologies (even if this means departing from traditional forms of legal regulation into broader forms of governance, as discussed below)."

  Gary E. Marchant, Braden R. Allenby, Joseph R. Herkert (eds.) (2011), *The Growing Gap Between Emerging Technologies and Legal-Ethical Oversight: The Pacing Problem* (Springer), chapter 2, 19.

- OECD recommendations for ex-post Regulatory Impact Assessment and evaluation through the policy cycle

  The OECD provides recommendations for improving the impact, performance and efficiency of government interventions.

  OECD recommendations on Regulatory Policy and Governance (2012): Comprehensive policy cycle in which regulations are designed, assessed and evaluated ex-ante and ex-post, revised and enforced at all levels of government, supported by appropriate institutions http://www.oecd.org/gov/regulatory-policy/2012-recommendation.htm

  OECD Regulatory Policy Outlook (2015): Recommendations for evidence-based policymaking includes the use of Regulatory Impact Assessment and closing the regulatory governance cycle through systematic ex-post evaluation. http://www.keepeek.com/Digital-Asset-Management/oecd/governance/oecd-regulatory-policy-outlook-2015_9789264238770-en#page2

- European Union "REFIT" program as part of "Better Regulation"

  As part of its "Better regulation" initiative, http://ec.europa.eu/smart-regulation/index_en.htm , the European Commission has undertaken efforts to review the "fitness" of existing regulatory policies over time, called "REFIT":

  REFIT Regulatory Fitness and Performance (REFIT): results and next steps" COM(2013)685 http://ec.europa.eu/smart-regulation/docs/20131002-refit-annex_en.pdf

  "Better Regulation for Better Results – An EU Agenda" COM(2015)21 http://ec.europa.eu/smart-regulation/better_regulation/key_docs_en.htm

  Example: evaluation and fitness check of the EC regulation of Pollutant Release and Transfer Register (E-PRTR) http://ec.europa.eu/smart-regulation/roadmaps/docs/2016_env_062_e-prtr_en.pdf

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The **International Risk Governance Council** (IRGC), based at EPFL, Lausanne, Switzerland, is an independent non-profit foundation whose purpose it is to help improve the understanding and governance of systemic risks that have impacts on human health and safety, the environment, the economy and society at large. IRGC's mission includes developing risk governance concepts and providing risk governance policy advice to decision-makers in the private and public sectors on key emerging or neglected issues. IRGC was established in 2003 at the initiative of the Swiss government and works with partners in Asia, the US and Europe.

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