A short introduction to
'Planned Adaptive Regulation'

This short note sets the scene for the conference on Planned Adaptive Risk Regulation (PAR) to be held by the International Risk Governance Council (IRGC) at University College London (UCL) on 7-8 January 2016. http://www.irgc.org/event/planning-adaptive-risk-regulation/

It is intended to assist speakers at the conference with preparing their presentations about PAR, including its main features, examples in practice, and reasons why PAR is desirable or may face challenges in each case.

1. 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-evaluations will be 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.

This conference will consider the features, pros and cons, and case study examples of planned adaptive regulation. Examples now in view may include air pollution control, flood control, autonomous vehicles, unconventional oil and gas drilling, biotechnology and synthetic biology, pharmaceuticals and precision medicine, and others.

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.

2. Elements for a definition

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.

3. 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 selforganization and social networking; (#6) decentralizing decisionmaking 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 capacityof 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 et al. (eds.) (2011), *The Growing Gap Between Emerging Technologies and Legal-Ethical Oversight*, 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