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Regulation of emerging technologies: Planned Adaptive Regulation (PAR)

Presentation at a workshop on Planned Adaptive Governance Hosted by the Brocher Foundation November 2018

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The Growing Gap Between Emerging Technologies and Legal-Ethical Oversight

The Pacing Problem

Editors: **Marchant**, Gary E., **Allenby**, Braden R., **Herkert**, Joseph R. (Eds.)

The Bridge | Expert Commentary | Aug 8, 2018

The Pacing Problem and the Future of Technology Regulation

Why Policymakers Must Adapt to a World That's Constantly Innovating

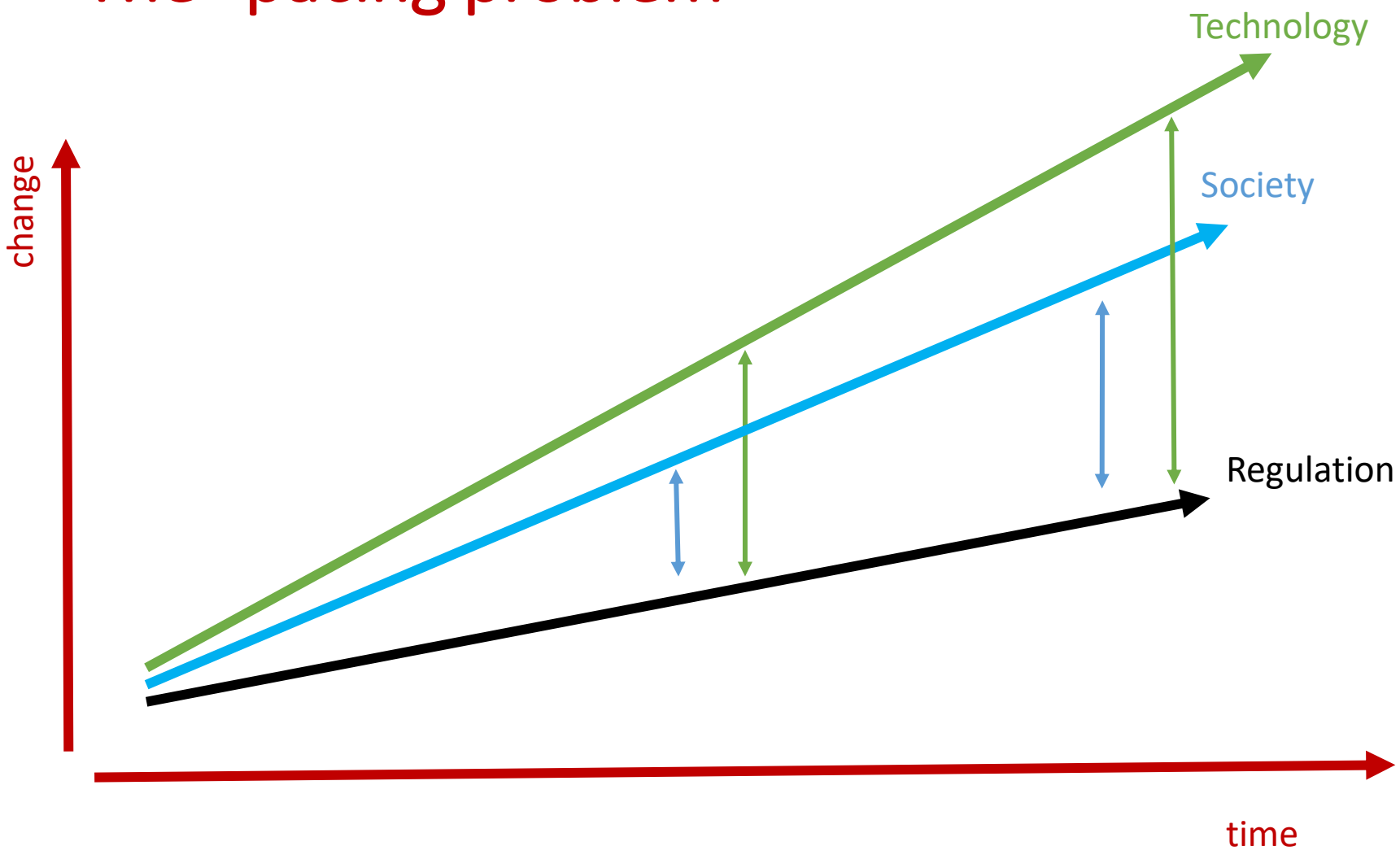
By **Adam Thierer** *Senior Research Fellow*

What happens when technological innovation outpaces the ability of laws and regulations to keep up?

This phenomenon is known as "the pacing problem," and it has profound ramifications for the governance of emerging technologies. Indeed, the pacing problem is becoming the great equalizer in debates over technological governance because it forces governments to rethink their approach to the regulation of many sectors and technologies.

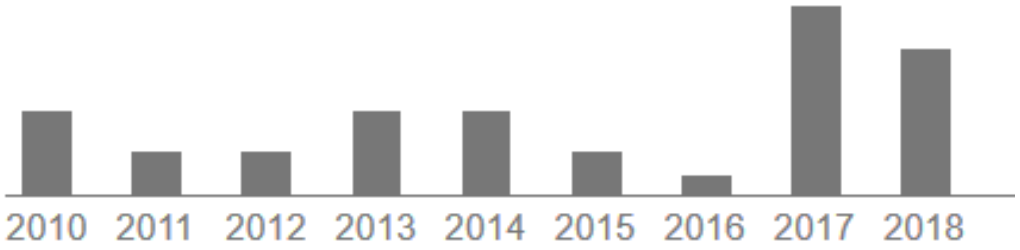
https://www.mercatus.org/bridge/commentary/pacing-problem-and-future-technology-regulation

The "pacing problem"



- The problem is not the gap between technology regulation and society
- **The problem is when the gap is increasing**
- Can adaptive governance serve to "reset the clock" when and as needed?

Interest for Planned Adaptive Regulation is increasing



Google scholar

ELSEVIER

Technological Forecasting and Social Change

Volume 77, Issue 6, July 2010, Pages 951-959

Planned adaptation in risk regulation: An initial survey of US environmental, health, and safety regulation

Lawrence E. McCray [a], Kenneth A. Oye [a], Arthur C. Petersen [b]

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https://doi.org/10.1016/j.techfore.2009.12.001

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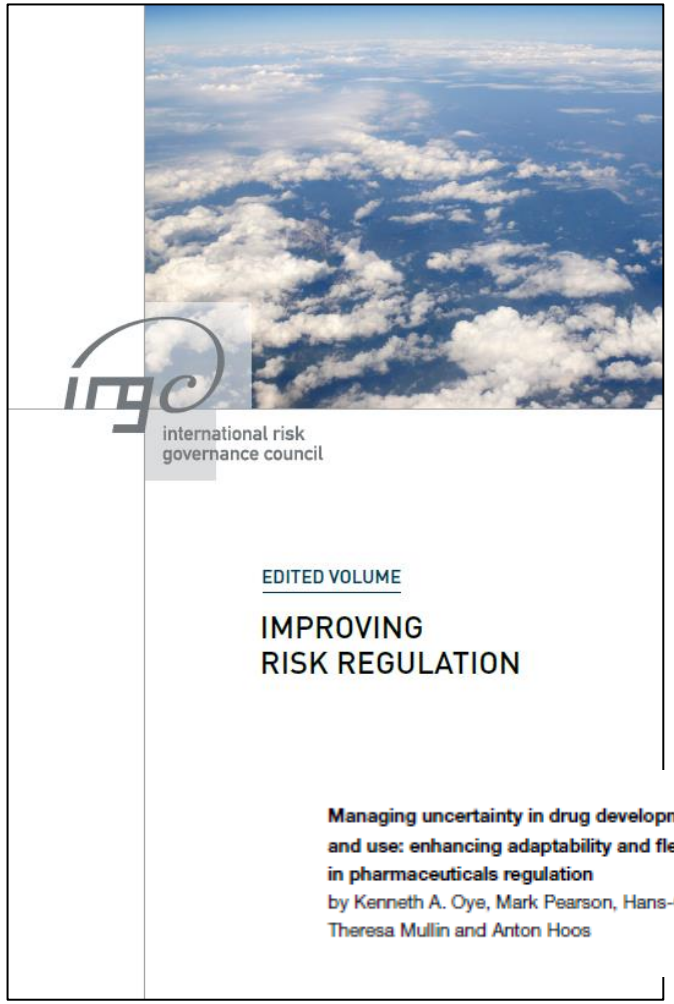
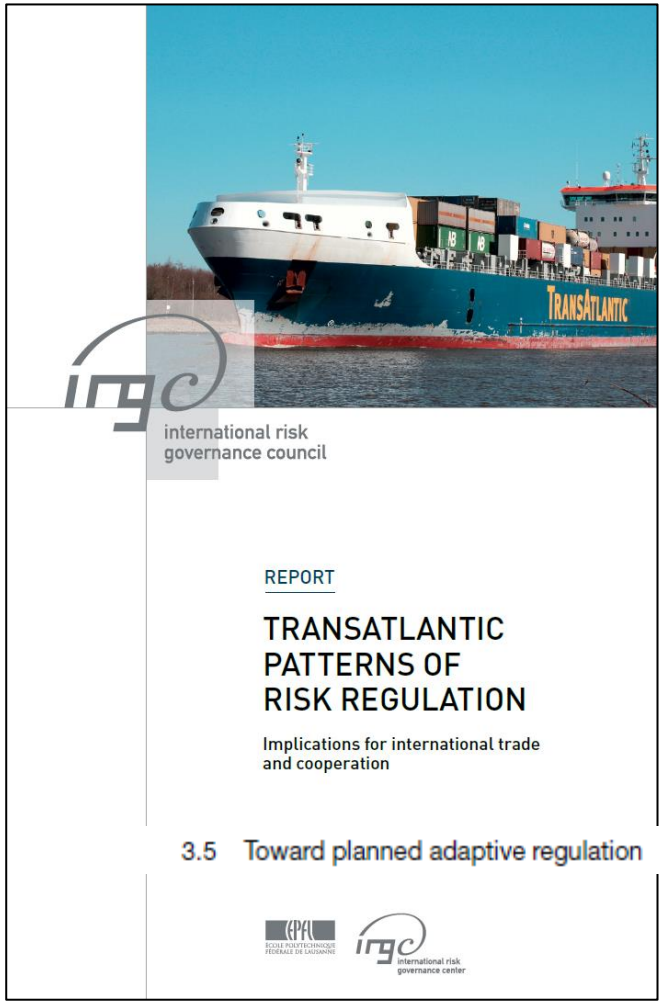
Abstract

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.

IRGC's work on Planned Adaptive Governance (PAG) / Regulation (PAR)





1. Principles of PAR
2. PAR is rarely used
3. Examples
4. Main criticisms and oppositions
5. WHEN? When is it appropriate to consider PAR?
6. WHAT? Planning adaptability of what & to what?
7. HOW? How to plan adaptability / what is adaptive?
9. Conclusion

1. PAR principles

- Planned adaptive regulation is an approach in which a regulation is designed from its initiation to learn from experience and update over time.
- In the face of uncertain evidence that was used to underpin a rule, regulators plan both for
  - scheduled adaptation of the rule, and for the
  - production of decision-relevant knowledge that further characterises or reduces the uncertainties pertaining to the risk regulated.

1. Planning for future review and revision of the governance arrangements
2. Funding of targeted research
3. Monitoring of performance and impact of existing arrangements
4. Review and revision

2. PAR is rarely used outside of the environmental field

- It is rare to see a purposeful combination of planning for future reviews and revisions (e.g., periodic review) and funding targeted research.
- And yet, it is often included in administrative law. For example:
  - EU Directives mandating further evidence gathering for e.g., environmental impact assessment, and involvement of stakeholders.
  - US Administrative Procedure Act 1946 and Executive Orders calling agencies to review existing rules. However, it is difficult to mobilise agencies to collect data on regulatory performance and to conduct and report their retrospective reviews.

3. Examples

- Dutch Delta Commission: Adaptation to sea level rise
  https://www.government.nl/topics/delta-programme/delta-programme-flood-safety-freshwater-and-spatial-adaptation
- US air quality regulation: US Clean Air Act and US National Ambient Air Quality Standards (NAAQS – review every 5 years)
  https://www.epa.gov/criteria-air-pollutants/process-reviewing-national-ambient-air-quality-standards
- European Medicine Authority (EMA): Adaptive licencing of new pharmaceutical drugs
  https://www.ema.europa.eu/en/human-regulatory/research-development/adaptive-pathways
  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
- Adaptive regulation in synthetic biology
  https://link.springer.com/article/10.1007/s11077-019-09356-0
- Lautenberg Chemical Safety Act (LCSA, 2016)
  https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act-law
- And also:
  - Automated driving
  - Swiss debt brake

Automated driving

UNECE

UNECE paves the way for automated driving by updating UN international convention

Published: 23 March 2016

A major regulatory milestone towards the deployment of automated vehicle technologies will be attained on 23 March 2016 with the entry into force of amendments to the 1968 Vienna Convention on Road Traffic. As of that date, automated driving technologies transferring driving tasks to the vehicle will be explicitly allowed in traffic, provided that these technologies are in conformity with the United Nations vehicle regulations or can be overridden or switched off by the driver.

Automated driving will be the next revolution in the field of mobility. As human errors are the main reason for road traffic accidents, driving automatically controlled by a computer is expected to make future road transport safer. It has also the potential to be more environmentally friendly, efficient and accessible.

A second major regulatory aspect currently under discussion is the introduction of technical provisions for self-steering systems. These include systems that, under specific driving circumstances, will take over the control of the vehicle under the permanent supervision of the driver, such as Lane Keeping Assist Systems (e.g. when the car will take corrective measures if it detects that it is about to cross a lane accidentally); self-parking functions and highway autopilots (e.g. when the vehicle would be self-driving at high speeds on highways).

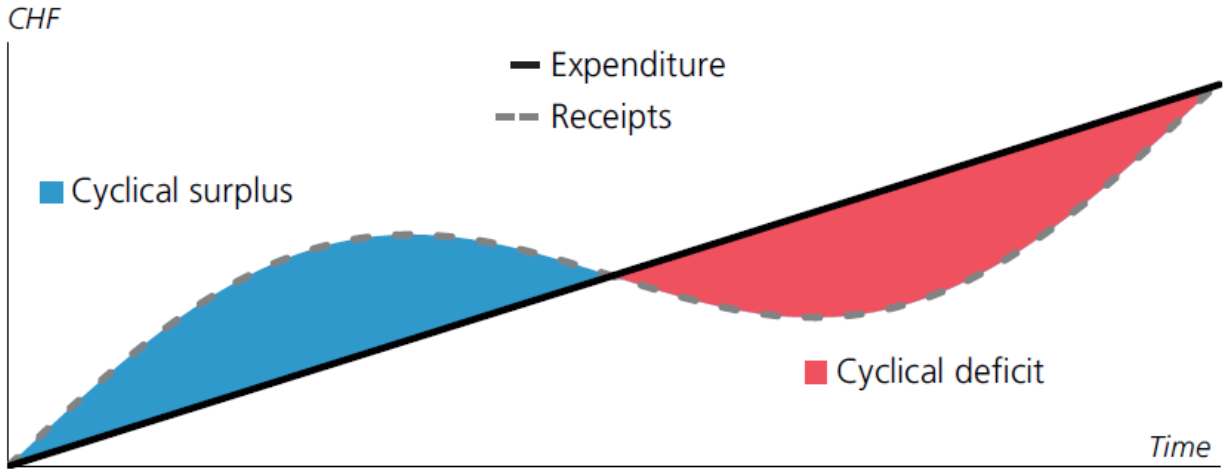
February 2014	Presentation by Scania of a Platooning project	GRRF-76-43 | Video
September 2014	Presentation from the supplier industry	GRRF-78-31
November 2014	Initial policy paper in November 2014	WP29-164-27
September 2015	Demo with a vehicle equipped with Remote Control Parking	More here
September 2015	Frankfurt, D: Transport ministers' declaration	Declaration
November 2015	Status report	WP29-167-04
November 2015	First meeting of the WP.1 informal group on Automated Driving	Link
February 2016	Review of external activities	GRRF-81-30
March 2016	Cyber security and data protection	8th ITS/AD
March 2016	EIF of the Amendment to the 1968 Vienna Convention	EIF Notification
April 2016	Confirmation by WP.1 that ADV testing do not require further amendments to the 1968 Vienna Convention	Report paras. 16 & 18
June 2016	Start of the drafting of guidelines on cyber security and data protection	
November 2016	Establishment of the Task Force on Cyber Security and Over-The-Air updates	Meeting docs
February 2017	Driverless shuttle demo at the 70th anniversary of ITC	Video
March 2017	Adoption of guideline on cyber security and data protection	ECE/TRANS /WP29/2017/46
April 2017	Status report of the IGE on AD (WP.1)	PPT
June 2017	Brainstorming on how to regulate AD at UNECE	PPT by UK
September 2017	EIF of the 02 series of amendments to UN Regulation No. 79 ("Lane keeping")	Consolidated document
November 2017	Discussion of approaches to certify the performance of automated vehicles	PPT by OICA PPT by Catapult
February 2018	ITC request for WP.29 to dedicate a GR to vehicle automation	ECE/TRANS/274, para. 52
March 2018	Interview TV CGTN (French)	Video
March 2018	Press article "La tribune de Genève"	Link
March 2018	Adoption of the 03 series of amendments to UN Regulation No. 79 ("Lane change")	Document
April 2018	Press article "Le Temps"	Link
May 2018	Draft Resolution by WP.1	Link
June 2018	Conversion of GRRF into GRVA	.../WP.29/1139, para. 33
September 2018	Review of draft GRVA recommendations on Cyber Security for automotive products and OTA issues	GRVA-01-17 GRVA-01-18
September 2018	Global Forum for Road Traffic Safety (WP.1) resolution on the deployment of highly and fully automated vehicles in road traffic	See Annex to the session report of the September 2018 session of WP.1

Steps to reach the goal

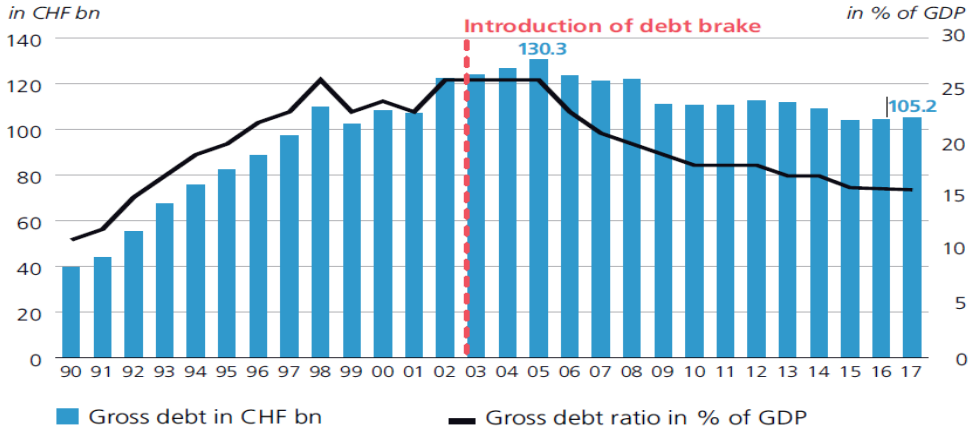
https://unece.org/press/unece-paves-way-automated-driving-updating-un-international-convention
https://unece.org/sites/default/files/2022-01/Brochure%20Automated%20Vehicles.pdf

Swiss Debt Brake System

Consistent path of expenditure and cyclically-dependent receipts



Debts of the Confederation 1990–2017

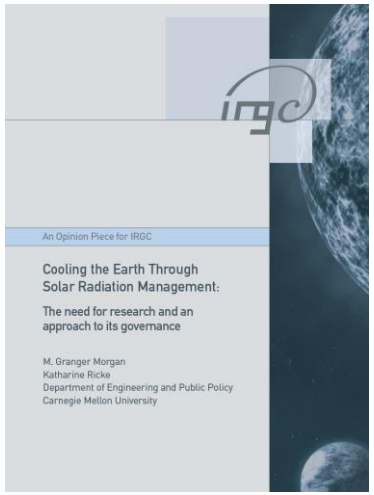


- The debt brake is designed to avert (chronic) structural imbalances in federal government finances and thereby prevent federal debt from soaring.
- It ensures a countercyclical fiscal policy by permitting limited cyclical deficits during downturn phases of the economic cycle and requiring surpluses when the economy is booming.
- The debt brake, therefore, addresses two classical **objectives** of fiscal policy: ensuring the sustainability of public finances and smoothing economic cycle and growth fluctuations.
- A simple rule: expenditure may not exceed receipts over an economic cycle. The annual **expenditure ceiling** is linked to the amount of receipts, which are adjusted using a factor that takes the economic environment into account (cyclical factor).
- If the total expenditure in the state financial statements exceeds the ceiling, compensation for this additional expenditure must be made in subsequent years.
- In the medium term, i.e., over an **economic cycle**, the federal budget is balanced with the debt brake: surpluses must be generated during a boom to offset the deficits of the subsequent recession.

The Swiss Constitution establishes the process that enables the country to reach the goal

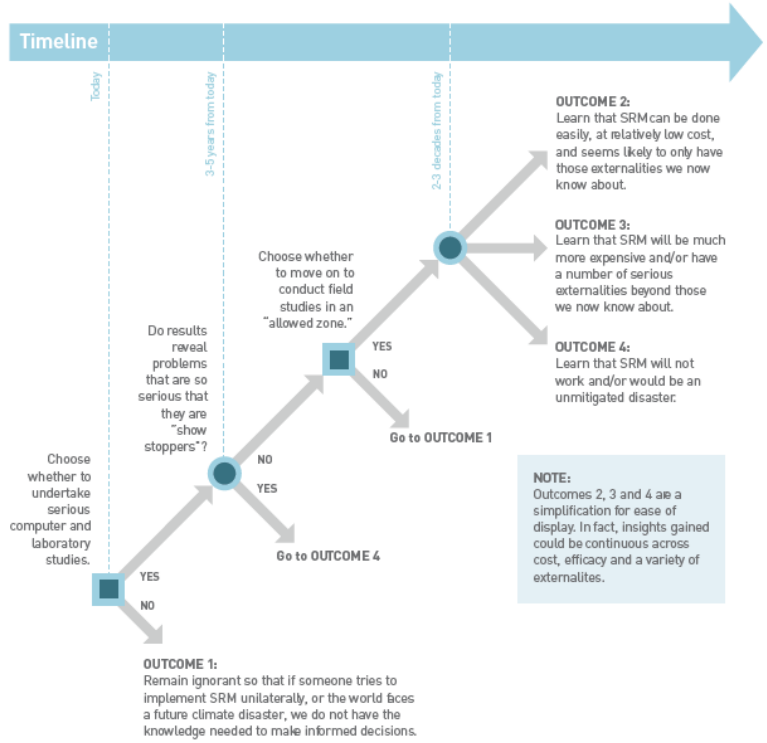
https://www.efv.admin.ch/dam/efv/en/dokumente/publikationen/schuldenbremse.pdf.download.pdf/Schuldenbremse_2017_e_web.pdf

A tentative application case: Solar Radiation Management (SRM) Timeline and a proposed decision tree for research



- If the warming effect of climate change reaches a dangerous level, there is a way to cool the planet quickly. Intentionally and purposely injecting SO_2 into the stratosphere can increase the albedo. SRM introduces a 'mask' to the climate change problem – by seeking to reflect sunlight into space to reduce temperature increase.
- The eruption of Mount Pinatubo in the Philippines in 1991 produced global scale cooling of about 0.5°C by lofting millions of tons of SO_2 gas and ash high into the stratosphere. SO_2 is converted into fine sulphate particles that reflect sunlight before it has a chance to penetrate deeper into the atmosphere and get absorbed.
- SRM could be efficient, cheap and fast, but the mechanism is imperfect and deploying it could have catastrophic consequences.
- A framework for the governance of SRM research should plan adaptability in relation to outcome.

https://www.epfl.ch/research/domains/irgc/wp-content/uploads/2023/04/IRGC-2009-Cooling-the-Earth-Through-Solar-Radiation-Management-The-Need-for-Research-and-an-Approach-to-its-Governance.-Opinion-piece.pdf



Priority = avoid irreversible adverse consequences
→ formal process to opt out of if needed

4. Criticism and opposition to PAR

- Industry: lack of clarity about the rule, uncertainty
- Regulators: expensive and complicated
  - Public bureaucracies prefer status quo
  - Conducting reviews can be costly and time-consuming
  - Regulatory agencies are busy with new policies
  - Budgets for data collection, analysis and writing are already stretched
- More importantly:
  - Need for regulations to be enforceable and credible to those who must comply with them. The anticipation of revisions may undermine the credibility of the initial rule.
  - Some regulated actors may favour maintaining the current regulation, especially if it serves as a barrier to entry for newcomers (technology lock-in and vested interests).

5. PAR: WHEN?
When is it appropriate to consider PAR?

Cost-benefit analyses → 'risk-based decisions' are not supported by sufficient evidence

Decisions under uncertainty → 'precaution-based decisions' may be needed

Key enabling / promising technologies → Need to balance precaution and innovation

Need to avoid the irreversibility of adverse consequences of a risk or decision about that risk

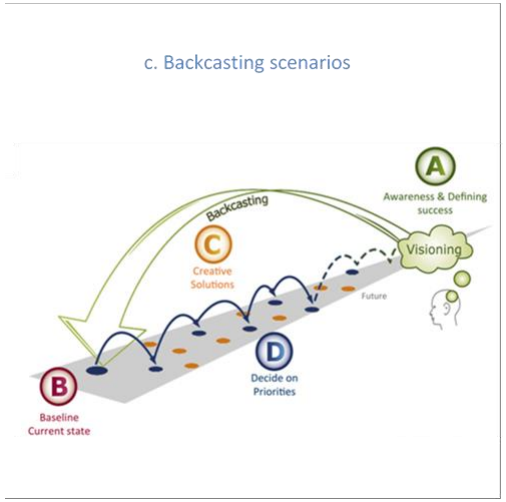
Need to prepare for, rebound from, recover and adapt to shocks and disruptions → Resilience

Planned-adaptive regulation

6. PAR: TO WHAT?
Planning adaptability of what to what?

- Adapting a regulation to a technological advance?
- Adapting a regulation to societal change?
- Adapting
  vs. Not adapting to preserve fundamental values that new technologies may put in danger?
- Adapting to reach a desirable vision of future society?
  vs. To prevent the realisation of a dystopian society?

→ need a vision of where society wants
to go or be in the future (explorative scenarios)
and then develop backcasting steps to reach this vision



Stephen Hawking predicted a race of superhumans will take over the world

STEPHEN Hawking made a grim prediction before his death that a race of superhumans will rise up and destroy the social fabric as we know it.

Nick Whigham @NWWHIGHAM

Stephen Hawking dies aged 76

THE late Stephen Hawking believed advances in genetic science would lead to a future generation of superhumans that could ultimately destroy the rest of humanity.

In newly published writings, Dr Hawking suggested an elite class of physically and intellectually powerful humans could arise from rich people choosing to edit their DNA and manipulating their children's genetic makeup.

"I am sure that during this century, people will discover how to modify both intelligence and instincts such as aggression," he wrote.

"Laws will probably be passed against genetic engineering with humans. But some people won't be able to resist the temptation to improve human characteristics, such as memory, resistance to disease and length of life."

Adopting an adaptive approach to governing developments in human gene editing to:
(1) make gene editing possible to benefit from scientific advancements and improve health outcome
and
(2) prevent undesirable outcomes

7. PAR: HOW?
How to plan adaptability? What is adaptive?

- PAR does not have to involve radical policy change. Regulation can often be updated within pre-defined limits or objectives:
  - Introduce performance-based management
  - Coordinate experimentation in different jurisdictions
  - PAR can be a mechanism for policy learning: from regulatory variation across countries and ongoing accumulation of knowledge over time to improve regulatory designs and outcomes.
- Governance is adaptive to:
  - Allow innovations from outside the core of the system that force adaptation
  - Handle the case of complex adaptive systems
  - Example: outcome-based payment for personalised therapies, such as gene therapies https://link.springer.com/article/10.1007/s10198-018-0989-8
- Adaptive regulation can require the adaptability of regulated entities
  - Example: regulation of connected medical devices to prevent cybersecurity risk https://www.fda.gov/medical-devices/digital-health-center-excellence/cybersecurity

US FDA medical devices 2017-2018

Need to deal with cybersecurity risk involved in connected medical devices

https://www.fda.gov/MedicalDevices/DigitalHealth/ucm373213

U.S. Food and Drug Administration
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Silver Spring, MD 20993
FDA.GOV

U.S. FOOD & DRUG ADMINISTRATION

FDA FACT SHEET

THE FDA'S ROLE IN MEDICAL DEVICE CYBERSECURITY

Dispelling Myths and Understanding Facts

As medical devices become more digitally interconnected and interoperable, they can improve the care patients receive and create efficiencies in the health care system. Medical devices, like computer systems, can be vulnerable to security breaches, potentially impacting the safety and effectiveness of the device. By carefully considering possible cybersecurity risks while designing medical devices, and having a plan to manage emerging cybersecurity risks, manufacturers can reduce cybersecurity risks posed to devices and patients.

The FDA has published premarket and postmarket guidances that offer recommendations for comprehensive management of medical device cybersecurity risks, continuous improvement throughout the total product life-cycle, and incentivize changing marketed and distributed medical devices to reduce risk. Even with these guidances, the FDA continues to address myths about medical device cybersecurity.

Dispelling the Myths	Understanding the Facts
The FDA is the only federal government agency responsible for the cybersecurity of medical devices.	The FDA works closely with several federal government agencies including the U.S. Department of Homeland Security (DHS), members of the private sector, medical device manufacturers, health care delivery organizations, security researchers, and end users to increase the security of the U.S. critical cyber infrastructure.
Cybersecurity for medical devices is optional.	Medical device manufacturers must comply with federal regulations. Part of those regulations, called quality system regulations (QSRs), requires that medical device manufacturers address all risks, including cybersecurity risk. The pre- and post- market cybersecurity guidances provide recommendations for meeting QSRs.
Medical device manufacturers … medical devices for cybersecurity.	Medical device manufacturers can always update a medical device for cybersecurity. In fact, the FDA does not typically need to review changes made to medical devices solely to strengthen cybersecurity.
…Os) can't update and patch	The FDA recognizes that HDOs are responsible for implementing devices on their networks and may need to patch or change devices and/or supporting infrastructure to reduce security risks. Recognizing that changes require risk assessment, the FDA recommends working closely with medical device manufacturers to communicate changes that are necessary.
…are changes made	The medical device manufacturer is responsible for the validation of all software design changes, including computer software changes to address cybersecurity vulnerabilities.
…security.	The FDA does not conduct premarket testing for medical products. Testing is the responsibility of the medical product manufacturer.
Companies that manufacture off-the-shelf (OTS) software used in medical devices are responsible for validating its secure use in medical devices.	The medical device manufacturer chooses to use OTS software, thus bearing responsibility for the security as well as the safe and effective performance of the medical device.

Adaptive approach to assess the capacity of the manufacturers to pro-actively address cybersecurity risks

The FDA encourages medical device manufacturers to address cybersecurity risks to keep patients safe and better protect the public health. This includes monitoring, identifying, and addressing cybersecurity vulnerabilities in medical devices once they are on the market. Working collaboratively with industry and other federal government agencies, the FDA continues its efforts to ensure the safety and effectiveness of medical devices, at all stages in their lifecycle, in the face of potential cyber threats. Learn more about medical device cybersecurity on www.fda.gov/MedicalDevices/DigitalHealth/ucm373213.

Medical device cybersecurity is part of the FDA's broader digital health technology platform. To learn more about the FDA's efforts to advance digital health technology visit http://www.fda.gov/MedicalDevices/DigitalHealth/default.htm, or email digitalhealth@fda.hhs.gov.

Resilience: A New Tool in the Risk Governance Toolbox for Emerging Technologies

Gary E. Marchant[†]* *& Yvonne A. Stevens*[**]

Emerging technologies like nanotechnology, synthetic biology, artificial intelligence, and many others present significant governance challenges. These challenges include highly uncertain benefits, risks, and trajectories associated with the technology, an extremely rapid pace of development and change, and a broad range of applications that implicate many different industries, regulatory agencies, and stakeholders. Traditional ex ante risk management approaches such as risk analysis and precaution have struggled to provide adequate governance of such technologies, in large part because of the difficulty in predicting in advance realistic risk scenarios. In the article, we propose a different approach that shifts much of the governance task and burden from the traditional ex ante approaches of risk analysis and precaution to focus more on the ex post strategy of resilience. Resilience seeks to minimize the harm from a bad outcome, and offers many potential advantages for dealing with emerging technologies with highly uncertain risks that cannot be predicted in advance. There are a number of potential resilience measures that could be used to help govern many emerging technologies — we identify and describe many such measures and define two categories. Procedural resilience measures put in place a decision-making process that will allow for more reflexive and adaptive decision-making, thereby facilitating early detection and

† Copyright © 2017 Gary E. Marchant & Yvonne A. Stevens. This article was initially developed as a policy paper for, and with an honorarium from, the University of Texas at Austin Center for Politics and Government. The authors express their appreciation for the helpful suggestions from Dima Shamoun and two anonymous reviewers.

* Regents' Professor and the Lincoln Professor of Law, Ethics & Emerging Technologies at the Sandra Day O'Connor College of Law at Arizona State University ("ASU"), and Faculty Director of the Center for Law, Science & Innovation at ASU.

** Faculty Fellow of the Center for Law, Science & Innovation, and on the full-time faculty of the Sandra Day O'Connor College of Law at ASU.

Figure 1: Four Principal Tools of Technology Governance (with Examples)

	Permissive	**Prohibitive**
Ex ante	Risk Analysis Example: New Chemical	Precautionary Principle Example: Genetic Modification of Flu Virus
Ex post	Resilience Example: Artificial Intelligence	Liability Example: Autonomous Vehicle Accident

PAR

"Resilience" involves both NORMATIVE and PROCEDURAL resilience governance tools:

- Adaptive management
- Mandatory Periodic Review Requirements
- Sunset Provisions
- Mandatory Adaption Planning
- Post-Market Monitoring
- Adaptive Product Approvals
- Polycentricity
- Emergency Authority

https://blogs.asucollegeoflaw.com/lsi/2017/11/17/new-model-governance-emerging-technologies/
https://lawreview.law.ucdavis.edu/issues/51/1/Symposium/51-1_Marchant_Stevens.pdf

Once it is determined that PAR is appropriate…

Planned-adaptive regulation

Establish processes for **governance**
(multi-stakeholder, institutions, rules & processes)

Determine and agree upon a societal –desirable- **goal**
that a new type PAG/PAR should enable to reach

Determine when **rules** must be put into **regulation**,
and in what forms (public, private, etc.)

Negotiate and establish an agreement about the conditions of
adaptability of the rules when evidence changes,
and the conditions and extent of possible revisions
(funding research, monitoring, feedback, etc)

Plan the framework, boundary and operating conditions for adaptability

8. Conclusion

The initial principles of PAR (conditions and success factors, slide 7) are complemented by three other principles

First set of principles:

1. Planning for future review and revision of the governance arrangements
2. Funding of targeted research
3. Monitoring of performance and impact of existing arrangements
4. Review and revision

Need also:

5. Vision of what the adaptability will enable to reach (goal)
6. Ability to respond to rapid changes
7. Adaptive governance is possible only if there is trustworthiness. Actors must collaborate to adapt the rules.

Litterature on PAR

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