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Acknowledgements

The EPFL International Risk Governance Center organises its activities in collaboration with the IRGC Foundation.

In 2016, the IRGC Foundation received support – both financial and in-kind contributions – from the following organisations and institutions:

IRGC would also like to thank all organisations and individuals who supported the Center and/or Foundation in 2016, namely:

- The IRGC Foundation Board, chaired by Philippe Gillet
- The IRGC Foundation Scientific and Technical Council, chaired by Granger Morgan
- The IRGC Foundation academic network partners
- EPFL management and faculty who supported IRGC and participated in its activities in 2016

IRGC also owes its gratitude to everyone who worked with and for IRGC in 2016: Speakers and participants at workshops and conferences, authors, contributors, researchers, reviewers, staff and support staff.
Foreword

Since 2016, IRGC consists of two distinct and independent entities, which collaborate with and support each other:

- EPFL International Risk Governance Center, a transdisciplinary centre at the École Polytechnique Fédérale de Lausanne
- International Risk Governance Council Foundation, an accredited organization of public interest, supervised by the Swiss Federal Government.

In this new institutional setting, IRGC continues to carry out its mission and activities, working towards improving the governance of risk issues marked by complexity, uncertainty and ambiguity.

IRGC will thereby collaborate closely with other entities at EPFL working towards similar goals, such as the newly established laboratory of Green Economy and Resource Governance, which focuses on the assessment and the governance of the transition towards a green economy that require coping with risks in a situation of uncertainty, conflicting objectives and, in general, complexity.

We are pleased to hereby share with you a brief report of IRGC’s activities for the year 2016. Change, innovation and risk remain high priorities for those who develop technology, take and bear risk or want to improve environmental sustainability, economic growth, the reduction of social inequality and overall societal welfare.

B. Oberle
Prof. Bruno Oberle
Professor of Green Economy and Resource Governance, EPFL
Academic Director, EPFL IRGC

M.-V. Florin
Marie-Valentine Florin
Managing Director, IRGC Foundation
Executive Director, EPFL IRGC
IRGC Mission

The EPFL International Risk Governance Center and the IRGC Foundation work together as a neutral platform for dialogue about emerging risks, focusing on opportunities and risks related to new technologies, with the aim of providing recommendations for their governance.

Innovation, risk governance and public policy

Considering that policymakers are interested in understanding which new risks they should address or how existing risks could be better managed, where technology goes, and how research and industry work together, a risk governance approach can help reap the societal benefits of innovation while ensuring citizens’ welfare, safety and security. Examples of promising technologies & industries that benefit from a risk governance approach include:

- **Precision medicine**: Ethical, economic and regulatory risks and uncertainties must be addressed early enough with all major actors, to organise patient and citizen consents, data collection and sharing, safety and efficacy assessment, new paying mechanisms
- **Cyber security**: A challenging technical and governance objective that requires a dynamic and forward-looking collaborative approach between researchers, industry, users, regulators and insurers
- **Autonomous cars**: Need to create the appropriate regulatory context for technology to improve road safety, support the development of sustainable transportation models, and deal with insurance, liability and perception issues
- **Transition to a circular economy**: Managing risk and creating resilience in strategies for resource efficiency, waste management and energy transition

Mission and role

Contributing a risk governance perspective to the interaction between technology, policy, and regulation, IRGC adds value by:

1. Identifying and analysing existing and emerging risks that both industry and public authorities should be aware of
2. Making sense of emerging scientific and technical opportunities that society can benefit from and that the public sector should support with appropriate policy and regulatory strategies
3. Acting as a neutral platform for multi-stakeholder dialogue on those risks and opportunities
4. Providing generic recommendations for risk governance

IRGC activities

In order to achieve its mission, IRGC focuses on three major work areas:

1. Development of concepts and instruments for risk governance
2. Application to specific issues and recommendations for risk governance guidelines
3. Outreach
Activities in 2016

WORKSHOPS & CONFERENCES

Governing Cybersecurity Risks and Benefits in the Internet of Things

Expert workshop
Zurich, 15-16 November

As part of an on-going workshop series and project work on cybersecurity, IRGC organised a one-day expert workshop on Governing Cybersecurity Risks and Benefits in the Internet of Things, applied to connected vehicles and medical devices. In these two sectors, connectivity improves performance. However attention to physical safety is often seen as more important than cyber security, with real risks to data protection, privacy, or data integrity across interconnected systems.

The invitation-only multidisciplinary workshop at the Swiss Re Centre for Global Dialogue in Zürich brought together 30 experts from research, technology, industry, regulation, insurance and other stakeholder groups in an open, facilitated roundtable discussion under Chatham House Rule.

The workshop discussed various options for mitigating the risk of lack of cyber protection at the device and network level, with appropriate technological and risk management solutions, including insurance and regulatory systems.

Using and Developing further IRGC Concepts and Instruments for Risk Governance

Workshop with risk managers in the public sector
Potsdam, 18-19 October

IRGC convened a group of policymakers and risk managers familiar with its concepts for risk governance. Collaborative discussions provided them with
new suggestions for improving risk governance in their organisations and provided IRGC thoughtful insights to develop further IRGC instruments. This will guide IRGC work in 2017, in particular about systemic risks: "what does it mean and involve for an organisation to address systemic risks".

Governance of Impacts of Precision Medicine

Expert workshop
Geneva, 24 September

IRGC organised an expert workshop at Campus Biotech in Geneva on the Governance of Impacts of Precision Medicine.

In an open, facilitated roundtable discussion, 30 experts in the field of precision medicine, from various countries, disciplines and stakeholder groups from research, policy, regulation, and industry convened to move forward an interdisciplinary and multi-stakeholder agenda for the development of precision medicine in the world.

Participants discussed a series of challenges that derive from the dynamic scientific advances in genomic research, biomedical data science and bio informatics. These advances are not yet accompanied by the necessary changes in how safety, efficacy and cost-effectiveness of precision medicine are assessed, how data is collected, stored, shared and accessed, how the medical practice adapts, how paying schemes are revised, and how patients and citizens are involved in the decisions, in particular about values and ethics.

The expected outcome from the workshop will be a roadmap, broadly outlining steps and challenges to developing precision medicine.

Risk and Opportunity Governance of Automated and Autonomous Cars

Expert workshop
Zurich, 15-16 June

In collaboration with the EPFL Transport Center (TRACE), IRGC organised an expert workshop on Risk and Opportunity Governance of Automated and Autonomous Cars. The workshop, conducted under Chatham House Rule, convened 30 participants from academia, regulatory agencies, insurance and industry.

The objective of this workshop was to improve the understanding of the various types of risks and opportunities related to automated and autonomous cars, and discuss how to create appropriate governance and regulatory context conditions.

The participants discussed that benefits range from increased road safety to air quality and traffic efficiency, with the potential to entirely novel modes of individual transportation. Issues of concern include how to evaluate the acceptable level of safety (considering that technology is not mature yet), issues of data collection and access, the need for new types of testing and more pilot cases and overall the fact that more collaboration between industry, regulators and insurers is expected, for progressive and adaptive authorisation and insurance models.

Planning Adaptive Risk Regulation

International public conference
London, 7-8 January

How can law and regulation keep up with advances in science and technology? If regulation becomes adaptive to change, how can regulated parties cope with flexibility and adaptability?

To address these questions, IRGC and the Department of Science, Technology, Engineering and Public Policy at University College London (UCL STEaPP) organised an international public...
conference on Planning Adaptive Risk Regulation.

The conference convened participants from academia, regulatory agencies and industry to discuss experiences, challenges and ways to improve regulation related to changing risk contexts, new scientific developments, and emerging technologies.

Speakers contrasted past and current cases and the 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.

Planned Adaptive Regulation (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.

There are various forms of PAR such as revision processes, sunset clauses, or planned rule adjustments. In all these cases, monitoring, assessment and learning mechanisms as well as communication are crucial to determine the success of PAR.

PUBLICATIONS & RESOURCES

Resource Guide on Resilience
Online resource guide, 2016
A compilation of major resilience schools and quantification approaches, this collection of over 40 authored pieces offers scholars and practitioners a review of concepts, approaches, frameworks, methodologies and case-studies for comparing, contrasting and integrating risk and resilience, and for developing resilience across sectors, focusing on possible measurement.

The IRGC Resource Guide on Resilience is developed in collaboration with the IRGC Foundation.

Demand-Side Flexibility for Energy Transitions
Report + Policy brief, 2016
These publications are the result of IRGC’s project work on ‘demand response’ (DR) and are a collaboration with the EPFL Energy Center.

The report provides an overview of the current debates about demand response development and policy options, i.e. how to introduce flexibility in electricity demand, for example in response to variability in renewable energy production. The traditional paradigm where supply follows demand is no longer sustainable in countries that have engaged in energy transitions.

The Policy brief is intended for an audience of policymakers, regulators and industry, who contemplate DR development. Based on international evidence, it recommends urgent implementation of policy reforms as well as the redesign of electricity markets.
Public Cybersecurity and Rationalizing Information Sharing

Opinion piece, 2016

In an opinion piece written for IRGC, Fred B. Schneider (Cornell University), Elaine M. Sedenberg (U.C. Berkeley), and Deirdre K. Mulligan (U.C. Berkeley) address the question of what if, like public health, cybersecurity was considered a public good? The authors argue that establishing cybersecurity as a public good would create the much needed overarching policy principle to define objectives and means, to bring cohesion to sectoral and specific, purpose-led policies and programs. It would help establish a framework under which information sharing proposals can be evaluated, and resolve the trade-offs between the rights and autonomy of individuals, versus benefits to the collective.

The views and policy prescriptions contained in an opinion piece are those of the authors, and are not a consensus judgment by IRGC, its reviewers, or its sponsors.

Comparing patterns of risk regulation in the EU and the US

Report, forthcoming

Based on a study commissioned by and written for the European Parliament in 2016, this report offers a descriptive transatlantic comparison of regulatory standards in four key sectors: Food, automobiles, chemicals, pharmaceuticals. Findings indicate that the EU risk regulation is not always or generally more stringent or precautionary than the US regulation. In fact, the reality is a complex mix of parity and particularity. While there is overall EU-US similarity, there is also variation.

In some risk matters, and across and within sectors, there is more precaution in Europe, whereas in others it may be in the US. Even if they are unusual deviations, and even if they go in both directions, transatlantic regulatory differences can still pose barriers to trade that may in some cases warrant harmonization. However, regulatory variation can also be the basis for learning to improve future regulatory design, both by comparing outcomes across regulations in different jurisdictions, and by planning adaptive regulation over time. International regulatory cooperation does not simply mean mutual recognition or adopting the current standard of one side or the other. It can also involve collaboration to reviewing existing regulations and designing new approaches that improve outcomes for all.
Outreach

PUBLICATIONS

In 2015, IRGC put in place a download registration system for its publication library. While downloading and using IRGC reports and core concepts remains free of charge, the registration system allows IRGC to have a better understanding of which report generate the most interest and in which sectors they are most read.

In 2016, IRGC publications were downloaded almost 3,000 times. The most downloaded report was the Introduction to the IRGC Risk Governance Framework (2012), followed by the original white paper on Risk Governance (2005). The more recent Guidelines for Emerging Risk Governance (2015) were also download over 300 times in 2016. The top 15 downloads for this period can be found below.
Overall, interest in IRGC’s work on core concepts of risk governance, in particular in its Risk Governance Framework, Emerging Risks, Governance Deficits, and Risk Regulation publications, continues to be strong. However, depending on the topic, there is substantial interest in issue-related publication as well.

**IRGC publication downloads: Issues vs. concepts**

<table>
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<tr>
<th>Core concepts of risk governance</th>
<th>74%</th>
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<td>Risk governance issues</td>
<td>26%</td>
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IRGC publications were downloaded by practitioners in all sectors, reflecting IRGC’s diverse audience.

**IRGC publication downloads by sector**

- **International Organisations**: 3%
- **Civil Society / NGOs**: 4%
- **Private**: 28%
- **Research**: 40%
- **Public**: 25%

Source: IRGC download manager

**WEBSITE**

With the full integration into EPFL, IRGC is now operating two websites: irgc.org (for the foundation) and irgc.epfl.ch (for the Center).


**NEWSLETTER**

As of January 2017, IRGC’s monthly newsletter, which includes latest publications, workshop summaries, and other relevant information, has 3,706 subscribers (2015: 3,210, 2014: <3,000).

On average across all campaigns, the largest readership is found in Switzerland, followed by the US, France, the UK and Germany.

**CONTRIBUTION TO EXTERNAL EVENTS AND ORGANISATIONS**

- IRGC participation in external events (selection):
  - In June, IRGC presentation on ‘Resilience in IRGC concepts and recommendations’ and participation in the panel ‘Risk vs. Resilience’ at a NATO Science for Peace Workshop ‘Resilience-based Approaches to Critical Infrastructure Safeguarding’, Azores, Portugal.
  - In August, conference session on resilience at the 6th International Disaster and Risk Conference, Global Risk Forum, Davos.
  - In September, organisation of a symposium roundtable on precision medicine at the Health 2030 Symposium on Personalized Medicine in the Digital Age, Geneva.

In September, IRGC module: ‘Risk governance’ in a course on risk and crisis management: Responding to the 21st century crisis, organised by the Swiss Federal Chancellery and Office of Civil Protection.

In September, IRGC presentation at an OECD meeting on gene editing, organised by Health Canada in Ottawa.

In December, presentation of the IRGC framework at the 26th Annual Session of the Working Party on Regulatory Cooperation and Standardization Policies (WP.6) in Geneva, on risk management in regulatory systems.

- IRGC participation in academic courses on risk governance:
  - In March, presentation in a Master’s course at the University of St. Gallen on ‘Risk-based regulation: Insights from risk governance’.

In September, presentation on ‘la gouvernance des risques’ at EPFL Risk Professional Training.

In the fall semester, organisation of a SHS course for CDH on ‘Risk and energy’.

- IRGC in advisory capacity to external projects and organisations:
  - IRGC (represented by its Executive Director, Marie-Valentine Florin) advises the World Economic Forum’s Global Risk Report, is a member of the Advisory Group for the European Commission’s Horizon 2020 programme ‘Science with and for Society’ as well as of the international commission of IMDR.
Academic References & External Applications

SELECTED ACADEMIC REFERENCES

IRGC publications continue to be cited widely in academic publications and business literature. In 2016, IRGC reports were referenced 247 times (2015: 220 times)¹.

The single most referenced report was the 2005 White Paper 1, Risk governance: Towards an integrative approach, which laid out the original IRGC Risk Governance Framework.

In terms of issues, IRGC’s work on nanotechnology and synthetic biology were cited often several times in 2016, with the publications on unconventional gas development also receiving attention.

IRGC publications were referenced across many issues and research domains (among others, EU, Australia, China, Kazakhstan, Malaysia, and the USA).

A selection of work that made reference to IRGC in 2016 includes:


¹ Source: Google Scholar
**SELECTED APPLICATIONS**

**European Commission**

Better Regulation, Toolkit #12: Risk Assessment & Management

*The IRGC Risk Governance Framework is a source of information for the development of the toolkit.*

**European Environment Agency**

Report of the EEA Scientific Committee seminar on emerging systemic risks, held on 24 February 2016 in Copenhagen.

*Application of the IRGC Risk Governance Framework for public sector governance of emerging systemic risks.*

**Chairman of the Joint Chiefs of Staff Manual - Joint Risk Analysis**

This manual establishes a Joint Risk Analysis Methodology and provides guidance for identifying, assessing, and managing risk. It introduces and describes a common risk lexicon to promote consistency across the US Department of Defense and Joint Force risk-related processes.

“Documents from the International Risk Governance Council (IRGC) were particularly informative in developing this manual. The IRGC white paper, “Risk Governance: Towards an Integrative Approach” provided key background and substantiated fundamental concepts used when producing this Manual.”

**Tyler H. Lippert, RAND Graduate School**


“Using climate and security literature to complement recent foresight and scenario analysis developed by NATO, the IRGC’s Risk Governance Framework is applied to identify the considerations and actions that could assist NATO in a context where climate and environmental factors more intensively shape security.”
Testimonials

IRGC EVENTS

“I like the exposure and interaction opportunities provided by the organizers. (...) it serves very well as an eye-opening and learning opportunities to interact with insurance company representatives and healthcare industry representatives.”
International Organisation on the expert workshop Governing IoT Cybersecurity

“Stimulated my own research and extended my professional network. Confirmed my understanding of IRGC as a useful resource.”
Academia, Norway on the conference Planning Adaptive Risk Regulation

“I liked the working group discussions in a kind atmosphere. The direct contact and exchange with practitioners from the public sector and risk agencies was useful to me.”
Academia (Netherlands) on the expert workshop IRGC Risk Governance concepts

“It has been a pleasure to participate. The workshop was excellent, well-structured and inspiring.”
International Organisation on the expert workshop on Precision Medicine

IRGC PUBLICATIONS AND RESOURCES

“(…) good mix of highly-knowledgeable people from academia and industry. I definitely learned a lot about the problems that non-academic organisations are facing (…).”
- Academia, Switzerland

“IRGC can be a major driver behind policy recommendations for resilience and emerging risks.”
Public/Government, USA on the expert workshop IRGC Risk Governance concepts

“I find the report well written and easy to read; I could get an overview quickly and dive deeper in some topics. I will use the report to frame my thinking and to support internal work on emerging risks.”
Insurance, Switzerland on the Guidelines for Emerging Risk Governance

“Thank you for (...) helping us develop a structured way to analyse and deal with risks. Keep up the good work.”
- Government, Netherlands

“(...) good mix of highly-knowledgeable people from academia and industry. I definitely learned a lot about the problems that non-academic organisations are facing (…).”
- Academia, Switzerland

“IRGC can be a major driver behind policy recommendations for resilience and emerging risks.”
Public/Government, USA on the expert workshop IRGC Risk Governance concepts

“I find the report well written and easy to read; I could get an overview quickly and dive deeper in some topics. I will use the report to frame my thinking and to support internal work on emerging risks.”
Insurance, Switzerland on the Guidelines for Emerging Risk Governance

“Thank you for (...) helping us develop a structured way to analyse and deal with risks. Keep up the good work.”
- Government, Netherlands
Outlook 2017

This is a selection of IRGC work priorities and activities for 2017.

**Development of concepts and instruments for risk governance**

Systemic risks

IRGC’s work will attempt to help bridge the gap between conceptual thinking in academia and constraints and concerns faced in the public and private sectors. The basic question will be how organisations can deal with systemic risks. Particular attention will be given to IRGC’s approach to "slow-developing catastrophic risks" and strategies for resilience. A first expert group meeting will be organised in March, with a larger expert workshop in October, both in collaboration with and held at IASS in Potsdam.

Refine and adapt IRGC’s main risk governance concept

While the IRGC Risk Governance Framework published in 2005 is still relevant and valuable today, IRGC will further develop and complement it in order to accommodate new scientific and social developments. This includes an update of the Introduction to the Framework with new and additional illustrations and linking it to other international organisations working on similar topics (e.g., OECD, UNISDR, ISO).

**Specific issues**

Precision medicine

A roadmap for developing and implementing precision medicine, resulting from the September 2016 workshop and roundtable, will be available in the spring 2017.

IRGC will then work to substantiate some of the recommended policy orientations, on matters such as data collection, access and use; privacy and confidentiality. An expert workshop is planned for autumn in Geneva.

Cyber risk governance

A publication following the November 2016 workshop about cyber security challenges in the Internet of Things will be published in the spring 2017. It will highlight the trade-offs between the search for efficiency and convenience on the one hand, and cyber security, privacy and confidentiality concerns on the other hand.

IRGC will continue its project work in this field with an expert workshop on governing the risks and benefits of distributed ledger technology applications, to be held in Zurich in June, with a particular focus on the health and medical sector, institutional governance, and insurance.

Autonomous cars

The IRGC report on autonomous cars will be published in 2017. It focuses on governance aspects related to (a) assessing and making decisions about acceptable safety levels (before a technology is deployed) and (b) placing autonomous driving in the context of new mobility and transportation patterns, with expected gains in fluidity, local air quality and CO2 emission reduction, but large investments needed in infrastructure and progress required to secure connectivity between vehicles and with infrastructure.

Other issues

IRGC generally supports all EPFL initiatives towards the creation of appropriate context conditions for technology to develop in a fair and sustainable manner, taking all opportunities and risks into consideration.
IRGC Foundation Members

The list below includes Members of the IRGC Foundation Board, Scientific and Technical Council and Advisory Committee (by alphabetical order):


The IRGC academic network includes:

North America:
- Carnegie Mellon University (CMU), Department of Engineering and Public Policy, USA
- Indiana University, School of Public and Environmental Affairs, USA
- Massachusetts Institute of Technology (MIT), Program on Emerging Technologies, USA

Europe
- EPFL, International Risk Governance Center, Lausanne, Switzerland
- University College London, Department of Science, Technology, Policy and Public Policy (STeAPP), UK
- IRGC Portugal, as a consortium of research institutions
- The Helmholtz Alliance ENERGY-TRANS, Germany

Asia
- Center for Science, Technology and Policy (CSTEP), India
- Tsinghua University, School of Public Policy and Management, host of IRGC in China
The **EPFL International Risk Governance Center** and **IRGC Foundation** work together as a neutral platform for dialogue about emerging risks, focusing on opportunities and risks related to new technologies, with the aim of providing recommendations for their governance.

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