

# AI Regulatory Sandbox

**A regulatory tool to enable innovation in  
highly regulated areas?**

**DigiKon | 19. November 2024 | Bonn**

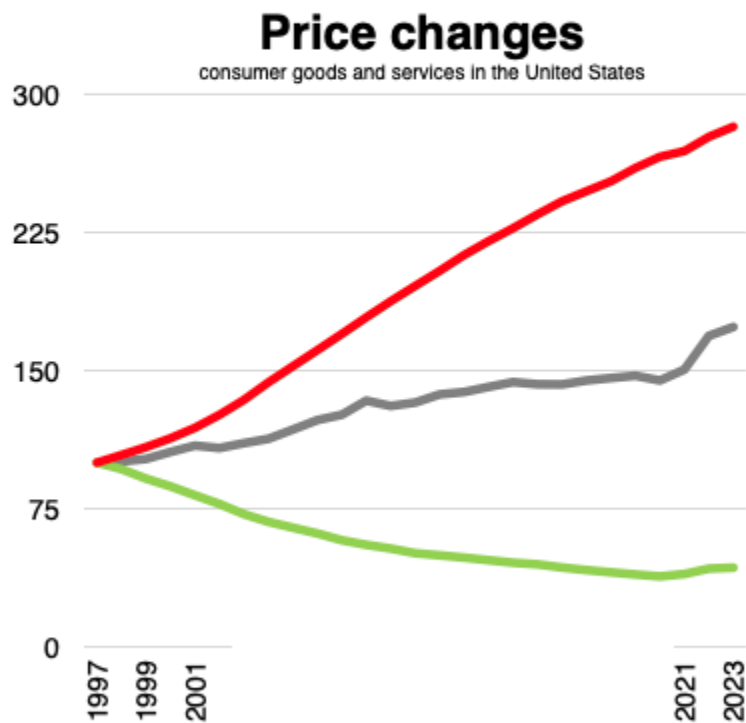


robotic beings you want to be with  
for social care

Philipp Schwarz  
COO

navel  
robotics





# Baumolscher Kosteneffekt

**Soziale Dienstleistung**

(Bildung, Pflege, Psychologie)

nicht automatisiert

**Lifestyle**

(Kleidung, Nahrung, Wohnen, Mobilität)

teilautomatisiert

**Produkte**

(computer, Autos, Spielzeug)

voll automatisiert



## Pflegealltag

Einsamkeit  
Apathie  
Unruhe

...

Stress  
Krankheit  
Ausfälle

...



navel  
robotics

Hohe Akzeptanz

Verbesserung des Wohlbefindens



Positiver kognitiver Effekt  
(Demenz, Angstzustände,  
Depression, Einsamkeit)



Langfristiges Engagement  
Vorteile für Pflegekräfte



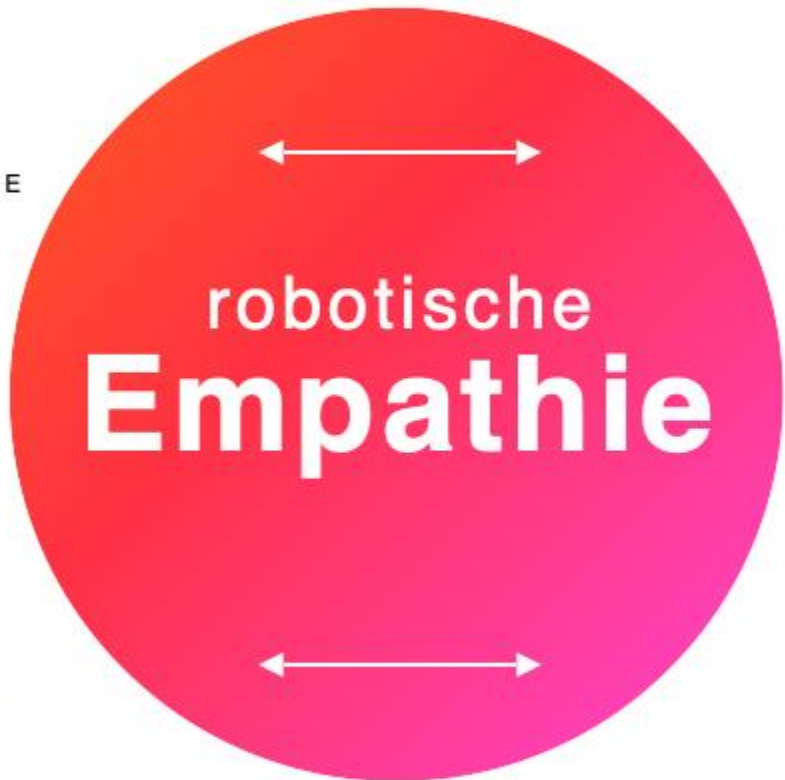
wissenschaftlich bestätigt

**KOGNITIV**  
EMPATHISCHE DIALOGE



Dynamische, kontext-  
spezifische Prompts für  
große Sprachmodelle (LLM)

→ soziales Verständnis



**AFFEKTIV**  
NONVERBALE INTERAKTION



Maschinelles Sehen und Audioanalyse  
auf dem Endgerät

→ geringe Latenz + hoher  
Datenschutz

# How can an AI Regulatory Sandbox foster innovation?



A joint  
initiative

**UNTER  
NEHMER  
TUM**

 **IPAI**





**Daniel Düsentrieb is the innovative mastermind in Disney's Duckburg universe.**

**Claiming “U name it, I can make it,” he invented amazing things.**

# Painpoint in highly regulated areas | Innovators will be confronted with a Chain of Uncertainty when putting their AI System on the market

## Legal Uncertainty

How to design a disruptive AI System in a compliant way?

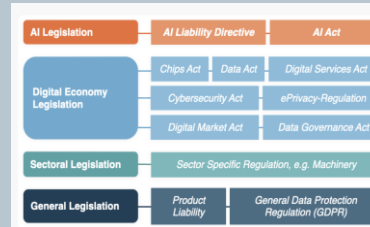
Uncertainty about Regulatory Barrier

- (i) Complex and Ambiguous Legal Language**
- (ii) Overlapping Laws & Authorities**
- (iii) Emerging tech - gray areas between prohibited vs high-risk**

## Practical Uncertainty

How the AI Systems performs in practice aka in the “real-world”?

Regulatory Market Entry Restrictions



## Supervisory Uncertainty

How will the supervisory authority react?

Pacing Problem & Regulatory Oversight

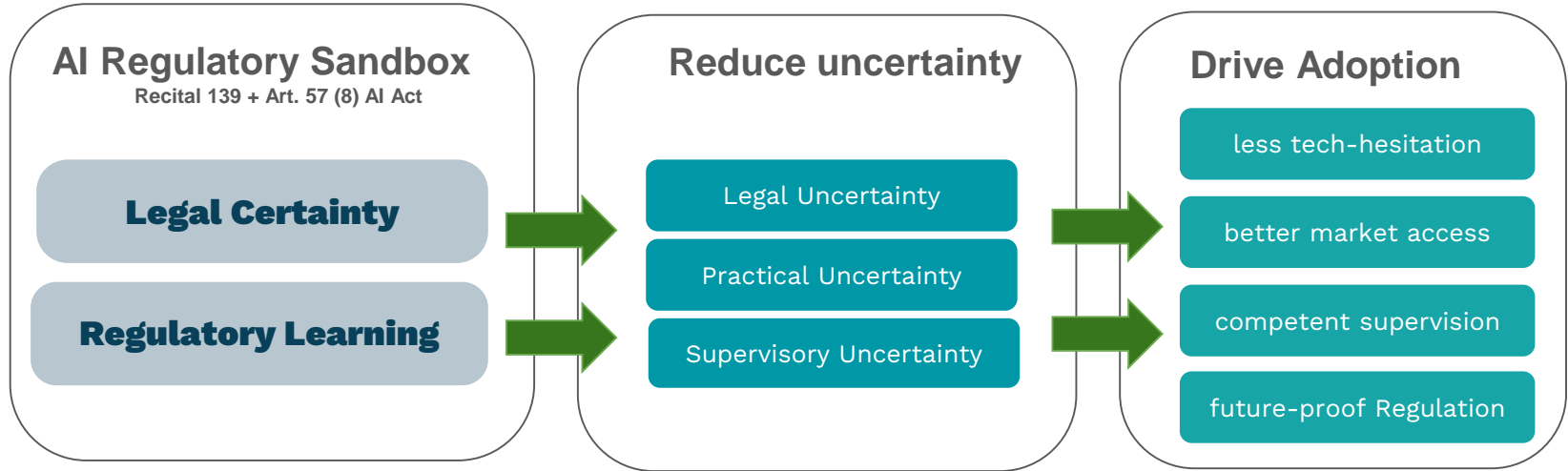
**Regulation follows Tech. Most competent authorities:**

- (i) know less about the technology than the private sector**
- (ii) decide risk-averse (precautionary principle)**

**Why a Regulatory Sandbox for experimentation? | Regulatory Flexibility in highly regulated areas is a necessary pass-through status to enable testing under real-world conditions**



# Purpose of a Regulatory Sandbox | Combat “the uncertainties” and follow the explicit goal to enhance legal certainty and regulatory learning by allowing experimentation.



**Take away:** Outcome of an AI Regulatory Sandbox is the relief of the chain of uncertainty and thereby enabling Innovation and tech-competent supervision in a faster & safer fashion - which makes the EU market more competitive despite heavy regulation.

# Practical Example for an AI Regulatory Sandbox under the AI Act.



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# Risk-based approach of the AI Act | Proportionality: the higher the risk of the intended use, the higher the requirements

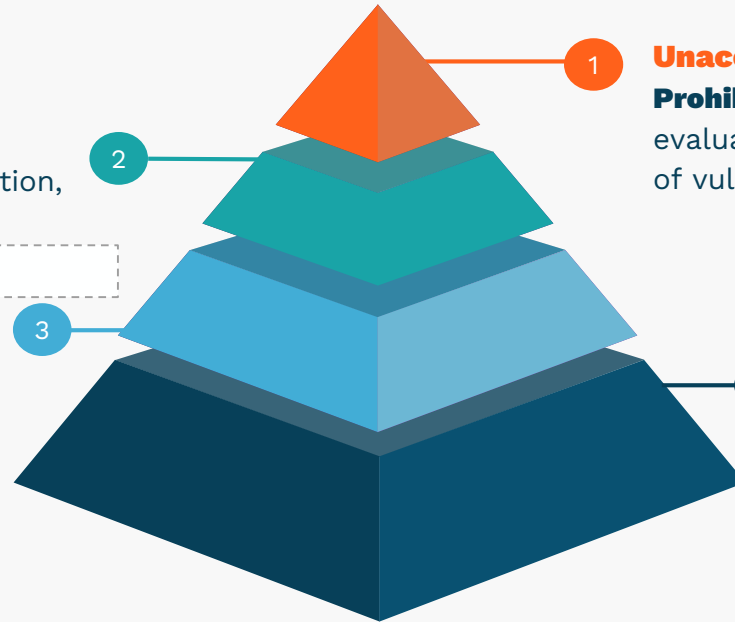
## High-Risk (Art. 6)

e.g. HR, medical devices, education, critical infrastructure

**Not mutually exclusive**

## Limited-Risk (Art 50.)

E.g. Chatbots



1

## Unacceptable-Risk (Art. 5)

**Prohibited** are, for example, social evaluation mechanisms or the exploitation of vulnerable groups

2

3

4

## Minimal-Risk

All other AI Systems

# Practical Example for an AI Regulatory Sandbox | Is the intended use of the AI System prohibited according to Article 5?



## Prohibited AI System according to Article 5 (1) (f) + Recital 44?

the placing on the market, the putting into service for this specific purpose, or the use of AI systems to infer emotions of a natural person in the areas of workplace and education institutions, except where the use of the AI system is intended to be put in place or into the market for medical or safety reasons;

(+) Area of workplace = The elderly home where the social robot is put into service is the area of work of the caregivers.

(-) No exception applies = The intended use case is not falling under the exception of the Medical Devices or safety reasons.

# Practical Example for an AI Regulatory Sandbox #1 | Is the intended use of the AI System prohibited according to Article 5?



## Legal assessment addressing:

(i) Is emotion recognition within the intended use case really happening?

Recital 18: “emotions or intentions such as happiness, sadness, anger, surprise, disgust, embarrassment, excitement, shame, contempt, satisfaction and amusement. **It does not include physical states, such as pain or fatigue ...**”

“This does also not include the **mere detection of readily apparent expressions, gestures or movements** ... such as a frown or a smile, or gestures such as the movement of hands, arms or head, or characteristics of a person’s voice, such as a raised voice or whispering.”



# Practical Example for an AI Regulatory Sandbox #2 | Is the intended use of the AI System prohibited according to Article 5?



## Legal assessment addressing:

(ii) Is there a concept of design to not fall into the workplace case?

What about a technical opt-out Design:

Caregivers opting out would undergo an enrollment process where their biometric data is securely registered. For example:

- Facial scan for facial recognition.
- Voice sample for voice recognition.

Result: As relief caregivers are not subject of any emotion recognition, Article 5 of emotion recognition is not applicable?

# **There are practical challenges for effective AI Regulatory Sandboxes!**



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# Practical challenge#1 | The challenge of operating an effective cross-sectoral AI Regulatory Sandbox

## The Situation

Establishing Authority operating the RSB has to take care off:

- (i) Building up the infrastructure & governance
- (ii) Gaining Technical & Legal know-how (Expert-Pools)
- (iii) Handling Overlapping Laws & Competent Authorities
- (iv) Ensuring Experimentation Clauses

## The Challenge

### Existing

#### “sectoral/traditional” Regulatory Sandbox

E. g. Drone Delivery, cars  
> relax sectoral law



### Planned

#### “AI Act” Regulatory Sandbox

E. g. any sector in Annex I + Annex III  
> relaxing AI Act alone is insufficient



# Practical challenge#1 | The challenge of operating an effective cross-sectoral AI Regulatory Sandbox

## For Discussion

Which competent authority operates the AI Regulatory Sandbox?



**What about a coordinating administrative body organising subject/theme batches?**

How to ensure (for each AI System) the needed sector expertise in an AI Regulatory Sandbox (with limited public resources)?



**Recruited external expertise in a flexible manner (individual researchers, Universities etc)**

Many national/EU sector laws miss experimentation clauses to offer Regulatory Flexibility.



**We need more experimentation clauses in sector law(s)**

## Practical challenge#2 | Open communication of the lessons learned & best practices with the entire ecosystem is crucial

**Public  
available Exit  
Reports are  
optional in  
the AI Act**

Article 57 (8) The exit reports of the AI RSB are not mandatory to be made publicly available - just in case the participating Innovator and the National Establishing Authority explicitly agree aka opt-in.

**... which is  
problematic,  
because ...**

AI RSB is paid with **taxpayer money**, so the wider society should benefit from it

**Regulatory Arbitrage**, as participating Innovators have priority access aka lobbying

**Scaling effect** is missing without making such learning available to everyone

Risk of **unfair competition**, as beneficial treatment to a limited number of Innovators

**Practical challenge#2 | Recommendation: Make any exit reports publicly available (with respect to IP + trade secrets), else there will be limited scaling effects**

**Norway Regulatory Sandbox Datalilsynet:**

*“Help Many By Helping One”\**

**Recommendation**

**The implementing Act (Article 58 (1) (a)) should recommend that national AI Regulatory Sandboxes should as eligibility criteria for entrance only accept innovators, if they explicitly agree upfront that their results and experiences are shared publicly via the single information platform - and shall provide a template for such publicly available exit reports.**

\*Source: <https://www.datatilsynet.no/en/news/aktuelle-nyheter-2022/sandbox-forever/>

## **Practical challenge#3 | The department operating AI Regulatory Sandbox should have some risk-appetite and trial & error mindset**

“

**By virtue of its novelty, innovation always involves the unknown and is therefore inherently risky. Experimentation in an AI Regulatory Sandbox therefore requires a considered acceptance of trial and error.**

**Any questions?**

**Feedback?**

