



Biorobotics Research &  
Innovation Engineering Facilities

# Internet of Things (IoT) & Liability

→ Study of what happens  
if something goes  
wrong

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# Presentation outline

Connection between national rules and EU  
rules that concern liability.

2 main groups of liability laws: private rules in case of contracts (ex. car driven by someone) → related to private people.  
State and individual concerning rules.  
↳ Criminal law

IoT. Recap

The IoT composition:  
hardware and  
software (preliminary  
outline)

Types of liability in  
private law  
(preliminary outline)

Structural problems  
and liability rules:  
contractual liability

The EU digital policy

Structural problems  
and liability: defective  
products

Structural problems  
and liability rules:  
Tort liability and AI

Future Perspectives

We will focus on the first one.

# IoT: a technology as elusive as it is present

Difficult to define of course! Even from a technical Pov, very versatile.



Definition problems from both a technical and legal point of view

Very versatile technology: can be applied from medicine to industry, from agriculture to the home



Structure: centralised, focused on the cloud layer



more vulnerable a cysec Pov

The peripheral part of the IoT system often lacks sufficient computational power and -especially in consumer applications- this prevents more extensive use of encryption and other technical protection measures



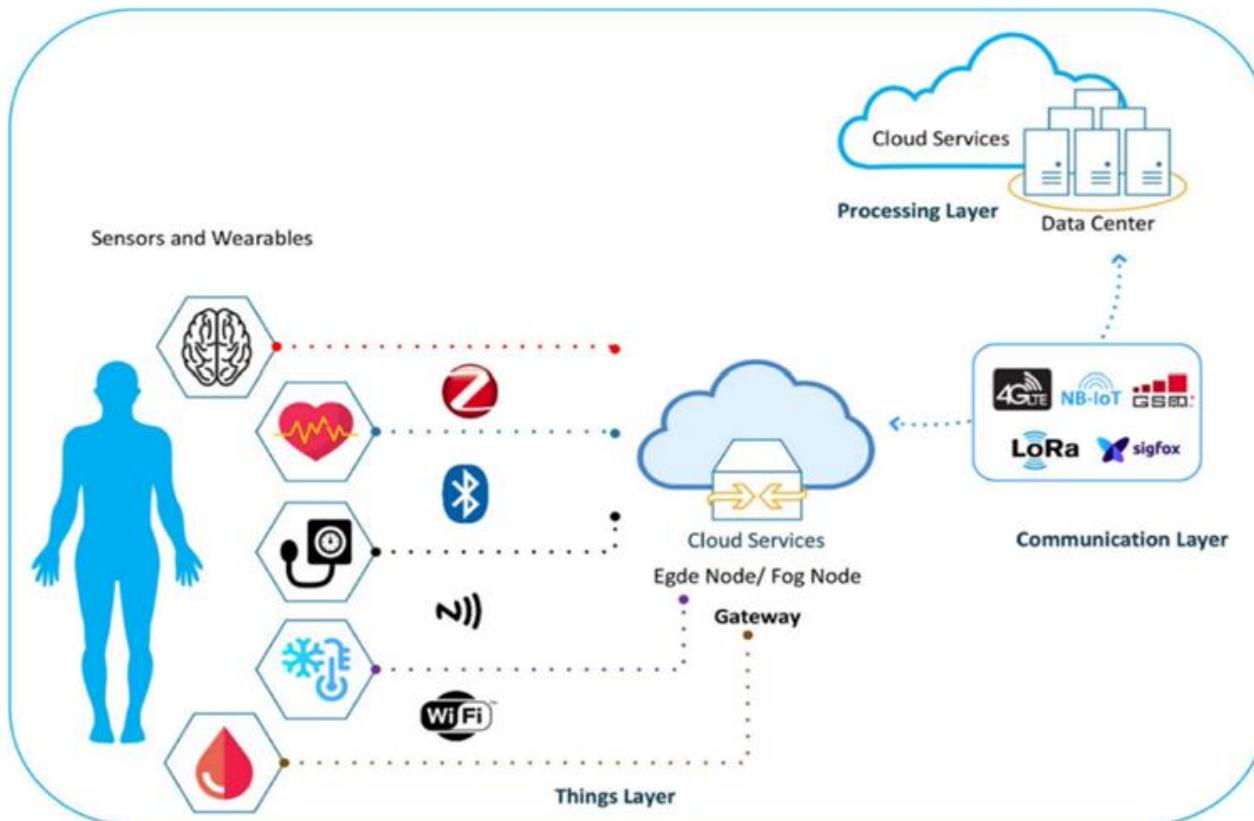
Problem: internet traffic (over-fitting) and data deluge



Problem: Technology-induced pollution

We don't want to abandon the stuffic.

## SECURING FUTURE TECHNOLOGIES OF SMART HEALTHCARE



**FIGURE 1.** Three-tier architecture of the IoT healthcare system.<sup>1</sup>

Strategy is also growing more computational power to edges or fog.

# The IoT composition: hardware and software. A preliminary outline.

If we look at any device to understand where damages come from, a scheme is useful.



Sensors

Actuators

Cloud

Applications

Cloud

Applications

Hardware

Software  
(Device)

Software  
(Third party)

It's so versatile that devices can have softwares,  
it can rely on cloud or on an application  
of the system. But it might be that on this  
device you have third parties providing SW,  
like apps for phone.

Third party softwares also are there.

Plus, there are medical applications that only have a SW. There's SW that integrates  
and drives the HW, we have medical SW certified as medical devices

# Preliminary outline: the various types of liability in Italian and EU private law



(2)

## 1<sup>st</sup> Scenario

**Negotiation before contract** ex:  
one party unexpectedly withdraws →  
**pre-contractual liability** (Articles  
1337-1338 Civil Code)



## 2<sup>nd</sup> Scenario

**Existing contract** but  
1) non-performance (default),  
2) delay in performance and  
3) improper performance of the  
contract → **contractual liability**  
(Articles 1218 et seq. 1321 et seq.)

(1)

## 3<sup>rd</sup> Scenario

**Two parties, lack of contract, one  
harms the other** → **non-contractual  
liability** (Article 2043 of the Civil  
Code) (now also applicable to GDPR  
personal damages) it is also known  
as tort or extra-contractual liability

(2)

## 4<sup>th</sup> Scenario

Dangerous building, animal, exercise  
of a dangerous activity, subordinate  
worker, uncapable person injures  
someone → form of specific non-  
contractual liability (**quasi-objective**  
or **aggravated liability**, Articles  
2047- 2054)

(3)

## 5<sup>th</sup> Scenario

Malfunctioning of a consumer object  
→ **product liability** (Consumer  
Code Legislative Decree 206/2005,  
Articles 114-127, transposition  
Directive 85/374/EC)

Warning it will  
need to be  
changed  
because of the  
PLDU  
approval



To understand liability: EU law come way after the national existing ones. We have similar laws in other EU MS but they also have differences for historical and cultural purposes.

- \* Case of selling PC: I could have spent my time in looking for other people
- (1) Ex. I bought something and you don't send it.
- (2) I don't have any relationship with the person that harmed me. It is a bit more complex to find liability: I have to explain the **LINK OF CAUSALITY** and the **NEGLIGENCE** or **VOLUNTARY ACTION**.
- (3) Bad condition building, fault of the owner. In this case: the owner needs to prove they did anything they could to prevent the damage to the person. For this reason quasi-objective liability.
- (4) Malfunctioning of a product. Is more similar to the 3rd scenario, but also a bit about it, because manufacturer should be the point of contact.  
This is at EU level. The implementation is in **CODICE DEL CONSUMO**, but we have a renewal now.

# When do I apply a kind of liability instead of another?



It depends on the **procedural civil rule laws** of the country which we examine



For instance, in Italy, it is possible to graduate and put an order to your claims and request the judge to ascertain that the counterpart can be liable because of contractual liability, and/or tort or strict liability ①



Generally, people will try to rely on **contract** (hence contract liability) as it is easier to demonstrate that the counterpart breached a duty or did not deliver an expected result. If we are talking about a consumer object that I bought and that injured me because of an internal malfunction I can also use the product liability rules. You can try both if procedural laws allow that because there was a **contract at the beginning (contractual liability)** and a **product (strict/extra contractual or tort liability)**



The rule described is not absolute: if I am run over by a **stranger** in a car there is no contract or product at stake. I will have to use non contractual liability

Is there a rule to choose liability rules? When I buy something, can I use contractual and product liability?

- ① Possible to go for different types of liability for liability. In other countries you can.

↳ Sale of goods and services

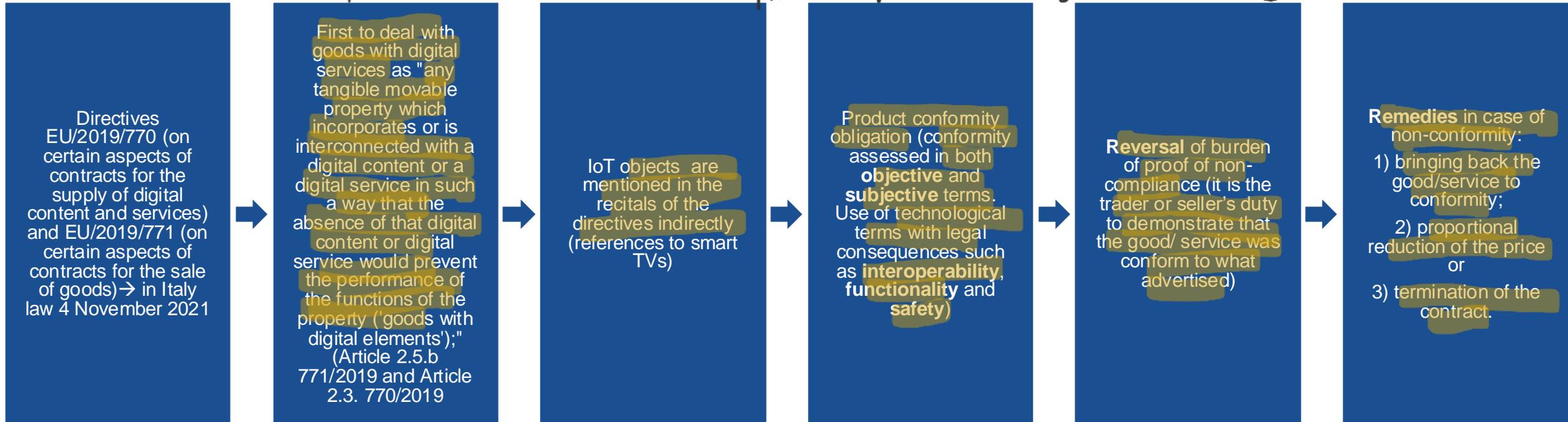
## Structural problems: IoT and contractual liability law

There are 2 directives in 2019 dealing with goods with digital services.

There is no EU act that mentions directly IoT. But it's in rentals, definition etc.

Here this was the definition of an IoT object.

(1)



(2)

Manufacturers define what a product can do (define conformity requirements), that can be objective (can do this because it has this components) and subjective ones: for example usability of the device. Something that is related to the user.

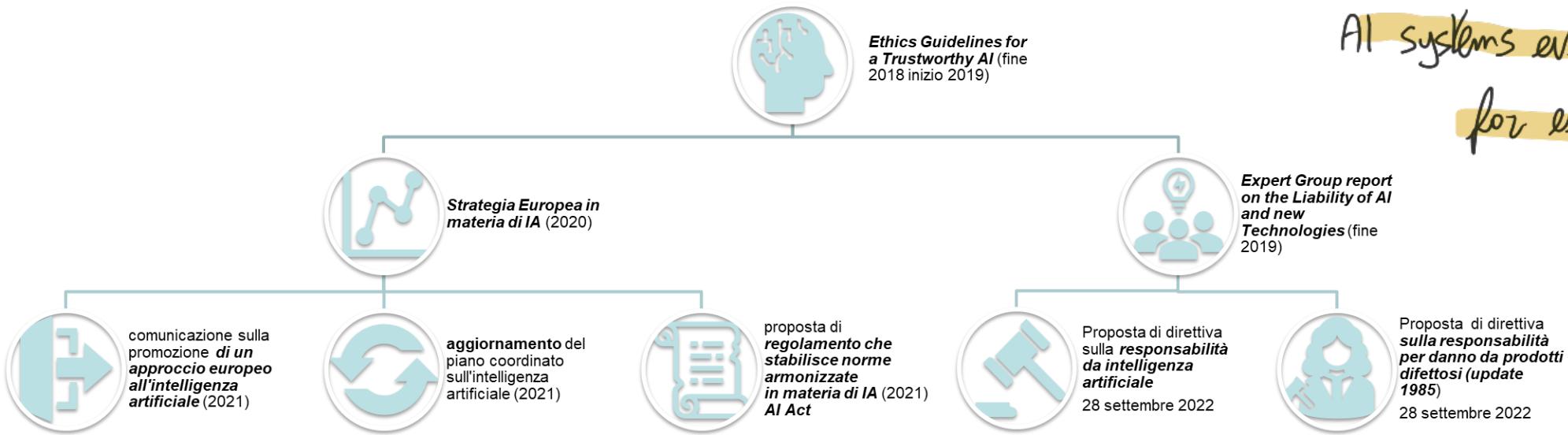
For the first kind, there is the use of integrity, functionality, safety are used in particular in this field.

- ① It's the part that had the damage that has to prove something, normally. Here not like wheel.
- ② Remedies that are limited to non-conf; manufacturer of IoT has different options.
  - | 2) "I want back 80% of the money".

So this is a case of contractual liability and have these tools to file a liability lawsuit.

# The European digital policy I. IoT: between AI and product liability

IoT and AI have different and different  
differences.



AI systems even at the edge  
for example!

It was clear to the EU legislators there was a need to understand what happens before and until you put AI on the market (AI act) but also what to do in case AI brings damages.

# The European digital policy II. 2024 a momentous year for digital policy

Approval of the AI act in March 2024 → Official publication in the EU Journal in July 2024 → Entry into force 1 August 2024.

We do not know! Relied a lot on 1st proposal of AI act. So this directive is a bit useless

Approval of the Product Liability Directive Update (PLDU) in March 2024 → Official Approval on 10 October 2024 by the council → Official Publication in the EU Journal on 18 November 2024

Applicable in 2026

# European Digital Policy III. The AI Act in short a)



'Horizontal' legislation concerning the use of AI systems



New Definition of AI (very general): 4(1) AIA 'AI system' means a **machine-based system** designed to operate with **varying levels of autonomy**, that may exhibit **adaptiveness after deployment** and that, for explicit or implicit objectives, **infers**, from the input it receives, **how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments**;



Article 5: prohibited AI systems: subliminal effects, vulnerability, social-scoring (reliability and trustworthiness)

*take advantage of*

*For many of them, if you demonstrate that there is no harm to the person, then you can do it. Very controversial*



Article 6: High-risk AI systems: if security component other product (Annex II) and conformity assessment considers it as high-risk + Annex III (e.g. biometric identification, management and operation of critical facilities)



Important high-risk AI systems: obligations on how to create and train AIs, obligations to certify algorithms with notified bodies, and registration in a common database

\* MVR stated that any derive system that also falls under these regulations,  
then this is a high risk - PDR is between those regulations.

A lot of overlapping and obligations etc.

# European Digital Policy IV. The AI Act in short b)



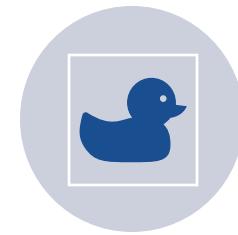
BUT... CHAT GPT HAPPENED, SO IN THE ORIGINAL PROPOSAL THE GENERAL PURPOSE AI (GPAI) MODELS WERE INTRODUCED. THEY CORRESPOND TO LLMS AND FOUNDATION MODELS.



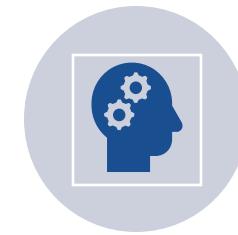
THEY HAVE **SPECIFIC RULES** (E.G. NO DEEPFAKES, TRANSPARENCY OBLIGATION)



THEY ARE DIVIDED IN 2 GROUPS: ABLE TO CREATE SYSTEMIC RISK OR NOT. THE DEFINITION OF SYSTEMIC RISK IS VAGUE BUT IT MEANS THAT THE NEGATIVE EFFECTS OF A GPAI CAN INTEREST A HUGE NUMBER OF EU CITIZENS AND ATTEMPT TO THEIR SECURITY, FREEDOM AND HEALTH

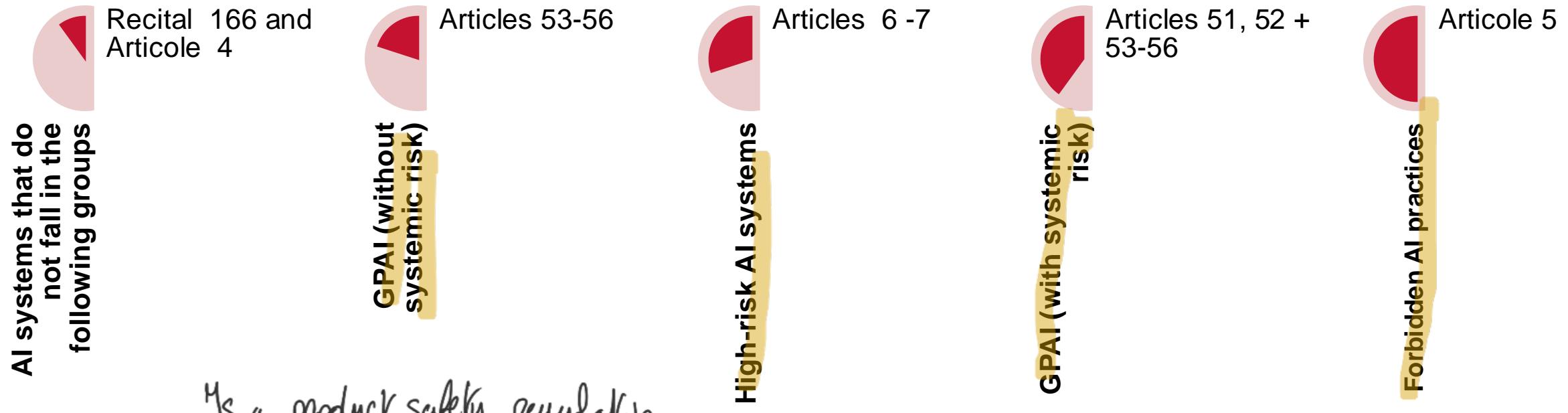


THE SYSTEMIC RISK IS PRESUMED ON THE QUANTITY OF FLOATING POINTS OF OPERATION (FLOPS) THAT THE MODEL CAN REACH. BEYOND 10 25 FLOPS A GPAI IS PRESUMED ABLE TO CREATE A SYSTEMIC RISK



HOWEVER... NOBODY KNOWS HOW TO ADAPT THESE RULES ESPECIALLY WHEN THE AI SYSTEM IS CONSIDERED AS HIGH RISK BY THE AI ACT (SUCH AS A MEDICAL SOFTWARE) AND USES A GPAI TO WORK (THE CHAT OF A CONVERSATIONAL AND REHAB ROBOT FOR KIDS WITH NEUROLOGIC DISORDERS). DOES THE RULE ON HIGH-RISK AI SYSTEMS COMBINE WITH THE ONES ON GPAIS? IT SHOULD BE BUT IT IS NOT CLEAR HOW

# European Digital Policy V. The AI Act in short c)



Is a product safety regulation.

Not so different from the MDR. The higher the risk, the more the manufacturer should

The higher the risk, the more the AI providers risk will be

be accountable and liable for changes.

# European Digital Policy VI. The AI Act in short d



not thought about at the beginning.

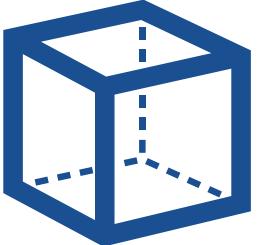
ex: buying a GPT and making your own from that one.

**AI provider:** creates the AI system

**AI 'downstream provider'** means a provider of an AI system, including a general-purpose AI system, which integrates an AI model, regardless of whether the model is provided by themselves and vertically integrated or provided by another entity based on contractual relations.

**AI deployer:** who uses the AI system. It could be a professional user (hospital) but also consumer.

# Structural issues: the IoT and product liability I



*real news of today: kind of ①.*

## Characteristics of product liability:

(Quasi-) **Strict liability**: Allegedly, more favourable for the consumer to prove against the producer than

Non-contractual liability

*They only have to prove damage, psychological damage, defectiveness but before, directive was of 1985, not up to date.*



## Elements to be proved:

**Damage**

**Defectiveness** of the product and  
**Causal link** between the first two elements  
(Possibility for the producer to exempt themselves)



## Innovation from EU law:

the directive has remained unchanged for more than 38 years without major changes

**BUT**

**Much contested** by some states that had a more protective tradition of consummation law

**AND**

**Radical technological change** in the last 5 years with IoT and AI development made it necessary to modify the directive

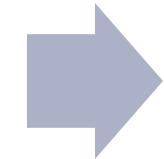
①

① SW intended generally (A) or not is considered a product! If a product is defective, the newly approved law applies.

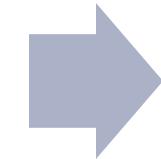
# Structural issues: the IoT and product liability I



Software, included AI systems is considered a product which can be defective



In fact, the AI act can be considered a safety legislation and like all safety legislations it sets standards to produce products

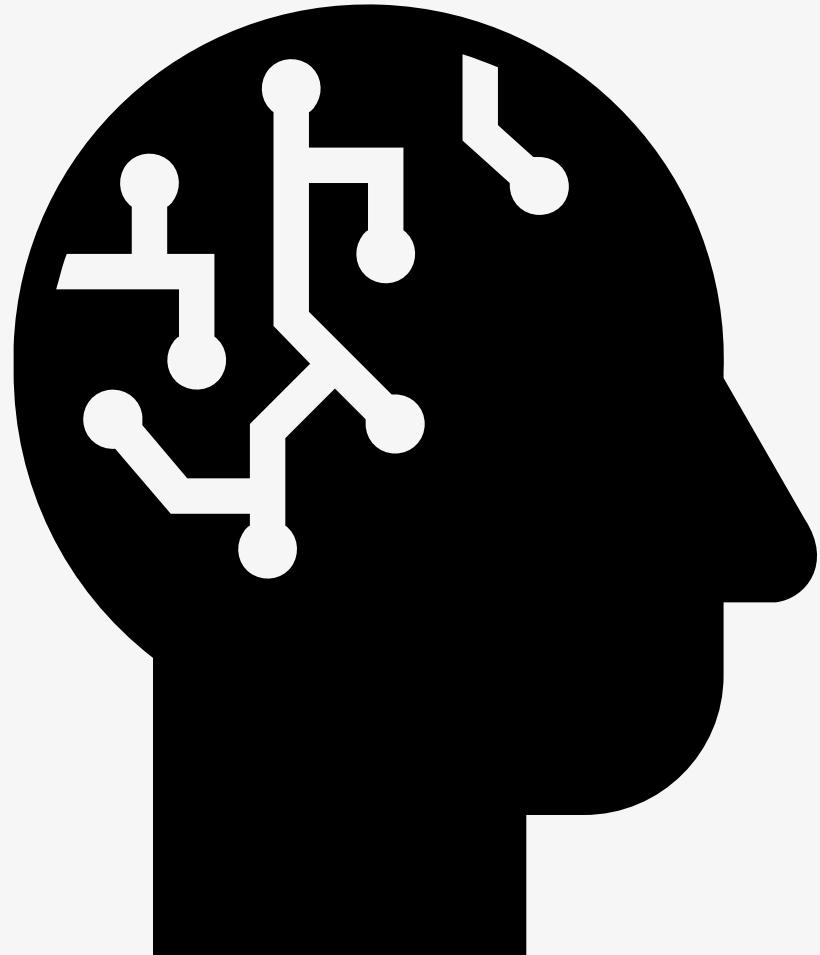


If the said product is defective, despite the fact that it is an AI system, the newly approved product liability directive applies!

# Structural problems: the IoT and the new product liability II

Providing a plausible cause of damages, without being able to prove how it is okay. As long as you give plausible cause. BUT, presumption will not be applied easily, you need serious or certified psychological evidence.





This only works  
for the consumer  
bank!

## Structural issues: IoT and non-contractual liability and the case of AI part I. The proposed directive on the civil (= tort, extracontractual) liability of AI

- Complementary to the AI act
- High v. low-risk AI systems
- *IoT and AI: what is their relationship? Important to decide which set of liability rules to apply* **What about the GPA?**
- AI act concerns software not covered by producer responsibility and those types of AI systems that are described as high-risk in the AI act
- The draft directive is very short, but two articles are crucial (3 and 4)

# Structural issues: the IoT and non-contractual liability. The case of AI part II

- ↑ ask to get access
- Article 3(1): **Disclosure of evidence** → on condition that *facts and evidence supporting the plausibility of the claim for damages* are brought to support it
  - Article 3(4): **Balance** between **disclosure** of evidence and **confidentiality** to also protect **intellectual property**
  - Article 3(5): if a **defendant refuses** to submit the evidence requested, their AI system is presumed to have caused the damage (simple presumption)

# Structural issues: IoT and non-contractual liability and the case of AI part III



- Article 4: divided into two parts depending on whether the AI system is considered high-risk by the AI act  
*Presumptions for causal links, not fault.*
- Part 1: Rebuttable presumption of causation in the case of fault only if all the following conditions are met:  
*You have to demonstrate of all 3*
  - (a) the claimant has demonstrated or the court has presumed pursuant to Article 3(5), the fault of the defendant, or of a person for whose behaviour the defendant is responsible, consisting in the non-compliance with a duty of care laid down in Union or national law directly intended to protect against the damage that occurred;
  - (b) it can be considered reasonably likely, based on the circumstances of the case, that the fault has influenced the output produced by the AI system or the failure of the AI system to produce an output;
  - (c) the claimant has demonstrated that the output produced by the AI system or the failure of the AI system to produce an output gave rise to the damage.

# Structural issues: the IoT and non-contractual liability. The case of AI part IV

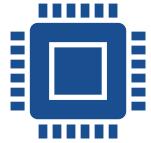


- Part two: if the IA system is high-risk and if the following requirements are not met, the IA system is presumed to have caused the damage *First condition proved but what about the other two?*
  - (a) the AI system is a system which makes use of techniques involving the training of models with data and which was not developed on the basis of training, validation and testing data sets that meet the quality criteria referred to in [Article 10(2) to (4) of the AI Act];
  - (b) the AI system was not designed and developed in a way that meets the transparency requirements laid down in [Article 13 of the AI Act];
  - (c) the AI system was not designed and developed in a way that allows for an effective oversight by natural persons during the period in which the AI system is in use pursuant to [Article 14 of the AI Act];
  - (d) the AI system was not designed and developed so as to achieve, in the light of its intended purpose, an appropriate level of accuracy, robustness and cybersecurity pursuant to [Article 15 and Article 16, point (a), of the AI Act]; or
  - (e) the necessary corrective actions were not immediately taken to bring the AI system in conformity with the obligations laid down in [Title III, Chapter 2 of

# Structural issues: the IoT and non-contractual liability. The case of AI part V



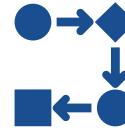
What is the problem with this proposal?



It is already old! It was presented in September 2022 and took into consideration the first AI Act proposal



In that proposal there was no mention of generative AI and the GPAI of the then approved AI Act

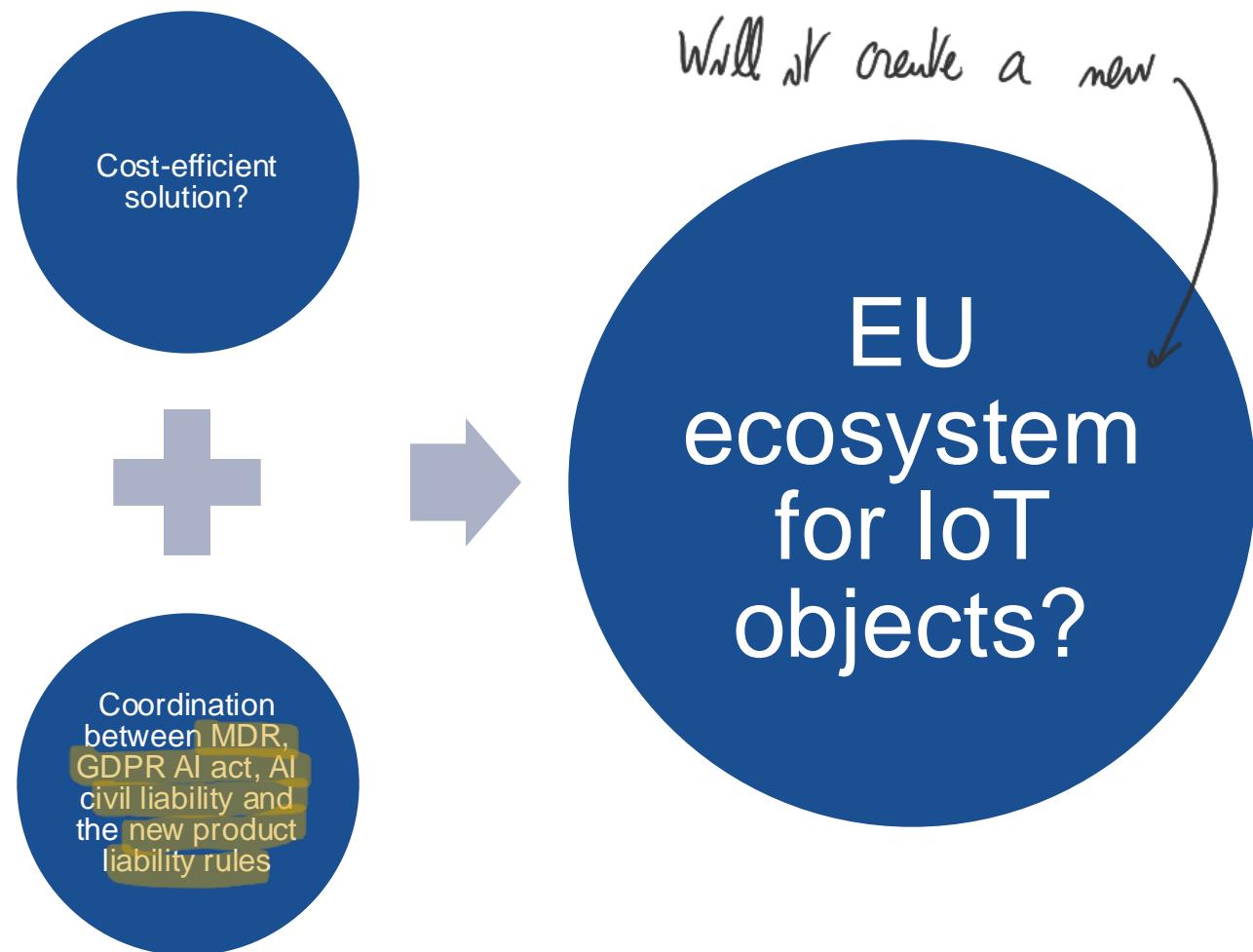


It needs to be updated and modified → But will it? It is a lengthy process

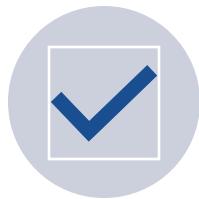


It is a minimum harmonization directive, that means that

# Structural problems: the IoT and product liability III (update proposal)



# Future perspectives: policy and technology



Until now there has been a need to regulate technology to avoid regulatory gaps and cause material and non-material damage (e.g. data breaches or cyber attacks)



Need to adapt existing legislation to the GDPR and to technological progress



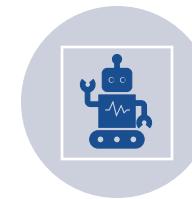
A shared technical-legal language is being created and solutions are being reshaped according to needs (e.g. operator obligations, presence or absence of notified bodies as in the medical device regulation and the cybersecurity regulations)



Many of these are still proposals, one cannot be sure that they will not change between now and their approval, but the theoretical framework will not change that much



Legislation has taken stakeholders' opinions into account, and proposals have been approved and will be applied shortly



Work in progress: hybridisation of IoT technology with others (AI, DLT/Blockchain, Digital Twins) that may require regulatory adaptation

# Any questions?



Thank you for your attention

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