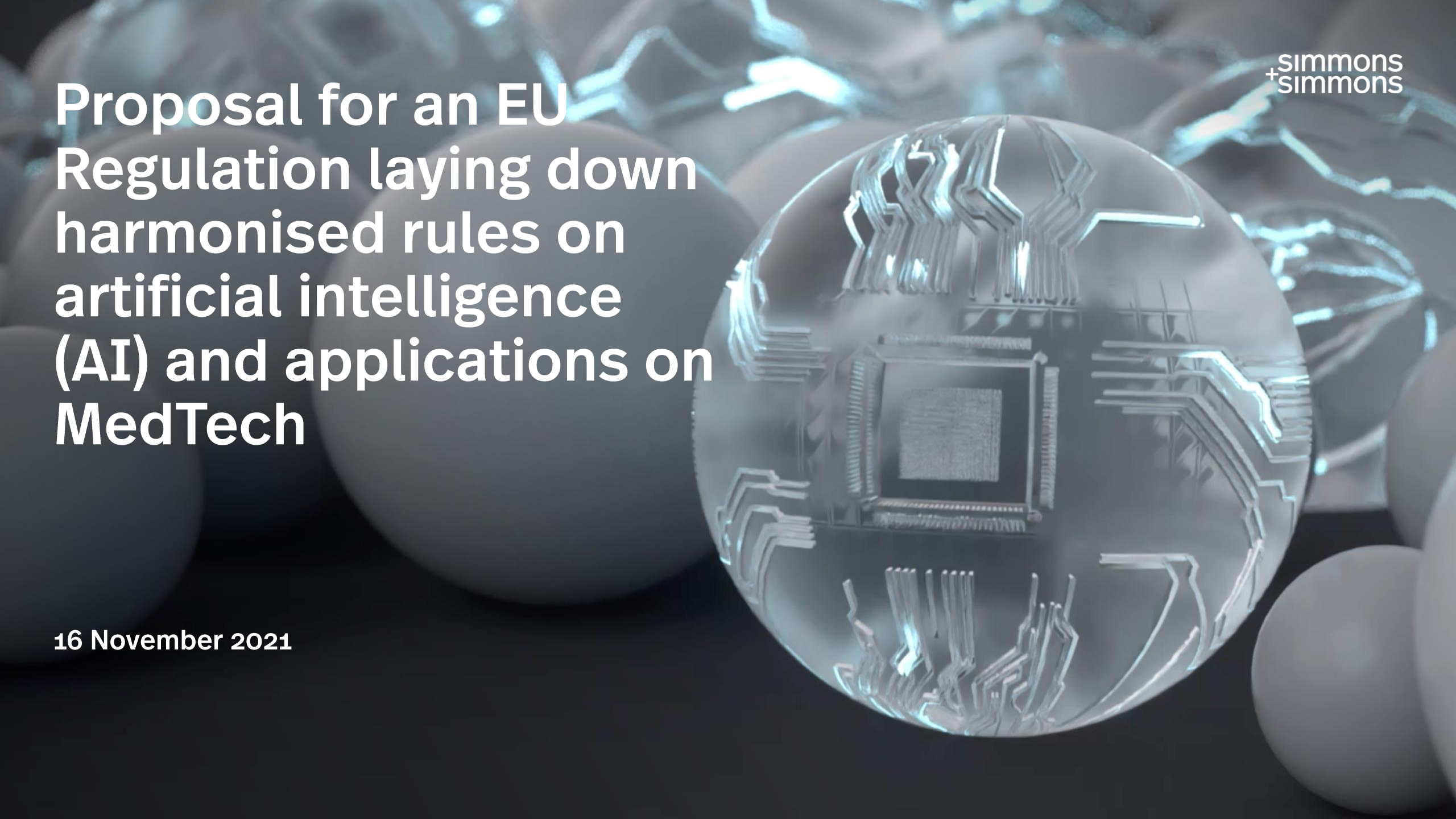

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Proposal for an EU Regulation laying down harmonised rules on artificial intelligence (AI) and applications on MedTech

16 November 2021

Draft (EU) Artificial Intelligence Act

Today's team

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Draft (EU) Artificial Intelligence Reg

Agenda

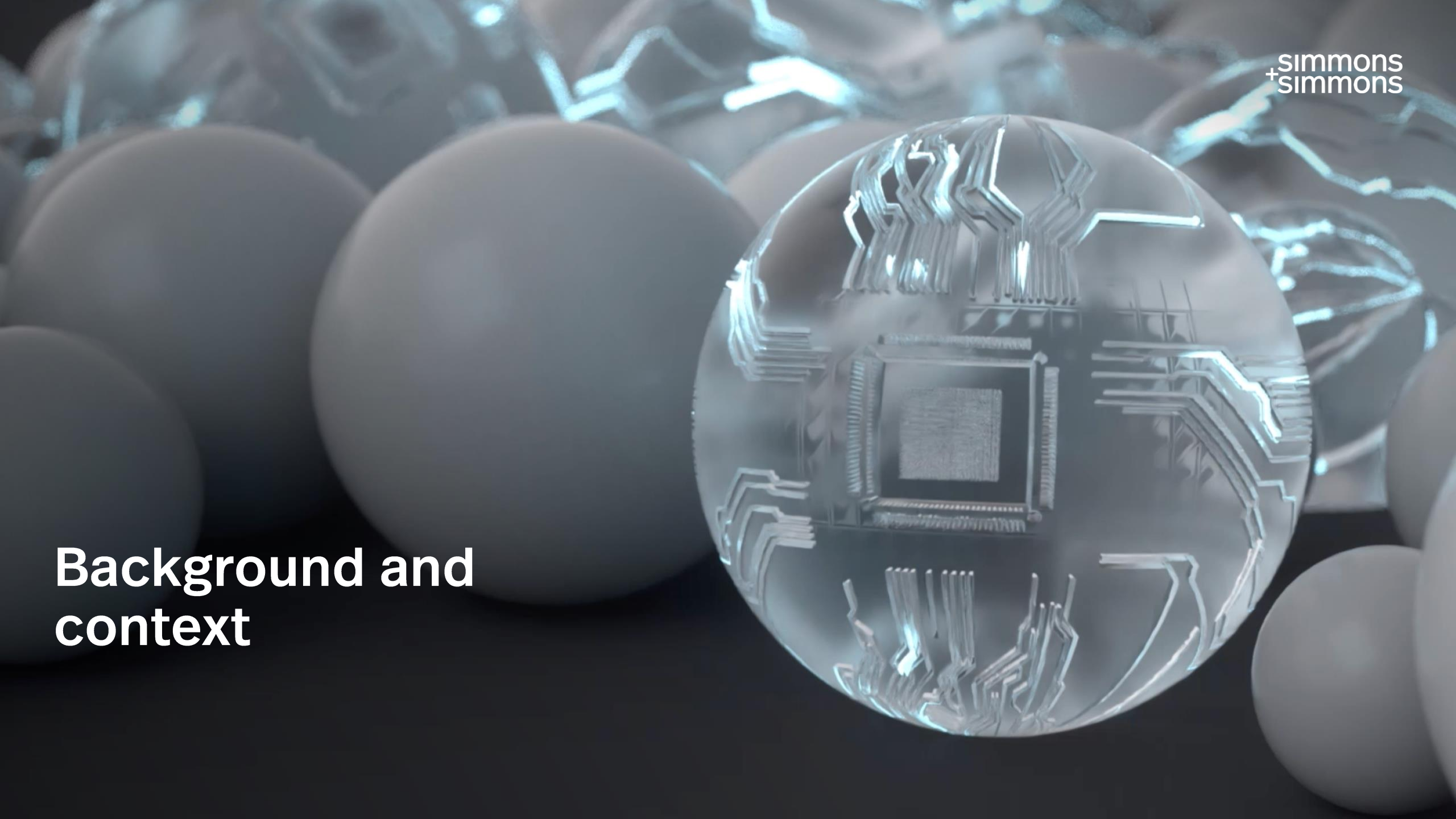
1 Background and context

2 High-level structure and key issues

3 Some key requirements for High-Risk AI Systems

4 High-Risk AI Systems and the (EU) Medical Devices Regulation

5 Financial penalties and practical steps



Background and context

Background and context

The New Legislative Framework ("NLF") for industrial products

Adopted in 2008 to improve the internal market for goods and strengthen the conditions for placing a **wide range of products** on the EU market

Toy Safety - Directive 2009/48/EU Transportable pressure equipment - Directive 2010/35/EU Restriction of Hazardous Substances in Electrical and Electronic Equipment - Directive 2011/65/EU Construction products - Regulation (EU) No 305/2011 Pyrotechnic Articles - Directive 2013/29/EU Recreational craft and personal watercraft - Directive 2013/53/EU Civil Explosives - Directive 2014/28/EU Simple Pressure Vessels - Directive 2014/29/EU Electromagnetic Compatibility - Directive 2014/30/EU Non-automatic Weighing Instruments - Directive 2014/31/EU Measuring Instruments - Directive 2014/32/EU Lifts - Directive 2014/33/EU ATEX - Directive 2014/34/EU Radio equipment - Directive 2014/53/EU Low Voltage - Directive 2014/35/EU Pressure equipment - Directive 2014/68/EU Marine Equipment - Directive 2014/90/EU Cableway installations - Regulation (EU) 2016/424 Personal protective equipment - Regulation (EU) 2016/425 Gas appliances - Regulation (EU) 2016/426 Medical devices - Regulation (EU) 2017/745 In vitro diagnostic medical devices - Regulation (EU) 2017/746 EU Fertilising products – Regulation (EU) 2019/1009 + now **High-Risk AI Systems** will be added to this list of industrial products / sectorial legislation covered by the NLF

Background and context

Purpose of the NLF

- Improves **market surveillance rules** to better protect both consumers and professionals from unsafe products, including those imported from outside the EU
  - In particular, this applies to procedures for products which can pose danger to health or the environment
- Sets clear and transparent rules for the **accreditation of conformity assessment bodies** (notified bodies)
- Clarifies the meaning of **CE marking** and enhances its credibility

European Commission, DG Grow, New legislative framework (online) https://ec.europa.eu/growth/single-market/goods/new-legislative-framework_en

Background and context

Purpose of the NLF

- Boosts the quality of and confidence in the **conformity assessment** of products through stronger and clearer rules on the requirements for the notification of conformity assessment bodies
- Establishes a common legal framework for industrial products in the form of a **toolbox of measures** for use in future legislation
  - This includes **definitions of terms** commonly used in product legislation, and **procedures** to allow future sectorial legislation to become more consistent and easier to implement

European Commission, DG Grow, New legislative framework (online) https://ec.europa.eu/growth/single-market/goods/new-legislative-framework_en

Background and context

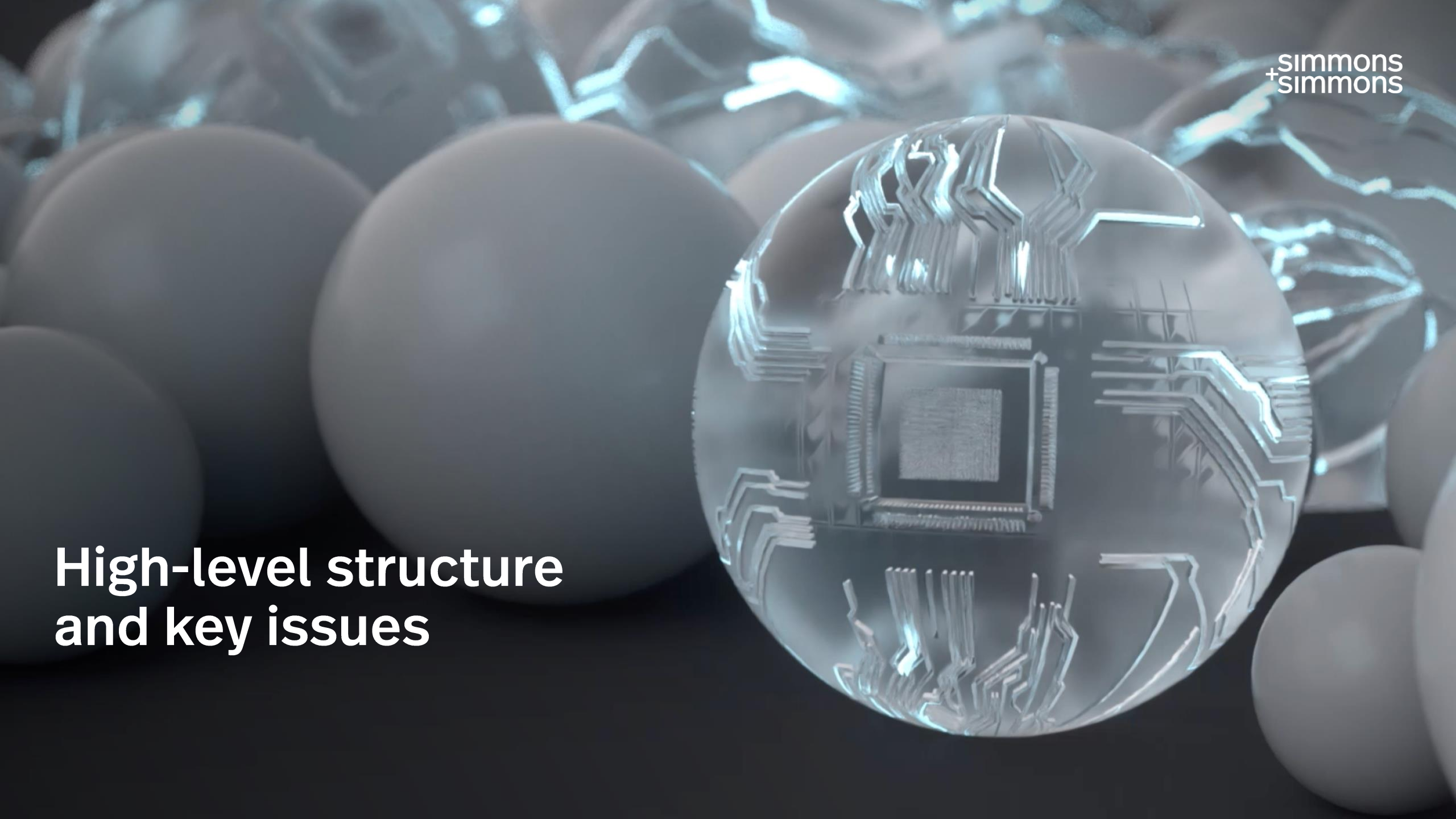
Draft (EU) Artificial Intelligence Act

- President von der Leyen promised (EU) Artificial Intelligence Act following her appointment
- “Regulation” ⇨ binding in its entirety and directly applicable in all EU Member States
- Draft Regulation April 21st, 2021 (2021/0106)
  - Improves the **functioning of the internal market** by laying down a uniform legal framework for the **development**, **marketing** and **use** of AI in Europe
  - Ensures the **free movement of AI-based goods and services cross-border**, thus preventing Member States from imposing restrictions on the development, marketing and use of AI Systems, unless explicitly authorised

Background and context

Subject matter

- Harmonised rules for the **placing on the market**, the **putting into service** and the **use** of Artificial Intelligence Systems (‘AI Systems’) in the Union
- **Prohibitions** of certain Artificial Intelligence practices
- Specific requirements for **High-Risk AI Systems** and obligations for operators of such systems
- Harmonised **transparency rules** for AI Systems intended to interact with natural persons, emotion recognition systems and biometric categorisation systems, and AI Systems used to generate or manipulate image, audio or video content
- Rules on **market monitoring** and **surveillance**



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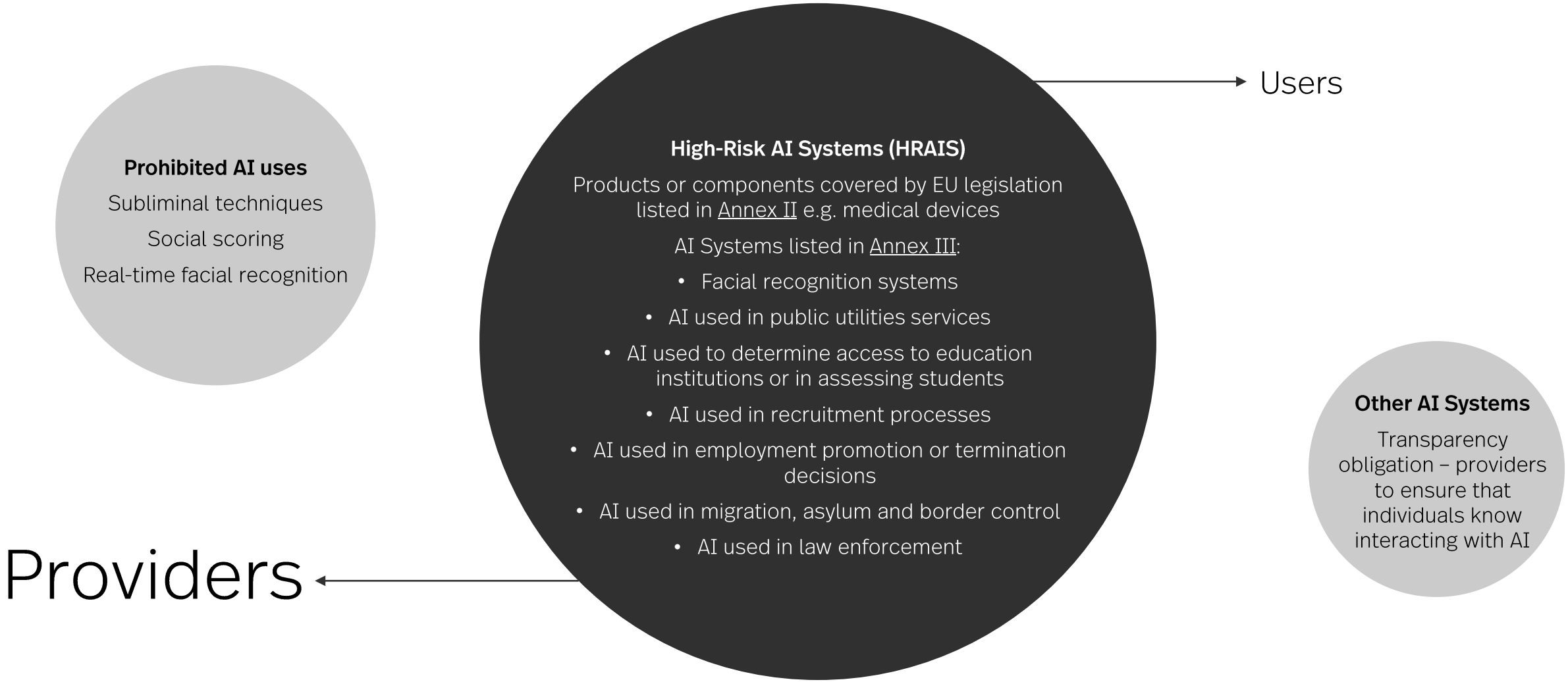
High-level structure and key issues

High-level structure and key issues

Overview of the Draft (EU) Artificial Intelligence Act



High-level structure and key issues

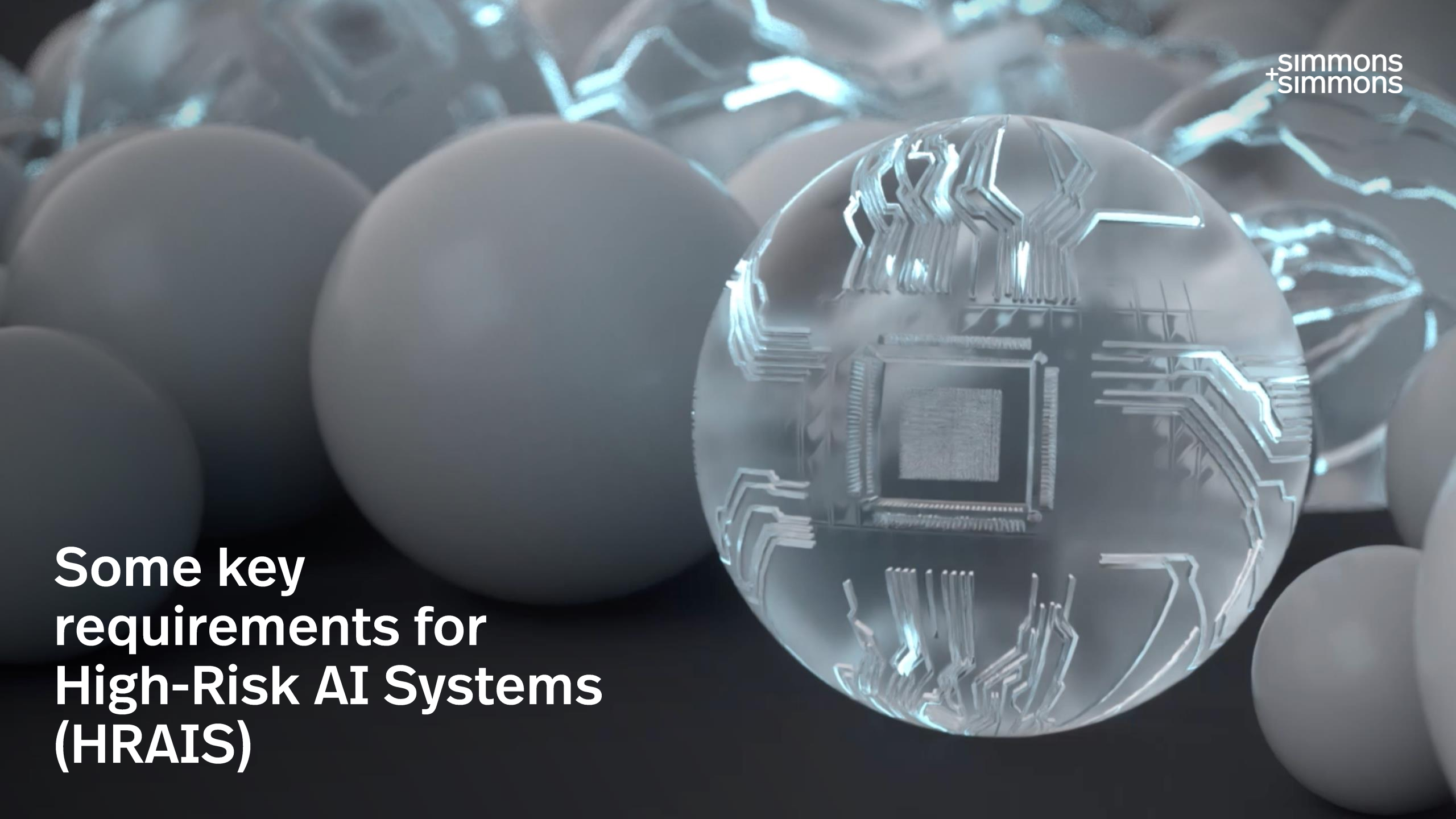
Key issues

- Territorial application – Draft (EU) Artificial Intelligence Act
  - will apply to **providers**, **users**, **importers** and distributors of AI Systems
  - will apply to non-EU organisations that supply AI Systems into the EU or where the output produced is in the EU
- Placing on the market vs putting into service vs output produced by the system

High-level structure and key issues

Key issues

- Material application – Key issue on scope of Draft (EU) Artificial Intelligence Act: definition of "**AI System**" (Article 3(1))
  - Software that is developed with one or more of the techniques and approaches listed in Annex I
  - "Which can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with"
  - Annex I includes: "logic- and knowledge-based approaches"



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Some key requirements for High-Risk AI Systems (HRAIS)

Some key requirements for HRAIS

Substantive obligations for providers

Risk management systems

Implementing process for entire lifecycle of HRAIS to identify, analyse and mitigate risks

Article 9

Data / data governance

Training and testing of HRAIS using data shall be undertaken in accordance with Article 10

Technical documentation

Drafting comprehensive "manual" for HRAIS which contains, at a minimum the Annex IV information

Article 11

Record-keeping

HRAIS must be designed to ensure automatic logging of events eg period of use and input data reviewed (Article 12) and providers must keep these logs

Article 20

Transparency

HRAIS must be accompanied by instructions for use which include detailed information including their characteristics, capabilities and limitations

Article 13

Human oversight

HRAIS must be designed so they can be overseen by humans, who should meet various requirements eg being able to understand the HRAIS and to stop its use

Article 14

Accuracy, robustness and cybersecurity

HEAIS must be accurate (with accuracy metrics included in instructions for use), resilient to errors or inconsistencies (eg through fail-safe plans) and resilient to cyber-attacks

Article 15

Quality management system

HRAIS providers must put in place a comprehensive quality management system which includes at least the extensive Article 17 information requirements

Post-marketing monitoring

HRAIS providers must document a system to collect and analyse data provided by users on the performance of the HRAIS throughout its lifetime

Article 61

Some key requirements for HRAIS

Data-related obligations (Article 10)

- Data obligations attract greater financial penalties and affect wider data strategy
- Data-related obligations include
  - Ensuring appropriate data governance and management practices for training, validation and testing data sets
  - Ensuring data sets are “relevant, representative, free of errors and complete”
  - Ensuring data sets “take into account… the characteristics or elements that are particular to the specific geographical, behavioural or functional setting within which the high-risk AI System is intended to be used”
- Practical issues around data-related obligations

Some key requirements for HRAIS

Data-related obligations (Article 10(5))

- The paragraph 5 establishes that providers may process special categories of personal data referred to in Article 9(1) of GDPR, when it is strictly necessary for the purposes of ensuring bias monitoring, detection and amendments in relation to the HRAIS.
- The special categories of personal data may be processed, subject to appropriate safeguards of the fundamental rights and freedom of individuals, including technical limitations on the use of security and privacy-preserving measures, such as pseudonymisation, or encryption where anonymisation may significantly affect the purpose pursued.

Some key requirements for HRAIS

Key practical points to consider

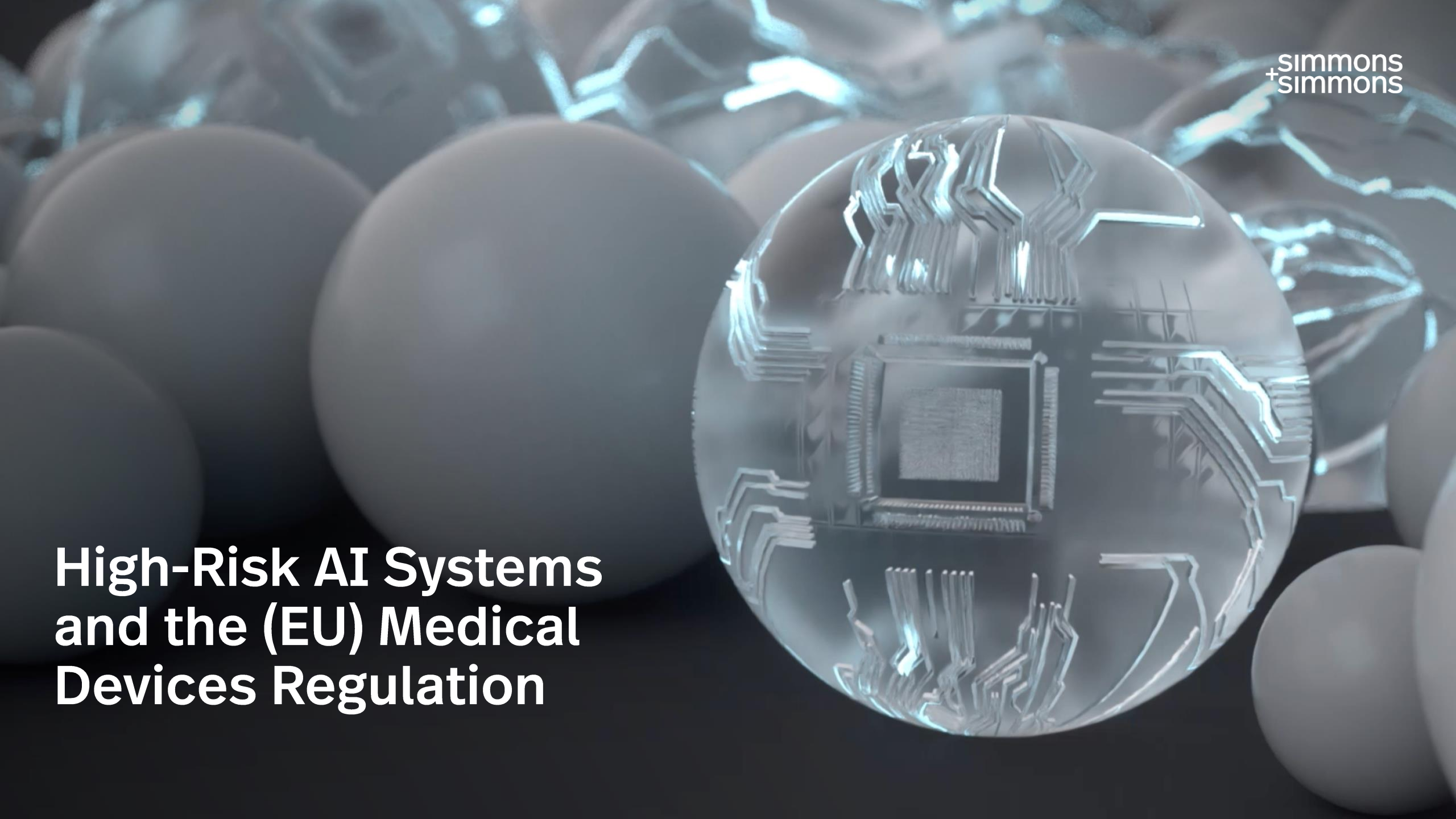
- Before a HRAIS is used
  - Document all the design choices, related assumptions and performance implications, including:
    - Transparently document the characteristics, capabilities and limitations/risks of the system (Article 13)
    - Data selection, processing, and governance (Article 10)
  - Produce accurate Technical Documentation (Article 11)

Design an auditable AI System including logging and allowing human oversight (Articles 12 and 14)

Some key requirements for HRAIS

Key practical points to consider

- Throughout the life of the HRAIS
  - Maintain a Quality Management System (Article 17) including systematic quality control and a documented strategy for regulatory compliance
  - Identify, analyse and mitigate risks (Article 9)
  - Keep records and logs of usage and important events (Article 20)



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High-Risk AI Systems and the (EU) Medical Devices Regulation

HRAIS and the (EU) Medical Devices Regulation

Relevance of the Draft (EU) Artificial Intelligence Act for Medtech

AI Systems may be regulated in two different ways

1. As **components of products** that are already covered by EU legislation (e.g. the EU MDR), such as Medical Device Software (MDS) or other devices
    - for those AI Systems intended to be used as **safety component** of products (MDS / devices) that are subject to third party conformity assessment
    - irrespective of whether the AI System is physically integrated into the product (**embedded**) or serves the functionality of the product without being integrated therein (**non-embedded**)

HRAIS and the (EU) Medical Devices Regulation

Relevance of the Draft (EU) Artificial Intelligence Act for medtech

AI Systems may be regulated in two different ways

1. As **components of products** that are already covered by EU legislation (e.g. the EU MDR), such as Medical Device Software (MDS) or other devices

In that case, the requirements for the HRAIS related to products covered by the EU MDR (e.g. MDS) will be checked as part of the **existing conformity assessment procedure** under the relevant legislation (e.g. MDR conformity assessment procedure)

This leads to an interplay of legal and regulatory requirements:

- **Safety risks specific to the AI System** ⇨ Covered by the AI Draft Regulation
- **Overall safety of the final product** ⇨ Covered by EU MDR, which may contain specific requirements regarding the safe integration of an AI System into the final product

HRAIS and the (EU) Medical Devices Regulation

Relevance of the Draft (EU) Artificial Intelligence Act for medtech

AI Systems may be regulated in two different ways.

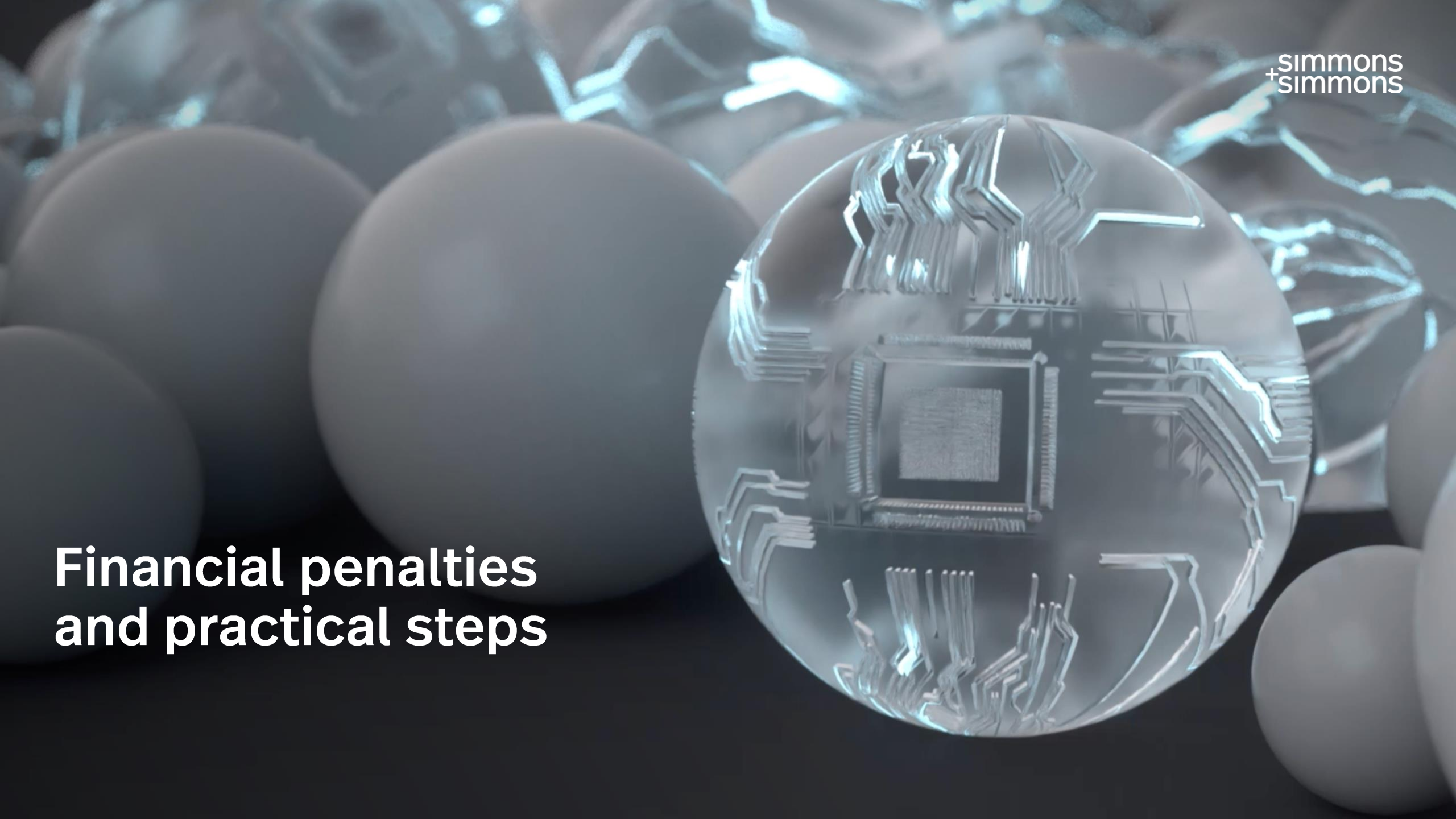
2. As **products in their own right**

   - for those AI Systems designed to operate with varying levels of **autonomy** and to be used on a **stand-alone** basis

HRAIS and the (EU) Medical Devices Regulation

10 convergence points

1. A High-Risk AI System for a **medical purpose** will have to comply with requirements set under MDR and AI Regulation
2. **CE-marking** requirements (all medical devices under MDR / only High-Risk AI Systems under AI Regulation)
3. **Providers** (AI Regulation) and **Manufacturers** (MDR) have similar obligations + **EU Database**
4. Similarly to the MDR, the AI Regulation envisages **notified bodies** (for certain HRAIS)
5. **Integrated** ex-ante (third party) conformity assessment
6. Both Regulations rely on a Risk Management System (**RMS**), Quality Management System (**QMS**), **TD**, etc.
7. **Human oversight** will be required for HRAIS embedded or qualifying as medical device software
8. Both Regulations impose (data) **accuracy**, **robustness** and **cybersecurity** measures
9. Both Regulations impose “post-market monitoring assessment” (= **PMS** under MDR)
10. Both Regulations impose **market surveillance** requirements



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Financial penalties and practical steps

Financial penalties and practical steps

Overview (as in art 71)

- Fines of up to EUR 30m or, in the case of a company, 6% of annual worldwide turnover for non-compliance with requirements relating to (a) Prohibited uses and (b) Data and data governance measures in Article 10
- Fines of up to EUR 20m or, the case of a company, 4% of annual worldwide turnover for non-compliance with other requirements (lower tier of fines for non-co-operation with regulators/authorities)
- Similar turnover based fines (and tiering) structure to those in GDPR, but the 6% is higher than the upper percentage tier of the fines under GDPR
- However, “company” is less expansive than the term “undertaking” which is used in equivalent GDPR provisions (covers corporate groups, with limited exceptions)

What should you do now?

§ Actions

Understand use of AI in organisation

Regulation will force organisations to identify and understand use of AI in business

Impact or Risk Assessment

Organisations should understand impact of Regulation on business because may be prudent to take action now

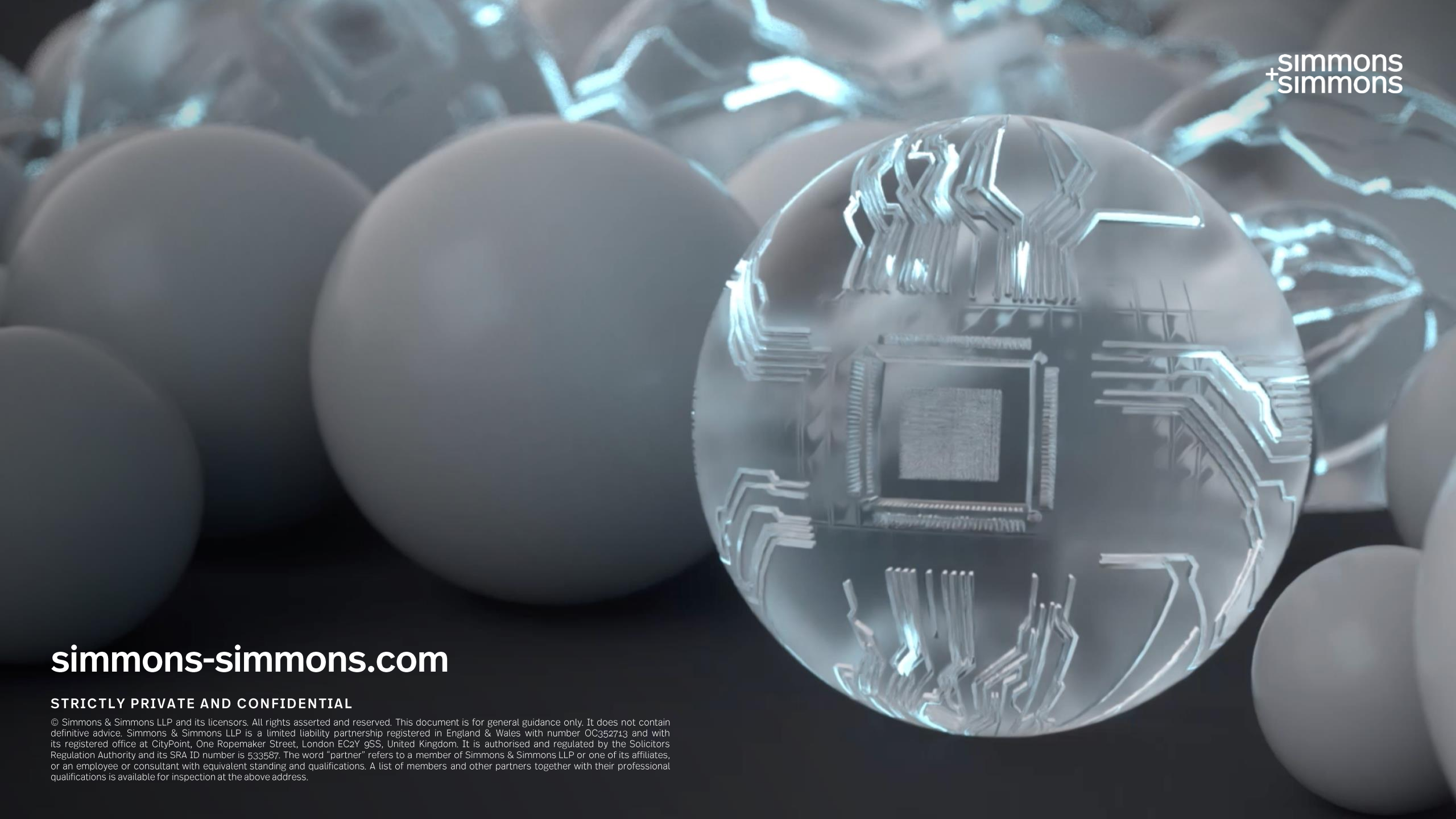
Implement governance

Action likely to be around implementing governance to comply with Regulation e.g. processes, requirements regarding AI Systems

Contractual / legal advice

Consider impact on contracts, any data-related issues and other legal issues which Regulation could create

Thank you



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