

# AI Regulation Draft

Francesca Hennig-Possenti

Senior Counsel – John Deere GmbH & Co KG



# What is AI?



## oecd definition of AI

An AI system is a machine-based system 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.



## EU Institutions definition of AI

“artificial intelligence system’ (AI system) means a **machine-based system that is designed to operate with varying levels of autonomy** and that can, for explicit or implicit objectives, **generate outputs such as predictions, recommendations, or decisions,** that influence physical or virtual environments;

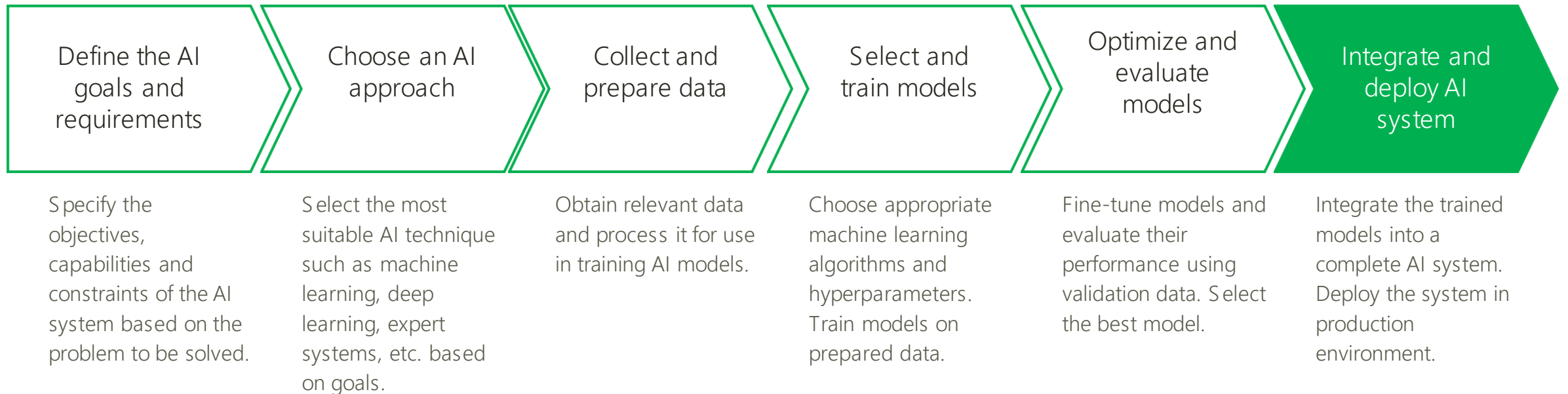


## Executive Order definition of AI

Artificial intelligence systems use machine- and human-based inputs **to perceive real and virtual environments; abstract such perceptions into models** through analysis in an automated manner; and use model inference to formulate options for information or action

Artificial Intelligence technology is a fluid concept, characterized by rapidly advancing technology and diverse areas of application.

# What AI actually is



# Competing laws and regulations



## Legal requirements from multiple regulations

Companies must comply with regulations from various government agencies that sometimes conflict or overlap



## Increasing regulatory burden over time

The number and complexity of regulations as well as the interaction between them has steadily increased over the past years



## High cost of compliance

Complying with complex and conflicting regulations requires significant time and money

Overlapping regulations and laws can become difficult for companies to efficiently comply with

# Overview of upcoming Directives and Regulations

## EU Digital Strategy

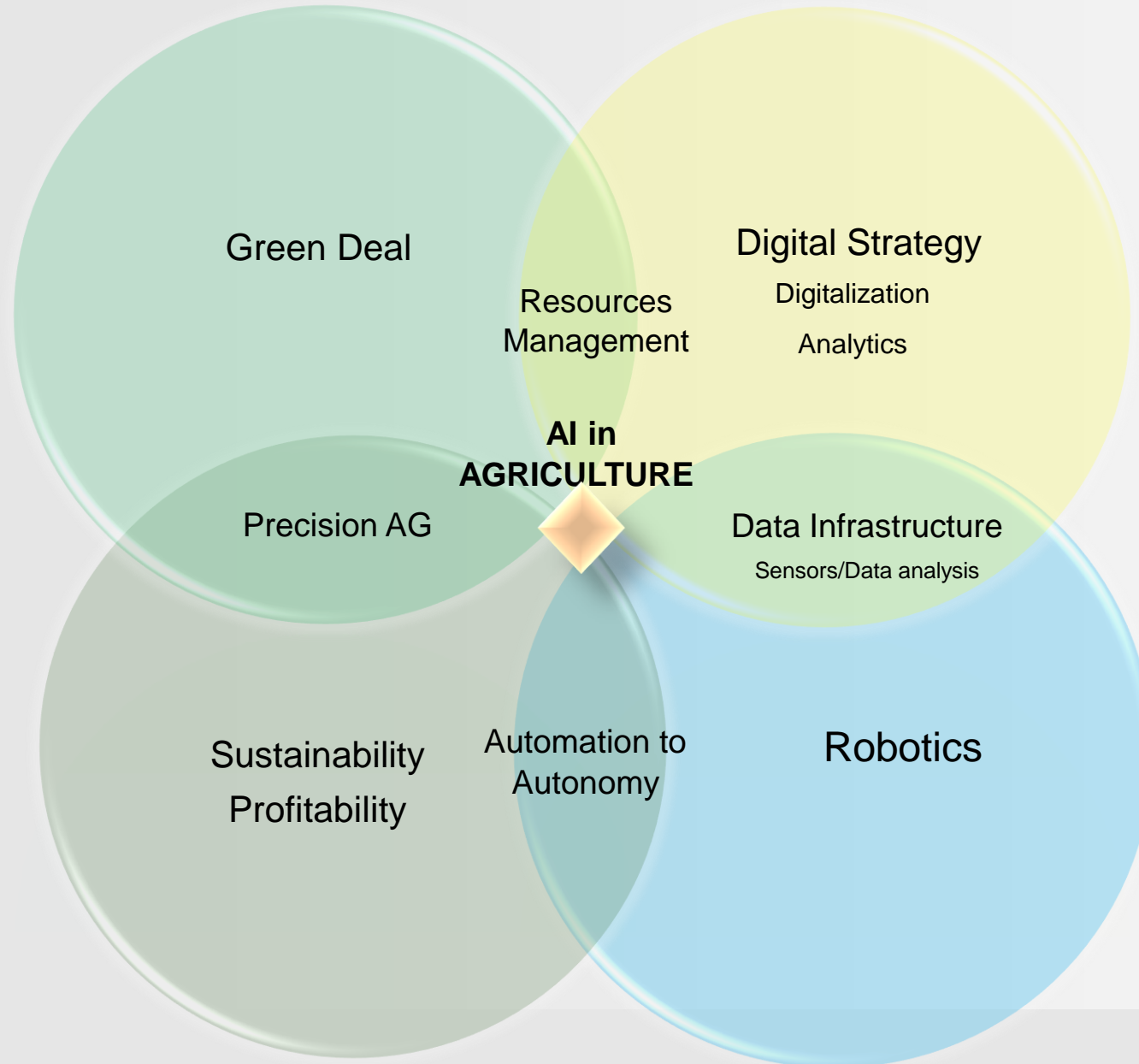
- AI Act (Regulation)
- AI Liability Act (Directive)
- Data Act (Regulation)
- Data Governance Act (Regulation)
- Data Privacy Act (GDPR Regulation)
- Digital Services Act (Regulation)
- Digital Markets Act (EU)
- Cybersecurity (Regulation)
- Cyberresilience (Regulation)
- Product Liability Act (Directive)
- Machine Regulation (Regulation)

# Overview of upcoming Directives and Regulations - 2

## Green Deal and other upcoming legislations

- Corp. Sustainability Reporting Directive
- Supply Chain Due Diligence Directive
- Battery Regulation
- Emission Trading System
- Klimagesetz
- Energy Tax Directive
- Effort Sharing Regulation
- Reg. Land Use Forestry & Agriculture
- Renewable Energy Directive
- Energy Efficiency Directive
- Alternative Fuel Infrastructure Regulation
- Carbon Border Adjustment Mechanism
- Reg. Land Use Forestry & Agriculture
- Renewable Energy Directive
- Energy Efficiency Directive
- Alternative Fuel Infrastructure Regulation
- Carbon Border Adjustment Mechanism

# Artificial Intelligence in Agriculture



# AI Act vs. AI Liability Act

## AI Act

- **Ex ante compliance Regulation (directly applicable in all EU)**
- **Differentiate between prohibited, high risk and moderate risk AI**
- **List compliance requirements to put high risk AI on the market**
- **High sanctions for not compliant AI**

## AI Liability Act

- **Ex post liability Directive (principles to be transposed in national laws)**
- **Defines liability resulting from damages caused by AI**
- **provides a presumption of fault for high risk AI and for non high risk but complex AI**
- **Introduces discovery procedures?**
- **Enhance class actions possibilities**



# EU Institutional process

Commission proposal for a Regulation laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) 2021/0106(COD)

Published on 21/04/2021

Council General Approach – Adopted on 06/12/2022

European Parliament Report on the AI Act – co-Rapporteurs Brando Benifei & Dragos Tudorache

Approved in the IMCO-LIBE Committees on 11/05/2023

Trilogue started to be completed by December 2023

Final Version of the AI Act to be published April/May 2023

# Fundamental Criteria of the Regulation

Recital 1

**Human centric AI (Recital 4)**

**Trustworthy AI**

**Protects (from harmful effects of AI):**

**Safety (Recital 2 c)**

**Health (Recital 2d)**

**Fundamental rights, (Recital 5)**

**Rule of law (Recital 5)**

**Environment**

**Personal data (Recital 2 new)**

**Shall not affect research and innovation (Recital 2f)**

# AI Regulation application range

- **Application range: to all Artificial Intelligence**
- **Territorial Application: all EU territories, products manufactured in Europe or output produced by the system is used in the European Union**
- **Scheduled for 2024**
- **Delay for implementation 18 months after publication**

## New definition of AI in Art. 3

3. 1.1a Definition of Risk: combination of the probability of an occurrence of harm and the severity of that harm

3.1.1b Significant risk: severity+intensity+probability+duration+ability to affect person/s

3.1.1d General purpose AI and 3.1c foundation models: different applications/purposes

3.1.11 putting into service: supply AI for the first use/own use in the EU

3.1.13 reasonably foreseeable misuse: not in accordance with the intended purpose and the instruction for use

3.1.23 substantial modification: modification of the AI after placing on the market who's risk was not assessed in advance

Art. 3.1.44 defines serious accident: death or health damage, disruption of critical infrastructure, breach of fundamental rights, serious damage to property or environment.

# Ethical understanding of AI in the EU

Regulation applies for several different applications of AI

- **Prohibited AI** - AI that create unacceptable risks
- **High Risk Systems** - High Risk AI require the fulfillment of a set of requirements and failure to comply is subject to heavy penalties
- **Regular AI that raises some risks** - Generative AI in the focus
- **Regular AI** – low risk applications

# Criteria applicable to all AI

Charter of value on with the EU is founded

## Art. 4a

- a) **Human oversight**
- b) **Technical robustness and safety**
- c) **privacy and data governance**
- d) **Transparency**
- e) **diversity non-discrimination and fairness**
- f) **Social and environmental well-being**

**Ethical requirements translate in assumptions, data and parameter**

# High Risk AI Systems in AI and Machine Regulation drafts

**High Risk definition Art. 6:**

**AI system may be classified as high risk if:**

- 1. it is a product covered by legislation in Annex II**
- 2. is intended to be used as a safety component for products listed in Annex II**

**AND**

**3. Is required by legislation in Annex II (eg. Machine Regulation) to undergo a third party assessment**

**3. if included in Annex III (critical infrastructures/targeted activities)**

## **Assessment criteria for AI (art 7)**

- a) capabilities and functionalities off the light independent of its intended purpose**
- b) nature and amount of the data processed**
- c) the extent to which the AI system acts autonomously**
- d) The extent to which the use of an AI system has already caused harm to health safety fundamental rights environment democracy and rule of law**
- e) Likelihood of adverse impact**
- f) potential extent of harm and adverse impact**
- g) intensity and ability to affect plurality of persons**
- h) Balance of powers the extent of the availability and use of effective technical solution and mechanism for the control reliability and corrigibility of the AI system**
- i) the magnitude and likelihood of benefit of the deployment of AI system for individual groups and society**
- j) the extent of human oversight and the possibility for human to intercede or override the decision**



# Requirement for High-Risk AI Systems – 1.

- **Risk management System (Art. 9.1-4)**
- **Test requirements (Art. 9.5-8)**
- **Data and Data governance requirements (Art. 10)**
- **Technical documentation (Art. 11)**
- **Record keeping (Art. 12)**
- **Transparency provisions for users (Art. 13)**
- **Human Oversight (Art 14)**
- **Robustness and Cybersecurity measures (Art. 15)**

# Risk Management Systems

## Art. 9

- **Requires producer to establish a risk management process**
- **Continuous process for the lifetime of the product (requirement of a post-market monitoring system)**
- **Integration in existing procedures**
- **Documentation of significant decision and actions taken by AI**
- **Reasonable foreseeable risks in High Risks systems**
- **Evaluation of emerging risks**
- **Definition of risk minimization procedures and systems**
- **Regular updates of processes based on experience**
- **Addressing risks that cannot be eliminated (eg. uncertainty element)**
- **Documentation of testing procedures**

# Data and Data Governance

Art. 10

**Governance practice for:**

- **Design choices**
- **Data collection**
- **Data preparation process**
- **Formulation of assumptions**
- **Assessment of availability, quantity and suitability of data sets**
- **Bias analysis**
- **Identification of possible gaps**
- **Trainings dataset**

# Technical documentation

## Minimum requirements

- a) intended purpose
- b) Interaction with Hardware
- c) the versions of relevant software (+updates);
- d) the description of all forms in which the AI system is placed on the market (e.g. software package, downloadable, API etc.);
- e) the description of hardware;
- f) photographs or illustrations showing external features, internal layout of those products;
- g) instructions of use;
- h) A detailed description of data governance and risk management



**JOHN DEERE**