European Union: AI Act
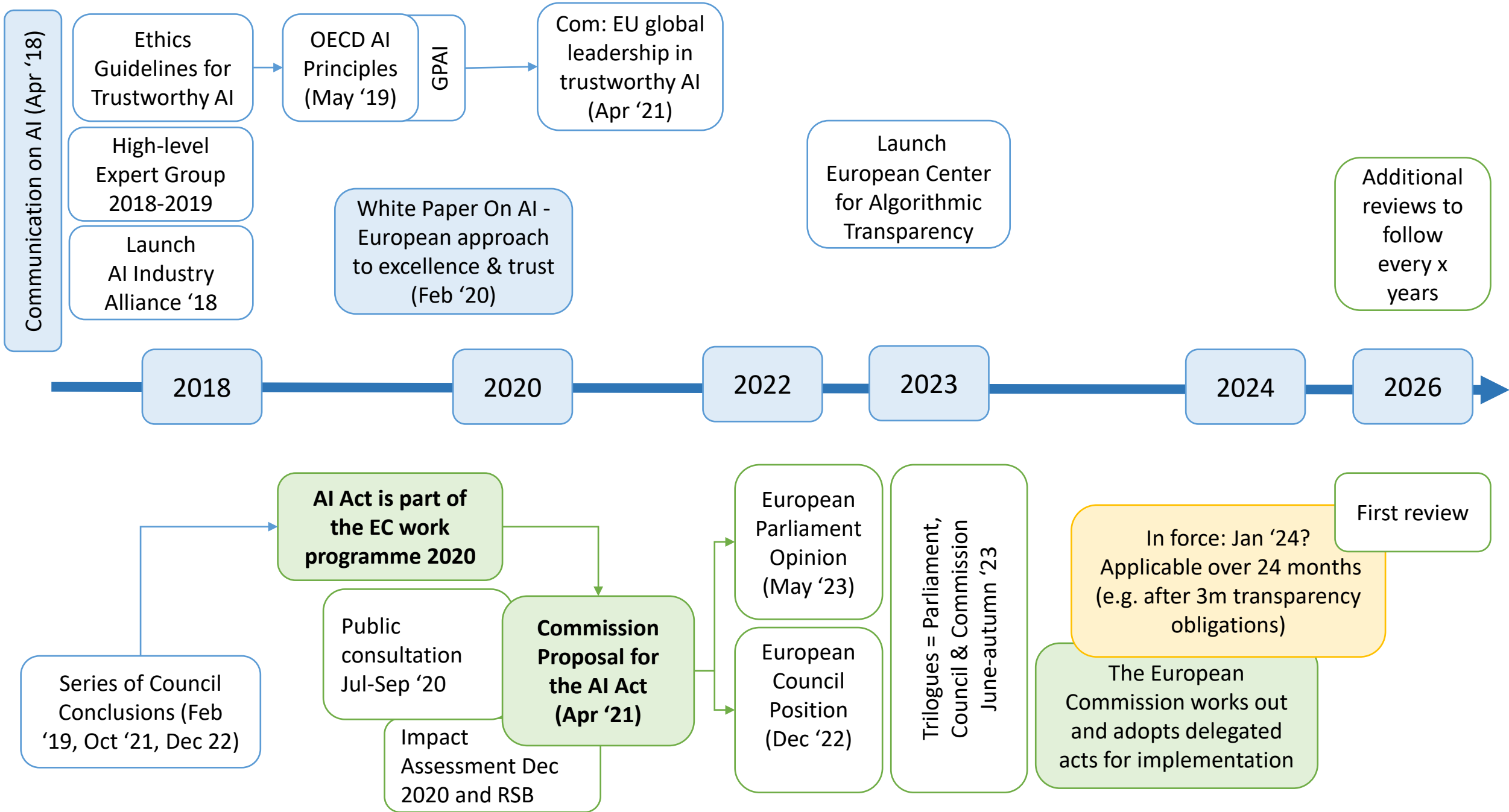
❖ People and businesses should be able to **enjoy the benefits of AI** while feeling safe and protected ("trustworthy AI").

❖ It's a **framework** regulation: 85 articles, 88 pages and still requires secondary legislation adopted by the European Commission (called **delegated acts**). Citizens, businesses, public sector and academia

❖ **Classic example** of how the regulatory sausage is made (meticulously)

❖ **Reviews**: 2026, then every 2-3 years

❖ In a **risk-based approach** it applies to all business.

❖ **It was proposed by the European Commission on 21 April 2021 and will soon enter into force**

... **but there is a story before and after ...**

Communication on AI (Apr '18)

Ethics Guidelines for Trustworthy AI

OECD AI Principles (May '19)

GPAI

Com: EU global leadership in trustworthy AI (Apr '21)

Launch European Center for Algorithmic Transparency

Additional reviews to follow every x years

High-level Expert Group 2018-2019

Launch AI Industry Alliance '18

White Paper On AI - European approach to excellence & trust (Feb '20)

2018   2020   2022   2023   2024   2026

AI Act is part of the EC work programme 2020

European Parliament Opinion (May '23)

Trilogues = Parliament, Council & Commission June-autumn '23

First review

Public consultation Jul-Sep '20

Commission Proposal for the AI Act (Apr '21)

European Council Position (Dec '22)

In force: Jan '24? Applicable over 24 months (e.g. after 3m transparency obligations)

Series of Council Conclusions (Feb '19, Oct '21, Dec 22)

Impact Assessment Dec 2020 and RSB

The European Commission works out and adopts delegated acts for implementation

Risk level	Examples of AI systems	Allowed in the EU?
Unacceptable risk	Social scoring used by governments; toys using voice assistance which encourages dangerous behaviour	No
High risk	Scoring of exams; AI application in robot-assisted surgery; verification of authenticity of travel documents	Yes, subject to mandatory requirements, ex-ante and ex-post enforcement
Limited risk	Chatbots; *"deep fake"* videos	Yes, subject to transparency requirements
Minimal risk	AI-enabled video games; spam filters	Yes

Is HC high-risk?

1) Ensuring health & safety is the overarching ambition:
- Regulation (EU) 2017/745 on medical devices
- Regulation (EU) 2017/746 on in vitro diagnostic medical devices

Example: emergency healthcare patient triage system

There are emergency exceptions possible

2) Public authorities healthcare (benefits/services) are high risk

3) Regulatory sandbox

More: https://digital-strategy.ec.europa.eu/en/policies/european-approach-artificial-intelligence