

Placing standalone
AI in the EU
market under the
proposed EU AI
regulation



Ex ante requirements, before AI is placed into the EU market:

Check if it is
banned

1

Check if it is
deemed High
Risk AI

2

If yes, follow
conformity
assessment

3

CE marking
required

4

Registration in
Eu database

5

Place on the EU
market & post
market
requirements
kick in.

6

Banned AI

Are used by or for public authorities for evaluation or classification of the trustworthiness and social scoring of natural persons.

Deploys subliminal techniques beyond a person's consciousness in order to materially distort a person's behavior in a manner that causes or is likely to cause that person or another person physical or psychological harm.

(a) placing on the market,
(b) putting into service ,
(c) use, AI Systems that:

Exploit vulnerabilities of a specific group of persons due to their age, physical or mental disability, in order to materially distort the behavior of a person pertaining to that group in a manner that causes or is likely to cause that person or another person physical or psychological harm.

Authorised however where strictly necessary

Use of 'real-time' remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement.

High Risk AI

Annex 2

AI in products or safety components of products

Covered, by EU Sectorial law including:

- (a) Transport
- (b) Radio equipment
- (c) Medical Devices
- (d) Machinery
- (e) Safety Equipment

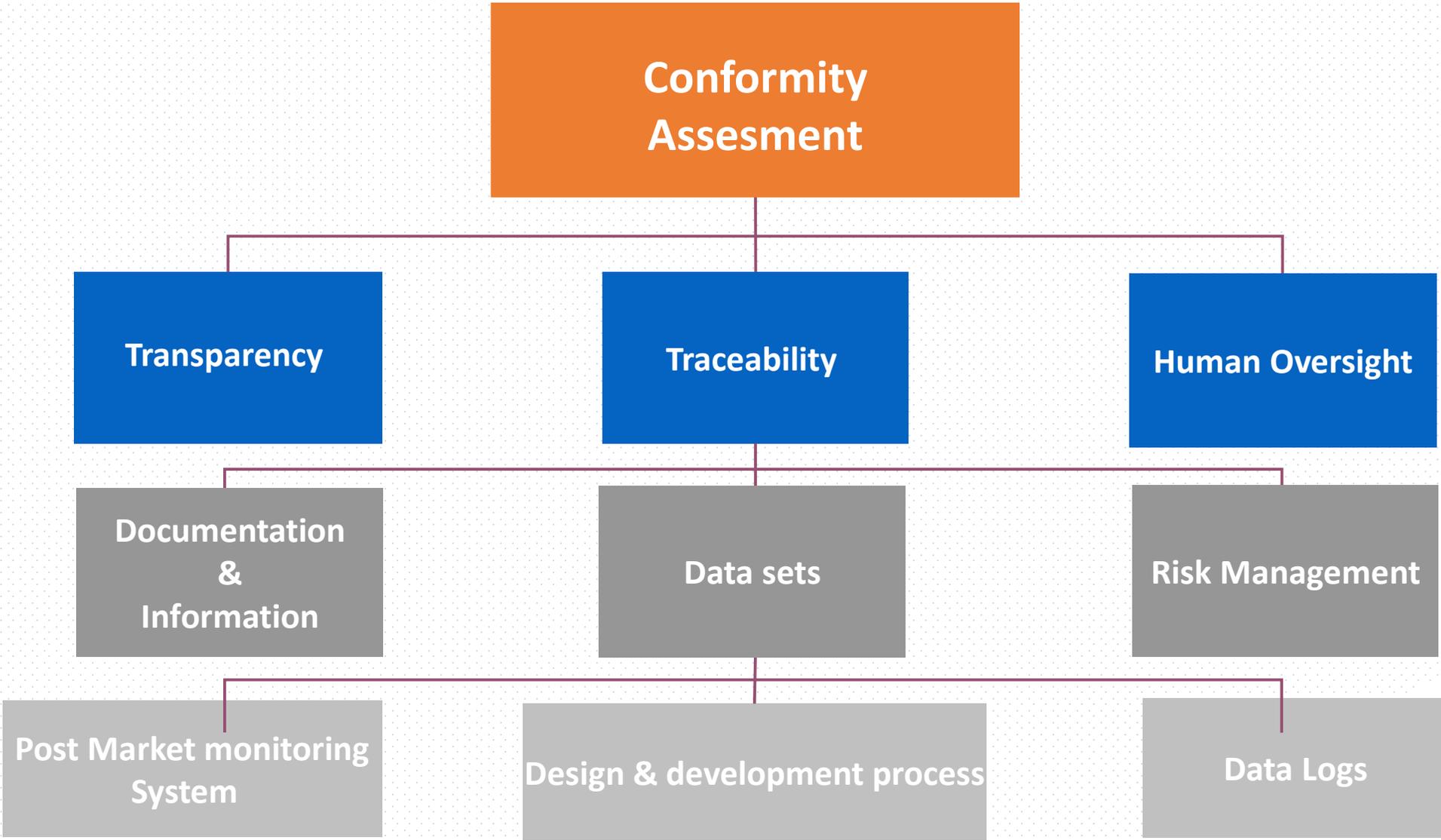
Conformity as per
Applicable EU Sectorial
Law.

Annex 3

Other high risk AI applications such as:

- (a) Biometric identification & categorisation of persons
- (b) Managing of critical infrastructure
- (c) Employment
- (d) Vocational & educational training
- (e) Access to essential private & public services
- (f) Administration of justice

The list can be updated by the EU subject through delegated acts.





CE Marking

- Follow Process for obtaining CE Mark under Regulation.
- CE marking shall be affixed visibly, legibly and indelibly for high-risk AI systems. Where that is not possible or not warranted on account of the nature of the high-risk AI system, it shall be affixed to the packaging or to the accompanying documentation, as appropriate.
- Where applicable, the CE marking shall be followed by the identification number of the notified body responsible for the conformity assessment procedures set out in Article 43. The identification number shall also be indicated in any promotional material which mentions that the high-risk AI system fulfils the requirements for CE marking.

Registration in a centralised EU register

Providing for a robust monitoring and evaluation mechanism by EU.



Establish a system for registering stand-alone high-risk AI applications in a public EU-wide database.



This registration will also enable competent authorities, users and other interested people to verify if the high-risk AI system complies with the requirements laid down in the proposal and to exercise enhanced oversight over those AI systems posing high risks to fundamental rights.



To feed this database, AI providers will be obliged to provide meaningful information about their systems and the conformity assessment carried out on those systems.

Ex post controls for AI

- Monitoring, investigating and reporting obligations for providers of AI systems related to AI-related incidents and malfunctioning.
- Market surveillance authorities would also control the market and investigate compliance with the obligations and requirements for all high-risk AI systems already placed on the market.
- Market surveillance authorities would have all powers under Regulation (EU) 2019/1020 on market surveillance to :
 - intervene in case AI systems generate unexpected risks, which warrant rapid action.,
 - monitor compliance of operators with their relevant obligations under the regulation
 - Investigate and request access were justified to any data and documents maintained pursuant to the regulation.
 - Impose fines and administrative actions
- This is without prejudice to the existing system and allocation of powers of ex-post enforcement of obligations regarding fundamental rights in the Member States.



Regulatory Capture

- To ensure legal certainty and facilitate regulatory compliance specific obligations apply for;
 - users,
 - Importers,
 - distributors or
 - any third parties.

Thank you!!

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