Tsibanoulis & Partners LAW FIRM

FRIA Essentials: Understand and Prepare Timely with Confidence

Tina Kamilaki, Senior Associate | 06 June 2025

The EU Artificial Intelligence (AI) Act (Regulation (EU) 2024/1689) outlines a regulatory framework in order to ensure that fundamental rights are safeguarded when high – risk AI systems are involved. According to Article 113 of the EU AI Act, obligations for high risk AI systems listed in Annex III (i.e. AI systems that are intended to be used for high-risk use cases such as in the areas of education, employment, law enforcement or migration) will apply from 2.8.2026, while obligations for high-risk AI systems listed in Annex I (i.e. AI systems which are embedded as a safety component in products covered by existing product legislation or constitute such products themselves, such as AI-based medical software) will apply from 2.8.2027.

Hence operators of high-risk AI systems should comply with certain obligations, whereas non - compliance could lead to administrative fines of up to 15,000,000 Euros or, if the offender is an undertaking, up to 3 % of its total worldwide annual turnover for the preceding financial year, whichever is higher (Article 99).

A key requirement of the AI Act is that organisations (such as banks, insurance companies, public authorities etc.) deploying high-risk AI systems must carry out a Fundamental Rights Impact Assessment (FRIA). Although the AI Act does not explicitly define the FRIA, it does clarify the purpose of the assessment and mentions what its minimum content should be. In outline, the FRIA, which should be conducted by organisations prior to deploying a high-risk AI system and which should always be updated, is a systematic examination of potential risks that an AI system might pose to fundamental rights and its objective is to evaluate and mitigate such risks (see recital 96 of the AI Act).

In accordance to article 27 (1) of the AI Act, the FRIA should consist of the following:

(a) a description of the deployer's processes in which the high-risk AI system will be used in line with its intended purpose;

(b) a description of the period of time within which, and the frequency with which, each high-risk AI system is intended to be used;

(c) the categories of natural persons and groups likely to be affected by its use in the specific context;

(d) the specific risks of harm likely to have an impact on the categories of natural persons or groups of persons identified pursuant to point (c) of this paragraph, taking into account the information given by the provider pursuant to Article 13 (transparency obligations);

(e) a description of the implementation of human oversight measures, according to the instructions for use;

(f) the measures to be taken in the case of the materialisation of those risks, including the arrangements for internal governance and complaint mechanisms.

The FRIA bears resemblance to the Data Protection Impact Assessment (DPIA) conducted pursuant article 35 of the General Data Protection Regulation (GDPR), highlighting the close connection between data protection and fundamental rights in the realm of AI system. Since many high-risk AI systems may process personal data and hence deployers should comply with GDPR, their connection is very strong, although FRIA assesses a broad spectrum of fundamental rights, including but not limited to data privacy obligations. Article 27(4) of the AI Act explicitly allows the use of an existing DPIA to fulfil the obligations of FRIA in connection with data privacy.
Conducting a FRIA is a challenging process that demands deep knowledge of Human Rights Law, AI Act and GDPR, in addition to the expertise needed to assess advantages against possible risks. A thorough, well – documented and comprehensive FRIA is essential in order for companies to demonstrate the responsible usage of AI practices, mitigate risks, avoid penalties and costly legal proceedings, as well as foster transparency and trust with users and regulators.

Tsibanoulis & Partners LAW FIRM

Key contacts

Dr. Dimitris Tsibanoulis
Senior & Managing Partner
d.tsibanoulis@tsibanoulis.gr

Tina Kamilaki
Senior Associate
t.kamilaki@tsibanoulis.gr

Tsibanoulis & Partners Law Firm
18 Omirou St.
106 72 Athens | Greece
T: +30 210 3675 100
W: tsibanoulis.gr