Position paper on general approach of the proposed Artificial intelligence Act

The Hub France IA is the catalyst of the **artificial intelligence ecosystem in France**. As an association, it federates more than 150 members and partners in order to accelerate the development of concrete proposals and solutions at national and European levels. The Hub France IA acts to promote the emergence of a **trustworthy and sovereign AI**, respectful of citizens and at the service of businesses and the public sector.

The members of the working group dedicated to the proposal for a Artificial intelligence Act wished to inform the European Parliament, the Council of the European Union and the Commission of their unified positions under the aegis of the Hub France IA and concerning the **general approach adopted within the WP TELECOM of 6 December 2022**.

In parallel to this position paper, the Hub France IA and its European partners (*appliedAI*, *KI Bundesverband*, *AI Austria*, *AI Poland*, *AI Sweden*, *NL AI Coalitie*, *etc.*) published on December 12, 2022, the conclusions of a survey on the impact of the AI Act on the European AI ecosystem, particularly with regard to startups. This survey warns of the risks of loss of competitiveness and investment for the European AI ecosystem[1].

In order to best accompany the future application of the proposed Artificial intelligence Act and to bring a unified position to the parliamentary debate or to the possible trialogue procedure, the members of the France IA Hub bring to your attention the following elements:

[1] The conclusions are available at the following URL: https://www.hub-franceia.fr/wp-content/uploads/2022/12/AI-Act-Impact-Survey_Report_Dec12.2022.pdf

- **On the definitions used, in particular for artificial intelligence systems**

The definition of an "artificial intelligence system" (AIS) in the general approach removes the list of technologies described in Annex I. Such a change reduces the possible market impacts that would have been caused by each change to the Annex. Conversely, the deletion of this annex obliges legislators to resort to a European regulatory procedure whenever they wish to amend the proposed definition.

The definition now adopts **a data-driven approach rather than one based on the use of one or more techniques**.

The addition of elements relating to system autonomy in the definition of an AIS tends to reduce the scope of the AI Act. However, this notion of autonomy introduces many legal uncertainties and an amalgam between analysis systems and decision systems.

- The elements of autonomy should be clarified either by a harmonised standard or by the doctrine of the governance body in charge of the application of the Regulation;
- If the definition of AIS refers to machine learning, it seems more accurate to prefer the notion of learning processes only (by deleting the term "machine").

The definition of "substantial modification" is a sensible addition made by the European legislator. We welcome the exclusion of training and self-learning carried out within the framework of the provider's predetermined modalities from this approach. However, a legal vagueness remains in this notion and needs to be clarified. This approach, as it stands, should either be the subject of a harmonised standard or common specification, or be specified in advance by the supplier in its technical documentation (thus opening up a risk during the negotiation phase).

The definition of "AI regulatory sandboxes" adopted by the Council of the European Union provides - from a legal point of view - a definition that is necessary for the generalisation of this type of experimentation, both within French and European law.

- We regret that the definition does not specify the possibility for the national competent authority to introduce exceptions to the regulatory obligations (currently referred to as a specific plan), as well as the need for the supplier to comply with the AI Act after a given time;

- The definition also does not state that this experimentation must be carried out on a defined sample, in particular in a specific space (see the definition of testing in real world conditions).

- **On general purpose artificial intelligence systems**

The introduction of the concept of a general purpose artificial intelligence system in the proposal for a regulation on artificial intelligence raises questions for the authors of this position paper.

However, as the paper stands, there are a number of questions:

- Placing these compliance requirements on the person(s) developing an algorithm does not reflect the technical reality. Some pre-trained models are made by a plurality of actors, who cannot necessarily consider all the purposes and use cases of their model or the interaction of their model with other resources. This is particularly the case when these bricks are offered in open source or from projects via GitHub;

- The current legal regime foresees to be clarified by implementing acts that "adapt the application of the requirements established in Title III, Chapter 2, to general purpose AI systems in the light of their characteristics, technical feasibility, specificities of the AI value chain and of market and technological developments". This approach provides flexibility in the decisions implemented by the EU Commission, but also creates a blurring of the application. It also seems important to adopt a graduated response according to the situation of the provider concerned, in particular in order not to reduce innovation and not to create strong constraints on start-ups;

- The introduction of a "presumption of a high-risk AIS" is an interesting approach, which may however become a de facto obligation. Indeed, a supplier may have a reverse burden of proof imposed on him, by having to expressly exclude the further use of his pre-trained model in a high-risk AIS. Moreover, the regime currently envisaged does not fully allow the supplier to exclude the use of its model in a high-risk AIS. Indeed, the latter must be motivated in good faith (i.e. it cannot be chosen if the general purpose AIS can legitimately be used in a high-risk AIS) and, where applicable, if the supplier finds that, despite its exclusion, a user has used the general-purpose AIS in a high-risk AIS, it must implement all the necessary measures to ensure that such a situation does not recur or to comply with the expected requirements ;

- It also seems essential to ensure that the requirements of Chapter 2 of Title III can be effectively applied to general purpose AIS. It seems complex to us to implement all these obligations, when the main purpose of the processing carried out by the final supplier (the one using a pre-trained model) is not necessarily known. Questions may also arise in terms of transparency or even human supervision, or even cyber security. In this respect, we also draw the attention of the European legislator to the articulation of this legal regime with the Cyber resilience act (CRA).

- **On high-risk artificial intelligence systems and their compliance**

The implementation of a compliance process for high-risk AIS is a concrete lever to make the European Union a trusted third party. The risk of an AIS must be assessed through its purposes, its use and the protections afforded to the data, in particular in accordance with fundamental rights. This compliance makes it possible to take up some of the ethical

principles as devised by the High Level Expert Group (HLEG) and integrate them "by design" into the design of an AIS.

- We appreciate the introduction of flexibility for suppliers, in particular in the evolution of the qualification of a high risk AIS. The current version of the text now excludes AIS "[...] referred to in Annex III [if] the output of the system is purely accessory in respect of the relevant action or decision to be taken [...]". **This consideration of the influence of the results according to their destination and/or purpose makes it possible to lighten the compliance procedure** according to significant imperatives;

- We question the appropriateness of adding as high risk AISs intended to be used for valuation and underwriting purposes in relation to individuals in life and health insurance;

- We welcome the need to introduce a specific reference to transparency in relation to AISs on the recognition of emotions;

- As regards the contractual relations between the various parties involved, it seems to us essential that the search for liability should focus first and foremost on the obligations of the natural or legal person who places an AIS on the market, as well as the obligations of the user(s). An action against another party to the contractual relationship must demonstrate compliance with the obligations of each of these parties. These obligations must be analysed in a reasonable manner in relation to the expected risks of use;

- Regarding the risk management system, transparency and provision of information to users, we note that the wording of "validation by testing" and the use of "probabilistic thresholds" may be more restrictive than usual practice. As such, we recommend the sole use of the notion of "validation" and believe that it is up to the harmonised standards to define the technical means to achieve the "validation" requirement which should be the requirement of this Regulation;

- On data governance and in particular the fight against bias, we welcome an obligation of means, as regards "examination in view of possible biases that are likely to affect health and safety of natural persons or lead to discrimination prohibited by Union law". This approach makes even more sense, as it reduces the scope of the obligations to only those purposes that may have risks on individuals, by also providing for a specific case of use of personal data with regard to the RGPD (in particular: "To the extent that it is strictly necessary for the purposes of ensuring bias monitoring, detection and correction in relation to the high-risk AI systems, the providers of such systems may process special categories of personal data ").

- **On harmonised standards and common specifications**

The legislative approach adopted by the legislators is based on the "New Legislative Framework" (NLF), adopted in 2008. This approach describes the general structure that European legislation follows and the tools available for its effectiveness, i.e. all the elements necessary for effective conformity assessment, accreditation and market surveillance. Moreover, by using harmonised standards and specifications on the basis of Regulation (EU) No 1025/2012, the proposed Regulation on artificial intelligence establishes general principles supplemented by European standards, whether or not

published in the Official Journal of the European Union. This legislative construction shifts the technical issues to the level of private law standardisation bodies.

- We regret the withdrawal of the use of harmonised standards or common specifications for compliance with the requirements for high-risk SIA;

- We consider it appropriate to introduce suitability criteria for notified bodies, so that the use of harmonised standards and common specifications in a system assessed by a notified body in a third country is automatically recognised by another country.

- **On measures in favour of innovation**

The introduction of the so-called "AI regulatory sandbox" approach is to be welcomed. This approach has undergone significant changes since the publication of the proposed regulation by the EU Commission:

- We draw attention to the implementation of experimentation, which, if not limited in time, is not necessarily limited to a specific sample. These elements have an impact on the French Constitution, in particular Article 37-1, as the Guide to Legislation also states;

- We welcome the possibility of testing in real world conditions (post-market), as well as the guarantees that must be provided by the competent national authorities in charge of experimentation;

- With regard to the complementary mechanism for testing high-risk AIS in real-life conditions, we welcome the importance given by the proposed Regulation on artificial intelligence to the issues of ethical review that may be required by national or European law. **This approach indirectly reinforces the need for an "ethical AI" approach**. We also appreciate the need for informed consent for a user to participate in such trials.

More specifically, with regard to startups, VSEs and SMEs, we appreciate the initial efforts made to strengthen the innovation potential of each Member State:

- Priority access to regulatory sandboxes;

- Specific support measures (training, compliance costs, information platform);

- Adaptation of the sanctions provided for in proportion to their size, the size of their market and other relevant indicators which remain to be defined.

- **On the articulation of the IA Act with other European texts**

The effective implementation of the proposed regulation on artificial intelligence requires that the link between this text and the multitude of texts adopted or being negotiated within the European Union be effective.

We therefore believe that it is necessary to take into consideration:

- The proposed **directives on liability in AI** including the Artificial Intelligence Liability Directive [AILD] and the revised Product Liability Directive [PLD]. These two texts define the rules on liability, intervening ex post, while the proposed AI Act provides for the contractual chain and presumptions of liability;

- The **General Data Protection Regulation** (GDPR), which sets out rules for the collection, use and protection of personal data. The general approach version already provides for a better articulation with this text, despite the emerging difficulty around the notion of "group" of persons (as it currently appears, notably in Articles 5, 7 and 10, as well as in Annexes III and IV of the GDPR). Finally, we hope that the designation of the EDPS as the European body in charge of the operational declination of the IA Act will allow for the harmonisation of the articulation of these two texts, the first of which is about data protection, while the second is about the related processing;

- The proposal for a **European regulation on horizontal cybersecurity** requirements for products with digital elements (Cyber resilience act) already provides for a link with the proposal for a regulation on artificial intelligence, which could be reinforced.

We are also paying particular attention to the increasing number of governance bodies established for each text. If digital technology is at the heart of European priorities, it seems essential to us to rationalise the number of governance bodies to the lowest common denominator, to reduce the risk of legal uncertainty that could impact on economic players. There is a real need for transparency on these aspects.

- **On the desire to adopt a text with extra-territorial scope**

The proposal for a regulation on artificial intelligence adopts an extra-territorial scope, following the example of the General Data Protection Regulation. This type of mechanism can give European companies a competitive advantage, particularly in a role of trusted third party and respect for the personal rights of users.

We believe that it is necessary to align the extraterritorial scope of this text with the draft convention on artificial intelligence, human rights and the rule of law envisaged within the Council of Europe, in particular with regard to the fundamental principles envisaged from development to operation of AIS.

In addition, other countries have indicated a willingness to act on artificial intelligence legislation, including:

- The UK's approach to AI regulation, published in July 2022 and to be the subject of a white paper;

- Canada's AI Bill C-27, which may also have extraterritorial application;

- The US "Blueprint for an AI Bill of Rights" and the "Technical Companion", setting out non-binding principles that could serve as a framework for possible future legislation.

Taking these elements into consideration has all the more impact, as they lead to a real challenge to participate in the standardisation of the various technical specificities relating to artificial intelligence.

- **On the entry into force and foreseeable dates of application of the text**

We support the new approach proposed by the general approach. The old wording allowed AIS placed on the market before the date of entry into force to remain available for three years before being brought into conformity or withdrawn from the market.

The new wording now considers that AIS placed on the market or put into service three years after the entry into force (instead of two years) are subject to the requirements of the IA Act, while AIS already on the market will only be subject to these requirements in case of significant changes in their design or purpose.

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