



ETSI Contribution to the consultation on the draft AI Regulation

Preamble

ETSI welcomes the draft Regulation on AI presented by the European Commission (EC) at <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52021PC0206>. The draft Regulation builds on the processes of the New Legislative Framework (NLF) putting harmonised European Standards into the focus of demonstrating compliance with the regulatory requirements. This is in line with the view of ETSI that "The NLF should be used for technical regulation in new areas including AI and data."

ETSI has analysed the draft AI Regulation in an activity involving the ETSI Board as well as ETSI's expert group on AI, set up across all technical committees and groups working on AI, the OCG-AI group. ETSI has many activities in the area of AI, focusing on applications in or using ICT. A concise overview from our working groups is available on the OCG-AI's web site at <https://portal.etsi.org/TB-SiteMap/OCG/OCG-AI-Co-ordination>.

With this document ETSI provides feedback on the draft Regulation based on the broad spectrum of expert knowledge available in ETSI. This includes in depth knowledge of AI technologies and systems as well as expertise present in ETSI on European standardisation, e.g. from the work on harmonised standards in support of other technical regulation and on the basis of ETSI's ENAP process for the development and adoption of harmonised standards.

ETSI also thanks the EC for the established close dialogue and exchange on the draft AI Regulation. This dialogue is very helpful for ETSI in its role as a European Standardisation Organisation to prepare for the upcoming tasks of developing harmonised European standards on AI.

1. On the technical aspects of the draft Regulation on AI

Overall, with the Regulation of AI, in a style similar to the NLF, Europe enters a new area in technical regulation by applying the NLF model to software. While there are some examples that this works well and that also the life-cycle of a product can be addressed well in that way, it is still a new area which also means that all parties will be on a learning curve.

ETSI has expertise - in particular with the EMCD, RED and Accessibility and their respective harmonised standards - ETSI is ready to leverage this expertise to achieve successful development of harmonised European standards in support of the future Regulation on AI.

Definition of AI

It has been noted that the current definition of AI as proposed by the EC in TITLE 1 Article 3(1) and in Annex I may be misinterpreted insofar as even the use of a spreadsheet for calculating some statistics may fall under the ANNEX 1 list of techniques at point (c)

We welcome the clarification made verbally by the EC that this is not what is intended and appreciate the readiness of the EC to provide written clarification of their definition of AI for the purposes of



standardisation. ETSI understands that the first step in application of conformance rules is to check if a software (AI) solution falls into the category of High-Risk, and only afterwards to check whether the technology is one that is described in the broad types listed in Annex 1. Therefore the clarity of classification of "high-risk AI systems" (Annex III) is very important.

ETSI invites the EC to engage in further discussions related to the definitions of AI and AI systems in order to clearly differentiate i) those AI functions and systems that are considered high-risk and fall under this regulation; ii) those AI functions and systems requiring recommendations to the industry to be applied; and iii) those AI functions and systems requiring no regulation.

Regulation of High-Risk Systems

The allocation of any particular AI application to a risk level (fitting the risk model of the Commission) is a first approximation, and it may need reviewing on a case by case basis as experience with deployed AI solutions shows that the AI solution use case is higher or lower risk than expected with regard to human values/lives. Such reviews must be performed transparently and with some transition period for changes. It would greatly aid efficient development of standards and detection of "standardisation gaps" if the EC would establish a collaborative effort to create examples of use cases that are definitively "high-risk".

No ex-ante Conformance requirements on "early adopter" AI Solutions

ETSI welcomes the assurance of the Commission that solutions entering the market prior to the AI Regulation coming into force will not be subject to ex-ante regulation and conformance testing. At the same time, it is understood that when substantial updates of such solutions are made, in the normal business of adaptive solutions, then the updated solution must be assessed to see whether it is subject to constraints under the AI Regulation. In such case, the standards and testing and conformance rules will apply that have in the meantime been established. With its role as an ESO and its open and inclusive standardisation processes ETSI will have a key role in assisting market participants as well as regulators here by providing all information about standards under development in the usual highly transparent manner so that all stakeholders can follow and participate in the development processes and prepare for adoption of the respective standards.

Monitoring of some AI Solutions in the market

Article 64 "Access to data and documentation" specifies that the market surveillance authorities shall be granted full access to the training, validation and testing datasets used by the provider, including through application programming interfaces ('API'). It is understood by ETSI from remarks made by the EC that this is not intended as a routine event, but for exceptional cases, and that the "API" need be openly defined but not the same in all cases, i.e. the API does not need to be a single interface for all the various AI solution on the market.

ETSI also recommends that documenting the processes utilized to ensure training data quality could be used by market surveillance authorities instead of accessing training data which would then need to be stored for an indefinite period of time. For example, collaborative federated solutions for obtaining and integrating training data across a number of distinct data holders demand a more flexible approach for quality assurance than accessing the training data itself.



In a similar approach, the documented process for obtaining datasets for validation (testing for types of bias, etc) is a more generally valid and efficient market surveillance exercise than is examination of the datasets themselves. The validation datasets are also different in nature to the Training datasets and need to be considered differently. ETSI would welcome a dialogue and possibly jointly agreed standards/guidelines on appropriate validation methodologies.

Mutual International Recognition of Solutions

ETSI is made up of members from all over the planet so we strongly appreciate efforts to create synergies of regulation concepts globally, to avoid barriers to trade. In the long term, after a period of testing in the market place, a number of bilateral Mutual Recognition Agreements with major trading partners would be to the benefit of EU citizens (who might use best-of-breed solutions including from international sources) and for EU businesses (which might market their solutions internationally without needing major re-fitting of software).

2. On the close collaboration between the European Commission and the ESOs

ETSI appreciates the regular exchange established with the three ESOs. Close collaboration is very important to ensure effective work in the ESOs and thus effective support for the implementation of the Regulation.

3. The European Artificial Intelligence Board (EAIB)

ETSI stands ready to contribute expertise towards tasks of the European Artificial Intelligence Board (see Article 58). ETSI proposes that the European Standardisation Organisations be allocated a Membership / Observer status to this Board so as to closely assist the work including minimising delays.

4. On the development of harmonised European Standards

It is important to have Standardisation Requests early in order to start working on mutual understanding of what is needed for the harmonised standards and to speed up their production.

ETSI welcomes the confirmation from the EC that :

- (i) it is intended to issue standardisation requests before the adoption of the Regulation, probably by the end of 2021 or early 2022 ; and
- (ii) the European Commission will actively participate in the standards development committees and be part of the development process from beginning to end.

These factors will help to ensure that the EC's requirements are met in a timely way and to support the respective technical committee(s) for meeting the detailed requirements of the respective standardisation requests. Finally, it will ensure that the final standards will be ready to be cited in the OJEU.



Such involvement of the EC will also address reservations against the provision in Article 41 which states that if harmonised standards "do not exist or where the Commission considers that the relevant harmonised standards are insufficient or that there is a need to address specific safety or fundamental right concerns" then the Commission may adopt other specifications. With the EC being an active participant and constantly monitoring the progress of the development of the harmonised standards, such a possible situation will be avoided. The NLF has proved to be highly effective and successful regarding the provision of safe and trusted products and technologies for the single European market.

ETSI will support involvement and interaction and close exchange with other organisations throughout the standards development process. ETSI's processes fully support this way of working. ETSI Staff support will further help ensure successful and results oriented standards development. The integration of European work with international standardisation work is welcomed, provided that it happens in a transparent way that involves all stakeholders. Moreover, ETSI has multiple cooperation and liaisons in place with other standards bodies worldwide and processes in place for adopting technical specifications from other sources.

ETSI recognizes that some fundamental aspects of AI solutions, and also the means to test and monitor them as required by the AI Regulation, may still require additional research and development. Some of the monitoring requirements of the AI Regulation may not be resolved for all important use cases and may require additional research. ETSI wishes to accelerate the development of appropriate standards through tighter integration with the EU research and development community and with various Horizon Europe programmes, and through cooperation with international standards setting organizations on development of AI standards. ETSI is already adapting processes and increasing its outreach to EC-funded R&D.

Conclusion

ETSI welcomes the AI Regulation in the current draft, as an important step forward for Europe and the world in the process of creating human-centric AI solutions. ETSI sees a need for (a) timely clarifications of the definitions of AI and "high risk" AI systems, respectively, in the Regulation; (b) promotion of some fundamental research/development topics needed for conformance checking; and (c) a focus on those use cases ("high risk") requiring very careful performance checking and results/bias checking to avoid risks of harm; (d) early start and close collaboration of the EC and the ESOs on defining Standardisation Requests; (e) timely agreement and progress on the SRs.