

Consultation on the White Paper on Artificial Intelligence – A European Approach

Section 1 – An ecosystem of excellence

- 1) In your opinion, how important are the six actions proposed in section 4 of the White Paper on AI (1-5: 1 is not important at all, 5 is very important)?

| | 1-Not important at all | 2- Not important | 3- Neutral | 4- Important | 5- Very important | No opinion |
|--|--------------------------|--------------------------|-------------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|
| Working with Member states | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Focussing the efforts of the research and innovation community | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| Skills | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| Focus on SMEs | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Partnership with the private sector | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Promoting the adoption of AI by the public sector | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |

Are there other actions that should be considered?

[Click or tap here to enter text.](#)

Revising the Coordinated Plan on AI (Action 1)

- 2) In your opinion, how important is it in each of these areas to align policies and strengthen coordination as described in section 4.A of the White Paper (1-5: 1 is not important at all, 5 is very important)?

| | 1-Not important at all | 2- Not important | 3- Neutral | 4- Important | 5- Very important | No opinion |
|--|------------------------------|--------------------------|--------------------------|-------------------------------------|-------------------------------------|--------------------------|
| Strengthen excellence in Research | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Establish world-reference testing facilities for AI | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Promote the uptake of AI by business and the public sector | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Increase the financing for start-ups innovating in AI | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Develop skills for AI and adapt existing training programmes | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Build up the European data space | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |

Are there other areas that that should be considered?

Startups should also follow the existing regulatory and legal requirements and have to demonstrate their compliance with existing regulation as a prerequisite for public funding.

A united and strengthened research and innovation community striving for excellence

- 3) In your opinion how important are the three actions proposed in sections 4.B, 4.C and 4.E of the White Paper on AI (1-5: 1 is not important at all, 5 is very important)?

| | 1-Not important at all | 2- Not important | 3- Neutral | 4- Important | 5- Very important | No opinion |
|---|------------------------------|--------------------------|--------------------------|--------------------------|-------------------------------------|--------------------------|
| Support the establishment of a lighthouse research centre that is world class | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |

| | | | | | | |
|---|--------------------------|--------------------------|--------------------------|-------------------------------------|-------------------------------------|--------------------------|
| and able to attract the best minds | | | | | | |
| Network of existing AI research excellence centres | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Set up a public-private partnership for industrial research | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Are there any other actions to strengthen the research and innovation community that should be given a priority?

[Click or tap here to enter text.](#)

Focusing on Small and Medium Enterprises (SMEs)

- 4) In your opinion, how important are each of these tasks of the specialized Digital Innovation Hubs mentioned in section 4.D of the White Paper in relation to SMEs (1-5: 1 is not important at all, 5 is very important)?

| | 1-Not important at all | 2- Not important | 3- Neutral | 4- Important | 5- Very important | No opinion |
|---|--------------------------|--------------------------|-------------------------------------|-------------------------------------|--------------------------|--------------------------|
| Help to raise SME's awareness about potential benefits of AI | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Provide access to testing and reference facilities | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Promote knowledge transfer and support the development of AI expertise for SMEs | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Support partnerships between SMEs, larger enterprises and academia around AI projects | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

| | | | | | | |
|--|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|-------------------------------------|
| Provide information about equity financing for AI startups | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
|--|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|-------------------------------------|

Are there any other tasks that you consider important for specialised Digital Innovations Hubs?

Any such initiatives should also follow the existing regulatory and legal requirements and have to demonstrate their compliance with existing regulation as a prerequisite for public funding.

Section 2 – An ecosystem of trust

- 5) In your opinion, how important are the following concerns about AI (1-5: 1 is not important at all, 5 is very important)?

| | 1-Not important at all | 2- Not important | 3- Neutral | 4- Important | 5- Very important | No opinion |
|---|--------------------------|--------------------------|-------------------------------------|-------------------------------------|--------------------------|--------------------------|
| AI may endanger safety | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| AI may breach fundamental rights (such as human dignity, privacy, data protection, freedom of expression, workers' rights etc.) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| The use of AI may lead to discriminatory outcomes | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| AI may take actions for which the rationale cannot be explained | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| AI may make it more difficult for persons having suffered harm to obtain compensation | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| AI is not always accurate | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Do you have any other concerns about AI that are not mentioned above? Please specify:

Please note that it is not “the AI” per se that could create harm but rather the specific context in which AI is integrated in a certain product or service and such products or services might potentially create harm in case of malfunctioning in the intended context: e.g. health/surgery or mobility.

6) Do you think that the concerns expressed above can be addressed by applicable EU legislation? If not, do you think that there should be specific new rules for AI systems?

- ☐ Current legislation is fully sufficient
- ☒ Current legislation may have some gaps
- ☐ There is a need for a new legislation
- ☐ Other
- ☐ No opinion

Other, please specify

There is broadly sufficient legislation available to govern AI. However we see the need for specific amendments to the Product Liability Directive (PLD) in order to capture software and more specifically AI and AI based applications.

7) If you think that new rules are necessary for AI system, do you agree that the introduction of new compulsory requirements should be limited to high-risk applications (where the possible harm caused by the AI system is particularly high)?

- ☒ Yes
- ☐ No
- ☐ Other
- ☐ No opinion

Other, please specify

Overall we support the risk based approach suggested by the EU Commission. In addition, we think that specific amendments to the Product Liability Directive (PLD) should be made for all AI applications. The legal protection and regress options should be available for any damage that is caused by malfunctioning AI systems, irrespective whether such AI application has been qualified high-risk before. Finally documentation and duty of information under the PLD should also be equally applicable to any AI

applications that can have an impact on customers and citizens, irrespective of the assumed qualification of high-risk. New compulsory requirements like ex ante testing and approval by authorities should be limited to high-risk applications only.

8) Do you agree with the approach to determine “high-risk” AI applications proposed in Section 5.B of the White Paper?

- ☒ Yes
- ☐ No
- ☐ Other
- ☐ No opinion

Other, please specify

We support to define high-risk AI applications by sector AND use with sufficiently clear abstract legal terms. Such legal definition must provide sufficient legal certainty to be innovation friendly and allow investors and producers to understand early on the dimension of regulatory scrutiny the project is facing.

9) If you wish, please indicate the AI application or use that is most concerning (“high-risk”) from your perspective:

AI use in medical and surgery context; mobility and air traffic; applications that may have an impact of the well-functioning of our democratic institutions. Overall we recommend to define “high-risk” by the intensity of potential harm to legal and societal values at stake by malfunctioning AI applications (i.e. life, bodily harm, elections, judicial judgements).

10) In your opinion, how important are the following mandatory requirements of a possible future regulatory framework for AI (as section 5.D of the White Paper) (1-6: 1 is not important at all, 6 is very important)?

| | 1-Not important at all | 2- Not important | 3- Neutral | 4- Important | 5- Very important | No opinion |
|-----------------------------------|--------------------------|--------------------------|--------------------------|-------------------------------------|--------------------------|--------------------------|
| The quality of training data sets | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

| | | | | | | |
|---|--------------------------|--------------------------|-------------------------------------|-------------------------------------|--------------------------|--------------------------|
| The keeping of records and data | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Information on the purpose and the nature of AI systems | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Robustness and accuracy of AI systems | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Human oversight | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Clear liability and safety rules | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

11) In addition to the existing EU legislation, in particular the data protection framework, including the General Data Protection Regulation and the Law Enforcement Directive, or, where relevant, the new possibly mandatory requirements foreseen above (see question above), do you think that the use of remote biometric identification systems (e.g. face recognition) and other technologies which may be used in public spaces need to be subject to further EU-level guidelines or regulation:

- ☐ No further guidelines or regulations are needed
- ☐ Biometric identification systems should be allowed in publicly accessible spaces only in certain cases or if certain conditions are fulfilled (please specify)
- ☐ Other special requirements in addition to those mentioned in the question above should be imposed (please specify)
- ☐ Use of Biometric identification systems in publicly accessible spaces, by way of exception to the current general prohibition, should not take place until a specific guideline or legislation at EU level is in place.
- ☐ Biometric identification systems should never be allowed in publicly accessible spaces
- ☒ No opinion

Please specify your answer:

[Click or tap here to enter text.](#)

12) Do you believe that a voluntary labelling system (Section 5.G of the White Paper) would be useful for AI systems that are not considered high-risk in addition to existing legislation?

☐ Very much

☒ Much

☐ Rather not

☐ Not at all

☐ No opinion

13) Do you have any further suggestion on a voluntary labelling system?

We strongly recommend that a labelling system should only be a voluntary system for systems that may have a direct customer impact. It must be avoided that other authorities take such voluntary system as new standard for supervision of AI applications. Such voluntary labelling system should NOT go beyond existing regulation but might rather provide best practice guidance on how to comply with the existing regulation.

14) What is the best way to ensure that AI is trustworthy, secure and in respect of European values and rules?

☐ Compliance of high-risk applications with the identified requirements should be self-assessed ex-ante (prior to putting the system on the market)

☒ Compliance of high-risk applications should be assessed ex-ante by means of an external conformity assessment procedure

☐ Ex-post market surveillance after the AI-enabled high-risk product or service has been put on the market and, where needed, enforcement by relevant competent authorities

☒ A combination of ex-ante compliance and ex-post enforcement mechanisms

☐ Other enforcement system

☐ No opinion

Please specify any other enforcement system:

Click or tap here to enter text.

15) Do you have any further suggestion on the assessment of compliance?

As much as there is no specific legislation “on AI” to which AI applications must comply but a plentitude of existing regulation that governs the context in which AI is applied, compliance has to be assessed accordingly in a sector and use related perspective. Given the nature of highly complex self/deep-learning AI applications, the focus of compliance assessment should be outcome oriented. In addition it should analyze whether sufficient internal governance and control mechanism are in place to continuously monitor the well-functioning of the system.

Section 3 – Safety and liability implications of AI, IoT and robotics

16) The current product safety legislation already supports an extended concept of safety protecting against all kind of risks arising from the product according to its use. However, which particular risks stemming from the use of artificial intelligence do you think should be further spelled out to provide more legal certainty?

☒ Cyber risks

☒ Personal security risks

☐ Risks related to the loss of connectivity

☐ Mental health risks

17) In your opinion, are there any further risks to be expanded on to provide more legal certainty?

The technical nature of self/-dep learning AI models implies that products might change their functioning over time. Therefore the Product Liability Directive should be amended to include ongoing monitoring and updating obligations to the developer and deployer of AI based products.

18) Do you think that the safety legislative framework should consider new risk assessment procedures for products subject to important changes during their lifetime?

☒ Yes

☐ No

☐ No opinion

19) Do you have any further considerations regarding risk assessment procedures?

For high-risk applications a regular update/assessment might be introduced to secure trust in AI based applications and prevention of harm.

20) Do you think that the current EU legislative framework for liability (Product Liability Directive) should be amended to better cover the risks engendered by certain AI applications?

☒ Yes

☐ No

☐ No opinion

21) Do you have any further considerations regarding the question above?

We propose a number of amendments and adaptation of the Product Liability Directive (PLD) to the era of AI in order to ensure legal security, in particular in relation to its application to AI systems. This involves acting on at least the following elements: 1. Definition of "Product" and "Producer": The concept of "product", as defined in the PLD should be reviewed in order to extend it to Software, AI systems or cloud technologies. In addition, under Article 3 of PLD, can be held liable: the first importer of the product into the EU, own brander of a product and downstream supplier when he fails to identify the producer to the claimant within a reasonable time. Accordingly, an AI systems owner or provider should be considered as a producer. 2.

Definition of "Defect": Under Article 6 of the PLD a product is considered defective when it does not provide the safety which a person is entitled to expect. Circumstances relevant to the consideration of whether a product is defective include the presentation of the product; the reasonably expected use of the product; and the time when the product was supplied. However, AI systems can be complex and evolving during its time of operation and use. Therefore, the concept of "defect" should be adapted to align with AI systems evolving nature. 3. Burden of Proof: Article 4 of the PLD provides that the burden of proof to lies with the claimant. This burden can represent an obstacle to obtaining compensation, especially with regard to new technological developments and increasing AI systems opacity. We consider the inversion of the

burden of proof acceptable and a “fair price” for an innovation friendly regime. 4. Review of Defences: Article 7(b) of the PLD indicates that a producer has a defence if the defect that caused the damage probably did not exist at the time when the product was put into circulation. By contrast, the evolving nature of certain AI methods, in particular machine-learning, means that the product using AI self-learning can develop defects that did not exist at the time of its launch. Consequently, this self-learning character is irreconcilable with defence under Article 7(b) of the PLD and this defence should not be applicable in the context of a self-learning AI system. 5.

Duty of Information: In the context of an AI system, the producer has a variety of separate contractual relationships with its component suppliers, software and data services providers. As a result, comprehensive information should be made available to the customer, including: (i) clearly define each party’s responsibilities (ii) product’s intended uses, appropriate instructions for use and warnings (iii) the security levels they can expect, and they need to know who to turn to if a failing in cybersecurity leads to material damage (iv) increase consumers' awareness of their rights and (v) assistance to consumers to obtain legal redress. Failure to provide this information should neutralize contributory negligence as well as misuse of the product defences.

22) Do you think that the current national liability rules should be adapted for the operation of AI to better ensure proper compensation for damage and a fair allocation of liability?

- ☒ Yes, for all AI applications
- ☐ Yes, for specific AI applications
- ☐ No
- ☐ No opinion

Please specify the AI applications:

Special focus may be given on AI applications that can cause immediate harm to humans (body, life) or democracy (elections, judicial judgement). However, we strongly advocate against a mandatory insurance concept for AI. AI applications per se are not made to cause harm but only the context in which it is used. And for such context (e.g. motor, health) there are already compulsory insurance schemes in place that provide adequate risk based coverage. An additional system to insure AI would cause risk of double insurance or even moral hazard.

23) Do you have any further considerations regarding the question above?

We believe that there should not be a differing level of protection for the same quality of damage depending on the initial qualification of the AI application as high-risk or normal risk.

Furthermore, the liability regime should be governed by a REGULATION to achieve legal certainty and level playing field across Europe and to secure harmonization in protection of citizens.