Attn. Mr Heikkilä
European Commission
DG CONNECT
1049 Bruxelles
Belgium

Dear Mr Heikkilä

PwC International Ltd (PwC), on behalf of the PwC network, welcomes the opportunity to respond to the European Commission's public consultation on the White Paper on Artificial Intelligence.

The White Paper sets out a series of actions, measures and potential legislation that the EC is considering in order to become a global leader in innovation in the data economy and its applications. With a strong digital infrastructure, existing legislative frameworks and history of world-class research, we believe Europe is well positioned to achieve its goal.

Although the White Paper is relatively jargon-free, which aids accessibility, certain core concepts would benefit from a rigorous definition. Notably, AI itself is categorised as a combination of "data, algorithms and computing power". Furthermore, clear definitions not just of AI, but the risks associated with it, supports the White Paper's proposed 'risk-based' approach by extending risk mitigation to proactive risk identification. How we determine the likelihood of potential harm from AI is a critical element of how targeted, clearly defined regulation and guidance can build trust, and avoid inhibiting innovation.

Notwithstanding the importance of clarity in these definitions, care should be taken to remain nuanced, especially with regard to high-risk applications. The definition needs to match the spirit of the framework and apply as closely as possible to only the intended applications.

Building an Ecosystem of Excellence

The actions proposed in the White Paper would go some way to encouraging the ecosystem of excellence. Actions which support organisational uptake are of particular importance, as they provide a cohesive network for development and innovation.

The focus on SMEs is crucial as there is a track record of rapid innovation in this area, and a shared focus on both public and private sectors enables a wide reaching approach. The

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necessity to support all enterprises in their journey to digitalisation should not be underestimated as the value of AI might be inhibited if the organisation's technological approach is immature. In particular, attention should be paid to the risk of positive feedback loops which favour first movers. Providing safeguards for fair competition is crucial for equitable distribution of cognitive capital.

Among the success factors, we highlight meaningful knowledge sharing, a genuine pan-European approach and a harmonisation between private and public sectors. To address these, we feel that it is important to identify a prioritised portfolio for investment to pool resources in advance. Included in this portfolio could include the establishment of world class research centres, mechanisms to align and support member state initiatives, and incentives for private sectors. In particular, we would welcome further investigation into the private-public partnership model as we believe there can be no excellence without new talent and retention of leaders developing the innovation and research culture of Europe's industries.

Building an Ecosystem of Trust

We recognise the relevance of all concerns prompted in the consultation process, and our focus is primarily on direct risks to individuals such as endangerment, discrimination and other breaches of fundamental human rights. We believe that the EC's goal of building trust is well suited to mitigating these concerns, as well as technological concerns such as accuracy.

In our experience, trust can be effectively built by accountability, transparency, monitoring, reporting and robust governance. We see these as crucial in the context of AI. We strongly believe that organisations within the EU have the attitudes and capabilities to comply with relevant legislation and take proactive measures to maintain that compliance when necessary.

Whilst AI brings additional complexities, building a framework which extends existing expectations (both legal and regulatory) in a logical manner empowers organisations in both public and private sectors. Such a framework facilitates accountability and the recognition of good practice.

The voluntary labelling system has the potential to be useful for lower risk AI use cases. Specifically, it may create more awareness of the scale of risks AI presents. Furthermore, it encourages a certain level of transparency and enables individuals to make a reasoned choice - building trust in the process. However, it should be noted that incentives and support should be made available, especially to the smaller enterprises which may find a labelling requirement onerous. There is also the behavioural concern that labelling may result in a false sense of safety for consumers; especially where rating methodology is not transparent. Whilst being recommended, we observe that there is little appetite in the market for it to be mandatory.

In terms of mandatory obligations, we feel that the focus should be on quality and clarity, both in terms of safety and liability rules, as well as training data and management information of AI applications. Having clear requirements limits the risk that a system is not attestable. Whilst we support the EC's desire to encourage human centric AI, we believe that any requirement should remain risk-based and in some cases mandate a simpler fail-safe. There are applications in which requiring human oversight may not be feasible, such as ad bidding on websites. In other applications AI/machine learning is used to derive additional structured data that feeds into a human-driven process, for example using Natural Language Processing to extract information from invoices.

We emphasise the need for pragmatic and technically feasible implementations to facilitate wide-spread acceptance. We also recommend considering how we can incentivise evaluation of these risks and associated harms at the process level, rather than explicitly at the model level. This should help facilitate the operationalisation of AI ethics, supporting organisations to translate principles into actions.

Risk Safety and Liability

We believe that the role of cyber security should not be underestimated in the effort to effectively monitor and mitigate risk. Two important suggestions to contextualise the landscape for AI are risk tiering and risk taxonomisation. On the former, lessons can be learned from the financial services industry which uses risk tiering for various models, e.g. categorising their models based on consumer harm, materiality and regulatory risk. This enables a flexibility and nuance to their categorisation approach and a similar concept could be applied in the definition of "high risk" applications. In this case, harm could be considered on an individual, organisational and societal level.

Where possible, concerns related to AI should be categorised into a taxonomy, preferably in alignment with traditional risk management approaches like those that exist within financial services and other highly regulated industries. This would enable organisations to consistently identify where existing risks (for example cyber security or data related issues) are likely to be exacerbated. In the event of novel risks, enterprises would be aided in identifying which teams and stakeholders are necessary to manage, monitor and mitigate the concerns. Furthermore, this kind of classification could facilitate an impact assessment, which organisations could then use to genuinely understand the potential benefits and harm at a broad level. Even organisations that have such processes in place should be prompted to reconsider their existing mechanisms and how emergent risks in the AI space may introduce other challenges. This is especially pertinent where AI has a broad use within an organisation, necessitating these processes to become more widespread and implemented in previously unconcerned areas.

We would also like to highlight the differences posed by business to business applications versus those which are consumer based. In business to business applications, models may be presented as vendor solutions. Organisations adopting these technologies may not have sufficient insight into these models or the broader capabilities that leverage these AI-based technologies. As such, the Commission would need to help organisations understand what liability companies will have that employ these third party models as well as what ownership they must take to understand how they work.

Many pragmatic actions included in the White Paper are an opportunity for forward thinking and proactivity in building trust in AI. PwC is interested in further developments of the framework, in particular the importance of accountability and end-to-end governance. We are committed to supporting the European Commission in this work and would like to contribute where possible.

We would be happy to discuss this further with you. If you have any questions regarding our response please contact Anand Rao at anand.s.rao@pwc.com

Yours sincerely,

Michael Stewart
Global Leader, Corporate Affairs and Communications

PwC IL is registered under number 60402754518-05 in the EU Transparency Register

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

Fields marked with * are mandatory.

Introduction

Artificial intelligence (AI) is a strategic technology that offers many benefits for citizens and the economy. It will change our lives by improving healthcare (e.g. making diagnosis more precise, enabling better prevention of diseases), increasing the efficiency of farming, contributing to climate change mitigation and adaptation, improving the efficiency of production systems through predictive maintenance, increasing the security of Europeans and the protection of workers, and in many other ways that we can only begin to imagine.

At the same time, AI entails a number of potential risks, such as risks to safety, gender-based or other kinds of discrimination, opaque decision-making, or intrusion in our private lives.

The European approach for AI aims to promote Europe's innovation capacity in the area of AI while supporting the development and uptake of ethical and trustworthy AI across the EU. According to this approach, AI should work for people and be a force for good in society.

For Europe to seize fully the opportunities that AI offers, it must develop and reinforce the necessary industrial and technological capacities. As set out in the accompanying European strategy for data, this also requires measures that will enable the EU to become a global hub for data.

The current public consultation comes along with the **White Paper on Artificial Intelligence - A European Approach** aimed to foster a European ecosystem of excellence and trust in AI and a Report on the safety and liability aspects of AI. The White Paper proposes:

- Measures that will streamline research, foster collaboration between Member States and increase investment into AI development and deployment;
- Policy options for a future EU regulatory framework that would determine the types of legal requirements that would apply to relevant actors, with a particular focus on high-risk applications.

This consultation enables all European citizens, Member States and relevant stakeholders (including civil society, industry and academics) to provide their opinion on the White Paper and contribute to a European approach for AI. To this end, the following questionnaire is divided in three sections:

- **Section 1** refers to the specific actions, proposed in the White Paper's Chapter 4 for the building of an ecosystem of excellence that can support the development and uptake of AI across the EU economy and public administration;
- **Section 2** refers to a series of options for a regulatory framework for AI, set up in the White Paper's Chapter 5;
- **Section 3** refers to the Report on the safety and liability aspects of AI.

Respondents can provide their opinion by choosing the most appropriate answer among the ones suggested for each question or suggesting their own ideas in dedicated text boxes.

Feedback can be provided in one of the following languages:
BG | CS | DE | DA | EL | EN | ES | ET | FI | FR | HR | HU | IT | LT | LV | MT | NL | PL | PT | RO | SK | SL | SV

Written feedback provided in other document formats, can be uploaded through the button made available at the end of the questionnaire.

The survey will remain open until 14 June 2020.

About you

* Language of my contribution
  - Bulgarian
  - Croatian
  - Czech
  - Danish
  - Dutch
  - English
  - Estonian
  - Finnish
  - French
  - Gaelic
  - German
  - Greek
  - Hungarian
  - Italian
  - Latvian
  - Lithuanian
  - Maltese
  - Polish
  - Portuguese
  - Romanian
  - Slovak
  - Slovenian
  - Spanish
  - Swedish

* I am giving my contribution as
  - ○ Academic/research institution
  - ○ Business association
  - ◉ Company/business organisation
  - ○ Consumer organisation
  - ○ EU citizen
  - ○ Environmental organisation
  - ○ Non-EU citizen
  - ○ Non-governmental organisation (NGO)
  - ○ Public authority
  - ○ Trade union
  - ○ Other

* First name

Jacomien

* Surname

van den Hurk

* Email (this won't be published)

jacomien.van.den.hurk@pwc.com

* Organisation name

255 character(s) maximum

PwC IL

* Organisation size
  - ○ Micro (1 to 9 employees)
  - ○ Small (10 to 49 employees)
  - ○ Medium (50 to 249 employees)
  - ◉ Large (250 or more)

Transparency register number

255 character(s) maximum

Check if your organisation is on the transparency register. It's a voluntary database for organisations seeking to influence EU decision-making.

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* Country of origin

Please add your country of origin, or that of your organisation.

- ○ Afghanistan
- ○ Åland Islands
- ○ Djibouti
- ○ Dominica
- ○ Libya
- ○ Liechtenstein
- ○ Saint Martin
- ○

- Albania
- Algeria
- American Samoa
- Andorra
- Angola
- Anguilla
- Antarctica
- Antigua and Barbuda
- Argentina
- Armenia
- Aruba
- Australia
- Austria
- Azerbaijan
- Bahamas
- Bahrain
- Bangladesh
- Barbados
- Belarus
- Belgium
- Belize
- Benin
- Bermuda
- Bhutan
- Bolivia
- Bonaire Saint Eustatius and Saba
- Bosnia and Herzegovina
- Botswana
- Bouvet Island
- Brazil
- Dominican Republic
- Ecuador
- Egypt
- El Salvador
- Equatorial Guinea
- Eritrea
- Estonia
- Eswatini
- Ethiopia
- Falkland Islands
- Faroe Islands
- Fiji
- Finland
- France
- French Guiana
- French Polynesia
- French Southern and Antarctic Lands
- Gabon
- Georgia
- Germany
- Ghana
- Gibraltar
- Greece
- Greenland
- Grenada
- Guadeloupe
- Guam
- Guatemala
- Guernsey
- Guinea
- Lithuania
- Luxembourg
- Macau
- Madagascar
- Malawi
- Malaysia
- Maldives
- Mali
- Malta
- Marshall Islands
- Martinique
- Mauritania
- Mauritius
- Mayotte
- Mexico
- Micronesia
- Moldova
- Monaco
- Mongolia
- Montenegro
- Montserrat
- Morocco
- Mozambique
- Myanmar /Burma
- Namibia
- Nauru
- Nepal
- Netherlands
- New Caledonia
- New Zealand
- Saint Pierre and Miquelon
- Saint Vincent and the Grenadines
- Samoa
- San Marino
- São Tomé and Príncipe
- Saudi Arabia
- Senegal
- Serbia
- Seychelles
- Sierra Leone
- Singapore
- Sint Maarten
- Slovakia
- Slovenia
- Solomon Islands
- Somalia
- South Africa
- South Georgia and the South Sandwich Islands
- South Korea
- South Sudan
- Spain
- Sri Lanka
- Sudan
- Suriname
- Svalbard and Jan Mayen
- Sweden
- Switzerland
- Syria
- Taiwan
- Tajikistan
- Tanzania

- British Indian Ocean Territory
- British Virgin Islands
- Brunei
- Bulgaria
- Burkina Faso
- Burundi
- Cambodia
- Cameroon
- Canada
- Cape Verde
- Cayman Islands
- Central African Republic
- Chad
- Chile
- China
- Christmas Island
- Clipperton
- Cocos (Keeling) Islands
- Colombia
- Comoros
- Congo
- Cook Islands
- Costa Rica
- Côte d'Ivoire
- Croatia
- Cuba
- Curaçao
- Cyprus
- Czechia
- Guinea-Bissau
- Guyana
- Haiti
- Heard Island and McDonald Islands
- Honduras
- Hong Kong
- Hungary
- Iceland
- India
- Indonesia
- Iran
- Iraq
- Ireland
- Isle of Man
- Israel
- Italy
- Jamaica
- Japan
- Jersey
- Jordan
- Kazakhstan
- Kenya
- Kiribati
- Kosovo
- Kuwait
- Kyrgyzstan
- Laos
- Latvia
- Lebanon
- Nicaragua
- Niger
- Nigeria
- Niue
- Norfolk Island
- Northern Mariana Islands
- North Korea
- North Macedonia
- Norway
- Oman
- Pakistan
- Palau
- Palestine
- Panama
- Papua New Guinea
- Paraguay
- Peru
- Philippines
- Pitcairn Islands
- Poland
- Portugal
- Puerto Rico
- Qatar
- Réunion
- Romania
- Russia
- Rwanda
- Saint Barthélemy
-
- Thailand
- The Gambia
- Timor-Leste
- Togo
- Tokelau
- Tonga
- Trinidad and Tobago
- Tunisia
- Turkey
- Turkmenistan
- Turks and Caicos Islands
- Tuvalu
- Uganda
- Ukraine
- United Arab Emirates
- United Kingdom
- United States
- United States Minor Outlying Islands
- Uruguay
- US Virgin Islands
- Uzbekistan
- Vanuatu
- Vatican City
- Venezuela
- Vietnam
- Wallis and Futuna
- Western Sahara
- Yemen
- Zambia

		Saint Helena Ascension and Tristan da Cunha	
Democratic Republic of the Congo	Lesotho	Saint Kitts and Nevis	Zimbabwe
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* Publication privacy settings

The Commission will publish the responses to this public consultation. You can choose whether you would like your details to be made public or to remain anonymous.

- **Anonymous**
  Only your type of respondent, country of origin and contribution will be published. All other personal details (name, organisation name and size, transparency register number) will not be published.
- **Public**
  Your personal details (name, organisation name and size, transparency register number, country of origin) will be published with your contribution.

☑ I agree with the personal data protection provisions

Section 1 - An ecosystem of excellence

To build an ecosystem of excellence that can support the development and uptake of AI across the EU economy, the White Paper proposes a series of actions.

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	○	○	○	◉	○	○
Focussing the efforts of the research and innovation community	○	○	○	◉	○	○
Skills	○	○	○	◉	○	○
Focus on SMEs	○	○	○	○	◉	○
Partnership with the private sector	○	○	○	○	◉	○
Promoting the adoption of AI by the public sector	○	○	○	○	◉	○

Are there other actions that should be considered?

500 character(s) maximum

All are important - a prioritisation mechanism could be by planned monetary efforts/resources for the specific action areas. Focus on needs in AI adoption for organisations by size: for large enterprises, focus on robust governance and risk management. For the SMEs and the public sector, stimulate AI adoption knowledge, expertise and financial support.
Collaboration across member states will enable better coordination of research efforts.

Revising the Coordinated Plan on AI (Action 1)

The Commission, taking into account the results of the public consultation on the White Paper, will propose to Member States a revision of the Coordinated Plan to be adopted by end 2020.

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	○	○	○	◉	○	○
Establish world-reference testing facilities for AI	○	○	◉	○	○	○
Promote the uptake of AI by business and the public sector	○	○	○	○	◉	○
Increase the financing for start-ups innovating in AI	○	○	◉	○	○	○
Develop skills for AI and adapt existing training programmes	○	○	○	○	◉	○
Build up the European data space	○	○	○	○	◉	○

Are there other areas that that should be considered?

500 character(s) maximum

Coordination of countries initiatives; share best practices
Identify a priority portfolio of investment for all member states to pool resources
Explore private-public partnership model to help with designing governance
Build EU knowledge repository for SMEs
Having access to multiple data platforms and flexibility can circumvent any issues. Building an EU data space will be costly

A united and strengthened research and innovation community striving for excellence

Joining forces at all levels, from basic research to deployment, will be key to overcome fragmentation and create synergies between the existing networks of excellence.

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 and able to attract the best minds	○	○	○	○	◉	○
Network of existing AI research excellence centres	○	○	○	○	◉	○
Set up a public-private partnership for industrial research	○	○	○	○	◉	○

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

500 character(s) maximum

Meaningful knowledge exchange, common agenda for research with priorities and challenges set up collectively to ensure research is focus on areas of interests and relevance
Foster the innovation and research culture within Europe's industry with incentives like a local tax break. The tax is offset by European Investment fund transfer to member state
Focus on creating new talent in research and provide the right incentives for them to continue to work in research

Focusing on Small and Medium Enterprises (SMEs)

The Commission will work with Member States to ensure that at least one digital innovation hub per Member State has a high degree of specialisation on AI.

In your opinion, how important are each of these tasks of the specialised 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	○	○	○	◉	○	○
Provide access to testing and reference facilities	○	○	○	◉	○	○
Promote knowledge transfer and support the development of AI expertise for SMEs	○	○	○	○	◉	○
Support partnerships between SMEs, larger enterprises and academia around AI projects	○	○	○	○	◉	○
Provide information about equity financing for AI startups	○	○	◉	○	○	○

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

500 character(s) maximum

Set up a european market place where ideas and innovations should be established.
Support also early education/experimentation activities for school-aged children focusing on Ai and Ethics
Use Mission-Oriented Innovation approach to define policy to boost innovation aimed to tackle societal and technological challenges.

Section 2 - An ecosystem of trust

Chapter 5 of the White Paper sets out options for a regulatory framework for AI.

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	○	○	○	○	◉	○
AI may breach fundamental rights (such as human dignity, privacy, data protection, freedom of expression, workers' rights etc.)	○	○	○	○	◉	○
The use of AI may lead to discriminatory outcomes	○	○	○	○	◉	○
AI may take actions for which the rationale cannot be explained	○	○	○	◉	○	○
AI may make it more difficult for persons having suffered harm to obtain compensation	○	○	◉	○	○	○
AI is not always accurate	○	○	○	◉	○	○

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

500 character(s) maximum

Explanation must be tailored to the use case and its stakeholder
The concept of accuracy is difficult to define in different forms of AI and may not be the right measure -- there is no common measure for performance, as it is context-specific
Models are stochastic -- most processes in regulation and risk management are structured for deterministic systems. Processes need to adjust accordingly

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

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

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

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

500 character(s) maximum

Define and quantify harms/unintended consequences on 3 level: individual, organisations and society
As a general rule safety critical applications should be highest risk. E.g. midair collision avoidance systems
Engage with industries to define and align the high risk applications

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) (1-5: 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
The quality of training data sets	○	○	○	○	◉	○
The keeping of records and data	○	○	○	◉	○	○
Information on the purpose and the nature of AI systems	○	○	○	○	◉	○
Robustness and accuracy of AI systems	○	○	○	◉	○	○
Human oversight	○	○	◉	○	○	○
Clear liability and safety rules	○	○	○	○	◉	○

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:

An independent oversight body to over the adoption and use that allows citizen reporting, queries or explanations
Until there is a regulation in place, cases should be limited to only public safety, not efficiency reasons, and be explicitly authorized by the EU. Except if people are explicitly informed about and have a choice of using biometric identification or not (e.g. airport gates).

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

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

500 character(s) maximum

Raise public awareness for AI risks, so that large companies adopt the voluntary labels to increase customer satisfaction and user adoption. This could also be a basic requirements for receiving financial support for AI innovation developments.

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
- [x] A combination of ex-ante compliance and ex-post enforcement mechanisms
- [ ] Other enforcement system
- [ ] No opinion

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

500 character(s) maximum

Firms can voluntarily engage with independent parties (accredited individuals or entities) to provide assurance against a recognised framework or standards. It may fall short of a certification until there is a standard to go along the voluntary labelling
Frameworks can guide local certification. It should be aligned with global initiatives on that. The EU should promote CEN to play an active role in the relevant ISO committees, as ISO is the primary source for technical certification standards

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

The overall objective of the safety and liability legal frameworks is to ensure that all products and services, including those integrating emerging digital technologies, operate safely, reliably and consistently and that damage having occurred is remedied efficiently.

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?

- [x] Cyber risks
- [ ] Personal security risks
- [ ] Risks related to the loss of connectivity
- [x] Mental health risks

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

500 character(s) maximum

Business continuity
Loss of explainability but from a non-technical perspective, may lead to loss of control/decision making /choice

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

Do you have any further considerations regarding risk assessment procedures?

500 character(s) maximum

Clear definition of AI within the context of risk mitigation, users, Risks, harms building on the EU definition of AI

Define the impact assessment to cover aspects such as people and mandated early in the life cycle. This would inform actions need across areas such as Safeguards, Business Continuity, alternative/back up, risk mitigation
Consider governance structures to monitor and respond to change in risk appetite, risk profile, likelihood etc, a command centre approach or similar

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

Do you have any further considerations regarding the question above?

500 character(s) maximum

It should be the starting point, but needs to be adjusted as best as possible
A new approach for EU legislative framework for liability on AI products should be considered as well in line with the fact Many risk management processes are built for deterministic systems. AI is probabilistic -- regulations and risk management should adjust accordingly

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

Do you have any further considerations regarding the question above?

500 character(s) maximum

Clear definition of liability in context of probabilistic systems is needed

Thank you for your contribution to this questionnaire. In case you want to share further ideas on these topics, you can upload a document below.

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