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:

1

- **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

Sascha

* Surname

MARSHANG

* Email (this won't be published)

sascha@epha.org

* Organisation name

255 character(s) maximum

European Public Health Alliance (EPHA)

* 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.

18941013532-08

* Country of origin

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

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

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

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

○ Democratic Republic of the Congo	○ Lesotho	○ Saint Helena Ascension and Tristan da Cunha ○ Saint Kitts and Nevis	○ Zimbabwe
○ Denmark	○ Liberia	○ Saint Lucia	

*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

> Especially in health and care, data challenges need to be tackled first. A multi-stakeholder dialogue needs to be created between digital and other sectors, including civil society, to improve awareness, education, and skill. End users need to be involved in the design, implementation and evaluation of AI solutions. Next to building up specific digital skills, it is important to focus on digital literacy, key in the health sector. Transparency and knowledge are crucial for ordinary people.

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 and collaboration must be strengthened not only between Member States but also between other stakeholders at national level. Extensive coordination and involvement of end users is needed to improve the understanding of the benefits of using e.g. personal health data for the public good. A "Health in all Policies" approach needs to be introduced in the technology sphere, too. Cross-sector bridges must be built to improve the understanding, meaning and deployment of AI solutions.

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

Public-private partnerships must involve civil society groups, such as patients, healthcare professionals and public health experts who are meant to be the beneficiaries of AI and data-driven healthcare solutions, including pandemic surveillance technologies. The further development of AI in healthcare must not be driven by technology firms, to ensure it will bring benefits for everybody and address real needs. Research should address how AI can tackle health inequalities and improve access.

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

> While AI holds potential for SMEs, and Digital Innovation Hubs may be one way of encouraging more research and investments in it, the creation of a multi-stakeholder ecosystem as outlined above is just as important. The solutions of SMEs must correspond to real societal needs and take into account end users' ethical concerns.

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

> Key ethical challenges need to be addressed by taking into account end users' needs and concerns: In heath and care, the right balance must be struck between harnessing the positive effects AI could generate and continuous respect for and safeguarding of core values. Protecting personal data and privacy is particularly important for society's most vulnerable. A thorough and inclusive reflection about ethics and governance is key in relation to the six concerns expressed above.

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

Additional Comments

500 character(s) maximum

> New legislation may be required to close gaps in grey zones not covered by existing EU legislation (GDPR, ePrivacy, cybersecurity, etc.) Compulsory requirements should not only be limited to high risk applications as such an approach overlooks that what is low risk for many people could be very risky for others, e.g. vulnerable and marginalised people could be disproportionately affected. Further clarification is required in order to gain a better understanding of high and low risks.

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

500 character(s) maximum

> EPHA being a public health membership organisation, we are most concerned about any AI applications in healthcare and public health that could be operating on the basis of biased algorithms (not taking into account gender, ethnicity, etc.) and that do not take into account the broader determinants of health and histories of individual patients. We are also concerned that increased machine-generated decisions could potentially exacerbate existing health inequalities, discrimination and exclusion.

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:

> There may be a use of biometric identification sytems in situations of crisis, which could also be a public health crisis. However, the use of such systems should be exceptional and subject to very strict rules to make sure that individuals do not suffer negative consequences or harm and misuse by state or private actors cannot occur. It really depends on the situation and purpose of deployment. There is always a risk of generalised surveillance beyond the declared purpose, which would impoverish democracy in Europe.

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

> It depends again on the purpose of the AI solution and perhaps on the sector. In health and care, there could be value in such labels for certain AI-solutions deemed to be not high risk but that could potentially generate ambiguous results or produce harm.

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

Do you have any further suggestion on the assessment of compliance?
500 character(s) maximum

N/a

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?

☑ Cyber risks
☑ Personal security risks
☐ Risks related to the loss of connectivity
☑ Mental health risks

In your opinion, are there any further risks to be expanded on to provide more legal certainty?
500 character(s) maximum

The impact of AI in workplaces needs to be further addressed, including in different healthcare settings. A more specific and legal approach to AI is a missing point given that its complexity of AI could produce unintended side effects for healthcare professionals, patients and citizens, in addition to causing mental health issues arising from, e.g. machine-generated decisions impossible to comprehend for lay persons.

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

N/a

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

> Yes it should be amended to better cover the risks engendered by certain AI applications due to its complexity. The EU product liability law has to keep pace with new technology and needs to reconsider certain definitions that could now lead to different outcomes. The interplay between hardware, software and services is becoming more intricate, most importantly as they can evolve without human input. There is increasingly a fine line between a physical product and the services it delivers.

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:

> As mentioned above, certain health and care solutions might be relevant here, especially if they are for use by patients in their own home. Adapting national liability rules is the only way to ensure a common and transparent approach in all Member States. A standardized approach for AI applications is desirable in healthcare, given that many are built through complex supply chains. The fault-based liability regimes in many Member States that apply in other scenarios may not be sufficient to protect those harmed by AI applications in all scenarios.

Do you have any further considerations regarding the question above?

500 character(s) maximum

> To ensure a proper compensation and a fair allocation of liability, rules should be adapted at EU and national level. The specific characteristics of many AI technologies, including opacity ('black box-effect'), complexity or partially autonomous behaviour, make it hard to verify compliance with, and may hamper the effective enforcement of, rules of existing EU law meant to protect fundamental rights.

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.

You can upload a document here:

886364eb-e65c-4d9e-8779-b2edce507997/EPHA_Moving_beyond_the-Hype_2019.pdf

Contact

CNECT-AI-CONSULT@ec.europa.eu