19 June 2020

DIGITAL SME input on the EC's White Paper on Artificial Intelligence (AI)

Position paper

Background

Artificial Intelligence (AI) can act as an enabler for other technologies in various fields. Some compare the potential impact of AI to that of the spread of electricity at the end of the 19th century. Electricity had an enabling effect on existing machineries and processes, which led to further innovation. Similarly to that, AI may be able to transform a variety of processes in different fields. It can be considered as the key general-purpose technology (GPT) of our times.[1]

The world is currently still at the beginning of a wide-spread uptake of AI. While Europe has a large number of AI researchers, there is a general perception that innovation seems to happen elsewhere, e.g. in the US or China. At the same time, AI can have a tremendous impact on different industries and is thought to bring great benefits to society if used well. The need to recognise and prioritise AI as a strategic technology and capacity has been recognised in the EU's Coordinated Plan on Artificial Intelligence adopted in December 2018 and is reflected in the EU's new Digital Strategy, which includes a White Paper on AI[2] and a European Strategy on Data.

It has been part of the EU's strategy to create a competitive edge in AI technology by focusing on "trustworthy" AI. As the European Commission put it: "The European approach for AI aims to promote Europe's innovation capacity in the area of AI while supporting the development

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[1] See: Brynjolfsson, E., & McAfee, A. (2017). The business of artificial intelligence: What it can and cannot do for your organization. Harvard Business Review; Trajtenberg, M. (2018). AI as the Next GPT: A Political-Economy Perspective. In The Economics of Artificial Intelligence: An Agenda.

[2] The White Paper proposes measures that will streamline research, foster collaboration between Member States and increase investment into AI development and deployment and 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. See: European Commission, "White Paper On Artificial Intelligence - A European approach to excellence and trust", 19 February 2020.

and uptake of ethical and trustworthy AI across the EU.[3]" This implies developing the necessary industrial and technological capacities for AI, but also includes measures that will enable the EU to become a global hub for data.[4]

Policy measures and a framework that is fit for innovation and SMEs

As a representative of 30 national and regional SME organisations and about 20,000 ICT SMEs across Europe, DIGITAL SME would like to put the emphasis on policy actions and regulatory measures needed to make AI technologies a success for SMEs in Europe. In this respect, DIGITAL SME has consulted its members as well the [SME Focus Group on AI](#)[5] about hurdles to AI innovation and adoption, and about the proposed legislative framework. As a representative of innovative frontrunners, we believe that it is important to take into account the voice of small companies, which are essential drivers of fast-track innovation in the context of an accelerating technology race. While SMEs bring about innovation, they have less capital and resources than larger players to learn and adapt to EU regulation. Therefore, a regulatory framework and policy measures need to be fit for innovation and SMEs.

To compile our position paper, we have also engaged with the SME Focus Group on AI via a survey and workshops led by the EU's Joint Research Centre (JRC). Some key points that were highlighted from this discussion:

- Innovation in AI by the SMEs in the focus group is largely driven by internal R&D (sometimes the initial research of the founder(s), customers, and users, and to a lesser extent academic research)
- Access to data and finance are mentioned as being the key barriers to innovation and development.
- The main drivers for the clients of the AI SMEs to adopt AI seem to be: improving predictions and decisions, and optimising internal resources.

What can we learn from these trends and statements? In practical terms, there seems to be a **need to support the vision for a strong European AI ecosystem** by providing the grounds in **terms of data and innovation policy,** but also by **strengthening market forces and disruption**

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[3] European Commission, "White Paper On Artificial Intelligence - A European approach to excellence and trust", 19 February 2020.

[4] See EC consultation: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12270-White-Paper-on-Artificial-Intelligence-a-European-Approach/public-consultation.

[5] SME Focus Group on AI launched by the European Commission's JRC and DIGITAL SME, see: https://www.digitalsme.eu/european-focus-group-on-artificial-intelligence/

rather than over-regulating. EU-market over-regulation is the major risk when it comes to SMEs based in Europe, especially the ones that sell both in the EU market and outside countries. Policy options here range from data spaces to regulatory measures that would grant business better access to data and/or developing the framework for industry-driven standardisation in APIs and data formats. When it comes to finance and innovation, there is an aspect often mentioned in conversations with our members and the companies in the SME Focus Group: the US and even China seem to be **quicker and less bureaucratic in providing cash to fund and scale innovative ideas**. Lastly, entrepreneurs point to a more fundamental problem: the current structure of the SME ecosystem in Europe, with a majority of family owned-businesses being in the hands of an older generation of entrepreneurs, who are no longer risk-prone but rather risk-averse when it comes to innovation. These structural and cultural issues may be the hardest to tackle when it comes to fostering innovation in AI in the business environment of the EU.

EXECUTIVE SUMMARY: A Strategy for AI that works for SMEs

DIGITAL SME represents frontrunner and innovator SMEs – those SMEs that will provide AI or other technology-based solutions to other businesses. SMEs rarely operate in an empty space – they are connected to other businesses via B2B relationships and value/supply chains. A successful European AI strategy, policy actions and a potential regulatory framework need to take into account the different needs and speeds of SMEs rather than proposing one-size-fits-all measures. With AI being a technology that will likely have a transversal impact, it is important that policy measures aimed at increasing AI uptake are broad enough to reach the wider SME-base, but also aimed at frontrunners that drive innovation.

Frontrunner AI companies need a broader variety of offers, including out-of-the-box solutions, to **raise capital and attract investment**. **Stock options for team members and investors** should be possible across the EU without complex tax regulation. A **favourable tax regime** that incentivises investment in AI-based technology solutions and/or research could provide the right enticements for SMEs. Such a tax regime could potentially aim to support risk-taking by offering more incentives for projects with early technology readiness levels (TRL), rather than supporting those that are already advanced in their maturity levels. Also, policymakers need to be able to distinguish between hype and real value: Innovative digital SMEs and start-ups **embedded in sectors and verticals where domain knowledge is combined with AI** are those which are truly **valuable, and in those areas Europe can still compete**. Lastly, in order to bring innovation in AI to the market and to different industries, **old industrial sectors may need to be**

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disrupted. This may be happening naturally, but large industrial structures that have developed over decades and may be rather hard to disrupt at this stage. Certain industries may be unwilling to innovate as long as business is still going fine, so there may be a need to **consciously and willingly disrupt our own industries** to make them tougher and globally more competitive. Some companies decide to do so on their own: They incubate and accelerate new business models based on AI and technologies within their own structures. The companies that are willing to innovate should be supported in their efforts. The current Covid-19 crisis is questioning the future of certain industries, but could also accelerate AI-driven innovation, which could be an opportunity for the EU.

AI and IoT will completely **change business models.** Businesses need to understand this fact and **think strategically** about emerging technologies instead of following shorter-term business goals. As regards the research and innovation ecosystem, there may be a need for **fiscal benefits to support SMEs in attracting, retaining and rewarding AI researchers, talents and data scientists.**

For technology-followers, other policy options may be considered. For instance, the research community often speaks a language that is far away from businesses. "AI communicators" could be identified to bring the results of research to innovators and therefore facilitate the translation into services and products. Raising awareness via **success stories in industry to raise the interest of executives** or investing in **thought-leaders and pioneers per industry** may help to create AI-aware ecosystems and actions. Other options such as "AI vouchers" or programmes to fund AI roadmaps within clusters or single companies could also be considered.

Additionally, while the digital transformation generally and AI specifically need to be taken up on a broad level, there is a need for caution when it comes to the role of governments. Public administrations and governments should not play the role of chief innovators via Digital Innovation Hubs (DIHs). While we agree that DIHs can be a good way to bring technology to the broad SME-base, it should be clear that DIHs cannot take over the role of service providers and start-ups, i.e. they should not have a market-deforming effect. On the contrary, DIHs should support the digitalisation of SMEs by connecting the innovative eco-system with traditional companies. The hubs should be led by business interests and economic reasoning, as innovation seldom happens in a top-down manner. DIHs may be the technology brokers between highly innovative SMEs and slower, more traditional organisations.

When it comes to the **regulatory framework**, it is equally important to ensure that any proposed **framework provides clear rules and legal certainty for SMEs**. Small companies are the first to

suffer from rules that are up to interpretation, e.g. when we regard regulation that requires interpretation and heavy documentation, such as the GDPR or sectoral regulation like the regulatory framework on Medical Devices. Any legal framework would first need to build on the development of a clear definition of AI as well as **a clear assessment method of high-risk applications of AI**, and it should be preceded by **an impact assessment which examines additional regulatory burdens on SMEs**. It is important that any regulatory proposal is fit for SMEs and avoids rules which are up to interpretation or require extensive documentation efforts. **Businesses, in particular SMEs, benefit from a harmonised, functioning, and competitive EU Single Market that avoids fragmentation through national rules and brings legal clarity.** At the same time, there is a recognition that even in areas not directly identified as "high-risk", AI could pose important problems not only on a societal/individual level, but also with respect to **economic and strategic dominance over other players**. In the long term, if complex models can anticipate trends in any field, this will provide unforeseeable and unlimited advantages to a player, be it at business level or at governance level. The high risks identified in the White Paper for society are important, **but high-risk may also have to be considered from a business and competition angle**.

Lastly, DIGITAL SME supports efforts to build European data spaces. Data spaces will be a vital part of a future European data and AI ecosystem. **The key to adopting AI will lie in the capacity to create and develop a European data ecosystem around well-defined use cases.** Further, there is need to **support SME access to data to build a competitive data economy. For instance, SMEs need access to data** to develop to circular economy models (e.g. repair and maintenance services) or to offer additional services to clients. Access to data needs to be supported by industry-driven standardisation in APIs and data formats and/or regulatory measures. At the same time, because AI is strongly connected to data collection as well as industrial applications like IoT, **an AI strategy must go hand in hand with a cybersecurity strategy and an industrial internet of things (I-IoT) strategy (i.e. a "triple helix").** Going beyond, this AI strategy could extend to a "quadruple helix" including ethics and community feedback.

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DIGITAL SME positions on the AI White Paper

Section 1 - An ecosystem of excellence that can support the development and uptake of AI across the EU economy and public administration

a. **Priority actions to support the development and uptake of AI** *(section 4 of the White Paper on AI)*

The majority of DIGITAL SME's members thought that the following key actions were "important" or "very important":

- 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

Additional measures that were mentioned by DIGITAL SME members:

- Members pointed to one missing element, which would be "**Sharing the best practices of AI adoption in public sectors between European member states**".
- Further, they remarked that these priorities may not be sufficient. There is some scepticism when it comes to the **willingness to innovate due to structural issues** (many family-owned businesses being handed down through generations and wanting to preserve rather than re-invent their business models). Also, companies will focus on their current customer base to keep those customers happy. As many **customers are not yet asking for analytics/data-driven products or AI-enabled physical products**, there is **no incentive to innovate** here. Further, larger companies may be willing to invest in new technologies during the COVID-19 crisis, and SMEs may fall behind further.

- Finally, it is equally important to ensure that any proposed legal framework provides clear rules and legal certainty for SMEs. Small companies are the first to suffer from rules that are up to interpretation. Any legal framework would first need to build on the development of a clear definition of AI as well as a clear assessment-method of high-risk applications and it should include an impact assessment which examines additional regulatory burden on SMEs. Businesses, in particular SMEs, benefit from a harmonised, functioning, and competitive EU Single Market that avoids fragmentation through national rules and brings legal clarity rather than rules which are up to interpretation or require extensive documentation efforts.

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b. Aligning policies and strengthening coordination (as described in section 4.A of the White Paper)

The majority of DIGITAL SME 's members thought that the following key actions were important:

- Strengthen excellence in research

- Establish world-reference testing facilities for AI

- Promote the uptake of AI by businesses 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

Additional measures that were mentioned by DIGITAL SME members:

- The need for **private capital and investment in AI-driven start-ups**. **Stock options for team members** and **investors and a favourable tax regime** for them would be options to drive capital inflow.
- There is a need to distinguish between hype and real value: Digital SMEs and start-ups **embedded in sectors and verticals where domain knowledge is combined with AI** are those which are truly **valuable, and in those areas Europe can still compete**.
- **Old industrials sectors may need to be disrupted**. As large industrial structures that have developed over decades may be stubborn and unwilling to innovate as long as business

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is still going fine, there may be a need to **consciously and willingly disrupt our own industries** to make them tougher and globally more competitive. Some companies decide to do so on their own: They build up competing digital models in their own structures.

- DIGITAL SME supports efforts to build European data spaces. Data spaces will be a vital part of a future European data and AI ecosystem. **The key to adopting AI will lie in the capacity to create and develop a European data ecosystem around well-defined use cases.** Further, there is need to **support SME access to data to build a competitive data economy. For instance, SMEs need access to data** to develop to circular economy models (e.g. repair and maintenance services) or to offer additional services to clients. Access to data needs to be supported by industry-driven standardisation in APIs and data formats and/or regulatory measures.

- At the same time, because AI is strongly connected to data collection as well as industrial applications like IoT, **an AI strategy must go hand in hand with a cybersecurity strategy and an industrial internet of things (I-IoT) strategy (i.e. a "triple helix").** Going beyond, this AI strategy could extend to a "quadruple helix" including ethics and community feedback.

- There may be a need to democratise AI, and involve the **public more in AI design, adoption, and monitoring. This would allow for rethinking and revising decisions over time**. Such a democratisation of AI could bring trust, foster a common understanding and ethos of AI, increase adoption and involvement, provide a global competitive advantage, and sustain a trustworthy, human-centric AI landscape. However, at the current stage, public involvement in AI development will be challenging to accomplish in practice, since there is no consensus on how to do it. More research is needed to understand if this is possible.

- It may be necessary **to change our perception of AI**. If society sees AI as an enemy that destroys jobs, this may lead to excessive regulation.

- **Testing facilities** and their **accessibility** are a must to accelerate the rise (and consolidation of) AI-focused businesses.

c. *Establishing world-class research* (sections 4.B, 4.C and 4.E of the White Paper on AI)

DIGITAL SME members found the following aspects very important:

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- Support the establishment of a lighthouse research centre that is world-class and able to attract the best minds

- Build a network of existing AI-research excellence centres

- Set up a public-private partnership for industrial research

Additional measures that were mentioned by DIGITAL SME members:

- **Fiscal benefits and cross border employment regimes** to attract, retain and reward AI researchers, talents and data scientists are needed. This is especially true in a context where more and more software companies operate remotely, and Europe has the opportunity to attract overseas talents. A common approach on EU blue cards, whereby countries would harmonise their procedures and strategies instead of competing against each other, would be desirable.

- Some experts have the impression that Europe, e.g. via individual researchers in its academic institutions, has had a more important role than China or the US in the algorithmic development of AI. At the same time, Europe seems to have been **completely ineffective in protecting this knowledge through the patent system**. This puts Europe at a competitive disadvantage against the hardware area, where China and the US are much stronger, and patenting is aggressive. An easy and unbureaucratic access to capital (€5,000-€100,000) for individual inventors for patenting purposes, e.g. with 10 % co-funding and/or in exchange for shares in the invention, could mitigate this.

- There is a need to **promote multidisciplinary approaches to AI**, taking into account cultural, societal, business, and academic needs. This is particularly needed in the culturally rich EU environment.

- The research community often speaks a language that is far away from business. "**AI communicators**" could be identified to bring the results of research to innovators and therefore facilitate its translation into services and products.

d. *Specialised Digital Innovation Hubs (mentioned in section 4.D of the White Paper in relation to SMEs)*

As regards the tasks of the specialised Digital Innovation Hubs, the following aspects were considered important:

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- Help to raise SMEs' awareness about potential benefits of AI
- Provide access to testing and reference facilities
- Promote knowledge transfer and support the development of AI expertise among SMEs
- Support partnerships between SMEs, larger enterprises, and academia around AI projects
- Provide information about equity financing for AI start-ups

Additional measures that were mentioned by DIGITAL SME members:

- Raising awareness via **success stories in industry to raise the interest of executives** or investing in **thought-leaders and "industry pioneers"** may help create AI-aware ecosystems and actions.
- While the digital transformation generally and AI specifically need to be taken up on a broad level, there is a need for caution when it comes to the role of governments. Public administrations and governments should not play the role of chief innovators via Digital Innovation Hubs. While we agree that DIHs can be a good way to bring technology to the broad SME-base, DIHs should not take over the role of service providers and start-ups, i.e. they should not have a market-deforming effect. On the contrary, they should limit their role to **connecting the innovative eco-system with traditional companies and they should be led by business interests and economic reasoning as innovation seldom happens in a top-down manner**.
- **AI and IoT** will completely **change business models.** Businesses need to understand this fact and **think strategically** about emerging technologies instead of following shorter-term business goals.

Section 2 - An ecosystem of trust refers to a series of options for a regulatory framework for AI

a. Important concerns about AI

DIGITAL SME members had the following important concerns about AI, while the risk of "The use of AI may lead to discriminatory outcomes" was considered as neutral:

- AI may endanger safety
- AI may breach fundamental rights (such as human dignity, privacy, data protection, freedom of expression, workers' rights etc.)
- 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

Additional measures that were mentioned by DIGITAL SME members:

- It should be well known to scientists **that data analysis is a complex process** and that outcome not only depends on the models used to interpret data, but also on the acquisition methodology.
- **Over-regulation** was equally mentioned as a concern about AI, **which prevents AI startups or scaleups to quickly implement go-to-market strategies and become leaders in their product or service-niche.**
- AI can breach fundamental rights, but the main issue at the moment is that the **data is collected/transferred to China and the US and companies based there are the owners of the data**. Citizens must be educated about the consequences of sharing personal data on social platforms. The first fight is about winning back the data and for it to be owned by **European companies under European law**.
- One member suggested that we may have to address not the concerns about AI (as a technology by itself) but the concerns over the application of AI technology in certain areas. For example, systems for automatic face recognition could be beneficial at airports for safety, but it would not be good to have them in public spaces, or in schools. The use of AI to collect data about student learning can support the development of pedagogical methods but AI should not be used to monitor individual behaviour and to give marks on how students behave or to report to their parents.

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b. Need for specific new rules for AI systems

The majority of DIGITAL SME's members thought that there may be some gaps in current legislation to address the concerns listed under the point above or that there may be a need for new legislation. At the same time, they expressed weariness about overregulation, and many identified this as an important risk.

Additional measures or concerns raised by DIGITAL SME members:

- Any new EU regulatory framework should complement—and not overlap with—existing rules. This requires an analysis of existing regulatory gaps, **a clear definition of AI**, clear assessment-methods of high-risk applications and particular checks on whether **regulation is fit for SMEs (i.e. not imposing extensive regulatory burdens)**.
- One DIGITAL SME member stated that regulations are not adapted. AI is already available to players such as Google and they are **already harvesting our data without anyone being able to say to what extent**. This is a complete contradiction to what is written in the white paper about how **use cases should be allowed only when all consequences are clearly understood and under control**.
- There is a tendency for **overregulation**. Many of the above-mentioned challenges can be solved **by better technology solutions** (de-biasing training datasets) and better product management.
- Overregulation is the major risk when it comes to AI legislation. EU SMEs would benefit from a gradual and iterative approach, where new requirements are based on consensus, and accompanied by unambiguous applicability boundaries. This would keep European SMEs competitive both in the EU and abroad.
- One member voiced the opinion that **new legislation is required only in fields and applications where it is not possible to identify who is responsible for** a specific action (i.e. autonomous vehicles causing an accident). At this moment, AI just only resolves specific problems with a really limited scope.
- Others stated that it should be mandatory to have a specific and new legislation to regulate AI systems, especially when **used in the public sector.** The public sector has been lagging behind in technology adoption, and it should be encouraged to adopt well-regulated and carefully-tested AI solutions.
- There is a risk when data and AI is trained outside the EU, e.g. when a European manufacturer assembles AI devices designed outside the EU without the context of

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European laws and moral rules. This may lead to devices **applying "biases"** that will have unforeseeable consequences. Such AI could become a "black box" for European companies using it. Even more if AI-based tools are provided from organisations with a cultural & moral framework that is very different from the European one. As AI is a powerful change agent, this may change the way of working (processes, perspectives etc.) of EU companies in a way which may have negative consequences; potentially generating a cultural shift in areas with a heavy reliance on AI.

- Lastly, the main challenge is to develop new legislation in a way that is highly **adaptable to changes in the digital transformation environment**.

> *c. **Compulsory requirements for "high-risk" AI applications** (Section 5.B of the White Paper)*
>
> DIGITAL SME's members had divergent views on whether 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). The majority agreed with the approach to determine "high-risk" AI applications proposed in Section 5.B of the White Paper.

Additional measures or concerns raised by DIGITAL SME members:

- While many members did not agree with the statement that the introduction of new compulsory requirements should be limited to high-risk applications, there is a **general weariness about over-regulation**. At the same time, there is a recognition that **even AI in areas not identified as "high risk" could pose problems** not only as regards the concerns identified about, but also with **respect to dominance over other players**. For instance, one member stated that, in the long term, cross-analysis of data can be as severe as having access to health or critical-infrastructures data. If complex models can anticipate trends in any field, this will provide unforeseeable and unlimited advantages to a player, be it at business- or at governance-level (influencing elections or strategic decisions).

- Regulation should be proportional to the level of risk, which is not the same for different applications.

- Europe **should think about how to address the strategic importance of AI technology in a geopolitical setting**. While it is currently impossible to work without solutions from abroad, it would be important to reduce the reliance on foreign powers which might

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want to interfere with European interests. At the same time, the EU should not limit import of AI technology that complies with its laws and regulations. Otherwise, European SMEs exporting their products might be at a risk of retaliatory trade barriers in this case.

- There should be requirements that refer to processes supporting a constant monitoring and reaction mechanism of problems related to AI. These processes could refer to self-regulation, but also public communication/transparency of decisions relating to AI systems. Also, an analogous process to environmental impact reports when initiating a disruptive AI application could be requested, requiring peer review to find solutions to identified risks.

d. High-risk areas

Some members chose to indicate AI applications or uses that are most concerning ("high-risk") from their perspective, among them autonomous vehicles and AI software applications in medicine and healthcare.

Additional high-risk applications raised by DIGITAL SME members:

- Autonomous vehicles and AI software applications in medicine and healthcare, if not directly supervised by humans.
- Legal AI and Health AI can have the most short-term-identifiable high-risk impact.
- Health insurance.
- At the same time, while those areas are high-risk, there can also be a high reward: For instance, autonomous vehicles can help reduce CO_2 emissions. Healthcare solutions can help increase the life expectancy of the EU population. Thus, 'high risk' should be clearly defined to avoid misunderstanding, and potentially be weighed against benefits.

e. Mandatory requirements of a possible future regulatory framework for AI (as section 5.D of the White Paper)

The following mandatory requirements of a possible future regulatory framework for AI (as section 5.D of the White Paper) were rated as very important:

- The quality of training data sets
- The keeping of records and data
- Information on the purpose and the nature of AI systems

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- Robustness and accuracy of AI systems
- Human oversight
- Clear liability and safety rules

Additional measures or concerns raised by DIGITAL SME members or experts:

- Quality of training data sets is secondary to the quality of the validation/testing process. The performance of the product depends on multiple factors outside of the training data set itself. Statements regarding intended use and possible biases of the product can only be based on careful testing and validation.
- Keeping of records and data requirement should be better specified, since keeping all the data from the model-building process is not practically feasible due to large datasets involved in the process.
- Human oversight requirement should be made more explicit in order to specifically allow products that can function without continuous human supervision once certified.

f. *Biometric identification systems – Need for further EU guidelines or regulation*

Answers from DIGITAL SME members were contradictory in this matter. Some thought that no further guidelines or regulations are needed and some thought that the 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. Others stated that special requirements in addition to those mentioned in the question above should be imposed but did not specify more details.

Additional measures or concerns raised by DIGITAL SME members or experts:

- Restricting biometric identification systems should be done extremely cautiously since many business processes depend on it. For example, distinction between at-distance facial recognition and contact fingerprint recognition must be made.

g. *Voluntary labelling system*

Our membership had divergent opinions. While it can be useful, there may be bureaucratic hurdles and such a system could be useless if only voluntary. This requires further discussion on the EU level involving different stakeholder groups, in particular SMEs.

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Additional measures or concerns raised by DIGITAL SME members:

- One DIGITAL SME member thought that it should be mandatory, not based on a voluntary process.
- Others expressed the **need to be careful with overregulation**. SMEs may move to other jurisdictions to test their products. There are examples of SMEs with entities in China that use those locations to test their new "predictive maintenance" products on their own machinery because it's easier to test this over there than in Europe.
- Equally, members expressed the need to **be careful with immediately restricting new uses of AI, e.g. face recognition**. There should be **room for experimentation** to find out what works and what doesn't "in real life". Thinking about these risks in abstract terms may lead to rules, regulations, and extra bureaucratic burden, which does not match real-life risks, but puts a brake on innovation.
- As a way out, governments could launch **public-private sandboxes** where AI can be tested "in production"– very much like we do during clinical trials. After a testing period, potential harms, but also added value, can be identified and challenges addressed. Full products as opposed to "AI part only" should be tested if such sandboxes are established.

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h. Best way to ensure that AI is trustworthy

The combined answers of DIGITAL SME's members led to the conclusion that a **combination of ex-ante compliance and ex-post enforcement mechanisms** is the best way to ensure that AI is trustworthy, secure and in respect of European values and rules. Among the compliance and enforcement mechanisms seen as important by DIGITAL SME members:

- 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

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Additional measures or concerns raised by DIGITAL SME members or experts:

- A member added **that data traceability with security locks to guarantee privacy** is a must and this should be achieved by design.
- Further, it would be useful to **have sandboxes where neither ex-ante nor ex-post mechanism apply, and companies can try out AI**.
- **Standardisation of the process to achieve compliance** of high-risk products or services could support trustworthy AI.
- It might be necessary to **create a certificate** which attributes "Explainability of the AI algorithms and methods used". However, introducing concrete explainability requirements into legislation should be done cautiously since the academic debate when it comes to explainability is still ongoing, and the consensus on that topic has not been reached yet.
- One expert voiced the view that sufficient external conformity assessment is already in place for some applications, e.g., healthcare as per Medical Device Regulation.

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

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a.   Product-safety legislation

The majority of DIGITAL SME's members thought that cyber risks and personal security risks should be further spelled out. Risks related to the loss of connectivity were also mentioned, while mental health risks were not mentioned.

Additional measures or concerns raised by DIGITAL SME members:

- Users should have more control over their own data and should be provided knowledge on who has access to their data and how they are using it.
- One member voiced the opinion that governments should start to provide safe e-mails that are not controlled by companies or governments.
- One option could be to assign identities to objects so that they could be traced back and potential failure could be traced back to a responsible entity. Requirements to store objects related to private information should be balanced with privacy risks.
- AI systems need to be compliant to specific AI/ML cybersecurity requirements, protected against cyber adversaries, and resilient. This requires a new specific set of standards and assessments to be included in the Cybersecurity Certification Schemes and in relation to the 2020 Rolling Plan for ICT Standardisation (chapters "Cybersecurity" and "Artificial Intelligence").
- DIGITAL SME generally and continuously advocates for the focus and applicability of cybersecurity standards and certifications to be adapted to SMEs. Thus, we would emphasise the importance of timely coverage of these areas for AI/ML. With the massive and quick uptake of AI-related innovations by SMEs, the "hidden risks and threats" in supply/value chains may jeopardise any classical measures for cybersecurity.

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b.   New risk-assessment procedures

The majority of DIGITAL SME's members agree that safety legislative framework should consider new risk-assessment procedures for products subject to important changes during their lifetime.

Additional measures or concerns raised by DIGITAL SME members:

- AI software products' safety regulation should be comparable to regulation of hardware devices or equipment and sold with guarantees of 1 or 2 years. There could be a CE-mark-like label for AI products, which would, however, need to take into account challenges associated with AI, such as evolving data models, which can influence how an AI-based software behaves.

- A member stressed that it will be difficult to conduct new risk assessments for IoT objects spread across different entities/countries. There may be a need for processes and procedures that address this challenge from the design-stage onward.

- If an autonomous vehicle creates harm or if an automatic cancer detection system fails, who is responsible and who has to ensure proper compensation for damages? Maybe, for specific AI applications, a CE stamp could be useful.

c. Product Liability Directive

DIGITAL SME's members had diverging views on whether the current EU legislative framework for liability (Product Liability Directive) should be amended to better cover the risks engendered by certain AI applications. There was no clear answer to this question by members.

Additional measures or concerns raised by DIGITAL SME members:

- COVID-19 is an example of how the entire world can suddenly behave in an unpredictable way. This type of unpredictable change can trigger reactions by algorithms affecting higher-ranking systems.

- If things are to be done properly, this will slow down business development. If the issues are not addressed properly it will be highly damaging to everybody. The main problem will be who is responsible when there is a failure of an extraordinarily complex process involving several players. This can be achieved only by strong authentication and traceability procedures of data and objects/users generating the data.

d. National liability rules to be adapted for the operation of AI

DIGITAL SME members agreed that the current national liability rules should be adapted for the operation of AI to better ensure proper compensation for damages and a fair allocation of liability, either for all AI applications or for specific AI applications (no agreement on the focus).

Conclusion

To conclude: If Europe wants to become a global leader in AI, we have to strengthen our digital frontrunners, many of which are SMEs and startups. To support these frontrunners with the best possible policy- and legal framework to innovate in AI, the Commission could install a **"Multi-stakeholder group on AI" that gives a strong voice to smaller player's needs**. This could help to provide proposals for a legal framework and regulatory measures, to ensure that those are "fit for SMEs" and avoid excessive regulation that hampers innovation. In addition, this group could contribute to policy measures and actions to support he uptake of AI, e.g. the development of frameworks/recommendations for sandboxes, proposals such as "AI communicators" or "AI vouchers" or fiscal support schemes. At the same time, such a group should focus also on the competitive aspects related to AI – i.e. aspects related to potential dominance of very advanced players if AI excellence is combined with access to data. **A level-playing field for SMEs can only be achieved if SMEs do not disproportionally suffer from overregulation and have adequate access to data and finance.**

At the same time, because AI is strongly connected to data collection as well as industrial applications like IoT, an AI strategy must go hand in hand with a cybersecurity strategy and an industrial internet of things (I-IoT) strategy (i.e. a "triple helix"). Going beyond, this AI strategy could extend to a "quadruple helix" including ethics and community feedback.

We are glad to have contributed to the Commission's consultation and stand ready to offer additional support.

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