BSA submission to the European Commission Consultation on the Inception Impact Assessment for a Proposal for a legal act of the European Parliament and the Council laying down requirements for Artificial Intelligence

BSA | The Software Alliance ("BSA")[1] welcomes the opportunity to offer thoughts on the European Commission Inception Impact Assessment on a possible Proposal for a legal act of the European Parliament and the Council laying down requirements for Artificial Intelligence ("the Proposal"). BSA is the leading advocate for the global software industry before governments and in the international marketplace. Our members are at the forefront of software-enabled innovation that is fueling global economic growth, including cloud computing and AI products and services. BSA members include many of the world's leading suppliers of software, hardware, and online services to organizations of all sizes and across all industries and sectors. BSA members have made significant investments in developing innovative AI solutions for use across a range of applications. As leaders in AI development, BSA members have unique insights into both the tremendous potential that AI holds to address a variety of social challenges and the governmental policies that can best support the responsible use of AI and ensure continued innovation.

BSA agrees with the fundamental proposition of the European Commission's White Paper on Artificial Intelligence ("the White Paper") that the public should "expect the same level of safety and respect of their rights whether or not a product or system relies on AI." Of course, the concerns presented by the European Commission are not unique to AI. The EU body of laws offers strong, technologically neutral safeguards against these concerns. BSA strongly recommends that the Commission take stock of this body of legislation in a targeted way, identify possible gaps and only propose new legislation if there is no other way to rectify them, AI-specific or not.

The White Paper acknowledges the challenges and promise of AI tools, and at the same time calls for a more thorough analysis of existing EU Legislation, to establish whether it is fit for purpose in protecting fundamental rights whilst fostering AI uptake. In the context of the work of the High-Level Expert Group on AI ("HLEG"), BSA prepared a detailed analysis of EU legislation impacting AI,[2] which could prove helpful as the Commission moves to evaluate the sufficiency of current laws. Moreover, BSA would like to emphasize that AI is not developed in a vacuum in the EU, and that while new technologies present new challenges, the protection and enforcement of Fundamental Rights in the EU remain as strong as ever. BSA and its Members continue to work

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alongside EU Institutions and Member States to support a strong EU body of law that provides safeguards for fundamental rights whilst fostering innovation.

As the Commission moves to implement the White Paper, BSA would like to reiterate how important it would be for the Commission to carry out an in-depth inventory of EU law, and its application to AI, before suggesting possible legislative actions. Consistent with the risk-based, context-specific approach the Commission has endorsed, any proposed legislative changes should avoid one-size-fits-all mandates. The AI ecosystem is broad, encompassing a diverse range of technologies, use cases and wide array of stakeholders. Legislative updates must therefore be flexible enough to account for the unique considerations that may be implicated by specific uses cases. For instance, Business-to-Business ("B2B") relations are radically different than Business-to-Consumer ("B2C"), and entail a completely different consideration and allocation of risk. In the B2B context, entities should remain free to use contractual negotiations as a mechanism for allocating risks, liabilities, and obligations in a manner that corresponds to the nature of the transaction.

BSA agrees that future legislative proposals should focus on high-risk scenarios where the deployment of AI-based technologies poses a threat to human life and fundamental rights. The scope of any regulatory obligations should be a function of the degree of risk and the potential scope and severity of harm. Many AI systems pose extremely low, or even no, risk to individuals or society. To this end, it will be important to carefully assess scenarios that should be deemed as high-risk and hence be subject to legal requirements. BSA strongly recommends ensuring stakeholder involvement in this context as much as possible, especially as it will be sector-dependent as much as use-case dependent. BSA and its Members have participated, and intend to continue to be active participants, to EU and Member States stakeholder consultations. BSA Members are uniquely positioned to provide essential insights in the assessment of high-risk scenarios and use-cases of AI.

BSA supports the possibility suggested by the White Paper to take an incremental approach by limiting regulation to AI systems that are (1) deployed in a high risk sector and (2) used in a manner that significant risks are likely to arise. Moreover, due consideration should be given to AI applications that enhance human decision-making, whereby the risk consideration – even when the two above conditions are fulfilled – is inevitably balanced by the human involvement and control. Furthermore, **BSA urges the Commission to extend this two-pronged approach to all possible high-risk scenarios**, rather than identifying specific sectors where – regardless of its purpose and use – AI would be considered high-risk by default. This would allow for a more homogeneous application and understanding of the possible requirements for high-risk AI, providing for the necessary proportionality and legal certainty as AI technologies and tools are developed and deployed.

Ensuring that the definition of high-risk is appropriately tailored will be critical. Given the potentially far-reaching requirements of new legislative requirements for high-risk AI, it is crucial for AI developers and users to be able to determine with certainty if their application might fall within the scope of high-risk. The complexity of defining "high-risk" AI is exacerbated by that fact that AI may be developed for a multitude of uses – and determining whether it is "high-risk" will turn on how it is deployed (i.e., whether it is deployed by an end-user in a high-risk sector and used in a manner that creates a significantly likelihood of risk.). The methodology behind the definition of high-risk sectors needs to be precise and robust, with only limited exemptions. This will guarantee that the list remains targeted and up to date as new technologies and use cases emerge.

BSA agrees with the Commission's analysis that legal requirements for high-risk AI applications "should be addressed to the actor(s) who is (are) best placed to address any potential risks" (White Paper p. 22). In many cases – especially in the cases of general-purpose AI systems – developers will not be in the position to know whether the technology is being deployed by an end-user in a manner that meets the definition of high-risk. Similarly, in B2B relations the allocation of risk will be one part of the contractual agreement between two entities, and once again the developer will not be best place to establish whether the application is to be deployed in an high-risk scenario, and what obligations that may entail in the specific sector. **Developers are better placed to describe the capabilities and limitations of an AI system, while disclosing the possible impact of AI use will typically need to be the responsibility of the deployer**.

In this context, and in a similar vein in the liability context (please see below in the relevant section for more information), **the Commission may want to draw from existing concepts for establishing which entity is "best placed to address any potential risk", i.e. the entity that determines the purpose of the AI, similar to the concept of a "controller" under the GDPR**. Article 29 Working Party guidance on controllers and processors (WP 169) describes this party as the "determining body" that decides the "how" and the "why" of a processing operation. Applying this concept in the context of AI, the "AI controller" will generally be the deployer of an AI system (e.g., a vehicle manufacturer that integrates an AI-driven language recognition system into an automobile, or a bank that uses an AI tool to score consumers for loans). In some instances, it may also be the operator of the AI system (e.g., a physician using assistive tools during surgery).

Under the GDPR, controllers and processors have different levels of responsibility for achieving privacy outcomes that reflect their different roles. In particular, controllers have primary responsibility for satisfying certain legal privacy and security obligations and for honoring data subject rights requests. On the other hand, processors, which handle data on behalf of the controller to implement the controller's objectives, are responsible for securing the personal data they maintain and following the instructions of a controller, pursuant to their agreements with relevant controllers. **The processor/controller distinction not only provides organizations with a clear picture of their respective legal obligations, it also helps to ensure that data subjects rights are adequately protected**. Accordingly, BSA recommends that the Commission preserves in possible AI legislation the careful distinction between controllers and processors, especially at a time when data protection legislation, such as the General Data Protection Regulation, is finally establishing a level-set amongst organizations that process data.

In the context of enterprise AI, the tools that BSA companies provide are generally AI systems that facilitate human decision-making, without replacing human decision-making. With this in mind, it becomes clear that a company using an AI service to enable its employees to make a decision acts as a controller in deciding how and why that data is processed, and the AI system is used as a tool for processing data on behalf of that controller. Accordingly, the company developing and providing the AI tool is appropriately treated as a processor. This key distinction could also help inform the Commission's AI workstreams, which will have to focus on sectors with very different definitions and approaches to risk management. **Ensuring that the definitions and requirements for the entities involved are the same in different sectors – and founded in well-established practices that are equally applied cross-sectorally – would ensure a more harmonized approach to AI**.

BSA recommends to the Commission not to establish pre-marketing conformity assessment for AI systems, as such obligations are liable to turn into barriers to enter the market. A more scalable approach would be self-attestation, which would also be least likely to

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unnecessarily extend time to market or unduly burden smaller operators. BSA believe that prescriptive regulation of AI, requiring for example that every possible use of an AI system is "fair" or "unbiased", will likely be unworkable in practice.

BSA urges the Commission not to pursue a regulatory scheme based on prescriptive conformity assessment requirements. The risks that AI poses and the appropriate mechanisms for mitigating those risks are largely context-specific. The appropriate mechanisms and standards for training data, record keeping, transparency, accuracy, and human oversight will vary depending on the nature of the AI system and the setting in which it is being deployed. The Commission should therefore avoid creating prescriptive, one-size-fits-all requirements around these categories. Such ex-ante requirements could impede efforts to address the very risks they are intended to address, add unnecessary costs and require extremely complex compliance checks.

Given the nascent nature of the technology and sociotechnical quality of many of its most significant challenges, BSA believes that a governance-based approach to legislation, which identifies broad objectives and the processes that developers and deployers should follow to achieve them, will be more effective than a prescriptive one. Consistent with a governance-based approach, the Commission should articulate a framework that will enable stakeholders to perform an "impact assessment" on high-risk AI systems. In this context, BSA recommends building upon the work done by the HLEG and many AI developers on the Assessment List for Trustworthy Artificial Intelligence, in particular as it may constitute a template for future assessment tools. **The goal of these governance processes should be to help developers and deployers of covered AI systems identify and quantify any relevant risks of harm to individuals or society and, where those risks are determined to be significant, to implement measures to mitigate against them**. Importantly, impact assessments allow for a more context-specific evaluation of the types of risk mitigation measures that are available, and which is ideally suited for the particular deployment scenario.

BSA acknowledges the Commission's concern that the deployment of biometric identification systems can implicate heightened risks for fundamental rights. BSA welcomes the White Paper's recommendation for the Commission to launch an inquiry to examine the appropriate regulatory framework for biometric systems, which is also reflected in the Inception Impact Assessment. While EU law already provides clear parameters for assessing the lawfulness of biometric technologies from a data protection perspective, the rules that govern the ethics and other risks of Facial Recognition Technologies ("FRT") deployments are less well defined. For that reason, **the Commission should consider specific rules governing the use of FRT by the public sector in particular, given the heightened risks inherent in governmental use of this technology**.

BSA agrees that public trust in AI is essential for "[promoting] the overall uptake of the technology". However, **we would urge the Commission not to pursue the creation of a blanket voluntary labeling system for all no-high risk systems**. Given the diverse range of AI products and services that will be considered "no-high risk AI applications", a one-size-fits-all labeling scheme would be unworkable. The benchmarks for evaluating whether AI systems are trustworthy are likely to be highly variable, driven in large part by system functionality and deployment context. The relevant benchmarks for evaluating the trustworthiness of an AI system that recommends restaurants are likely to be quite different from those that are relevant to an AI system that is designed to identify what objects are in a photograph. A methodology for a labelling system that could apply to the entire universe of "no-high risk AI" would necessarily be very complex, which would limit customers' understanding and engagement. Similarly, the governance

of such a scheme would be exceedingly complex and would necessarily have to cover diverse sectors and technologies – likely in almost all industrial EU activities.