BDVA/DAIRO position paper
Response to the European Commission's proposal for AI Regulation

04th August 2021

BDVA/DAIRO welcomes the opportunity to provide **feedback to the European Commission's proposal for AI Regulation** as there is a clear need for a solid AI European approach based on European values.

BDVA/DAIRO supports the idea that there should be a **balance between regulation and innovation, and that new rules should facilitate investment and innovation**. For this reason, the specific objective of the proposed regulatory framework to "ensure legal certainty to facilitate investment and innovation in AI" is highly supported by the BDVA/DAIRO community. However, the **cost, time, infrastructure and knowledge needed to implement this regulation** may be burdensome. Small companies, research and education organizations might not be able to easily follow the regulatory developments and might be affected negatively e.g. by a **lack of sufficiently qualified personnel**, resulting in hard implementation that can hinder innovation and competitiveness. Very solid **investments for the implementation of this regulation are needed** and in this respect BDVA/DAIRO observes that the European Commission's Coordinated Plan on AI considers and supports the implementation of the future AI Regulation.

To **accelerate the adoption of Industrial and Trustworthy AI in Europe**, the association stresses the **need to develop and invest in engineering and standardisation frameworks for Industrial and Trustworthy AI** (such as the one BDVA is developing in collaboration with the Franco-German initiative) and **calls for strong collaboration with national initiatives working on Industrial AI to align and coordinate efforts on this matter**.

The association supports and highlights the **importance of Data quality and Data governance for AI** as paramount, and underlines the fundamental connection between AI and Data. BDVA/DAIRO welcomes also the link to other legislative acts, such as the GDPR, and underlines the alignment needed with the Data Governance Act and the upcoming Data Act. In relation to Data quality, the BDVA/DAIRO community has also emphasized the topic as a mean to, among other benefits, achieve fairness and avoid discrimination. The **need for different metrics** has been stressed by the community in areas such as Data quality, interpretability, explainability, predictive accuracy, robustness, fairness, computational complexity and very importantly in risk-assesment in **alignment with standardisation efforts and results**.

In addition to the above-mentioned topics (Data and Data Governance for AI, the need to develop frameworks and tools to speed up the adoption of industrial AI, and the balance innovation-regulation) the BDVA/DAIRO community has stressed the importance of and provided feedback and recommendations to i) the scope and impact of the draft AI regulation; ii) the notion and components of trustworthiness in the regulation; iii) risk assessment and classification: iv) life-cycle of products, and v) opportunities for SMEs.

The recommendations consider also the need for the establishment of **safe environments for better testing**. **Access to knowledge, testing, experimentation and ecosystem** are key factors for success in particular for SMEs. The association acknowledges that the proposed plan for an AI Regulation comes with a new updated Coordinated Plan on AI addressing these topics, but calls up for the importance of investing in federated experimental networks such as the European Federation of i-Spaces or Big Data Innovation Hubs. These networks can not only provide access to knowledge, innovation, testing and ecosystem to SMEs and startups in context of the new AI regulation, but can offer opportunities to legislators in supporting collaboration between innovators and standardisation experts.

Building on these considerations and on a series of workshops held with the association's members, BDVA/DAIRO wishes to underline a few important elements concerning both identified challenges and recommendations from the research & innovation community linked to the European Big Data industry. This response to the feedback request covers in particular eight aspects of the proposal for AI Regulation. The document is therefore structured as follows:

- Scope and impact of the draft AI Regulation
- Data and Data governance for AI
- Notion and components of trustworthiness in the AI Regulation
- Risk-assessment and risk classification
- Balance innovation - regulation and elements of supporting innovation
- How the regulation lower barriers, opportunities for SMEs
- Life-cycle of products
- Engineering and Standardisation frameworks for Industrial and Trustworthy AI
- Other topics

1. Scope and Impact of the Draft AI Regulation

BDVA/DAIRO appreciates that the proposal addresses the basic concept of sustainability for the technology field of AI, as it includes elements of environmental conditions, social aspects, and governance. This is considered to support adjustments that may become necessary in the future. For the time being, however, the association sees also a number of issues.

The **definition of AI** is generally quite broad, and could create issues or future uncertainty and lack of clarity. First, it is important to note that **the Regulation should address AI Systems and not AI as a field**. The notion of AI Systems is present and addressed all the way through the EC Proposal. However, the clear distinction between AI at large and AI Systems seems to be implied and never explained. For this reason, we would strongly recommend to add a clear definition at the begininning of the AI Regulation proposal explaining the semantic and conceptual choice. **The definition of AI systems shall be reviewed**, possibly taking into account how **current standardization efforts** define AI systems[1].

Second, the **definition of AI system also covers far more than what is subjectively understood as AI**. Based on such definition, even the simplest search, sorting and routing algorithms could be considered AI systems, or being subject of this Regulation, risking the creation of a set of rules for high-risk software systems.

Third, it is **not clear how components of larger AI systems should be treated**, like pre-trained AI components from other manufacturers, or components that are not released independently (e.g would such components need an independent certification?) We would recommend this part to addressed with more clarity.

BDVA/DAIRO acknowledges the importance of creating an annex to the Regulation listing the technologies affected by the regulation **and welcomes the possibility to amend it as foreseen in paragraph (85).** In fact, the association supports the idea of annexes which are also reviewed periodically given that the choice to horizontally regulate technology leads to some issues. **When updating the Annex I of the Regulation, proactivity of policymakers** shall be needed in order to protect citizens from new threats of a very dynamic technology. This would cover AI system technologies and also specific application areas. Regularly review and evaluate these annexes with stakeholders from sectors and on national level.

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[1]e.g. https://joinup.ec.europa.eu/collection/rolling-plan-ict-standardisation/artificial-intelligence

In some **verticals** there may be different developments, effects or regulations. It should be possible to **create sector-specific exceptions**, which could also be included in an annex that is reviewed and updated regularly. In both cases, the review of the appendix could contain a proactive element so that citizens are protected from new dynamically evolving potential threats.The AI Regulation proposal **does not seem to give any exception for research**. Many researchers develop AI systems and publish them in open access journals or in a repository, such as GitHub, free of charge and with an open license, in order to disseminate knowledge and to let other researchers improve them. Those models are not intended to be commercialized, but, due to the nature of the licenses most commonly used, it is always possible that the models are used by other entities, even incorporated in other models, and put into the market. There should be a provision similar to art. 89 of GDPR, in order to allow researcher to publish their model for academic purposes without falling into the definition of "putting into the market/ into service". **The situation in which researchers collaborate with industry, hospitals or other entities should be regulated separately**.

Regarding startups and SMEs, one source of concern is the Commission's power[2] to unilaterally extend the list of sectors covered by the regulation by delegated acts. Industry - including professional associations - should be consulted before any decision is taken that may have an impact on the scope of the Regulation.

2. Data and data governance for AI

BDVA/DAIRO highlights the importance of Data Quality and Data governance as paramount and welcomes article 10 of the draft regulation. The association also welcomes the reference to the Data Governance Act (in preparation) and the ethical guidelines of the HLEG (as reported).

The **definition of data quality** in the proposal for regulation is too absolute and misleading although BDVA/DAIRO agrees that it is important to have one. In **Article 10**, the Commission does not define the **criteria for measuring the quality of the data sets.** There should also be an explicit mention of a **need for data quality metrics in place** (e.g. predictive accuracy, robustness, fairness of trained machine learning models). The responsibility and/or accountability for data quality (in testing, experimentation, and operation) may need to be clarified.

It is impossible to guarantee that training datasets are completely free of errors and biases, and the obligation in this respect must necessarily be a **best effort obligation**, taking into account the state of the art and industry practices, as is envisaged in terms of security in Article 15. The following wording would be more appropriate: "Adequate efforts must be made to ensure that the data sets are sufficiently relevant, representative, error-free and complete".

Our community believes also that **more emphasis should be placed on achieving fairness through data quality in the regulation** although the achievement of fairness through data quality is true for some types of systems (such as facial recognition systems) but not for others (such as classification of satellite images). Efforts should be made to ensure representativeness achieving fairness through **data quality**. Contextual assessment could be used, meaning that data quality should be coupled to a certain application/goal/task and only be assessed in that respect. Also it should be considered the potential use of low-quality data derived from socio-technical inequalities in implementation in social contexts as well as algorithm/model deployment.

The establishment of **testing facilities, methodologies and standards should be foreseen** for better testing (also with data) and MLOps (Paragraph 44). Another weakness is that **no explicit provisions for the validation of testing and experimentation data sets** (and related metrics) **are provided** (Paragraph 45, 46 and Article 10). Also**, implications of the utilization of aggregated data** (from

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different providers) or **implicit data** (as from third party suppliers of AI elements in embedded systems) need to be addressed.

The Regulation shall also **ensure consistency with existing EU legislations.** BDVA/DAIRO welcomes that the proposed Regulation complements the GDPR, although overlaps in scope and application should be avoided. Today, most AI systems are based on the processing of massive data so, it is essential that **the AI Regulation is aligned with the GDPR**. As it stands, this text represents new risks of legal insecurity due to its difficult reconciliation with existing regulations. The **principle of quality of data sets**, which is essential for the development of efficient and unbiased AI, is **difficult to reconcile with certain principles of the GDPR**, in particular the principle of data minimization, the limitation of retention periods, the consent to collect certain types of data and the principle of informing users about the purpose of the processing at the time of collection.

Finally, the **end-to-end lifecycle approach is needed** to ensure that the Regulation is considering mitigations beyond data quality, such as how the model is designed and built, and whether developers and researchers should use blocklists or other technical measures to disallow inappropriate content

3. Notion and components of trustworthiness in the AI regulation

The notion of trustworthiness of AI is thoroughly present in the proposal for AI Regulation. This notion, as a general concept, is welcomed by BDVA/DAIRO. A **supporting framework to explicitly and practically define trustworthiness of Industrial AI** in different (high risk or not) sectors and foster the adoption of norms, can really promote and accelerate adoption of Industrial AI. This reduces risks and will also enable sector-specific optimizations.

BDVA/DAIRO is currently conducting several activities in relation to Industrial and Trustworthy AI[3] to set out a comprehensive industrial and trustworthy AI framework that clusters the priority area for AI research, innovation and deployment and calls **for strong collaboration with national initiatives working on Industrial and Trustworthy AI to align and coordinate efforts on this matter.** Also, **adequate standards supporting industrial AI and trustworthiness** are fundamental such as adequate metrics for interpretability, explainability, predictive accuracy, robustness, fairness, computational complexity.

Regarding the **management of complex systems composed of several AI systems** (especially using different underlying AI methods), BDVA/DAIRO believes that the proposal for a Regulation should be more clear on whether separate components would be individually required to conform to the AI Regulation, or if that would be considered only as part of the system as whole. Moreover, there is an open question on whether there would be implications for liability when components are not compliant.

When referring to the link between trustworthiness and **labelling**, it is important to consider **digital literacy** as very important. Additionally, **a label is always context dependent**, and it should contain **at least two dimensions**: **technology and organisation**. Some AI applications may seem to be unfair or discriminatory, but that depends on the contexts of deployment. Therefore, rules to distinguish between legitimate bias and unfair bias may be considered by the legislator.

Measures to address aspects like non-discrimination and fairness are not explicitly required for high risk AI in the proposed regulation. This may be necessary because biases do not merely result from low-quality data, but also from socio-technical inequalities in implementation in social contexts as well as algorithm/model deployment

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Finally, an **explicit mention of a need for trustworthiness metrics in place** (e.g. predictive accuracy, robustness, fairness, interpretability, computational complexity) of machine learning models shall be added.

4. Risk-assessment and risk classification

BDVA/DAIRO welcomes the risk-based approach that aims to look at the effects of AI rather than trying to formulate bottom-up technical requirements. Balancing innovation, human rights and strategic autonomy is a delicate exercise and the current proposal is a big step in the right direction. The proposal of a Regulation on AI is in line with our concerns about the need for risk-assessment and risk classifications. The association welcomes the idea of having an Annex (i.e., Annex III to the Regulation), for listing the risks and apply a set of criteria and risk assessment methodology. It would be very helpful to include a **definition** of the respective levels and applications and the respective risk levels. The AI risk classification and assessment criteria and metrics could be aligned explicitly with international **standardization** results. The **standard risk metrics** could be used to make Article 9 (Risk Management system) more specific, especially for article 9.2 (risk assessment process).

Some issues should be considered: on the one hand, a more **detailed classification of risk** could be necessary for industry to perform self-assessment of risk associated with their products. Risk and levels cannot be easily generalized over many application of AI. Moreover, risk granularity is coarse (High Risk, Low Risk etc). On the other hand, **risk management** need **standard metrics**, as in finance and other regulated fields. Additionally, the issue of **bias** shall be looked at closely. BDVA/DAIRO underlines that there is still no established practice in research to deal with bias in general, and that a framework would be welcome. Finally, the current text does not specify the means that the European Commission intends to deploy to ensure the compliance of high-risk AI developed outside the EU.

In general, regulation would need to **constantly move with research** and innovation efforts, in particular, for the definition of risk-assessment and risk classification patterns and the Regulation would need to be based on the **continuously updated standards based on ongoing research.**

5. Balance innovation-regulation and elements supporting innovation

BDVA/DAIRO is very much aligned with the idea that the regulation should not hinder innovation, but rather facilitate investment and innovation. For this reason, it supports the specific objective of the proposed regulatory framework on AI to *ensure legal certainty to facilitate investment and innovation in AI* (page 3 of the Proposal). However, the regulation might create difficulties to establish balance innovation-regulation on a constant basis. At the moment it might be an administrative burden especially to universities, research centers and SME. On the other hand, BDVA/DAIRO agrees that a Regulation can drive innovation. Thus, regulatory actions and innovation shouldn't view these as antithetical to each other.

The Regulation should come along with strong investments in implementation, definition of European frameworks to support adoption, skills development programmes and support to SMEs.

BDVA/DAIRO welcomes the proposal of **Regulatory sandboxes as to establish protected environments to experiment innovation.** This is a major advance in European law that will bring the EU in line with the standards of its international competitors. A **close monitoring** to assess whether such regulatory sandboxes and the way those are implemented in practice, actually facilitate innovation is needed and strongly recommended. Moreover, **the conditions for access to and use of sandboxes need to be clarified**. BDVA/DAIRO recommends that for startups the scheme should be strengthened with a precise definition of eligible actors, the duration of the scheme and, above all, the list of obligations from which the scheme should exempt them. The Commission should not delegate

all decisions on the implementation of sandboxes to Member States, in order to avoid fragmentation of regulatory regimes and a possible race to the bottom between countries competing to attract AI innovators. The idea would be to avoid the concentration of companies in countries with the least restrictive rules, a problem that has already emerged with tax rules and the GDPR with Ireland and Luxembourg.

Art 10 could be "suspended" for short period of time to allow the introduction of new AI-based services and to assess if bias exists. This, as to promote a kind of safe conduct for a predefined and fixed time. "Clinical trials" might give a good reference framework for suspensions. A proposed solution would be to put easily accessible ethics commissions first. Those, could also give guidance to SMEs.

6. Lowering barriers and increasing opportunities for SMEs

In line with the previous section BDVA/DAIRO agrees with the idea that **a clear and consistently applied and interpreted Regulation sets a common ground that can facilitate innovation particularly in SMEs**. In other words, Regulations should be considered as guidelines instead of a set of constrains, like for GDPR or PSD2. Under this light, it can be considered as a source of technological innovation, opening new business opportunities and competitive advantages against less agile entities (in particular those not used to EU ethical principles). New business roles can potentially be generated, opening the playing field for new service and solution providers.

Access **to knowledge, testing, experimentation and ecosystem** are key factors for success in SMEs. The association acknowledges that the proposed plan for an AI Regulation comes with a new updated Coordinated Plan on AI addressing these topics, but stresses the **importance of investing in federated experimental networks such as the European Federation of i-Spaces or Big Data Innovation Hubs[4]**. These networks can not only provide access to knowledge, innovation, testing and ecosystem to SMEs and startups in context of the new AI regulation, but can offer opportunities to legislators in supporting collaboration between innovators and standardisation experts.

The establishment of a European Artificial Intelligence Board is also positively considered in order to ensure the consistent application and interpretation of the Regulation among the different national authorities. However it is not clear what the role of private entities (and in particular SMEs and startups) within the European Artificilal Intellingence Board will be, and how their voice will be caught and brought into the board. Also, as previously mentioned, an element of notice is the establishment of regulatory sandboxes to foster AI innovation and to accelerate the access to markets by reducing potential barriers for SMEs and startups. However, the conditions by which SMEs (but in general all the businesses) will be allowed to access and use the regulatory sandboxes is not clear.

The AI field is characterized by a high variability and new developments, so part of the Regulation could be affected by obsolescence in respect to the actual evolution of the field and consquently a sense of feeling lost from the SME perspective and, even worse, high risk of investiment waste. This is particularly critical during the boosting phase of start-ups. Support to SMEs and startups needs to go beyond "preferential access". **Best available technology principles** should be shared so SMEs can understand and contribute to the SOTA. Also, SMEs should have **easy access to the market**, and hurdles to enter it being lowered. As data is the key element for many AIs and access to data is paramount it is fundamental an alignment between the proposal for AI Regulation and the Data Act. Additionally, **repositories of AI trustworthy capabilities** can be created (models, patterns, source code) and shared.

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[4] For example, see the federation of Big Data Innovation Hubs created by the EUHubs4Data project: https://euhubs4data.eu/

7. Life-cycle of products

BDVA/DAIRO highly appreciates the Commssion's awareness regarding the specifics of the AI systems' life-cycle and the efforts to integrate proper risk management of high-risk AI systems, including the creation of synergies with other instruments such as the Proposal for a Regulation on Machinery Products. The creation of dynamic, evolutionary state of the art, relevant for the legal assessment of disruptive technologies such as AI is of great value for the industry as well as the society, ensuring de facto legal certainty and reinforcing the notion of trustworthiness.

The Engineering and Standardisation framework for Industrial and Trustworthy AI should be taken into account and enhanced. As stated in previous BDVA/DAIRO's position papers, standards and standardisation can be employed as a mechanism to leverage international best practice to build trust and confidence in AI products, services, tools, and processes[5].

BDVA/DAIRO stresses upon the need to **leverage international best practice to build trust and confidence in AI products, services, tools, and processes**. Regarding the life-cycle of products, the association recognises that AI engineering is not sufficiently established in science and industrial practice. Also, the multi-technology and multi-disciplinary requirements should be considered. Furthermore, there are open questions such as how to cope with context changes and what is the 'best before' date of a trained model. It is also important to take such approach when designing and implementing innovation facilitation solutions, such as regulatory sandboxes, which in their traditional shape and format concentrate predominantly on the risks posed by products, services and business models prior their access to the market. It is highly recommendable to broaden the scope of the performed tests and evaluation in order to mitigate risks for consumers and businesses associated with the requirements aligned with the greater awareness of the AI systems' lifecycle.

Additionally, there is a need to **define what a failure is**, since a wrong prediction has a probability of happening. This, links to the concept of explainable AI: How to evaluate the accuracy of an explanation and how to integrate it into the AI-lifecycle for decision making?

Finally, in addition to the product as a whole, at least **3 different elements must be taken into account in a life-cycle assessment of a product or service**: the training system and associated training data, the resulting AI intelligence model, the application which uses AI and associated application data.

8. Towards an Engineering and Standardisation Framework for Industrial and Trustworthy AI

As stated in paragraph 61 of the Regulation proposal, "*standardisation should play a key role to provide technical solutions to providers to ensure compliance with this Regulation*". The association agrees also with the recognition, by the European Commission, to the need of "*adopting common technical specifications in areas where no harmonised standards exist or where they are insufficient*" (paragraph 61, page 32).

For this reason, the BDVA/DAIRO community proposes that the European Commission shall consider the following **tools and methodologies**:

- To support the design, test, validation, verification, and maintainability of AI-based functions and systems.
- To address the development of AI-based process and systems to demonstrate its integration into new products and services

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[5] Source: BDVA's response to the European Commission's Whitepaper on Artificial Intelligence "A European approach to excellence and trust" May 2020

- To do model evaluation (currently own datasets are being used, but trusted independent datasets for stakeholdersis something Member States and/or sector oversight bodies will need to develop)

On a governance perspective, a **coordinated organisation** to promote common standardisation, technical framework and roadmaps shall be considered. A successful example that shall be considered is the Franco-German initiative on speeding up industrial AI and trustworthiness[6]. BDVA/DAIRO has joined forces with this initiative with the objective of developing a European Engineering and Standardisation Framework for Industrial and Trustworthy AI and calls for national initiatives on Industrial AI to engage in this initiative.

BDVA/DAIRO also recommends supporting **process-based certification schemes instead of re-assessing high-risk AI systems**. In other words, according to Article 43 paragraph 4, high-risk AI systems should undergo a new conformity assessment every time they are subject to substantial modifications. This would lead to excessive administrative stress as well as increasing costs, especially for SMEs. This, would lead to processes hindering innovation due to excessive testing and audits, discouraging innovators and undermining competition in Europe. For this reason, a process-based certification scheme for high-risk AI systems should be put in place.

Such certification scheme would focus on the AI system and its coherence with the ethical development, deployment and operation with regard to the effectiveness of the company or the wide AI system process. Hence, the best practices of AI ethics can be provided and therefore applied to the development and deployment activities of each AI system. The definition of the evaluation criteria and methodology shall be created as to make a process-based certification scheme the baseline for transparent and effective processes for developing trustworthy AI systems across industries.

9. **Other topics**

BDVA/DAIRO believes that the Regulation should concentrate on fully auditable AI. This means that the question of IP rights on models and managing them legally as data products should be addressed. The definition of **IP rights on models and the legal management of them as data products** would be an important first step to preserve IPR.

BDVA/DAIRO also calls the attention to take into account relevant EU legislation such as the GDPR in the case of requesting providers to keep documentation for 10 years, the Trade Secrets Directive in the case of granting market surveillance authorities access to datasets, source code of high-risk AI systems and the EU Cybersecurity Act in the case of requesting cyber security measures and incident notifications from providers.

Moreover, the Regulation should adopt a balanced approach to human rights and technology, ensuring that no right or freedom would be limited unless provided by law and with appropriate guarantees that the essence of these rights would be preserved according to Article 52 of the Charter of Fundamental Rights of the European Union.

Finally, BDVA/DAIRO welcomes the arrangement of the European Commission for the Regulation to be reviewed and evaluated after 5 years, as outlined in Chapter 5.1 of the Proposal.

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[6] https://bit.ly/3x4yHIo

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This paper is the result of a cooperative work that gather inputs from the almost 150 BDVA/DAIRO members that participated in the following:
- Workshop with BDVA/DAIRO members – Feedback to AI Regulation proposal (07th June 2021)
- Workshop on BDVA/DAIRO Position Paper on Industrial and Trustworthy AI (18th June 2021)
- Consolidation Workshop on BDVA/DAIRO Feedback to AI Regulation proposal (30th June 2021)

The final document has been drafted during the month of July 2021, thanks to a join effort of the main editors in coordination with the BDVA/DAIRO Secretariat.

About BDVA/DAIRO

The Big Data Value Association – BDVA, (from 2021, DAIRO - Data, AI and Robotics aisbl), is an industry-driven international not–for-profit organisation with more than 230 members all over Europe and a well-balanced composition of large, small, and medium-sized industries as well as research and user organizations. BDVA/DAIRO focuses on enabling the digital transformation of the economy and society through Data and Artificial Intelligence by advancing in areas such as big data and AI technologies and services, data platforms and data spaces, Industrial AI, data-driven value creation, standardisation, and skills. BDVA/DAIRO has been the private side of the H2020 partnership Big Data Value PPP, it is a private member of the EuroHPC JU and is also one of the founding members of the AI, Data and Robotics Partnership. BDVA/DAIRO is an open and inclusive community and is always eager to accept new members who share these ambitious objectives

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