S H E R P A

Shaping the ethical dimensions of smart information systems– a European perspective (SHERPA)

Feasibility of a new regulator and proposal for a European Agency for AI

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Abstract	The report explores the feasibility of a bespoke/new regulator for AI and big data at the EU and/or Member State levels. The report assesses the factors indicating the need for such a regulator, its mandate, and how it would fit or interact with existing regulatory bodies and structures. Pros and cons, and challenges are identified. The report proposes terms of reference for a European Agency for AI.
Key Words	Artificial intelligence, regulation, regulator, feasibility, European Agency for AI, terms of reference, challenges.

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Executive Summary

Background

There have been many calls for a new regulator for artificial intelligence, big data, and robotics[1], including calls from the EU Parliament and some Member States for the creation of an EU Agency for AI. At the time of writing, there are no AI- or big data-specific regulatory bodies in the EU at either the transnational or national level.[2] The EU has yet to take a clear position on this. Some experts believe there are many factors that make AI and big data difficult to regulate.

Objectives

Given the nature of the risks and potential harms, there is a need to open the debate and make concrete proposals. The objectives of this report, as outlined by the SHERPA project Grant Agreement, were to:

Explore

Feasibility of a bespoke/new regulator for AI and big data at the EU and/or Member State levels

Assess

Factors indicating need for a regulator and how it would fit or interact with existing regulatory bodies and structures

Outline

Terms of reference (ToR)

Structure

The report first **explores the feasibility of such a regulator** at different levels. It:
- summarises views and positions on new AI regulators,
- presents proposals made, and examples of new bodies established at EU and Member State levels,
- assesses factors indicating the need for a new regulator, and,
- examines the case against.

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[1] European Parliament Resolution of 16 February 2017 with Recommendations to the Commission on Civil Law Rules on Robotics (2015/2103(INL), doc. no. P8_TA(2017)0051, http://www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P8-TA-2017-0051&language=EN&ring=A8-2017-0005 (EU Agency for Robotics and Artificial Intelligence); https://techxplore.com/news/2020-02-facebook-zuckerberg-new-style-eu.html; https://www.theguardian.com/technology/2017/jan/27/ai-artificial-intelligence-watchdog-needed-to-prevent-discriminatory-automated-decisions

[2] Rodrigues, Rowena, "Analysis of the Legal and Human Rights Requirements for AI and Robotics in and outside the EU", 2019, p. 88. https://doi.org/10.5281/zenodo.4066812

Second, the report:

- **sets out ToR for a proposed European Agency for AI**, the value added by the Agency, its challenges, and how they could be addressed.

Summary of views and positions on new AI regulators

The EU has yet to take a clear position despite calls from the EU Parliament and some Member States for the creation of an EU Agency for AI. Member States have broadly assigned regulatory concerns regarding AI and big data to pre-existing regulatory bodies. Different positions on new regulators are evident at the national level and there are currently no examples of new bodies being established to regulate AI and big data. There is one example of an advisory body in the UK.

Case for new regulator

Arguments advanced in favour of a new regulator at the EU or Member State level suggest that it might help:

Address complexity of AI technical, legal and ethical considerations
Obtain access to the technical details of algorithms (if genuinely independent)
Address concerns about the inadequacy and lack of enforcement
Boost human rights
Provide guidance on the implementation of existing laws
Bring consistency and urgency to regulation.

Case against establishing a new regulator

Arguments advanced against establishing a new regulator at the EU or Member State level suggest it might be:

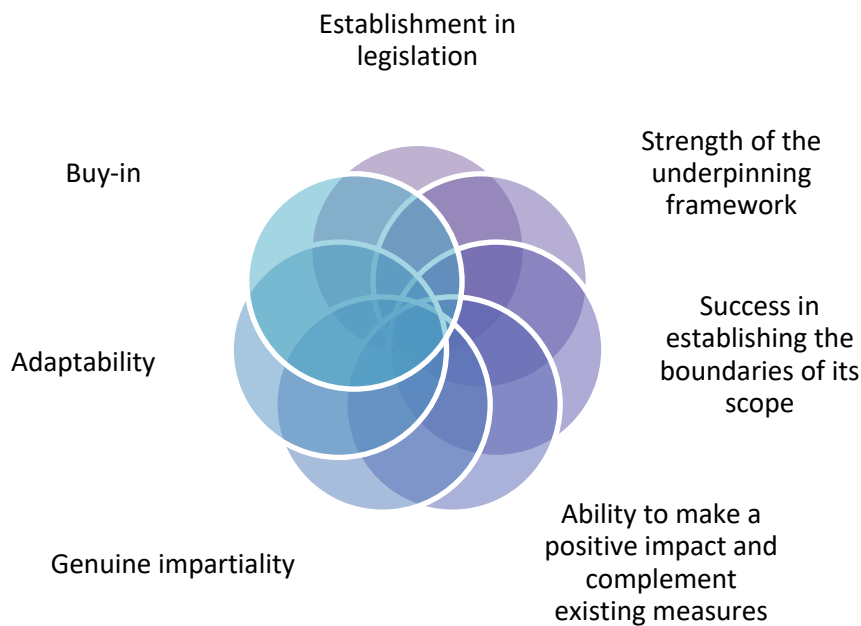| |
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| Duplicative (of the work of existing bodies) |
| Burdensome (limiting development) |
| Risk of 'mission creep' |
| Distracting: a panacea or replacement |
| Unfocussed (may give insufficient consideration to some issues) |
| Incompetent (lack technical know-how) |
| Might introduce conflict and resistance. |

Factors which affect the feasibility and sustainability of a regulator

There are a number of factors which affect the feasibility and sustainability of a regulator. These include:

Establishment in legislation

Buy-in

Strength of the underpinning framework

Adaptability

Success in establishing the boundaries of its scope

Genuine impartiality

Ability to make a positive impact and complement existing measures

Proposed ToR for a European Agency for AI

This report outlines proposed ToR for a **European Agency for AI**, for consideration by the European Commission, Parliament and the Council in the development of a regulatory framework for AI at the EU-level. The ToR set out the nature and scope of such an Agency, including relation to existing bodies and structures, legal basis, purpose and objectives, roles and functions, structure and governance, operational principles and procedural rules, reporting and auditing, evaluation and review, funding and sustainability.

The ambition is to create an **independent** Agency that, inter alia,

- will support other EU-level institutions, particularly the European Parliament, the European Commission (and already established committees) and national competent authorities in Member States to ensure the ethical and human rights compliant development, deployment and use of AI,
- protect the rule of law, and
- help foster a common regulatory vision in the EU for AI and high levels of ethics, protection and safety.

Roles and functions of the proposed Agency

Make **recommendations** addressed to the European Parliament, the Council, or the Commission for legislative amendments and adjustments

Identify potential **red lines or restrictions** for AI development, deployment and use

Develop and promulgate **general guidance** on legal concepts and regulatory issues of AI

Set **benchmarks for enforcement**

Support, work with and **advise** EU-level institutions, bodies and agencies

Maintain an AI **risk alert system**

Assist in **coordinating the mandates** and actions of the national competent authorities of Member States

Develop **harmonised and objective criteria for risk assessment** and/or conformity assessment

Monitor and/or **coordinate the evaluation of the operation of conformity assessment and/or certification schemes** for meeting ethical and human rights requirements

Cooperate, liaise, exchange information, promote public dialogue

Ensure **complementarity and synergy** between its activities and other Community programmes and initiatives

Promote the adoption of regulatory sandboxes

Promote the Union's AI approach through international cooperation

Value-added by the proposed Agency

♦ It could provide valuable support and guidance to the EU-level institutions, particularly the European Parliament, the European Commission (and already established committees) and national competent authorities in Member States to ensure the ethical and human rights compliant development, deployment and use of AI, protect the rule of law, and foster a common regulatory vision.
♦ It would promote coordination and international cooperation on regulation of AI, and create a collaborative environment for AI policy and regulation.
♦ It would promote the adoption of a unified message on AI regulation to the extent possible and/or required.
♦ It could help avoid over-regulation, by helping close existing legal loopholes, and providing legal certainty for businesses and individuals.

Potential challenges for the proposed Agency

♦ Lack of political will and/or resistance to the creation of an Agency by co-legislators
♦ Disagreement on location of the Agency's headquarters

- Competing priorities of different institutions (if the Agency's roles and functions overlap or clash with their primary missions)
- Addressing the balance and relationships between regulation, risk management and innovation
- Addressing the intersection between AI policy and European data protection law and policy
- Future-proofing the Agency in line with technological or policy developments and changing societal values.

Actions that would mitigate these challenges

- A strong proposal and good business case
- Effective and targeted lobbying for the Agency
- Clearly setting out the terms of the Agency (this report is the first step in this respect)
- Including provisions for review and evaluation.

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List of acronyms/abbreviations

Abbreviation	Explanation
ACER	The European Union Agency for the Cooperation of Energy Regulators
AI	Artificial intelligence
AI HLEG	High-Level Expert Group on Artificial Intelligence
BEREC	Office of the Body of European Regulators for Electronic Communications
CAHAI	Council of Europe Ad-hoc Committee on Artificial Intelligence
CLAIRE	Confederation of Laboratories for Artificial Intelligence Research in Europe
CEPOL	European Union Agency for Law Enforcement Training
CoE	Council of Europe
DoA	Description of Action
EASO	European Asylum Support Office
EBA	European Banking Authority
EC	European Commission
EDPB	European Data Protection Board
EDPS	European Data Protection Supervisor
EEA	European Economic Area
EFTA	European Free Trade Association
EIGE	European Institute for Gender Equality
EIOPA	European Insurance and Occupational Pensions Authority
EMCDDA	European Monitoring Centre for Drugs and Drug Addiction
ENISA	European Union Agency for Cybersecurity

Abbreviation	Explanation
EQUINET	European Network of Equality Bodies
ERGA	European Regulators Group for Audiovisual Media Services
ESMA	European Securities and Markets Authority
EU	European Union
eu-LISA	European Union Agency for the Operational Management of Large-Scale IT Systems in the Area of Freedom, Security and Justice
EURODAC	European Asylum Dactyloscopy Database
Eurojust	European Union Agency for Criminal Justice Cooperation
Europol	European Union's law enforcement agency
FDA	US Food and Drug Administration
FRA	Fundamental Rights Agency
Frontex	The European Border and Coast Guard Agency
FTC	Federal Trade Commission (US)
G20	Group of Twenty
IAIO	International Artificial Intelligence Organisation
IEC	International Electrotechnical Commission
ISO	International Organisation for Standardisation
JURI	European Parliament's Committee on Legal Affairs
KPI	Key performance indicators
ML	Machine Learning
OECD	The Organisation for Economic Co-operation and Development
ToR	Terms of Reference
SIS	Smart Information Systems
SMEs	Small and Medium Enterprises
UK	United Kingdom
UN	United Nations
US	United States

Table 1: List of acronyms/abbreviations

Glossary of terms

Term	Explanation
Decentralised agency	Agency set up by the EU to perform technical and scientific tasks that help the EU institutions implement policies and take decisions.[3] They have their own basic sectoral regulation, often adopted by co-decision.[4]
Decision (in ToR)	A "decision" is binding on those to whom it is addressed (e.g., an EU country or an individual company) and is directly applicable.[5]
European Union Agency	EU agencies are distinct legal entities set up by secondary legislation to carry out specific technical, scientific or managerial tasks that help the EU institutions design and implement policies. Many are highly visible and have significant influence in important areas of European citizens' daily life, such as health, safety, security, freedom and justice. They are independent bodies, with their own legal personality. Broadly, they can be divided between executive agencies and decentralised agencies.[6]
Opinion	An "opinion" is an instrument that allows the institutions to make a statement in a non-binding fashion (i.e., without imposing any legal obligation on those to whom it is addressed). An opinion is not binding. It can be issued by the main EU institutions (Commission, Council, Parliament), the Committee of the Regions and the European Economic and Social Committee. While laws are being made, the committees give opinions from their specific regional or economic and social viewpoint.[7]
Recommendation (in ToR)	A "recommendation" is not binding and allows the institutions to make their views known and to suggest a line of action without imposing any legal obligation on those to whom it is addressed.[8]
Regulation	A "regulation" is a binding legislative act. It must be applied in its entirety across the EU.[9]

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[3] https://europa.eu/european-union/about-eu/agencies/decentralised-agencies_en

[4] European Parliamentary Research Service, EU Agencies, Common Approach and Parliamentary Scrutiny, European Implementation Assessment, November 2018.

[5] https://europa.eu/european-union/law/legal-acts_en

[6] Ibid.

[7] https://europa.eu/european-union/eu-law/legal-acts_en

[8] https://europa.eu/european-union/eu-law/legal-acts_en

[9] https://europa.eu/european-union/law/legal-acts_en

Term	Explanation
Regulator/ Regulatory body	Regulatory bodies have different objectives and scopes. In this report, the term 'regulatory body' is interpreted broadly to encompass as wide a scope as possible. Such bodies could be, (a) bodies appointed (by the government) to establish standards, or policies for compliance (b) bodies/public authorities that regulate an entire sector (c) independent authorities that uphold rights in public interest and carry out enforcement action (d) independent advisory bodies (with statutory footing) tasked by government to investigate and advise on technology regulation matters.
Regulatory sandbox	A regulatory sandbox is a framework set up by a regulatory body to allow small-scale, live testing of the distribution and use of innovations by stakeholders in a controlled environment under the regulator's supervision. The regulator determines the criteria for participants, the scope and capacity of the sandbox, the testing parameters and conditions, the evaluation methodology and the exit criteria It is not a regulatory mechanism itself but a way to allow regulators and other stakeholders to test proposed regulatory schemes for new technologies in a controlled manner.[10]
SIS	The combination of Artificial Intelligence and big data analytics.
Terms of reference/ToR	Definition and/or statement that sets out clear details on, e.g., objectives, roles and functions, composition, working arrangements, reporting and review. ToR provide a common understanding of scope, objectives and operational processes.

Table 2: Glossary of terms

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[10] Rodrigues, Rowena, A Panagiotopoulos, B Lundgren, S Laulhé Shaelou, A Grant, *Regulatory options for AI and big data,* SHERPA D3.3, December 2019, Annex 4.31. https://doi.org/10.21253/DMU.11618211.v4.

1. Introduction

One of the trends identified in SHERPA's previous regulatory options research[11] was proposals for the creation of a regulatory agency/body with mainly soft law powers. There have been many calls for a new regulator for AI, big data and robotics[12]. At the same time, some experts believe there are many factors that make AI and big data difficult to regulate. However, given the nature of the risks and potential harms, there is a need to open the debate and make concrete proposals.

This report contributes to this debate by exploring the feasibility of a bespoke new regulator for AI and big data at the EU and/or Member State levels and what its Terms of Reference (ToR) should include. First, it **explores the feasibility of such a regulator** at the EU and/or national level (section 3): this section summarises views and positions on new AI regulators; presents proposals made, and examples of new bodies established at EU and Member State levels; assesses factors indicating the need for a new regulator, and examines the case against. It outlines the factors on which the feasibility and sustainability of such regulator depend. After setting out the context, it **proposes ToR for a European Agency for AI** (section 5), the value-added by it and its challenges (section 6).

2. Scope and overall methodology

Our work in SHERPA as scoped by its Grant Agreement includes three objectives:

1. **Explore the feasibility** of a bespoke/new regulator for AI and big data at the EU and/or Member State levels
2. **Assess factors indicating the need for a regulator** and how it would fit or interact with existing regulatory bodies and structures
3. **Outline its ToR.**

Regulatory bodies have different objectives and scopes. In this report, the term 'regulatory body' is interpreted broadly to encompass as wide a scope as possible. Such bodies include
- bodies appointed (by the government) to establish standards, and/or policies for compliance,
- bodies or public authorities that regulate an entire sector,
- independent authorities that uphold rights in public interest and carry out enforcement action
- independent advisory bodies (with statutory footing) tasked by government to investigate and advise on technology regulation matters.

There are many permutations a regulator can take, based on established practice. E.g., a Commissioner, digital authority, fundamental rights protection agency, independent watchdog, inspectorate, licensing body or authority, network of regulators, professional conduct authority, professional regulator, public

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[11] Rodrigues, et al, op., cit., 2019.

[12] European Parliament Resolution of 16 February 2017 with Recommendations to the Commission on Civil Law Rules on Robotics (2015/2103(INL), doc. no. P8_TA(2017)0051. http://www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P8-TA-2017-0051&language=EN&ring=A8-2017-0005 (EU Agency for Robotics and Artificial Intelligence); https://techxplore.com/news/2020-02-facebook-zuckerberg-new-style-eu.html; https://www.theguardian.com/technology/2017/jan/27/ai-artificial-intelligence-watchdog-needed-to-prevent-discriminatory-automated-decisions

sector regulator, standards agency, statutory registration board, supervisory agency or task force. These are examples based on established practice. Some of these, such as the Digital Authority (UK), and the network of regulators (as proposed in the EC White Paper Feb 2020)[13] have been researched and/or considered as potential options for AI regulation, while others listed have not been deeply explored in policy or academia.

The work on which this report is based used a combination of methods: (a) desktop research to elicit views and positions on new regulator(s), (b) interviews with stakeholders, (c) inputs from other SHERPA activities e.g., focus group[14], (d) meeting and inputs from the SHERPA Stakeholder Board. Further methodological detail is presented in the respective sections.

In the following section, we look at the feasibility of a bespoke new regulator at the EU and national level to draw some insights for our proposal for the ToR for a regulator for AI.

3. Feasibility of a bespoke new regulator

This section examines the existing regulatory environment (and existing calls for such an environment) for AI and big data at the international, EU and national levels (EU Member States, and other countries such as the UK and the US (a country of significant interest in relation to technological and regulatory developments in AI and big data). It includes

- a **summary of views on new AI regulators** at the international, EU, Member State and non-EU levels (sub-section 3.1),
- **considers new bodies** (those created since 2018) with regulatory or advisory capacity concerning AI and big data (sub-section 3.2),
- provides an **overview of calls for new regulatory or advisory bodies** (sub-section 3.3),
- summarises **arguments in favour of** (sub-section 3.4) and **against** a new regulator for AI (sub-section 3.5), and
- presents the **factors that affect the feasibility and sustainability** of a regulator (sub-section 3.6)

The final part (sub-section 3.7) provides a conclusion to this section.

The examples of new bodies, proposals for those bodies and summaries of arguments made for and against them have been drawn primarily from desk research, with all relevant sources quoted. Input has also been sought from the SHERPA Stakeholder Board, and a focus group as sources of external expertise.

3.1. Summary of views and positions on new AI regulators

This section summarises views and positions within the EU on new AI regulators within the EU. At the time of writing,[15] there are no AI- or big data-specific regulatory bodies in the EU at either transnational or

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Member State level.[16] The EU has yet to take a clear position on this at a transnational level, despite calls from the EU Parliament and some Member States for the creation of an EU Agency for AI. Member States have broadly assigned regulatory concerns regarding AI and big data to pre-existing regulatory bodies.

International-level views and positions

At the international (e.g. UN) level, no new regulators have been established. Some calls have been made for new regulatory bodies, such as the proposal for an International Artificial Intelligence Organisation(IAIO)[17] but these have as yet received little traction in terms of public policy. On 11 September 2019, the Committee of Ministers of the Council of Europe (distinct from the EU)[18] set up an Ad-hoc Committee on Artificial Intelligence (CAHAI)[19] to examine the feasibility and potential elements of a legal framework for the development, design and application of artificial intelligence, on the basis of broad multi-stakeholder consultations, based on the Council of Europe's standards on human rights, democracy and the rule of law.

EU institutions views and positions

Different positions on new regulators are evident. In 2017, the EU Parliament called on the European Commission to, amongst other things, create an EU Agency for Robotics and Artificial Intelligence.[20] The Commission did not consider the creation of a new agency necessary, but instead proposed the creation of "a high-level advisory body on robotics and artificial intelligence which could provide knowledge and expertise to the Commission". This became the High-Level Expert Group on Artificial Intelligence ("AI HLEG").[21] Some Member States (e.g., France, see below) have called for a new regulator at the EU-level.

The European Commission *White Paper On Artificial Intelligence - A European approach to excellence and trust* (Feb 2020)[22] discusses a European governance structure on AI in the form of a **framework for cooperation of national competent authorities** which could have a variety of tasks: as a forum for a regular exchange of information and best practice, identifying emerging trends, and advising on standardisation activity as well as on certification. It could also play a key role in facilitating the implementation of the legal framework, such as through issuing guidance, opinions and expertise. To that effect, it should rely on a network of national authorities, as well as sectorial networks and regulatory authorities, at national and EU level. This proposal by the Commission therefore sees the role of a European governance structure and regulatory body as similar to that developed in the General Data Protection Regulation (GDPR), which institutes a forum for exchange of information and best practice at the EU-level through the European Data Protection Board (EDPB) while relying on a network of national

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[16] Rodrigues, SIENNA, op. cit., 2019, p. 88.

[17] Erdélyi, Olivia J., and Judy Goldsmith, "Regulating artificial intelligence: Proposal for a global solution," *Proceedings of the 2018 AAAI/ACM Conference on AI, Ethics, and Society*, ACM, 2018. https://par.nsf.gov/servlets/purl/10066933

[18] The CoE is an international organisation in Strasbourg which comprises 47 countries of Europe. It was set up to promote democracy and protect human rights and the rule of law in Europe. https://www.coe.int/en/web/about-us/do-not-get-confused

[19] CAHAI - Ad hoc Committee on Artificial Intelligence. https://www.coe.int/web/artificial-intelligence/cahai

[20] European Parliament, *Civil Law Rules on Robotics*, European Parliament resolution of 16 February 2017 with recommendations to the Commission on Civil Law Rules on Robotics (2015/2103(INL)). http://www.europarl.europa.eu/doceo/document/TA-8-2017-0051_EN.pdf

[21] European Parliament, Follow up to the European Parliament resolution of 16 February 2017 on civil law rules on robotics. http://www.europarl.europa.eu/meetdocs/2014_2019/plmrep/COMMITTEES/JURI/DV/2017/11-20/A8-0005-2017_EN.pdf

[22] https://ec.europa.eu/info/publications/white-paper-artificial-intelligence-european-approach-excellence-and-trust_en

authorities (i.e., the Data Protection Authorities) for enforcement of the Regulation. As such, it envisages the creation/use of national-level regulators akin to the DPAs. However, this approach has not as yet been embraced by Member States.

EU Member States' views and positions

The European Commission's White Paper on AI has noted that, "member States are pointing at the current absence of a common European framework. … If the EU fails to provide an EU-wide approach, there is a real risk of fragmentation in the internal market, which would undermine the objectives of trust, legal certainty and market uptake."[23] This report confirms the assessment of the EC White Paper and the 2019 SIENNA report that within Europe, there are currently no new regulators dedicated to AI use or development.[24] Where AI is a deep concern in specific sectors, most EU Member States use existing sectoral regulators. This has occurred primarily in the areas of finance and competition law, where there are strong, well-established existing regulatory frameworks. New regulation of AI does not appear to have occurred in other regulation-heavy areas, such as healthcare or security, beyond existing laws on export restrictions in the case of security.

In France, minister for Digital Affairs, Cédric O, has called for "a clear regulatory framework and a new type of regulator" at the European level, but not at the Member State level.[25]

The German Data Ethics Commission has called for a five-level risk-based system of regulation that would go from no regulation for the most innocuous AI systems to a complete ban for the most dangerous ones.[26]

Denmark has introduced a prototype Data Ethics Seal which would provide a recognition that systems meet a baseline standard. [27]

Sweden established a new Ministry of Infrastructure in January 2019, which has responsibility for digitalisation (formerly under the purview of the Ministry of Finance) as well as physical infrastructure and postal services, with support from the unit of Digital Government.[28]

Placing AI regulation, as a part of digital regulation, in the portfolio of an existing government department has been a common response across 19 of the 27 EU Member States, including:

- Austria (Federal Ministry for Digital and Economic Affairs),[29]
- Belgium (Federal Government Department for Information and Communication Technology (Fedict)),[30]
- Croatia (the Central State Office for the Development of the Digital Society, which performs administrative and professional tasks related to the development, standardisation, and security

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[23] EC, AI White Paper, op. cit., 2020.

[24] Rodrigues, SIENNA D4.2, op. cit., 2019.

[25] Dillet, Romain, "How France's New Digital Minister Plans to Regulate Tech", *TechCrunch*(blog), 3 April 2019. http://social.techcrunch.com/2019/04/03/how-frances-new-digital-minister-plans-to-regulate-tech/

[26] EC, AI White Paper, op. cit., 2020.

[27] EC, AI White Paper, op. cit., 2020.

[28] European Commission, "Digital Government Factsheet 2019: Sweden", 2019.

[29] European Commission, "Digital Government Factsheet 2019: Austria", 2019.

[30] European Commission, "Digital Government Factsheet 2019: Belgium", 2019.

recommendations for the use of state IT infrastructure, which falls under the Ministry of Public Administration),[31]

- Cyprus (the Department of Information Technology Services (DITS), which falls within the Ministry of Finance),[32]
- Czechia (two expert advisory bodies: the Government Council for Information Society and the Government Council for Public Administration, both of which fall under the Ministry of the Interior),[33]
- Denmark (the Ministry of Industry, Business, and Financial Affairs),[34]
- Estonia (the Information System Authority (RIA), a part of the Ministry of Economic Affairs and Communications),[35]
- Finland (the Development and Coordination Committee of Information Management within the Ministry of Finance),[36]
- France (the National Digital Council (CNNum) is an advisory body to the government concerning regulation involving digital technologies, full responsibility for which lies with the Secretary of State for Digital Affairs),[37]
- Germany (the Office of the Commissioner for Information Technology within the Federal Ministry of the Interior, Building and Community),[38]
- Greece (the Ministry of Telecommunications and Media Policy),[39]
- Hungary (the Deputy State Secretary for Informatics, Ministry of Interior),[40]
- Latvia (the Ministry of Environmental Protection and Regional Development),[41]
- Luxembourg (the Ministry for Digitalisation),[42]
- Netherlands (the OBDO, an intergovernmental consultative body on digital government which advises the state secretary about the common policy),[43]
- Poland (the Ministry of Digital Affairs),[44]
- Portugal (the Administrative Modernisation Agency (AMA) within the Ministry of State Modernization and Public Administration),[45]
- Slovakia (the Division of the Information Society Governance within the Deputy Prime Minister's Office for Investments and Informatisation of the Slovak Republic),[46]
- Sweden (the Ministry of Infrastructure).[47]

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[31] European Commission, "Digital Government Factsheet 2019: Croatia", 2019.
[32] European Commission, "Digital Government Factsheet 2019: Cyprus", 2019.
[33] European Commission, "Digital Government Factsheet 2019: Czech Republic", 2019.
[34] European Commission, "Digital Government Factsheet 2019: Denmark", 2019.
[35] European Commission, "Digital Government Factsheet 2019: Estonia", 2019.
[36] European Commission, "Digital Government Factsheet 2019: Finland", 2019.
[37] European Commission, "Digital Government Factsheet 2019: France", 2019.
[38] European Commission, "Digital Government Factsheet 2019: Germany", 2019.
[39] European Commission, "Digital Government Factsheet 2019: Greece", 2019.
[40] European Commission, "Digital Government Factsheet 2019: Hungary", 2019.
[41] European Commission, "Digital Government Factsheet 2019: Latvia", 2019.
[42] European Commission, "Digital Government Factsheet 2019: Luxembourg", 2019.
[43] European Commission, "Digital Government Factsheet 2019: Netherlands", 2019.
[44] European Commission "Digital Government Factsheet 2019: Poland", 2019.
[45] European Commission, "Digital Government Factsheet 2019: Portugal", 2019.
[46] European Commission, "Digital Government Factsheet 2019: Slovakia", 2019.
[47] European Commission, "Digital Government Factsheet 2019: Sweden", 2019.

Non-EU countries views and positions

The UK government's Committee on Standards in Public Life has explicitly stated that it does not see the need for an AI regulator.[48] The CDEI functions in the UK as a government advisory body to investigate and advise on how the benefits of data-enabled technologies, including AI, can be maximised, and to identify measures needed to strengthen and improve the way data and AI are used; promote best practice and advice on how Government should address potential gaps in the regulatory landscape. This body is not a regulator in the traditional sense but a regulatory advisory body.

The US Food and Drug Administration (FDA) published a discussion paper on a "Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD)" which, if it were to be enacted in law, would see the FDA take on additional regulatory responsibilities of AI-enabled devices in healthcare in the US.[49] This suggests that other agencies overseeing areas in which regulation is well-established may also see an increase in responsibilities to include AI and big data regulation.

3.2.   New bodies established (2018-2020)

At the time of carrying out this research, there were no examples of new bodies being established at EU-level. There is just one example of a regulatory advisory body in the UK, i.e., the Centre for Data Ethics and Innovation (CDEI).[50] The CDEI, established in 2018, is an independent advisory body dealing with AI and big data ('data-driven technologies') and part of the UK Department for Digital, Culture, Media & Sport, set up and tasked by the UK Government to investigate and provide independent, impartial and expert advice on how to maximise the benefits of data-driven technologies. In this context, the CDEI explores the legal, ethical and societal tensions in data-driven technologies. It is funded by the Department for Digital, Culture, Media and Sport with £2.5 million in 2019/20 and £5 million in 2020/21. Some criticisms expressed of it include that it may not be effective if not part of a uniform regulatory approach to AI on a supra-national level,[51] and as a publicly-funded body its operation may be subject to budget constraints (which challenges the principle of its independence).[52]

The US perspective

Looking further afield, new laws in the US have sought to provide additional/new powers to existing bodies for the regulation of aspects of (or aspects closely linked to) AI and big data. Such new powers have been assigned to the Federal Trade Commission (FTC) in the Algorithmic Accountability Act (HR2231)[53]

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[48] Committee on Standards in Public Life, "Artificial Intelligence and Public Standards: A Review by the Committee on Standards in Public Life", February 2020.

[49] US FDA, *Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD)*. https://www.fda.gov/media/122535/download

[50] Centre for Data Ethics and Innovation, "Centre for Data Ethics (CDEI) 2 Year Strategy", 21 March 2019, https://www.gov.uk/government/publications/the-centre-for-data-ethics-and-innovation-cdei-2-year-strategy/centre-for-data-ethics-cdei-2-year-strategy

[51] Rodrigues et al., SHERPA D3.3, op. cit., 2019, p. 62.

[52] Ibid., p. 233.

[53] Clarke, Yvette D., "H.R.2231 - 116th Congress (2019-2020): Algorithmic Accountability Act of 2019", 2019, https://www.congress.gov/bill/116th-congress/house-bill/2231/all-info

and to the Attorney General in the "Deep Fakes" Accountability Act (HR3230).[54] The US FDA has also explored expanding its own regulatory powers in respect to adaptive AI/ML,[55] and Senator Elizabeth Warren has proposed subjecting big tech companies to anti-trust legislation.

Taking these in turn, the Algorithmic Accountability Act (HR2231) 2019 requires the US Federal Trade Commission to implement regulations to require covered entities that use, store or share personal information to conduct impact assessments for any high-risk automated decision system that makes a decision (or facilitates a human decision) that impacts consumers, and to reasonably address the results of the impact assessments in a timely manner. It provides basic protection for personal data used in automated decision systems on a national level and requires data protection impact assessments for high-risk automated decision systems. However, the law does not require covered entities to make the results of the algorithmic assessments public, leading some commentators to suggest that there is insufficient transparency.[56] Likewise, while the act requires covered entities to conduct required assessments in consultation with external third parties (e.g., independent auditors and independent technology experts) if reasonably possible, some commentators have suggested that the law does not go far enough to require neutrality in the assessment.[57] Finally, the law does not specify how often algorithmic assessments must be updated (using instead the phrase, "as frequently as the Commission determines is necessary"). Some commentators have suggested this could be unduly burdensome given the iterative nature of software development.[58]

The "Deep Fakes" Accountability Act (HR 3230) 2019 obliges the US Attorney General to submit a quinquennial report to Congress, containing a description of the impact of intimate and sexual deep fakes on women and marginalized communities, and provide official guidance to Federal prosecutors regarding any potential legal concerns that may impede such prosecutions absent clarification.[59] Some concerns have been raised regarding this Act and its potential to introduce a chilling effect on citizens regarding the production of satirical or parodic political videos.[60] This law responds to very specific concerns regarding one element of AI, however, and is a long way from providing an "AI and big data" regulatory framework.

The US FDA has explored options to expand its remit to include a regulatory function regarding adaptive AI and Machine Learning (ML) in medical use. This would entail that the FDA adopt policies and processes that require pre-market review and approval of any software update that introduces a new risk or modifies an existing risk that could result in significant harm; changes risk controls to prevent significant harm; or significantly affects clinical functionality or performance specifications of the device.[61] Current regulatory processes are based on approval of a static design, with re-approval required for material changes, and the FDA exploratory paper notes that this is not feasible for dynamic software systems using

[54] Clarke, Yvette D. "H.R.3230 - 116th Congress (2019-2020): Defending Each and Every Person from False Appearances by Keeping Exploitation Subject to Accountability Act of 2019", 2019, https://www.congress.gov/bill/116th-congress/house-bill/3230

[55] US FDA, *Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD)* (FDA, 2019).

[56] Jones Day, 'Algorithmic Accountability Act Targets AI Bias', June 2019, https://www.jonesday.com/en/insights/2019/06/proposed-algorithmic-accountability-act; Joshua New, 'How to Fix the Algorithmic Accountability Act', *Center for Data Innovation* (blog), 23 September 2019, https://www.datainnovation.org/2019/09/how-to-fix-the-algorithmic-accountability-act/

[57] Jones Day, op. cit., 2019.

[58] New, op. cit., 2019.

[59] Rodrigues et al., SHERPA D3.3, op. cit., 2019, pp. 45, 52.

[60] Rodrigues et al., SHERPA D3.3, op. cit., 2019, p. 46; Clarke, H.R.3230 - 116th Congress (2019-2020): Defending Each and Every Person from False Appearances by Keeping Exploitation Subject to Accountability Act of 2019.

[61] FDA, op. cit., 2019.

artificial intelligence and machine learning.[62] The benefits of this approach include the fact that such an extension may also be useful for regulation of autonomous AI/ML enabled systems outside the medical context, such as drones and autonomous vehicles.[63] However, the proposed framework does not address testing for and remediating racial and gender bias in existing datasets and health/medical care algorithms, nor does it address data privacy for patient data.[64] Hence the FDA has proposed a feasible option which adapts a current regulatory approach to the more flexible requirements of AI/ML medical systems.[65] Furthermore, this option appears to be sustainable insofar as the initial comments provided to the discussion paper were generally supportive of the approach, with suggestions for changing some of the specific categories, criteria or steps.[66] Whether this would be future-proof depends on a number of factors. In particular, a flexible review and approval process may help to increase communication between the regulators and developers. As the technology changes, the change processes and protocols that are submitted for review and approval will change and so, with increased communication between the regulators and developers, the regulator's approval criteria may be sufficiently flexible to change. [67]

Alongside the FDA's exploration into whether it should increase its regulatory powers, Senator Elizabeth Warren has called for the existing US anti-trust framework to be used in regulation of some big tech corporations to reverse illegal and anti-competitive tech mergers.[68] This has significance for the regulation of big data, requiring legislation that would see large technology platforms designated as "Platform Utilities" and broken apart from any participant on that platform, supported by regulators committed to reversing illegal and anti-competitive tech mergers.[69] Warren's proposal aims to "restore the balance of power in [US] democracy, to promote competition, and to ensure that the next generation of technology innovation is as vibrant as the last," [70] as well as seeking to "promote healthy competition in the market — which will put pressure on big tech companies to be more responsive to user concerns, including about privacy."[71] Warren argues that, "more competition means more options for consumers and content creators, and more pressure on companies like Facebook to address the glaring problems with their businesses."[72] Indirectly, then, this proposal might also help generate greater transparency and oversight of the actions of dominant technological companies, particularly in the wake of the Cambridge Analytica scandal.[73]

However, Warren's proposal has been heavily criticised for a number of reasons: that it is "too fuzzy";[74] that it will not solve problems that are of concern to lawmakers and citizens (e.g., privacy);[75] and that it is

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[62] Rodrigues et al., SHERPA D3.3, op. cit., 2019, p.195

[63] Ibid.

[64] Rodrigues et al., SHERPA D3.3, op. cit., 2019, p.195

[65] Rodrigues et al., SHERPA D3.3, op. cit., 2019, p.195

[66] Rodrigues et al., SHERPA D3.3, op. cit., 2019, p.195

[67] Rodrigues et al., SHERPA D3.3, op. cit., 2019, p.195

[68] Warren, Elizabeth, "Here's How We Can Break up Big Tech", *Medium,* 11 October 2019. https://medium.com/@teamwarren/heres-how-we-can-break-up-big-tech-9ad9e0da324c; Cass, Ronald A. "Antitrust for High-Tech and Low: Regulation, Innovation, and Risk", *JL Econ. & Pol'y* 9, 2012, p. 169.

[69] Warren, op. cit., 2019.

[70] Warren, op. cit., 2019.

[71] Warren, op. cit., 2019.

[72] Warren, op. cit., 2019.

[73] Warren, op. cit., 2019; Macnish, Kevin, and Jai Galliott, eds., *Big Data and Democracy*, Edinburgh University Press, Edinburgh, 2020.

[74] The Economist, "Dismembering Big Tech", *The Economist*, 24 October 2019. https://www.economist.com/business/2019/10/24/dismembering-big-tech

[75] Ibid.

not feasible, given that such breaks-ups are rare and hard to achieve due to their complexity.[76] Furthermore, critics have noted that the proposal might strip companies of their best prospects for growth,[77] risks reducing competition and innovation from new products,[78] and threatens consumer welfare, especially in fast moving markets.[79]In addition, the proposed remedies, such as limiting the collection and use of big data or forcing large firms to share with rivals, have been criticised as likely to harm competition and innovation, and may raise privacy concerns.[80] There are also concerns regarding the limitations in antitrust enforcement officials' knowledge and the potential impact of ill-advised investigations and prosecutions on markets,[81] and even on defining which conduct contravenes antitrust law.[82] Finally, the passage and enforcement of new legislation to enact this proposal would face significant opposition from the current US administration and reluctance from the current US Supreme Court.[83]

3.3. Proposals for new regulators/regulatory bodies and their assessment

Annex 1 presents proposals made since 2015 for new regulators and/or regulatory bodies and their assessment. While it is not a complete overview, it presents proposals made by EU-level and/or national policy-makers and academics which have gained significant traction in academic and popular press. The seven proposals covered include the following:
- o A EU Agency for Robotics and Artificial Intelligence
- o An EU Taskforce of field specific regulators for AI/big data
- o A Network of national authorities, as well as sectoral networks and regulatory authorities;
- o the proposal for a Digital Authority (UK),
- o An independent regulator under the new statutory duty of care for online harms (UK),
- o A FDA for Algorithms (US)
- o A Federal Trade Commission to regulate robotics (US).

3.4. Case for a new regulator

This section identifies arguments advanced in favour of a new regulator at the EU or Member State level. This information summarises data from SHERPA report D3.3 and SIENNA report D4.2, as referenced. A full methodology can be found in each of those documents.

General level
- The management and regulation of AI involves a complex understanding of technical, legal and ethical considerations. It could therefore be helpful to bring these together in one body.
- A regulator could demand access to the technical details of algorithms if it were genuinely independent, leading to the institution of state-backed guarantees, similar to kite marks.
- A regulator might boost human rights, by:

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[76] Matsakis, Louise, "Break Up Big Tech? Some Say Not So Fast", *Wired*, 7 June 2019. https://www.wired.com/story/break-up-big-tech-antitrust-laws/
[77] Waters, Richard, "Three Ways That Big Tech Could Be Broken Up", *Financial Times*, 7 June 2019.
[78] Rodrigues et al., SHERPA D3.3, op. cit., 2019, p. 238.
[79] Ibid.
[80] Daniel Sokol, D. and Roisin Comerford, "Antitrust and Regulating Big Data", *Geo. Mason L. Rev.* 23, 2015, p. 1129.
[81] Cass, op. cit., 2012.
[82] Cass, op. cit., 2012.
[83] Rodrigues et al., SHERPA D3.3, op. cit., 2019, p.238.

- Requiring assessments to identify and reduce risks of high-impact automated decisions (e.g., Algorithmic Accountability Act of 2019)
- Protecting democracy and privacy by promoting healthy competition (e.g., anti-trust regulations)
- Safeguarding and enhancing human rights more comprehensively, such as the right to privacy and freedom from discrimination, in the context of predictive algorithms (e.g., register of algorithms used in government)
- Introducing compliance mechanisms to monitor, prevent and manage risks to human rights (e.g., the legislative framework for independent and effective oversight; legal frameworks for human rights impact assessments).[84]
- Existing regulations are not adequate to regulate AI issues, such as whether data protection regulation is sufficient to protect privacy (perhaps it is too soon to tell).
  - This has been raised in at least Germany and The Netherlands.[85]
  - In the US, concerns have been raised regarding guidance on the implementation of existing laws to new technologies, in the absence of which, the interpretation will fall to courts, which could lead to inconsistent and unpredictable results.[86] An independent regulatory advisory body could identify gaps in legislation and provide guidance on specific issues of interpretation.

EU-level
- At the EU level, a regulator will need the ability to respond to reflect the legal specificities of each Member State and respond to the policy and technological needs and priorities.[87]

National level
- A bespoke system tailored to individual states may not be effective if it is not part of a uniform regulatory approach to AI on a supra-national level.[88]

3.5.   Case against establishing a new regulator

This section briefly comments on arguments against establishing a new regulator at EU or Member State level. As with sub-section 3.4, this information is a summary of data in SHERPA report D3.3 and SIENNA report D4.2, as referenced. A full methodology can be found in each of those documents.

General arguments
- Unnecessary
  - Regulatory agencies may duplicate the work of existing EU or national agencies[89]
  - Existing regulatory bodies, with the help of new regulations, can and do cover any new challenges posed by AI and/or robotics[90]
- Burdensome
  - A lack of transparency and clarity on the operation, powers, scope and relationships of a regulator with regards to other regulatory authorities (e.g., CDEI and IAIO) could be

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[84] Rodrigues et al., SHERPA D3.3, op. cit., 2019, p.49.
[85] Rodrigues, SIENNA, op. cit., 2019, p. 86.
[86] Rodrigues, SIENNA, op. cit., 2019, p.86.
[87] Rodrigues et al., SHERPA D3.3, op. cit., 2019, p.54.
[88] Rodrigues et al., SHERPA D3.3, op. cit., 2019, p.62.
[89] Rodrigues et al., SHERPA D3.3, op. cit., 2019, p.41.
[90] Rodrigues et al., SHERPA D3.3, op. cit., 2019, p.68; House of Lords, "House of Lords Select Committee on Artificial Intelligence, Report of Session 2017-19, AI in the UK: Ready, Willing and Able?", 16 April 2018.

deeply problematic. A similar limitation relates to the lack of management stability, weak collective control and oversight[91]

- o Mission-creep concerns[92]
- o A concern regarding over-regulation of the market[93]
- o "For SMEs, being under the control and monitoring of AI oversight bodies may be a disincentive or hindrance in engaging with AI, especially for start-ups, or may result in cover-ups of ethical issues (Legislative framework for independent and effective oversight) neither of which are ideal for the future regulation and responsible development of AI."[94]

- Distracting
  - o There is a risk that a new regulator could be viewed as a panacea or replacement for existing frameworks, rather than a means of enforcing those frameworks.[95]
- Problems of focus
  - o A regulator may lead to an excessive focus on the risks of AI while neglecting the relevant benefits and advantages. This might extend to a disproportionate focus on bias and discrimination, at the loss of examination of other fundamental rights and freedoms. Alternately, a regulator may give insufficient consideration to issues of racial and gender bias or privacy.[96]
- Incompetent
  - o A regulator may lack understanding of the features and capabilities of AI.[97]
  - o There is a risk of providing false assurances of fair, trustworthy and/or ethical AI[98]
  - o Lack of an accountability framework providing for sanctions in the case of failure to apply an option.[99]
- Introduce conflict
  - o Where a new regulator might require the publication of AI-sensitive information, there may be conflicts with intellectual property rights and prohibitions of releasing sensitive information to the public[100]
  - o Resistance from actors to share sensitive information from impact assessments[101]
  - o Lack of consistency and consideration of the legal and political specificities where a new regulator has a supranational effect.[102]
- Insufficient clarity
  - o E.g., where proposed and/or suggested very briefly, without detailed explanation, often lacking critical details,[103] or 'too fuzzy'.[104]

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[91] Rodrigues et al., SHERPA D3.3, op. cit., 2019, p.40.
[92] Rodrigues et al., SHERPA D3.3, op. cit., 2019, p.41.
[93] Rodrigues et al., SHERPA D3.3, op. cit., 2019, p.64.
[94] Rodrigues et al., SHERPA D3.3, op. cit., 2019, p.46.
[95] Rodrigues et al., SHERPA D3.3, op. cit., 2019, p.41.
[96] Rodrigues et al., SHERPA D3.3, op. cit., 2019, p.40.
[97] Rodrigues et al., SHERPA D3.3, op. cit., 2019, p.40.
[98] Rodrigues et al., SHERPA D3.3, op. cit., 2019, p. 41.
[99] Rodrigues et al., SHERPA D3.3, op. cit., 2019, p. 42.
[100] Rodrigues et al., SHERPA D3.3, op. cit., 2019, p.41.
[101] Rodrigues et al., SHERPA D3.3, op. cit., 2019, p.42.
[102] Rodrigues et al., SHERPA D3.3, op. cit., 2019, p.40.
[103] "E.g., EU Taskforce of field specific regulators … for AI/big data" – see Rodrigues et al., SHERPA D3.3, op. cit., p.43
[104] This is evident in relation to the proposal to use anti-trust regulations to break up big tech and appoint regulators to reverse illegal and anti-competitive tech mergers. See: The Economist, "Dismembering big tech", *The Economist*, 24 Oct 2019. https://www.economist.com/business/2019/10/24/dismembering-big-tech; see also Rodrigues et al., SHERPA D3.3, op. cit., 2019, p.43.

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3.6. Factors which affect the feasibility and sustainability of a regulator

There are a number of factors upon which the feasibility and sustainability of a regulator depend. These include:[105]

- The ability to adapt to reflect technological developments/developments in AI/big data/ICT
- The buy-in and support (trust) from other stakeholders such as industry
- The ability to meet changing societal needs over time
- The ability to accommodate changes in societal expectations and values
- The use of informal governance techniques to support its growth and ability to exist
- The attraction of funds and human resources and sound management of such funding
- Sufficient guaranteed funding
- The ability to deliver good outputs
- Regular reviews and updates
- Market incentives and forces
- Protection from competing priorities and conflicts (e.g., of the bodies housing the new body and those forming it)
- Genuine impartiality
- Establishment in legislation
- Strength of the underpinning (technical or regulatory) framework
- Whether it is able to make a positive impact and complement other existing measures
- Success in establishing the boundaries of its scope.[106]

3.7. Summary

Arguments in favour of the creation of a new regulator for AI at either national or EU level are by no means uncontested.

A central issue at play is whether existing legislation and regulatory authorities are sufficient to oversee the development of AI, and it is perhaps too early to tell, given new legislative and technological developments. Certainly, the approach taken by most EU Member States has been to place regulation of AI within the purview of government departments. These are sometimes advised by external bodies, but there have been no independent regulators established in the EU. Others argue that existing legislation and regulatory apparatus are not sufficient for the task at hand and so advocate new regulatory bodies for the reasons stated above.

A new regulatory body would bring together a complex understanding of the technical, legal and ethical issues involved in AI, and, if genuinely independent, could access algorithms and deliver guarantees of standards through issuing some form of approval, similar to the kitemark system. A regulator could also boost human rights observance, although it would need to be careful to apportion its attention appropriately. Key factors as to the success of a regulatory body include its funding and independence

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[105] Rodrigues et al., SHERPA D3.3, op. cit., 2019, p. 54.
[106] Ibid.

from government, buy-in from stakeholders, and its ability to keep up-to-date with technological developments.

Alongside the position that a dedicated AI regulator would be unnecessary, are further arguments that such a body would be burdensome (to the extent of limiting development), distracting, risk being incompetent, lack focus, introduce conflict both internally and internationally, and risk being unfair to (at least some) businesses. Above all, a lack of clarity as to the proposals put forward in favour of the establishment of new regulatory bodies has hampered the debate.

Having considered the views and positions and the state of play in setting up new bodies and proposals related to these, along with the pros and cons, in line with the SHERPA Grant Agreement requirements we set out in section 4 the ToR for a proposed European Agency for AI. This takes into account the learnings from this section, and particularly current policy and regulatory developments on AI.

4. Context for proposing the ToR

The current regulatory landscape for AI in the EU is fragmented, and concerns have been raised regarding cooperation, coordination and consistent application of EU law.[107] Though efforts are ongoing to reduce this fragmentation[108] and develop a unified vision – not just of AI, but also of AI regulation (at the European Commission, e.g., AI HLEG work, and European Parliament levels) – we believe a stronger central, and independent body[109] is needed to act as a proactive champion and strengthen harmonisation, cooperation and consistency in the regulation of AI, especially at the EU-level. The current EU regulatory landscape for AI therefore requires the establishment of a new EU-level entity to strengthen harmonisation, cooperation and consistency in the regulation of AI[110] and to help address new opportunities and challenges, particularly those of cross-border nature in the research, development, deployment and use of AI systems and solutions.

The ambition is to create an independent Agency that will help foster international cooperation on AI issues, provide much-needed clarity at the EU-level, create a collaborative environment for EU AI policy and regulation, and promote good regulation at the Member State level:
- support other EU-level institutions, particularly the European Parliament, the European Commission (and already established committees) and national competent authorities in Member States to ensure an ethical and human rights compliant development, deployment and use of AI,
- protect the rule of law, and

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[107] See, e.g., European Commission, "White Paper On Artificial Intelligence - A European approach to excellence and trust," Brussels, 19.2.2020 COM(2020) 65 final.

[108] As noted, "Fragmentation from diverse national regulatory regimes should be avoided through a coordinated approach. It is important to create the right framework conditions to encourage the cross-border development and scaling-up of innovative solutions". "Innovative And Trustworthy AI: Two Sides Of The Same Coin", *Position paper on behalf of Denmark, Belgium, the Czech Republic, Finland, France Estonia, Ireland, Latvia, Luxembourg, the Netherlands, Poland, Portugal, Spain and Sweden, Oct 2020.* https://em.dk/media/13914/non-paper-innovative-and-trustworthy-ai-two-side-of-the-same-coin.pdf.

[109] Iordanou, et al, op.cit., 2020, p.51.

[110] See Report with recommendations to the Commission on a framework of ethical aspects of artificial intelligence, robotics and related technologies Committee report tabled for plenary, single reading on 19 October 2020 (2020/2012(INL)) https://www.europarl.europa.eu/doceo/document/A-9-2020-0186_EN.html

- help foster a common regulatory vision in the EU for AI and high levels of ethics, protection, safety.[111]

The human rights referred to include (but are not limited to) all rights and freedoms enshrined in the Charter of Fundamental Rights of the European Union.[112]

For the purpose of the proposed ToR, we use the definition of AI provided by the AI HLEG in *Guidelines for Trustworthy AI* (and reiterated in the ALTAI):[113]

> Artificial intelligence (AI) systems are software (and possibly also hardware) systems designed by humans that, given a complex goal, act in the physical or digital dimension by perceiving their environment through data acquisition, interpreting the collected structured or unstructured data, reasoning on the knowledge, or processing the information, derived from this data and deciding the best action(s) to take to achieve the given goal. AI systems can either use symbolic rules or learn a numeric model, and they can also adapt their behaviour by analysing how the environment is affected by their previous actions. As a scientific discipline, AI includes several approaches and techniques, such as machine learning (of which deep learning and reinforcement learning are specific examples), machine reasoning (which includes planning, scheduling, knowledge representation and reasoning, search, and optimization), and robotics (which includes control, perception, sensors and actuators, as well as the integration of all other techniques into cyber-physical systems).

We expect the definition will be clarified (and potentially broadened[114]) in the anticipated European AI legislation[115]; and this should be followed by the Agency.

The Agency itself should be instrumental in further assessing and clarifying the definition for usefulness and applicability, taking into account the dynamic nature and applications of AI. The definition will also need to be more fluid to consider AI designed by non-humans. SHERPA recommends any definition of AI is clearly defined in each context with regard to relevant issues.[116]

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[111] European Commission, Communication From The Commission To The European Parliament, The European Council, The Council, The European Economic And Social Committee And The Committee Of The Regions, Coordinated Plan on Artificial Intelligence, Brussels, 7.12.2018 COM(2018) 795 final

[112] European Union, Charter of Fundamental Rights of the European Union, *Official Journal of the European Communities*, 18 December 2000 (2000/C 364/01), 26 October 2012.

[113] Independent High-Level Expert Group On Artificial Intelligence (AI HLEG), The Assessment List For Trustworthy Artificial Intelligence (ALTAI) For Self Assessment, 17 July 2020. Doi:10.2759/002360. See also https://ec.europa.eu/digital-single-market/en/news/definition-artificial-intelligence-main-capabilities-and-scientific-disciplines

[114] Noting, e.g., The European Parliament JURI report (version of 8 Oct 2020), for instance, recommends that the "Union's regulatory framework for AI should cover all the components of artificial intelligence, robotics and related technologies developed, deployed or used in the Union". https://www.europarl.europa.eu/doceo/document/A-9-2020-0186_EN.html

[115] The European Commission is expected to propose this early 2021. https://ec.europa.eu/digital-single-market/en/artificial-intelligence. Once a proposal from the Commission is put forward, the co-legislative procedure can begin – meaning that both co-legislators (Parliament and Council of the EU) can jointly amend and adopt the text. The procedure consists of up to three readings. As the two co-legislators have equal rights and obligations - neither of them can adopt legislation without the agreement of the other, both co-legislators have to approve a final identical text.

[116] See SHERPA D4.3 Recommendations (forthcoming 2021).

5. Terms of Reference for a European Agency for AI

This section sets out the SHERPA ToR for a proposed European Union Agency for AI, for consideration by the European Commission, Parliament and the Council in the development of a regulatory framework for AI at the EU-level.

5.1. Development process – research and expert consultations

The European Parliament's Committee on Legal Affairs (JURI), in April 2020, outlined a proposal[117], where it again made a call[118] for a "European Agency to ensure a harmonised approach across the Union and address the new opportunities and challenges…"[119]. In the light of this development, and based on our SHERPA previous research, we took a fresh look at the subject and progressed to carry out further research and develop a draft ToR for a EU Agency as this would be most useful at this point to feed into proposals for an EU legislation/regulatory framework on AI (expected in 2021). The European Commission has not so far favoured the creation of an "EU agency on AI" but instead presented a model for governance based on cooperation of national regulators.[120]

The ToR was developed using research and expert consultations. The underpinning research was previous work in SHERPA (Task 2.2 Stakeholder interviews,[121] Task 3.3 Regulatory Options[122]), and the exploration of the feasibility of a bespoke and/or new regulator for AI and big data at the EU and/or Member State levels including the factors indicating the need for a regulator, the case against, critical success factors and challenges (Task 3.6, documented in section 3 of this report).

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[117] Under its right of legislative initiative. https://www.europarl.europa.eu/RegData/etudes/BRIE/2020/646174/EPRS_BRI(2020)646174_EN.pdf

[118] European Parliament, Draft report on AI ethical framework, 2020/2012(INL), 21 April 2020. https://www.europarl.europa.eu/doceo/document/JURI-PR-650508_EN.pdf

[119] The European Parliament has repeatedly made calls for the creation of an EU agency on AI. E.g. the call for an "European Agency for Robotics and Artificial Intelligence' in the European Parliament, Civil Law Rules on Robotics, European Parliament resolution of 16 February 2017 with recommendations to the Commission on Civil Law Rules on Robotics (2015/2103(INL)). https://www.europarl.europa.eu/doceo/document/TA-8-2017-0051_EN.html?redirect. Also in its Resolution of 12 February 2019 on a comprehensive European industrial policy on artificial intelligence and robotics, the Parliament called on the Commission and the Member States to consider the creation of a European regulatory agency for AI and algorithmic decision-making. See https://www.europarl.europa.eu/doceo/document/TA-8-2019-0081_EN.html. The European Parliament adopted on 20 October 2020 (along with two others) the framework of ethical aspects of artificial intelligence, robotics and related technologies (Rapporteur: Iban García del Blanco, S&D, Spain) underlines the importance of coordination at the EU-level and asks the Commission to reflect whether existing Union bodies and institutions are sufficient for those tasks or a new body for Artificial Intelligence needs to be created. European Parliament Committee for Legal Affairs (JURI), Report with recommendations to the Commission on a framework of ethical aspects of artificial intelligence, robotics and related technologies, Committee report. Adopted. (2020/2012(INL)) https://www.europarl.europa.eu/doceo/document/TA-9-2020-0275_EN.html

[120] European Commission, White Paper, op. cit., 2020.

[121] SHERPA D2.2 Report of interview analysis (forthcoming). Two interviews were conducted one with a national policy-maker and one with an international legal expert specifically on the need for a new regulator, its potential to work with existing regulators, good models, whether remit of existing regulators is sufficient, and any other recommendations. Their insights informed these ToR.

[122] Rodrigues et al, SHERPA D3.3, op. cit., 2019.

On 23 March 2020, the underpinning research was presented to the SHERPA Stakeholder Board, and three key questions were discussed:

(1) Do we need a new regulator/body for AI and big data at the EU or national level?
(2) What international, EU or national policy directions are relevant to consider in the creation of such a new regulator?
(3) If no new regulator is deemed necessary, what other regulatory options are the most desirable and feasible?

The results of the SHERPA Stakeholder Board meeting were discussed at the SHERPA General Assembly Meeting on 24 March 2020. Several points were made by the Board members. One point made was that it depends on what we want to regulate. Another point was that we have not yet defined what we are trying to protect/regulate. Maybe what is needed is different forms of new regulation, rather than regulator. The added value of a new regulator seemed unclear; we could use existing regulators. A regulator also needs to be fit for purpose and tackle the right problem. The regulator should not make the rules but enforce them. There were concerns about a single regulatory body for a wide range of issues/applications. The potential for self-regulatory mechanisms and a range of other tools was also highlighted. These initial concerns expressed though similar to found in our research (section 3) were not reiterated after the first ToR draft was shared with the Board. They have been considered in the development of our proposed ToR (e.g., by setting out the gap it would fill, setting specific and clear roles and functions and relationship to existing regulatory structures).

On 26 June 2020, SHERPA held a focus group with five experts to discuss a new AI regulator. A Google Form questionnaire (see Annex 2) was circulated to the participants in advance of the meeting. The questionnaire was completed by nine invited participants. The results are documented in D4.2 SHERPA.[123] Key messages from the focus group included:

- a regulator should emphasise the protection of human rights and ethics;
- relationship with other regimes and bodies (e.g., data protection) should be addressed;
- it should not coordinate funding of AI;
- it should come up with criteria and their categorisation (though it might be a big task to come up with criteria that is actionable and usable);
- an EU regulator is important and essential (e.g., it would have access to better resources compared to national bodies) but could look at the broader impact dynamics, and each national government should decide for themselves how to implement;
- Commissioners, standards agency and supervisory agencies would not be good models for EU-level regulators;
- regulation should come from EU-level, then for national level;
- the body should be able to have power and leverage that could influence companies and national governments when things go wrong;
- it should not be a body that operates in isolation from other regulators;
- and, it should also be composed of different experts.

The focus group results have been considered in the proposed ToR.

An impromptu Twitter Poll conducted on 9 July 2020[124] gave SHERPA contacts an opportunity to provide input into the discussion. It posed the question: "If there is a new regulator for AI, should it (a) clarify legal

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[123] Iordanou, Kalypso, Josephina Antoniou, Eleni Christodoulou, "SHERPA D4.2 Evaluation Report", 2020. https://doi.org/10.21253/DMU.12917717.v1
[124] https://twitter.com/project_sherpa/status/1281190177885564929

issues, (b) certify compliance, (c) improve enforcement, or (d) strengthen harmonisation. Five votes favoured 'improve enforcement', four votes favoured 'clarify legal issues', two votes favoured 'certify compliance' and none favoured 'strengthen harmonisation'.

We consulted and compared the ambitions expressed in the SHERPA D3.3 proposal of an EU Taskforce of field specific regulators for AI/big data, the Framework for cooperation of national competent authorities outlined in the European Commission White Paper of February 2020, and the European Parliament Draft Report with recommendations to the Commission on a framework of ethical aspects of artificial intelligence, robotics and related technologies.[125] We looked at the role of EU bodies, especially their remits and functions (e.g., ACER, EDPB, EDPS, EU Taskforces, ENISA, FRA). This research fed into the drafting of the ToR.

We then carried out a consultation in August-September 2020 with 10 experts (using interviews). The experts were given a draft ToR document and asked specific questions about the proposed terms. Experts came from a range of European and national institutions, and included policy makers, legal advisors, a Member of Parliament, industry experts, civil society and policy analysts. Using their feedback, and consulting some founding regulations (e.g., the ACER Regulation, the General Data Protection Regulation, European Union Agency for Fundamental Rights Regulation[126]) and operational documents for existing EU agencies, the ToR were revised and finalised.

The next steps included feedback from the SHERPA Stakeholder Board[127], interested stakeholders[128], SHERPA partners,[129] and colleagues[130] on the proposal before finalisation and submission in the D3.6 report to European Commission on 30 October 2020.

The ToR set out the following for a European Agency for Artificial Intelligence:
- nature and scope, including relation to existing bodies and structures,
- legal basis,
- purpose and objectives,
- roles and functions,
- structure and governance,
- operational principles and procedural rules,
- reporting and auditing,
- evaluation and review,

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[125] 21.4.2020. https://www.europarl.europa.eu/doceo/document/JURI-PR-650508_EN.pdf
[126] Council Regulation (EC) No 168/2007 of 15 February 2007 establishing a European Union Agency for Fundamental Rights, *OJ L* 53/1. 22.2.2007.
[127] There was a brief discussion of the recommendation at the SHERPA Stakeholder Board meeting on 6 October 2020 after which a few changes were made to the text before general circulation to all members of Board for further feedback. A new draft was circulated to the Board for feedback with the following questions: *Are there any critical roles and functions for the Agency that we have missed out? If yes, which ones and why are they important to include? Are there any overlaps of functions of the Agency with that of any existing EU agencies? If so, which ones? What will be the key challenges of implementing this proposal and how could they be overcome? Is the proposed timeline feasible? What changes would you recommend?* We acknowledge feedback from SHERPA Stakeholder Board Members Chiara Giovannini, ANEC; Adrienn Kovacs, SAP; Yoan Michie, Nokia Bell Labs; Susana Solis Perez, MEP, European Parliament; Mick Yates, University of Leeds; Carl Wiper, Information Commissioner's Office.
[128] Two requests were made to see the draft.
[129] We acknowledge feedback from Stéphanie Laulhé Shaelou, University of Central Lancashire Cyprus; Kevin Macnish, University of Twente; Tijmen Schep, Pineapple Jazz.
[130] We acknowledge feedback from Anaïs Resseguier, Trilateral Research.

- funding and sustainability.

Where relevant, explanatory notes related to each ToR have been added.

5.2.   Nature and scope

The European Agency for AI should be an independent European Union agency[131] with legal personality. It shall be represented by its Executive Director.

> **Explanatory note:**   The advantages of a separate and independent legal entity are well-recognised - i.e., it would meet the need for special expertise and make the 'credible commitments' required in relation to its objectives.[132] It is essential that its work is of high quality and not influenced by political or contingent considerations.[133] Its independence should be both in relation to its functioning and of the persons managing it. Vos et al outline the elements of institutional independence as including: own legal personality, availability of necessary resources, personal independence of members of the boards and managers, personal independence of staff.[134] Functional independence is seen as "the requirement neither to seek nor to take instructions from any other party," (though full functional independence is often not possible). Guarantees of the Agency's independence should be provided in its founding legislation.
>
> It is also important that the Agency avoid a conflict of interest situation, i.e., "a situation where the impartiality and objectivity of a decision, opinion or recommendation of an Agency is or might be perceived as being compromised by a personal interest held or entrusted to a given individual. Relevant personal interest may be of financial or non-financial nature and it may concern a personal or family relationship or professional affiliations (including additional employment or 'outside' appointments or former employments or appointments) and other relevant outside activities."[135] For this the Agency should have monitoring mechanisms and develop key performance indicators (KPIs) to detect and manage conflicts of interest and "publish its policies and rules for the management or prevention of conflict of interest, in a clear and easily identifiable manner".[136]
>
> The Agency's powers will not affect any responsibilities which the Treaty of the European Union has explicitly conferred on the European Commission. It will provide additional expertise on regulation of AI

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[131] Note, "The Regulatory Agencies Can Be Categorised Roughly On The Basis Of Their Functions: Adoption Of Individual Decisions; Technical Or Scientific Advice To The Commission and the Member States; responsibility for operational activities; information and networking services; services to other agencies and institutions." Communication from the Commission to the European Parliament and the Council of 11 March 2008: European Agencies – The way forward {SEC(2008) 323} [COM(2008) 135 final]

[132] Vos, Ellen, Natassa Athanasiadou, Laura Dohmen, "Study Requested by the PETI committee. EU Agencies and Conflicts of Interests", European Parliament, January 2020, p.15 https://www.europarl.europa.eu/RegData/etudes/STUD/2020/621934/IPOL_STU(2020)621934_EN.pdf. Citing Busuioc, M., *The accountability of European agencies, legal provisions and ongoing practices,* Eburon, 2010, p. 15; Fischer- Appelt, D., *Agenturen der Europäischen Gemeinschaft* (Duncker & Humblot 1999), p 38.

[133] Communication from the Commission, "The Operating Framework for the European Regulatory Agencies", COM(2002) 718, 11 December 2002, at 5.

[134] Vos et al, op. cit., 2020.

[135] European Commission, Guidelines on the prevention and management of conflicts of interest in EU decentralised agencies, 10 December 2013. https://europa.eu/european-union/sites/europaeu/files/docs/body/2013-12-10_guidelines_on_conflict_of_interests_en.pdf

[136] Vos et al, op. cit., 2020.

to the EU institutions, bodies and agencies. The Agency should operate as a point of reference establishing trust and confidence by virtue of its independence and its work. In its nature and scope, the transversal and cross-sector nature of AI must be considered. The Agency should also not duplicate the roles of existing agencies/authorities[137] and its purposes and objectives have been drafted in line with this in mind. A review of the roles of existing European Union agencies[138] (e.g., EDPB, EDPS, ENISA) that might conflict should be carried out and potential for merging roles and functions and any interrelationships should be addressed through impact assessment.

5.3. Legal basis

Its legal basis should lie in the new European Union AI legislation and/or a new founding regulation that would set out its mandate and operational procedures.

Explanatory note: There is "no explicit legal basis for the creation of agencies or general definition or description of agencies and their competences and task", but "they have been deliberately created by the EU legislator in line with the principle of conferral of powers, on the basis of different provisions of the Treaties. The Lisbon Treaty has formally recognised agentification of the EU executive by introducing EU agencies formally into the Treaties".[139] Many existing agencies have their legal basis under Article 308 of the Treaty establishing the European Community[140], others were created under sectoral treaty basis. Article 114 TFEU[141] has been used as the basis for ENISA and ESMA (as they contribute to 'harmonisation' measures under EU internal market law).

New legislation to set up the body was deemed largely more favourable in the long term (along the lines of the ENISA founding Regulation[142]) by stakeholders consulted by SHERPA. While a new legislative measure might be costly and time-consuming, it is necessary to avoid confusion and inefficiencies. The new measure would define basic concepts (or cross-reference), and set out the role, mandate, specific competencies, and operational procedures and governance of the Agency, coordination and cooperation role, while taking into account relevant aspects of sectoral regulation whilst creating a general horizontal approach. The planned new EU AI legislation is timely and could provide the founding basis for the Agency and give it an appropriate legal mandate and the necessary resources, based on the proposal outlined here.

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[137] E.g., AI-powered medical devices fall under the (Medical Devices Regulation) and competent authorities would assess the conformity of those devices.

[138] Noting, some challenges might arise in merging roles where agencies are based in Member States.

[139] European Parliament Committee on Constitutional Affairs, Report on the implementation of the legal provisions and the Joint Statement ensuring parliamentary scrutiny over decentralised agencies (Rapporteur: György Schöpflin) (2018/2114(INI)). https://www.europarl.europa.eu/doceo/document/A-8-2019-0055_EN.html

[140] Article 308 states: If action by the Community should prove necessary to attain, in the course of the operation of the common market, one of the objectives of the Community, and this Treaty has not provided the necessary powers, the Council shall, acting unanimously on a proposal from the Commission and after consulting the European Parliament, take the appropriate measures. European Union, Treaty establishing the European Community (Consolidated version 2002)*OJ C 325,* 24.12.2002, p. 33–184.

[141] European Union, Consolidated version of the Treaty on the Functioning of the European Union, *OJ C* 326, 26.10.2012, p. 47–390

[142] European Parliament and the Council, Regulation (EU) 2019/881 of the European Parliament and of the Council of 17 April 2019 on ENISA (the European Union Agency for Cybersecurity) and on information and communications technology cybersecurity certification and repealing Regulation (EU) No 526/2013 (Cybersecurity Act). https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:32019R0881

The alternative of amending existing legislation[143] to provide the basis for the Agency may take less time, but could lead to more confusion and a less holistic approach. A less optimal alternative, or stop-gap solution, may be to extend the scope of EU bodies' competencies to house the role and functions of the EU Agency for AI, e.g., EDPS and/or the BEREC, or the ERGA. Extending the scope of existing bodies would need a determination and thorough assessment of which body might be best placed to take this on, whether it has the resources and expertise in place to carry out the roles and functions proposed here and whether its original purposes might conflict with what is required of a European Agency for AI. It might mean amending the founding legislation of such bodies.

5.4.   Purpose and objectives

The Agency shall, inter alia:

- Foster effective application and enforcement of existing EU and national legislation, including the new legal regulation on AI (if/when implemented);
- Assist, and coordinate with EU institutions, bodies, agencies and competent authorities to promote and protect Union values and fundamental rights, including those enshrined in the EU Charter of Fundamental Rights, from adverse impacts of AI in all phases of the AI lifecycle and particularly safeguard the rule of law;
- Promote and strengthen common governance, consistency and harmonised approach across the European Union, and work to reduce fragmentation of responsibilities;
- Provide the relevant institutions, bodies, agencies and authorities of the Community and its Member States when implementing Community law with information, assistance, expertise and recommendations on the regulation of AI to support them when they take measures or formulate courses of action within their respective spheres of competence to fully respect EU values and fundamental rights and their enforcement;
- Collaborate, deliver advice to sectoral and national bodies upon request and improve regulatory capabilities in the regulation of AI, and
- Deliberate on and discuss AI developments (e.g., as identified by the European Commission's AI Watch[144], as they happen to determine which need binding rules, or other regulatory measures.

Explanatory note: The purposes and objectives of the Agency have been defined in line with the gaps and concerns expressed in relation to the regulation of AI and the human rights perspective, based on our research in the SHERPA project, and stakeholder consultations.

In creating such an Agency, the European Union has a tremendous opportunity for leadership in helping protect the rights and freedoms of individuals, along with the rule of law. We believe there is need for the Agency to help the EU adapt its regulatory strategies to the challenges AI presents to society and humanity. There is need for flexibility and yet at the same time to shed light on AI regulatory complexities and can help foster good policy and regulation, and address the gaps in knowledge. At the same time, there is a need for a body to work in cooperation with numerous existing international, EU-level[145] and national bodies to make AI regulation and policy more effective.

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[143] This would fall within the European Commission's competence and responsibility and should be done in a transparent manner with the involvement of industry, so this does not lead to any extra confusion.
[144] E.g., European Commission AI Watch. https://ec.europa.eu/knowledge4policy/ai-watch_en
[145] E.g., https://europa.eu/european-union/contact/institutions-bodies_en

Innovation and economic success have intentionally not been included as an explicit objective or purpose of this Agency, as there are other agencies and bodies at the EU-level devoted to promoting AI-based innovation and adoption (e.g., DG CONNECT, CLAIRE); this Agency should work with them to foster responsible innovation. Innovation, and safeguarding innovation, are important so society can reap the benefits[146] and compete globally, but this must not impede the ability of this Agency to make strong contributions to the regulation of AI and the minimisation of harms to individuals, society and human rights. At the same time, the Agency should help support the goal of agility of regulation.

5.5.   Roles and functions

The Agency should:

- Make **Recommendations[147] addressed to the European Parliament, the Council, or the Commission for legislative amendments and adjustments**[148], after carrying out fitness-for-purpose checks, to boost implementation and enforcement of legislation at the EU-level, related to AI;[149]
- **Identify potential red lines or restrictions[150]** for AI development, deployment and use that violates human rights and/or has significant negative societal impacts addressed to the EU institutions and to feed into European Commission Decisions;
- **Develop and promulgate general guidance** on legal concepts and regulatory issues of AI -based on its discussions and deliberations of AI developments;
- **Set benchmarks for enforcement** and present its position via Opinions or Intervention/Enforcement Advisories for enforcement authorities;
- **Support, work with and advise EU-level institutions, bodies and agencies,** e.g., European Commission, European Parliament and the Council, EDPB, EDPS, FRA **and national competent authorities in Member States** to fulfil their ethical and human rights obligations and to protect the rule of law where AI is researched, commissioned, developed, deployed and used;
- **Maintain an AI risk alert system** (notifications of direct or indirect risks to human life and health) to competent authorities from the development, deployment and use of AI systems, services and products[151] via its Network;

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[146] Benefits include new business opportunities, job creation, improved services, e.g., in healthcare, transportation, security.

[147] See glossary for explanation.

[148] As stated by the EP report 2020, these may be necessary to reflect the digital transformation and address new challenges posed by the use of artificial intelligence. Furthermore, "legislation may no longer be fit for purpose to effectively tackle the risks created by artificial intelligence, robotics and related technologies".
https://www.europarl.europa.eu/doceo/document/A-9-2020-0186_EN.html

[149] This role was particularly strongly supported by experts and one Stakeholder Board member.

[150] Red lines/restrictions refer to thresholds, boundaries, limits which should not be crossed E.g., one red line would be using facial recognition technologies for emotion detection based decision-making that can have serious and harmful effects on individuals and vulnerable groups or AI-based racial profiling.

[151] This could be inspired by the Rapid alert system for food and feed. See Commission Regulation (EU) No 16/2011 of 10 January 2011 laying down implementing measures for the Rapid alert system for food and feed *OJ L* 6, 11.1.2011, p. 7–10. Another relevant example is the Safety Gate: the rapid alert system for dangerous non-food products.
https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/content/pages/rapex/index_en.htm

- **Assist in coordinating the mandates and actions** of the national competent authorities of Member States;[152]
- **Develop harmonised and objective criteria for risk assessment** and/or conformity assessment including certification of ethical and human rights requirements of AI and related technologies in the EU and issue guidance on their application;[153]
- **Monitor and/or coordinate** the evaluation of the operation of conformity assessment and/or certification schemes established for such purposes;
- **Cooperate, liaise, exchange information**, **promote public dialogue**, best practices and training activities[154] with international, EU, national AI regulatory bodies and/or supervisory authorities think-tanks, civil society, technology community, and other underrepresented stakeholders when proposing new regulations;
- **Ensure complementarity and synergy** between its activities and other Community programmes and initiatives[155];
- **Promote the adoption of regulatory sandboxes** to allow live testing of the distribution and use of AI innovations by stakeholders, including the public, in a controlled environment under regulators' supervision;
- **Promote the Union's AI approach through international cooperation** with relevant bodies such as the UN, OECD, G20 and regional legal orders by participating/inviting participation in common interest regulation-related activities. It should also play a greater coordinative role in shaping the development of international standards for AI, through the International Organisation for Standardisation (ISO) and International Electrotechnical Commission (IEC) to harmonise the technical requirements of AI.

Explanatory note: These roles and functions are seen as critical based on SHERPA research and stakeholder consultation. These should be seen as minimum requirements for the Agency. The Agency should have the possibility of increasing its roles and functions in line with needs that cannot be foreseen at the present time.

The outlined functions need good allocation of resources (financial, human and time) and a variety of expertise in the Agency (lack of adequate and diverse expertise will be detrimental to its effectiveness).

The Agency should also take into account the specific needs of regulatory guidance for SMEs particularly start-ups. It should engage such organisations in its activities and provide them with compliance guidance.

5.6.   Structure and governance

The Figure below illustrates the proposed structure of the Agency.

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[152] E.g., The Agency could guide Member States in creating or designating national competent authorities for AI. The Agency could first oversee and ensure that Member States create/designate within a certain timeframe. The Agency could also develop a set of standards that the national competent authorities must meet (e.g., independence, dedicated funding, certain representation of technical, legal and ethical experts.)

[153] If the new EU AI legislation calls for identification of high-risk AI applications, the Agency could ensure that objective criteria are used so as not to identify wrongfully some AI uses as high-risk and as a result hinder innovation and technological development unnecessarily.

[154] See Iordanou, et al, op.cit., 2020, p. 25.
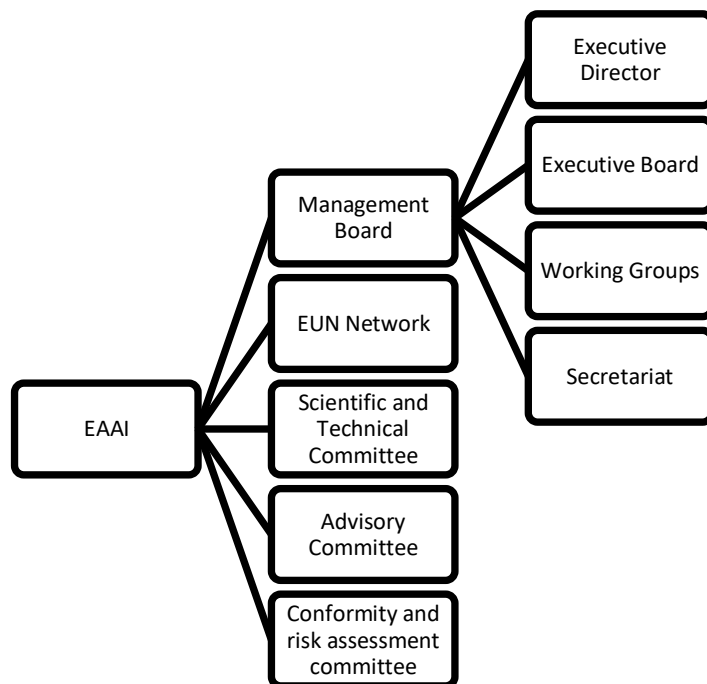
[155] E.g., AI Watch.

Fig 1: Proposed Agency structure and governance

- A **Management Board** ensures the Agency carries out its tasks under conditions which enable it to serve in accordance with its founding Regulation. It has authority over the agency's work programme, budget and annual report. The Management Board will make final decisions on the adoption of Decisions, Opinions, Recommendations, Guidelines, Advisories and other documents (prepared by the Executive Board). The Management Board will nominate an Executive Director. The members of the Management Board will be appointed by the Parliament, the Commission (in equal number) and the Council (same number as the other two plus one extra). The European Commission will be represented on the Board without the right to vote.[156] The term of office of the members of the Board will be four years, renewable once.

- An **Executive Board** will prepare Decisions, Opinions, Recommendations, Guidelines, Advisories and other documents (coordinated by Rapporteurs[157]) to be adopted by the Management Board. The Executive Board will consult and/or delegate specific tasks to the scientific/technical committee, the advisory committee and its working groups and Rapporteurs.

- An **Executive Director** will be responsible for managing the Agency and performing duties independently. The Director will be the legal representative of the Agency and will be in charge of its day-to-day management; prepare and participate in the work of the Boards and have the overall responsibility for implementing the decisions adopted by the Management Board, draft, consult upon, and publish opinions, recommendations and decisions; and be responsible for implementing the Agency's annual work programme under the guidance of the scientific/technical committee and the administrative control of the Management Board.

- A **network of EU and national competent authorities** that facilitates the exchange of information between the Agency and EU Member States for the consistent and effective application of the EU AI regulatory framework and the AI risk alert system[158]. Relevant EU agencies that should be

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[156] To maintain independence of the Agency and avoid any conflict of interest.

[157] The Rapporteurs will coordinate the efforts, draft the documentation, lead discussions and consultations, and the preparation and presentation of the document.

[158] Members of the network can send alert notifications to the Agency contact point without undue delay from the moment the risk was reported to them using designated templates. The Agency contact point would transmit alert notifications to all members of the network within a reasonable time after reception (to be defined).

represented include the EDPB, EDPS, Frontex, eu-LISA, EASO, EIGE, EMCDDA, CEPOL, Europol, Eurojust, EURODAC, FRA, EQUINET, EIOPA, EBA, ESMA, field-specific agencies and national competent authorities (or designated AI bodies) from the EFTA, EEA states etc. The Agency should have a dedicated presence in each Member State (via notification of one national competent authority[159] as its main liaison). The Network will closely cooperate with the Agency and help monitor the impacts of the AI Regulation. The Agency should be open to the participation of third countries which have concluded agreements with the Union and which have adopted and are applying the relevant rules of Union law in the field of AI.

- A **scientific/technical committee** that ensures the high scientific quality of the work of the Agency and guides its work by means of scientific objectivity.

- An **advisory committee (with representation of diverse backgrounds, including industry – small and large companies, civil society organisations, particularly those representing those vulnerable groups)**[160] that focuses on regulatory issues relevant to stakeholders and brings them to the attention of the Agency

- **Working groups:** The Executive Director will establish, in consultation with the Advisory Committee, ad-hoc Working Groups composed of experts. The Working Groups will address specific technical and scientific matters not addressed by other committees in the Agency. Experts could be drawn from e.g., CLAIRE,[161] European AI PPP (joint SRIDA[162] of the Big Data Value Association and euRobotics AISBL), and EU-funded AI projects.

- **Conformity and Risk Assessment Committee: will coordinate the mandates and actions** of the national competent authorities of Member States and/or develop harmonised and objective criteria for risk assessment and/or conformity assessment, including certification of ethical and human rights requirements of AI and related technologies in the EU.

- A **Secretariat** will offer analytical, administrative and logistical support to the Management Board and the Agency (preparation of documents, and organising meetings and communication). The head of the secretariat shall be responsible for the due and timely performance of the tasks of the secretariat.

Explanatory note: The above is an indicative structure (presented in line with features of existing decentralised Agencies) and should be adapted to meet the specific needs of AI regulation and the specific role of the national competent authorities needs to be taken fully into account. The Agency is intended to be more than a gathering of national regulators and needs the right competencies and powers.

5.7.   Operational principles and procedural rules

The Agency should operate based on the following principles: [163]

- Principle of respect for human rights/human-centric approach;
- Principle of independence[164] and impartiality;
- Principle of fairness;
- Principle of transparency;

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[159] This would be a body notified by the Member State. It could be a supervisory body like the national data protection authority or a dedicated AI body/authority if there is one.

[160] This should be an aim for all the committees as this is a persistent problem.

[161] Confederation of Laboratories for Artificial Intelligence Research in Europe. https://claire-ai.org

[162] Strategic Research, Innovation and Deployment Agenda (SRIDA).

[163] Partly drawn from the EDPB operational principles and based on the results of the stakeholder consultations.

[164] When carrying out its tasks, the Agency shall act independently, objectively, and in the interest of the Union. It shall take autonomous decisions, independently of private and corporate interests.

- ▪ Principle of proactivity;
- ▪ Principles of good governance, integrity and good administrative behaviour;
- ▪ Principle of collegiality, inclusiveness and diversity;
- ▪ Principle of cooperation;
- ▪ Principle of efficiency and modernisation.

The Agency's rules of procedure[165] could be modelled upon the rules of procedure set out for existing Union agencies such as ACER,[166] or the EDPB.[167]

5.8.   Reporting and auditing

The annual report shall contain an independent section concerning the Agency's diverse regulatory activities during that year. The Management Board will adopt and publish the annual report on the Agency's activities, and will submit that report to the European Parliament, the Council, the Commission, and the Court of Auditors.

The auditing of accounts should be undertaken by an independent external auditor in accordance with Article 107 of Commission Delegated Regulation (EU) No 1271/2013 Commission Delegated Regulation (EU) No 1271/2013 of 30 September 2013 on the framework financial regulation for the bodies referred to in Article 208 of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council.[168] The Board will also ensure appropriate follow-up to findings and recommendations stemming from the internal or external audit reports and evaluations, as well as from investigations of the European Anti-Fraud Office (OLAF).

Explanatory note: Reporting by the Agency should be regular and transparent.

5.9.   Evaluation and review

Every five years, the European Parliament, with the assistance of an independent external expert, should carry out an evaluation to assess the Agency's performance in relation to its objectives, mandate and tasks.[169] The expert may request information from the Member States in this respect. The evaluation will address the possible need to modify the Agency's mandate, and the financial implications of any such modification. The report will also evaluate the Regulation underpinning the Agency and may include proposals to amend the Regulation, consider developments in AI and the technological state of progress. The report will be tabled and discussed. Where the Parliament considers that the continued existence of the Agency is no longer justified with regard to its assigned objectives, mandate and tasks, it may propose that this Regulation be amended accordingly or repealed after carrying out an appropriate consultation of stakeholders and the Agency. The findings of the evaluation should be made public.

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[165] The rules of procedure of such Agencies can be quite detailed running into many pages; each element in the governance structure has its own rules of procedure, and therefore we have chosen to keep this open at this stage.
[166] See http://www.acer.europa.eu/en/The_agency/Organisation/Administrative_Board/Pages/Rules-of-Procedures.aspx;
http://www.acer.europa.eu/en/The_agency/Organisation/Board_of_Regulators/Documents/BoR91-04.4_BoR%20RoP_approved_17062020.pdf
[167] https://edpb.europa.eu/sites/edpb/files/files/file1/edpb_rop_version_6_adopted_20200129_en.pdf
[168] *OJ L* 328, 7.12.2013, p. 42
[169] Adapted from the ACER Regulation.

5.10. Funding and sustainability

The Agency would be financed by European Union funds allocated on an annual basis by the European Union budgetary authority, i.e., the European Parliament (directly elected MEPs) and the Council of the European Union (representatives of the Member State governments). It would operate under the rules of the general Financial Regulation.[170]

Explanatory note: In order to guarantee the full autonomy and independence of the Agency and to enable it to perform additional and new tasks, including unforeseen emergency tasks, the Agency should be properly resourced and granted a sufficient and autonomous budget to enable it to carry out its tasks. The Agency should not be dependent in any way on funding from business, industry and other vested interests.

5.11. Plan and timeline

Below we present a timeline from impact assessment to full operationalisation of the new Agency.

Fig 2: Projected implementation timeline for the Agency

Step1. Research, stakeholder consultation and proposal ToR (year 0, current)
This first step of this process is complete in SHERPA via the carrying out of the study into regulatory options for AI and big data (SHERPA Task 3.3) and the proposal of the ToR for a new regulator (Task 3.6). The proposal will be submitted to the Commission and disseminated to other policy-makers at the EU-level, particularly the European Parliament and the Council so that this can be considered and/or taken into account in the ongoing discussions and legislative activity on AI.

Step 2. Discussion and impact assessment by EU bodies (year 1)
The EU institutions, particularly the European Commission, should discuss and carry out an impact assessment to create and set up the proposed Agency, in line with the Common Approach requirement.

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[170] The general Financial Regulation contains certain essential rules concerning in particular agencies' establishment plan, the application of the framework financial regulation for agencies, the consolidation of their accounts with those of the Commission, and the discharge by the European Parliament. In addition, the framework financial regulation lays down common rules governing the establishment and implementation of their budget, including control aspects.

Step 3. Adopt founding regulation (year 2-5)

A legal basis for the new Agency., i.e., a new founding regulation (based on standard provisions) will need to be prepared and adopted. A decision will also have to be made regarding the location of the Agency.[171] Decentralised agencies have their own basic sectoral regulation, often adopted by co-decision (on average for each completed ordinary legislative procedure, a first reading takes take 17 months, second reading takes 40 months.[172]

Step 4. Establish Agency (year 5)

This step involves the creation and establishment of the Agency and the commencement of its activities.

Step 5. Fully operationalise (year 7)

This step involves the Agency becoming fully functional and ready to fulfil all its assignments as required by its regulatory framework.

It is critical that the EU institutions act as fast as possible to explore options and include this proposal in the new AI legislation. It is important to make the Agency operational as soon as possible even if on a provisional or pilot basis. This is to take into account current increasing investments in AI research at the EU-level[173], the increasing deployment and use of new AI-based systems (e.g., to address COVID-19[174]) and the concurrent need for guidance on regulatory issues, appropriate restrictions and benchmarks for enforcement. Furthermore, technology will change significantly.

6. Value added by the Agency and challenges

To recap, the value added by the proposed Agency would include:

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[171] In line with the following: European Commission, *Guidelines with standard provisions for headquarters agreements of EU decentralised agencies*, 10 December 2013. https://europa.eu/european-union/sites/europaeu/files/docs/body/2013-12-10_guidelines_hq_agreements_en.pdf ; European Commission, *Communication Handbook for the EU Agencies*, December 2013. https://europa.eu/european-union/sites/europaeu/files/docs/body/2013-12-10_communication_handbook_en.pdf ; European Commission, *Roadmap on the follow-up to the Common Approach on EU decentralised agencies* (undated). https://europa.eu/european-union/sites/europaeu/files/docs/body/2012-12-18_roadmap_on_the_follow_up_to_the_common_approach_on_eu_decentralised_agencies_en.pdf (see its Annex which provides the legal and procedural steps that must be followed for the establishment of an EU agency, its operation, evaluations, audits and for the management of financial and human resources and budgetary process.

[172] European Parliamentary Research Service Blog, "Number And Average Length Of Co-Decision Procedures", 13 April 2018. https://epthinktank.eu/2014/11/26/european-parliament-facts-and-figures/19-lenght-of-codecision-2/

[173] "The Commission invested €50m under the current Horizon 2020 programme, after an initial investment of €20m for the creation of AI4EU, the AI-on-Demand-Platform that allows the exchange of AI tools and resources across Europe". https://ec.europa.eu/digital-single-market/en/news/towards-vibrant-european-network-ai-excellence

[174]   See   https://ec.europa.eu/digital-single-market/en/news/using-ai-fast-and-effectively-diagnose-covid-19-hospitals

♦ The valuable support it could provide EU-level institutions, particularly the European Parliament, the European Commission (and already established committees) and national competent authorities in Member States to ensure the ethical and human rights compliant development, deployment and use of AI, protect the rule of law, and foster a common regulatory vision.

♦ It would promote coordination and international cooperation on regulation of AI and would create a good collaborative environment for AI policy and regulation.

♦ It would promote the adoption of a unified message on AI regulation to the extent possible and/or required.

♦ It could also help avoid over-regulation, by helping close existing legal loopholes, and providing legal certainty for businesses and individuals.

At the same time, the establishment of the Agency has challenges including:

♦ Lack of political will and/or resistance to the creation of an Agency by co-legislators, as usually the creation of a new agency is adopted by co-decision,

♦ Disagreement on the headquarters (the case of ENISA was cited, where the battle of the headquarters lasted very long),

♦ Competing priorities of different institutions (if the Agency's roles and functions overlap or clash with their primary missions),

♦ Addressing the balance and relationships between regulation, risk management and innovation.

♦ Addressing the intersection between AI policy and European data protection law and policy,

♦ Future-proofing the Agency in line with technological or policy developments and changing societal values.[175]

There are no straightforward answers but actions that would mitigate these challenges include:
♦ presenting a strong proposal and good business case (for which further research and in-depth evaluation is also required as a next step),

♦ effective and targeted lobbying for the Agency,

♦ carefully setting out the terms of the Agency (and this proposal has taken the first step in this respect, e.g., setting out roles and functions that would not overlap with other Agencies rather complement them with additional dedicated resources and expertise), and

♦ including provisions for review and evaluation (so if the Agency's mandate needs to be expanded.

7. Conclusion

This report summarised views at the EU and national level, before considering new bodies with regulatory or advisory capacity concerning AI and big data. It also provided an overview of calls for new regulatory or advisory bodies to be created, and summarised arguments for and against a new regulator for AI and big data. As of March 2020, there were no AI- or big data-specific regulatory bodies in the EU at either transnational or national level.[176] The EU has yet to take a clear position on this, despite calls from the EU Parliament and some Member States to create an EU Agency for AI. Member States have broadly assigned regulatory concerns regarding AI and big data to pre-existing regulatory bodies.

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[175] Iordanou, et al, op.cit., 2020, p.26, 51.
[176] Rodrigues et al, op. cit., 2019, p.88.

A new regulatory body would bring together a complex understanding of the technical, legal and ethical issues involved in AI and could also boost human rights observance. Arguments in favour of the creation of a new regulator for AI at either national or EU level are by no means uncontested. A central issue at play is whether existing legislation and regulatory authorities are sufficient to oversee the development of AI, and it is perhaps too early to tell, given new legislative and technological developments. Above all, a lack of clarity as to the proposals put forward in favour of the establishment of new regulatory bodies has hampered the debate.

Key factors as to the success of a regulatory body include its funding and independence from government, buy-in from stakeholders, and its ability to keep up-to-date with technological developments.

This report presents a proposal for a European Agency for AI **for consideration by the European Commission, Parliament and the Council** in the development of a regulatory framework for AI at the EU-level. It is timely as the EU AI legislative framework is in development and is expected in 2021. We strongly believe that a stronger central, **independent** body is needed to act as a proactive champion and strengthen harmonisation, cooperation and consistency in the regulation of AI, especially at the EU-level. Such a body will foster international cooperation on AI issues, provide much-needed clarity at the EU-level, create a collaborative environment for EU AI policy and regulation, and promote good regulation at the Member State level.

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Annexes

1. Summary of proposals for new regulatory bodies and their assessment

This annex presents a summary of proposals for regulatory bodies at the EU, Member State or non-EU country level. It presents the bodies, proposer, year of the proposal, the level they have been proposed, what they regulate (AI, big data), gaps filled, identified pros and cons, and presents an assessment, i.e., are they feasible and sustainable (e.g., supported by policy and market incentives) and future-proof? Or are they be adversely affected by future developments e.g., technological, policy changes, social demands? [177]

Name of proposed body and proposer	EU Agency for Robotics and Artificial Intelligence[178] Proposer: EU Parliament Year: 2017
Level /country	EU-level
What does it regulate	Robotics and Artificial Intelligence
Gap filled/need met	Currently there is no systematic public tracking system for autonomous systems that have been deployed. Suppliers of autonomous systems may keep records (such as system serial numbers) for deployed systems, but there is no public visibility into these proprietary records.[179]
Identified pros	A uniform registration system would facilitate safety notifications and recalls, similar to the vehicle identification number system for cars today.[180]
Identified cons	Rejected by European Commission, which founded the AI HLEG instead to investigate further.[181]
Final assessment	Insufficient detail provided to establish feasibility, sustainability and future-proofing.[182]

Name of proposed body and proposer	The EU Taskforce of field specific regulators for AI/big data[183] Proposer: SHERPA Stakeholder Board Year: 2019
Level /country	EU-level
What does it regulate	AI and big data
Gap filled/need met	It might help address shortcomings in the areas of cooperation, coordination, consistent application of Union law related to AI/big data, also, e.g., cross-border risks from AI and big data applications.[184]

Name of proposed body and proposer	The EU Taskforce of field specific regulators for AI/big data[183] Proposer: SHERPA Stakeholder Board Year: 2019
Identified pros	It will promote cooperation on AI/big data legal issues and provide clarity at the EU-level. The task force could create a good collaborative environment for EU AI policy and regulation and promote the adoption of a unified message on AI/big data regulation to the extent possible/required.[185]
Identified cons	Task forces are limited often by the capacity of their members. If established without a clear mandate, it might duplicate the work of existing EU agencies. It might cause further frustrations amongst stakeholders. Changing regulatory culture of the EU. Managing conflicts, limited resource. Funding issues and personnel turnover.[186]
Final assessment	Feasibility and sustainability depend on internal and external buy-in and EU political will to create and keep it going. It might also be affected by competing priorities of the different bodies that might be expected to house and/or form it. The task force would also need to allay the concern of participating bodies that such participation may conflict with their primary mission.[187]

Name of proposed body and proposer	Network of national authorities, as well as sectoral networks and regulatory authorities, at national and EU level.[188] Proposer: European Commission Year: 2020
Level/country	EU-level
What does it regulate	AI
Gap filled/need met	Current fragmentation of responsibilities and standards, increase capacity in Member States, and make sure that Europe equips itself progressively with the capacity needed for testing and certification of AI-enabled products and services. "Some specific features of AI (e.g. opacity) can make the application and enforcement of existing legislation more difficult. For this reason, there is a need to examine whether current legislation is able to address the risks of AI and can be effectively enforced, whether adaptations of the legislation are needed, or whether new legislation is needed."[189] Current absence of a common European framework.[190] Mandatory conformity assessment for high-risk AI applications.[191] A forum for a regular exchange of information and best practice, identifying emerging trends, advising on standardisation activity as well as on certification. It should also play a key role in facilitating the implementation of the legal framework, such as through issuing guidance, opinions and expertise.[192]
Identified pros	Would support a European governance structure on AI in the form of a framework for cooperation of national competent authorities. A clear European regulatory framework would build trust among consumers and businesses in AI.[193]

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[185] Ibid.

[186] Rodrigues et al., SHERPA D3.3, op.cit., 2019, p.159.

[187] Ibid.

[188] European Commission, White Paper, op. cit., 2020.

[189] European Commission, White Paper, op. cit., 2020, p.10.

[190] Ibid.

[191] European Commission, White Paper, op. cit., 2020, p.23.

[192] European Commission, White Paper, op. cit., 2020, p.24.

[193] European Commission, White Paper, op. cit., 2020, p.10.

Name of proposed body and proposer	Network of national authorities, as well as sectoral networks and regulatory authorities, at national and EU level.[188] Proposer: European Commission Year: 2020
	A solid European regulatory framework for trustworthy AI will protect all European citizens and help create a frictionless internal market for the further development and uptake of AI as well as strengthening Europe's industrial basis in AI.[194]
Identified cons	Conformity assessment could be burdensome on SMEs.[195]
Final assessment	Feasible: Given existing European frameworks for oversight of related issues, and calls for increased regulatory oversight by large member states (France and Germany), this could be a feasible option. Sustainable: "Such a regulatory framework should be consistent with other actions to promote Europe's innovation capacity and competitiveness in this field."[196] "It should establish close links with other EU and national competent authorities in the various sectors to complement existing expertise and help existing authorities in monitoring and the oversight of the activities of economic operators involving AI systems and AI-enabled products and services."[197] "Must ensure socially, environmentally and economically optimal outcomes and compliance with EU legislation, principles and values."[198] Future-proof: "Given how fast AI is evolving, the regulatory framework must leave room to cater for further developments. Any changes should be limited to clearly identified problems for which feasible solutions exist."[199] "Particular account should be taken of the possibility that certain AI systems evolve and learn from experience, which may require repeated assessments over the life-time of the AI systems in question."[200]

Name of proposed body and proposer	Digital Authority[201] Proposer: UK House of Lords Year: 2019
Level/country	UK
What does it regulate	AI - does not have independent monitoring, oversight or enforcement mechanisms.
Gap filled/need met	Assessment of regulation in the digital world and recommendations where additional powers are necessary to fill gaps; Establish an internal centre of expertise on digital trends which helps to scan the horizon for emerging risks and gaps in regulation; Help regulators to implement the law effectively and in the public interest; Inform Parliament, the Government and public bodies of technological developments; Provide a pool of expert investigators to be consulted by regulators for specific investigations; Survey the public to identify how their attitudes to technology change over time, and to ensure that the concerns of the public are taken into account by regulators and policy-makers; Raise awareness of issues connected to the digital world among the public;

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194 Ibid.
195 European Commission, White Paper, op. cit., 2020, p.23.
196 European Commission, White Paper, op. cit., 2020, p.10.
197 European Commission, White Paper, op. cit., 2020, p.24.
198 European Commission, White Paper, op. cit., 2020, p.10.
199 Ibid.
200 European Commission, White Paper, op. cit., 2020, p.23.
201 House of Lords, Regulating in a Digital World: 2nd Report of Session 2017-19. Report, 2019. https://publications.parliament.uk/pa/ld201719/ldselect/ldcomuni/299/299.pdf

Name of proposed body and proposer	Digital Authority[201] Proposer: UK House of Lords Year: 2019
	Ensure that human rights and children's rights are upheld in the digital world; Liaise with European and international bodies responsible for internet regulation, addressing shortcomings in cooperation, coordination, consistent application of EU law related to AI/big data.[202]
Identified pros	It is expected to help regulators to implement the law effectively and in the public interest and bring a new consistency and urgency to regulation. It could help eliminate overlaps in legislation.[203] One of its key proposed functions includes ensuring that human rights and children's rights are upheld in the digital world.
Identified cons	May become over-prescriptive.[204] The expense involved in setting up a new body.[205] Overregulation of the digital world.[206] Mission creep.[207]
Final assessment	Proposal details unclear (with respect to its functions, instruction remit, relationships with other bodies).[208] No independent monitoring, oversight and enforcement mechanisms.[209] Effectiveness will depend on proper funding, ability to coordinate and instruct different regulators, ability to remain politically impartial and independent of the Government, and democratic scrutiny.[210] Its sustainability will depend on the policy and funding model adopted and its usefulness in regulating the digital world.[211]

Name of proposed body and proposer	New statutory duty of care for online harms[212] Proposer: UK Government - White Paper Year: 2019
Level/country	UK
What does it regulate	AI - A new regulatory scheme regarding online harmful user-generated content ("UGC"), to be managed by a new independent regulator.[213]
Gap filled/need met	The new regulatory scheme would apply to entities that offer services or tools that allow users to: • share or discover UGC, or • interact with each other online. Currently most of the covered entities are only required to remove or restrict harmful content when they are notified or become aware of it, but not to take proactive steps to monitor for harmful content.[214]

[202] House of Lords, op. cit., 2019.

[203] Hill, Rebecca, "UK Peers Suggest One Big "Digital Authority" to Watch the Tech Watchers, Tighten up Regulation", *The Register*, 9 March 2019. https://www.theregister.co.uk/2019/03/09/lords_communications_committee_internet_regulation/

[204] Rodrigues et al., SHERPA D3.3, op.cit., 2019, p.55.

[205] Rodrigues et al., SHERPA D3.3, op.cit., 2019, p.218.

[206] Ibid.

[207] Rodrigues et al., SHERPA D3.3, op.cit., 2019, p.218.

[208] Rodrigues et al., SHERPA D3.3, op.cit., 2019, p.43

[209] Rodrigues et al., SHERPA D3.3, op.cit., 2019, p.46.

[210] Rodrigues et al., SHERPA D3.3, op.cit., 2019, p.61.

[211] Rodrigues et al., SHERPA D3.3, op.cit., 2019, p.218.

[212] Department for Digital, Culture, Media and Sport and Home Office, "Online Harms White Paper", White Paper (House of Commons, 8 February 2019). https://www.gov.uk/government/consultations/online-harms-white-paper

[213] Ibid.

[214] Department for Digital, Culture, Media and Sport and Home Office, op. cit., 2019.

Name of proposed body and proposer	New statutory duty of care for online harms[212] Proposer: UK Government - White Paper Year: 2019
Identified pros	Designed to reduce illegal, dangerous and otherwise harmful UGC and user interactions. Achieving this goal supports the right to life, freedom from slavery, the right not to be discriminated against, and the right to participate in free elections. The regulatory scheme is intended to reduce deception, intimidation, and other content or activities that promote harm to individuals or groups. Implementation will increase market demand for (and spur further development of) tools to analyse content and online behaviour.
Identified cons	This regulatory scheme does not directly regulate smart information systems. (AI is one tool that covered entities may use to monitor for harmful UGC.)[215] Excessive monitoring and control of UGC can jeopardize free expression, freedom of assembly, and the right to privacy.[216] Places too much faith in technology to help covered entities comply with the oversight requirements.[217] Lacks a clear delineation of legal but "harmful" content to be regulated.[218] Does not identify responsibility for oversight of the regulator.[219]
Final assessment	Feasible: Insufficiently defined to assess. Sustainable: Insufficiently defined to assess. Future-proof: The regulator would have the ability to update codes of practice to reflect changes in technology, but rapidly changing technology may make it challenging for the regulator and covered entities to keep up.[220]

Name of proposed body and proposer	FDA for Algorithms[221] Proposer: Andrew Tutt Year: 2017
Level/country	USA
What does it regulate	AI - A new specialist federal-level regulatory agency to be created to regulate algorithmic safety. (1) to organize and classify algorithms into regulatory categories by their design, complexity, and potential for harm (in both ordinary use and through misuse). (2) to prevent the introduction of algorithms into the market until their safety and efficacy has been proven through evidence-based pre-market trials. (3) broad authority to impose disclosure requirements and usage restrictions to prevent algorithms' harmful misuse.[222]
Gap filled/need met	Gaps in current remedies offered by tort/civil and criminal law.[223]
Identified pros	Could develop comprehensive policy.[224] Could quickly respond to new products and practices.[225] Could also ensure that consumers are adequately protected.[226]

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[215] Digital Action, "Online Harms White Paper: Seven Expert Perspectives", April 2019.

[216] Digital Action, op. cit., 2019.

[217] Ibid.

[218] Digital Action, op. cit., 2019.

[219] Ibid; Smith, Graham, "Cyberleagle: Users Behaving Badly – the Online Harms White Paper", 18 April 2019, https://www.cyberleagle.com/2019/04/users-behaving-badly-online-harms-white.html

[220] Rodrigues et al., SHERPA D3.3, op.cit., p.199.

[221] Tutt, Andrew, "An FDA for Algorithms", *Administrative Law Review* 69, no. 1, 2017, pp. 83–124, https://doi.org/10.2139/ssrn.2747994 ; Groth, Olaf J., Mark J. Nitzberg, and Stuart J. Russell, "AI Algorithms Need FDA-Style Drug Trials", *Wired*, 15 August 2019. https://www.wired.com/story/ai-algorithms-need-drug-trials/

[222] Tutt, op. cit., 2017.

[223] Rodrigues et al., SHERPA D3.3, op. cit., 2019, p.230.

[224] Tutt, op. cit., 2017.

[225] Tutt, op. cit., 2017.

[226] Ibid.

Name of proposed body and proposer	FDA for Algorithms[221] Proposer: Andrew Tutt Year: 2017
	Could add significant value in the centralized expertise.[227]
Identified cons	As covered entities are not required to make assessments public or to report assessments to authorities, it's unclear how the FTC or state AGs would become aware of the need for assessments.[228] Negative impact on innovation.[229] Resource constraints.[230] Too soft or too tough a mandate.[231] Challenge in determining what is excessive and/or insufficient regulation.[232] Excessive regulatory authority.[233] Addressing any internal knowledge gaps.[234]
Final assessment	The US FDA is part-funded by federal budget authorization and the other part is paid for by industry user fees. Sustainability of the proposed (new) FDA for algorithms will have to be similarly ensured and guaranteed.[235] It is susceptible to policy changes (e.g., deregulation) and the restriction of its powers by changes to policy/legislation.[236] An FDA for algorithms would need a depth of technical know-how, and a rich diversity of expertise to grasp the breadth of society; it would also need distinct trigger points on when to review and at what level of scrutiny.[237]

Name of proposed body and proposer	US Federal Trade Commission to regulate robotics[238] Proposer: Various, Woodrow Hartzog Year: 2015
Level/country	USA
What does it regulate	AI - Federal Trade Commission ("FTC") to be given primary responsibility for overseeing regulation of autonomous systems.[239]
Gap filled/need met	Autonomous systems are currently regulated (inconsistently) by multiple federal agencies based on their function.[240]
Identified pros	Could build a rich cross-industry knowledge base and experience base for regulation of a wide spectrum of autonomous systems, avoiding knowledge "silos".[241]
Identified cons	Regulation of autonomous systems in highly specialised environments (such as medical uses) or in environments presenting risk of injury or death to bystanders (drones and autonomous vehicles) may require specialized knowledge that is already in place in other agencies.[242] The FTC's jurisdiction does not extend to federally regulated financial institutions, common carriers, or non-profit

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[227] Tutt, op. cit., 2017.

[228] Ibid.

[229] Tutt, op. cit., 2017.

[230] Rodrigues et al., SHERPA D3.3, op. cit., 2019, p.230.

[231] Ibid.

[232] Rodrigues et al., SHERPA D3.3, op. cit., 2019, p.230.

[233] Ibid.

[234] Rodrigues et al., SHERPA D3.3, op. cit., 2019, p.230.

[235] Ibid.

[236] Rodrigues et al., SHERPA D3.3, op. cit., 2019, p.230.

[237] Ibid.

[238] Hartzog, Woodrow, "Unfair and Deceptive Robots", *Maryland Law Review* 74, no. 4, 2 June 2015, p.785.

[239] Hartzog, op. cit., 2015.

[240] Rodrigues et al., SHERPA D3.3, op. cit., 2019, p.235.

[241] Rodrigues et al., SHERPA D3.3, op. cit., 2019, p.235.

[242] Ibid.

Name of proposed body and proposer	US Federal Trade Commission to regulate robotics[238] Proposer: Various, Woodrow Hartzog Year: 2015
	organisations.[243] The FTC does not have the power to approve or certify medical devices, passenger vehicles or aircraft.[244]
Final assessment	Feasible: Yes (the FTC already regulates a wide variety of businesses).[245] Sustainable: Yes, supported by policy.[246] Future-proof: Possibly. Since its establishment in 1914, the FTC has shown the ability to adapt its regulatory approach to new technologies and new issues. However, this is primarily a political choice and will require political will to be adopted and implemented.[247]

[243] Rodrigues et al., SHERPA D3.3, op. cit., 2019, p.235.
[244] Rodrigues et al., SHERPA D3.3, op. cit., 2019, p.235.
[245] Rodrigues et al., SHERPA D3.3, op. cit., 2019, p.52.
[246] Rodrigues et al., SHERPA D3.3, op. cit., 2019, p.235.
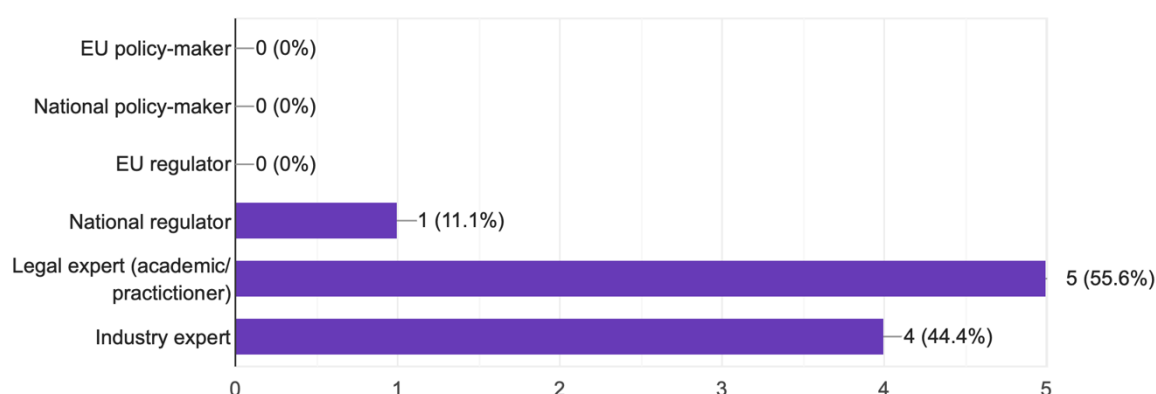[247] Rodrigues et al., SHERPA D3.3, op. cit., 2019, p.62.

2. SHERPA Focus Group: New AI regulator: questionnaire

The objective of the focus group questionnaire was to gather thoughts on the feasibility of a bespoke new regulator for AI and big data at the EU-level and determine ToR. It was administered using Google Forms in advance of the focus group meeting held on 26 June 2020. The results and discussion fed into this report, particularly the development of the ToR. Nine participants completed the questionnaire and the raw results are presented here.
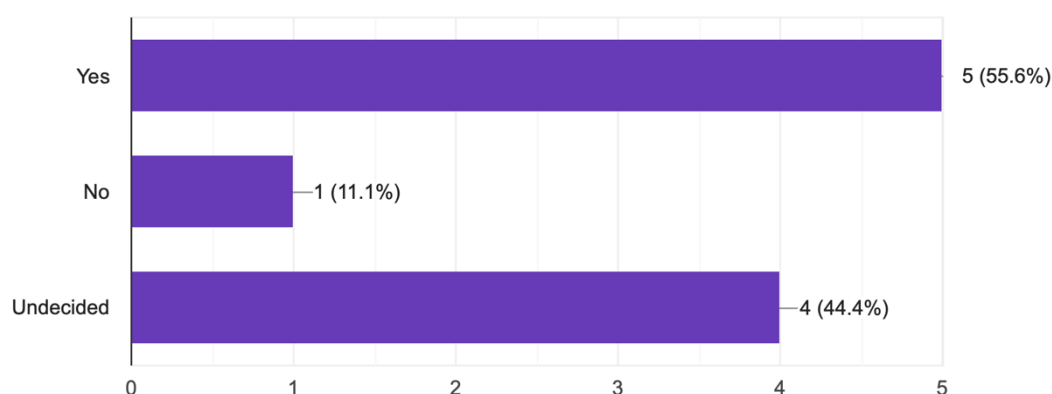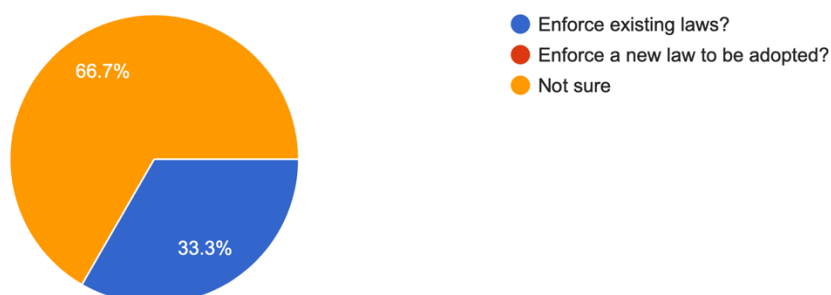
You are:
9 responses

EU policy-maker	0 (0%)
National policy-maker	0 (0%)
EU regulator	0 (0%)
National regulator	1 (11.1%)
Legal expert (academic/ practitioner)	5 (55.6%)
Industry expert	4 (44.4%)

Question 1: Do we need a new or bespoke regulator for AI and big data at the EU level?
9 responses

Yes	5 (55.6%)
No	1 (11.1%)
Undecided	4 (44.4%)

Question 2: Should the new regulator:

9 responses

- Enforce existing laws?
- Enforce a new law to be adopted?
- Not sure

66.7%

33.3%

Question 3: What should its mandate be? E.g., should it protect specific human rights? Or regulate particular applications? Or particular industries? Regulate use and implementation? 9 responses

All of the above

Protecting human rights, operating as a regulatory advisor, and collaborating in creating best practices for the industry ("light standardization")

Differentiate between more/less consequential applications. And regulate more consequential applications, e.g., in health, judiciary, security, finance, employment. Build all rights in the Charter of Fundamental Rights of the EU.

At one hand it should cover the possibility for developing models. I don't believe there is shortcoming in privacy-legislation.

Assess a new or existing technology in view of its potential (or actual) impact on society and individuals with the aim to regulate its distribution and use

Protect all kinds of rights but also the emergence of a strong AI & big data european industry

A new regulator is undesirable given the the fuzzyness of the target. Three years ago we worried a lot about Big Data, now it is AI and Big Data, tomorrow it will be called differently. What it is that needs monitoring/regulating is unclear. Focus on technology is wrong. I am by far convinced a new regulator is required, hence the questions below are premature
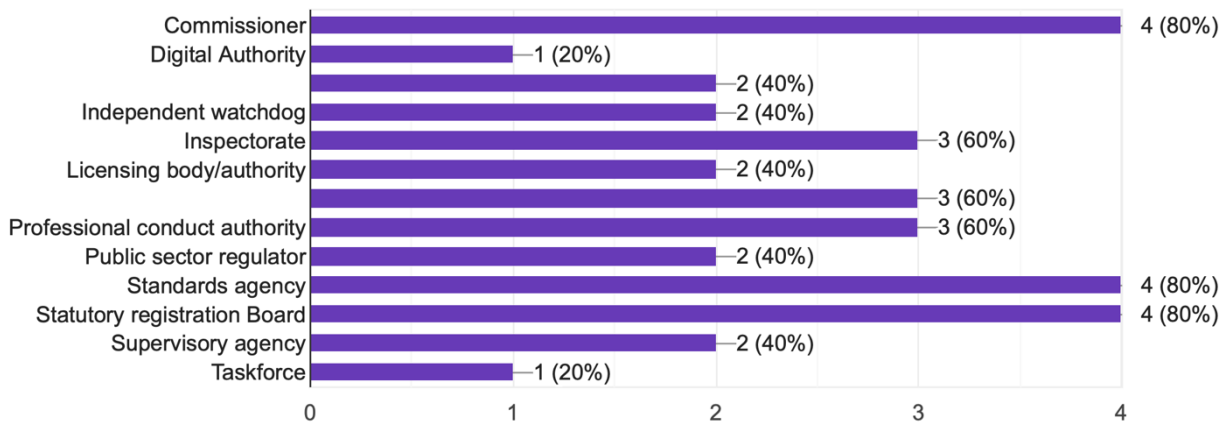
Regulate implementation of AI, and conduct audits (notably) on the basis of complaints from citizens/end users/customers/etc.

The main problem is not Privacy, Security, Artificial soldiers, Anthropomorphism, Fake news, Ethics etc. Really important problems but used for covering the most important and underlying ones; and for misleading us: The AI revolution (economic, social, cultural, ..) is empowering whom?? Ai is not scientifically oriented but servant of business; it's creating unbelievable powers over society and new capitalistic power concentration.

Question 4: Which of the following types of bodies would NOT be a good model for a new AI regulator at the EU-level? Please tick all that should not be considered.

5 responses

Question 5: How should the new regulatory body be constituted? Who should its members be?
7 responses

policy makers, legal experts, AI academicians, industry experts

Academics, policymakers/regulators, industry experts and civil society organizations should for an advisory board for the regulator. Data Protection Agency model could be working, if those agencies would stay efficient and agile but well-resourced (not the case with the DP agencies, atm)

Not sure at the moment.

Specific AI regulators/experts, technology developers (the industry), end users (multiple and with different background), lawyers (human-rights, customer rights, and any other relevant legal-counselor), any potential stakeholder which could be impacted by the technology at stake

It should be integrated inside an already existing EU institution

legal experts and data scientists, alongside with a group of sector experts specific to each case at stake.

Not only business men, technologists, scientists, politicians but also social stakeholders (social movements (like women movement), trade unions, philosophers, ...)

Question 6: What would its role and functions be? 7 responses

1) To identify the criteria to be taken into account during the design, evaluation, and use of AI systems, both general, and application/domain/industry specific ones, and 2) to inspect (and report) the use of AI systems in public and private sector.

To enforce and supervise the selected application areas/themes. For example, face recognition could be one area/theme. The amount of areas/themes should be limited to a few to keep it efficient, and the themes could be updated over time.

Not sure at the moment.

Ensure all outcomes or uses of a technology are accounted for or predicted. This should be part of a risk-assessment process. Based upon multiple analyses conducted by the regulator (or body of

regulators), it should be ensure that the technology is compliant with and does not breach any of the EU/UN human rights. The use and implementation of this technology should be regulated according to the results of these (and other) analyses in order to guarantee the beneficial impact of the technology on society.

Monitor industry behavior/practices

Regulate implementation of AI tools (as much in the private as in the public sector), making audits and investigations, raising awareness and teaching citizens/end users/customers etc. about the risks, benfits, and main principles of AI.

Identify the emergent problems (ethical, political, and social); analyze them, discuss possible causes and solutions; proposals of interventions

Question 7: How should it be governed? To whom would it report? 6 responses

-

Not sure at the moment.

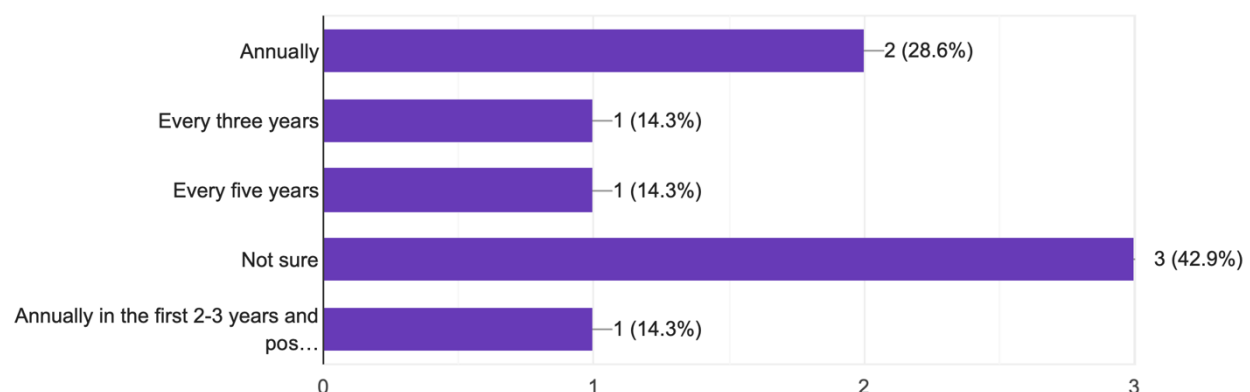Members of states and European parliament.

EC

it should be an independant authority, reporting (accountability) to the public at large, and responsible before the Commission.

To scientifico associations and universities; government; public opinion

Question 8: How often should its terms of reference be reviewed?

7 responses

Question 9: Are there existing regulators for other issues (e.g., data protection, health) that are good models? 7 responses

GDPR and Health related ones may be good examples

Data protection agencies are operating with a relatively good model, but might need a bit more extra resources.

Don't know.

Health/pharma regulatory models

No information to answer

Member states' data protection authorities are a good example, but such a regulator should be primarily constituted at EU level with subsidiaries in Member States (i.e. more decisionnal power than EDPB, for instance).

I don't know

Question 10: What best practices could/should be carried over to a bespoke regulator for AI?
5 responses

I would emphasize collaboration with the universities and civil society. Instead of having straightforward regulatory agency, the best practices should be created and maintained with the close collaboration with other organizations.

Don't know.

Supervison and regulation

N/A

Discussion on these issues in AI conference and meeting; in the AI courses for students. Meeting of AI people with social scientists, humanists, philosophers,...

Question 11: What would be some challenges and barriers to its success? 6 responses

To grow too bureautic. The agency should stay relatively small, compared to the size of each country. It should emphasize open collaboration and discussion with different parties, instead of being buried in the "regulatory machine".

How can the EU regulate technologies that are largely developed in the US and China?

difficulties in fully understanding and predicting the use of a technology risk assessment (understanding the side effects of technology) communication amongst stakeholders could be hampered by the different walks of life and vocabulary Potential lack of transparency from stakeholders or misunderstandings regarding the use and potential application

Asymmetric regulation, enforcement, other regions no regulation

Access to, and understanding of, relevant information from undertakings under investigation; granting such powers at EU level for Member States; having enough staff to deal with sufficient number of cases/year to be efficient.

To reduce the concentration of economic and political powers over society; to increase people awareness; to readdress research towards knowledge as priority, not technology.

Question 12: Are there any other policy or other considerations that need to be taken into account? 6 responses

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How can the EU promote the development of AI by EU member states? See, e.g. CLAIRE (https://claire-ai.org/).

potential influence on other (unforeseen) fields (for instance, an AI application for the healthcare sector might also impact or have a spill-over effect on other sector of society)

European industry and jobs

A clear legal framework on AI is needed (new laws or clear interpretation of existing ones in relation to AI) for such a regulator to be able to manage its tasks.

AI is an anthropological radical revolution of human mind, sociality, knowledge, powers.