


EOOSC-Pillar



Recommendations

for Legal and Policy
Harmonisation of
Open and FAIR
Science in the EU



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Disclaimer

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1. Introduction

The realisation of cross-border, multinational management of FAIR research data and the related participation of EU Member States in EOSC services require substantial efforts for legal reforms. As highlighted by a gap analysis, the European copyright and data protection legal frameworks present considerable flaws, which call for a prompt intervention by both EU and national policymakers. The issuance of a wide variety of calls for action and/or recommendations on the topic of Open Science, broadly intended, corroborates this need for policy guidance.

Most of the existing recommendations focus on a sector, if not a case-specific perspective relating to the stakeholders advancing them. Taking stock and building on old and new developments of the European policy landscape on Open Access, Open Science and FAIR research principles, the recommendations presented in the following pages boast the added value of embracing a holistic perspective on both copyright and data protection laws. Thus encompassing a multi-faceted account of the legislative and non-legislative reforms needed to pave the way towards effective, open, and inclusive research environments in Europe.

The recommendations presented here reflect a selection of the most relevant identified shortcomings of the current regulations, which have been operated based on three criteria:

1. The relevance of the legal obstacles at comparative level (e.g., profound regulatory fragmentation and divergences across the five EOSC-Pillar Member States);
2. The relevance of the legal obstacles to the guidelines issued for the benefit of individual stakeholders (e.g., specific needs to facilitate good practises);
3. The urgency of intervention upon provisions, whose modernization has been deemed to be long overdue.

2. Regulatory Gaps and Policy Recommendations

The basis for the formulation of these regulatory gaps and recommendations is provided by a study conducted to identify the legal constraints hindering the full development of Open Access and Open Science principles in EOSC-Pillar member states (included in “Legal and Policy Framework and Federation Blueprint”)². The gap analysis and the legal constraints focus, in particular, on copyright law and regulations and the protection of personal and non-personal data. This analysis has been useful to define interventions needed to tackle the gaps and constraints that are still making it difficult to realise a well-functioning FAIR ecosystem and fully unfold the potentials of Open Science and Open Access in the EU Research environment.

[2. EOSC-Pillar D4.6 Legal and Policy Framework and Federation Blueprint, in 10.5281/zenodo.5647948](https://doi.org/10.5281/zenodo.5647948)

Accordingly, the most significant gaps observed are:

1. The system of exceptions and limitations (E&L) makes it impossible for the copyright system to respond to the changing needs of the research ecosystem and the evolution of technologies.
2. Copyright contracts that are not standardised and are not compatible with the principle of OS and OA.
3. The process towards the open data strategy has not been completed yet.
4. There is a legislative fragmentation at the national level (Open data and PSI Directive and Non-Personal data flow Regulation).

Here follows a detailed description of areas that require interventions to fill up regulatory gaps, remove obstacles and achieve EU-wide harmonisation to the realisation of FAIR ecosystems and the implementation of Open Access and Open Science policies. The identified gaps are followed by possible measures policy makers can implement towards tackling the obstacles.

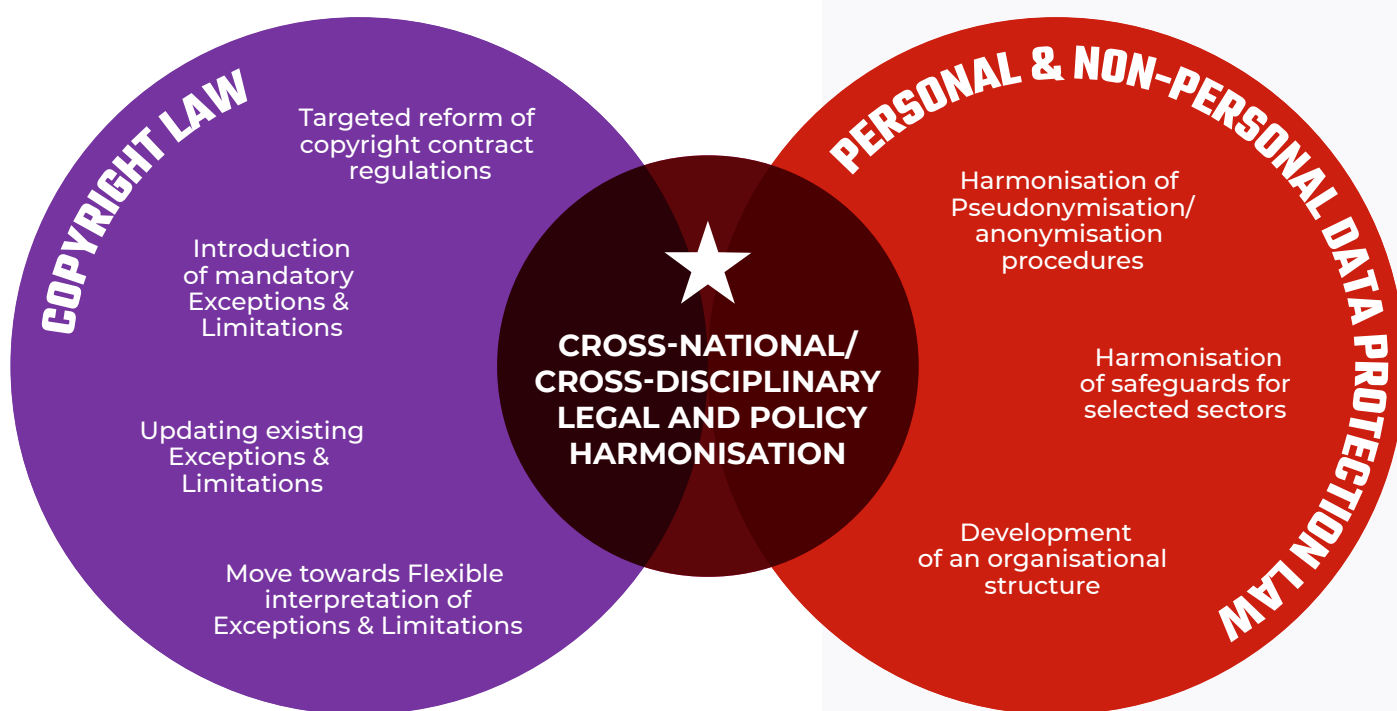


Figure. Summary of Recommendations for legal and policy harmonisation of Open Access, Open Science, and FAIR research environments in the

2.1 Copyright Law

2.1.1 Regulatory gaps

The main legal constraints for the implementation of FAIR principles and the realisation of OA and OS policies stemming from national and EU copyright laws are related to:

1. The scope and enforcement of exclusive rights,
2. The strict reading and lack of flexibilities of exceptions, and
3. The ample room left for freedom of contract. The latter often is exercised in a manner conducive to the imposition of additional constraints to free use and the enhancement of rights holders' control over protected works.

Alongside these barriers to FAIR data, the uncertainty surrounding specific areas, such as the breadth of the definition of protected works or the non-maximum harmonisation of important areas (For example, E&L, all factors impacting the scope of copyright law) have a constraining effect on the full development of FAIR data ecosystems and the correct implementation of Open Access and Open Science.

2.1.2 Recommendations

Exceptions and Limitations (E&L)

Strict interpretation of copyright E&L makes it difficult for copyright laws to meet the changing needs of the contemporary research ecosystem, particularly due to the fast evolution of relevant technologies. Overcoming the numerus clausus design of E&L is not realistic as a feasible policy option. However, the effects of a more flexible and open balancing clause can be achieved by way of sectoral reform of the existing provisions.

A possible policy path ahead may be to intervene with a threefold EU harmonisation directed to:

- (i) Introduction mandatory E&Ls,
- (ii) Updating existing E&Ls, and
- (iii) Move towards greater flexibility in the interpretation of E&L.

Only an EU legal regime of mandatory harmonisation of E&L would overcome the current fragmentation of the legal framework and guarantee a homogeneous implementation and evolution of the "room" for balanced flexibility needed to achieve cross-border Open Access and Open Science. The most recent developments following the adoption and implementation of the Copyright in the Digital Single Market (CDSM) directive (in particular Art 3, 4, 5), where mandatory E&L for text and data mining and digital teaching is introduced, show a promising future for EU copyright lawmaking.

A strongly harmonised system of E&L should also ensure that their scope is up to date with the current and foreseeable future technological and societal context of their application. This would imply efforts towards an efficient and timely legislative process, capable of promptly intervening with apt solutions to arising issues. Also, in this case, the CDSM directive proves a good example, yet overly limited in its scope.

Lastly, injecting flexibility into the E&L system is the key but potentially most problematic reform needed to tackle the gaps above. The consolidated closed list of exceptions and their strict interpretation represents an obstacle to the opening-up towards flexible legal tools and clauses. However, an adequate and strategic recourse to general principles of law, especially if expressly included in the legislation, would have the potential of further and effectively incentivizing uses covered by E&L. This unexplored design of EU copyright law would complement and add consistency to the support provided by the fundamental rights framework and by the autonomous interpretation of EU law concepts in the Court of Justice of the European Union (CJEU)³ case law, thus ensuring a sound case-by-case judicial decision-making process.

3. https://european-union.europa.eu/institutions-law-budget/institutions-and-bodies/institutions-and-bodies-profiles/court-justice-european-union-cjeu_en

Reform of Copyright Contract Law

Similar efforts to those promoted by the EU and national legislators to strike a balance between authors and publishers in publishing contracts should be promoted in the context of open research environments and FAIR research principles. The following targeted reforms would generate beneficial impact:

- (i) Scientific publications and research outcomes should be explicitly included in the scope of copyright contract regulations. In this way, individual researchers could be acknowledged as weaker contractual parties, and thus be subject to adequate protection and safeguards from contract law asymmetries and disequilibrium.
- (ii) A regime of ad hoc copyright contract law rules specifically addressing licence agreements in the scientific sector would majorly facilitate the emergence of good practises between authors, investors, and publishers, and lead to a more sympathetic perception and stronger incentives towards Open Access and Open Science.
- (iii) Evolution towards an “open repository right”, or “second publication right” of individual authors of publicly funded research, hints at viable options to establish and promote the effective functioning of open research infrastructures.

2.2 Personal and Non-personal Data Protection Law

2.2.1 Regulatory gaps

Three main barriers prevent concrete harmonisation of practices enabling Open Science research data:

1. Even though topics are regulated by EU initiatives, the national implementations are not enacted by equivalent legal sources; because national legislators introduce exceptions both by hard law and soft law instruments. Therefore, the same provision may encounter a different level of effectiveness in different legal systems.
2. National safeguards have also been developed following different and sometimes conflicting approaches, including those dealing with technical and organisational measures and/or those identifying some boundaries under the general research purposes regime and/or those bridging consistency mechanisms between data protection laws and other sectoral legislations.
3. Moreover, in this context of possible overlapping and conflicting laws, relevant norms do not rely on the technical standards required to achieve interoperability.

The integration with the legal framework applicable to non-personal data, copyright, and IP protections aimed at enhancing FAIR principles could be frustrating unless these issues are properly addressed from a standardisation perspective.

2.2.2 Recommendations

Policy recommendations hereby are advanced concerning four main legal aspects that may contribute to overcoming the above-mentioned barriers. In particular, they are deemed of particular relevance and urgency in light of the ongoing evolution of data-related legal issues and practises to mitigate the envisaged risks of overlapping and conflicts of laws.

Harmonisation of Private/Public Data Controllers

Research activities can be undertaken both by private and public bodies and an equivalent legal framework shall find application. Any different regime between private and public data controllers who process personal and non-personal data for research purposes shall be harmonised under a unique legal framework.

4. Cfr. Italian Ethics Code Italian, Legislative Decree 231 of June 8, 2001, Approved by Edizione's Board of Directors on December 11, 2017; Research Organisation Act (FOG), Federal Law Gazette No. 341/1981.

In the context of the EU, most of the differences between national laws are removed, because the GDPR applies to data processing in private as well as in public sectors. However, for example, art. 89 of GDPR refers to the derogation related to processing for archiving purposes in the public interest, scientific or historical research purposes, or statistical purposes and it may apply only to institutes or entities that are defined in national law as "research institutes". In this context, there are different approaches in some national laws.⁴

The harmonisation of the legal regimes for private and public research entities would facilitate cross-border and inter-sectoral FAIR ecosystems.

(i) Harmonisation of Pseudonymisation/Anonymisation Procedures: The GDPR compliance constitutes a logical priority to enable research data towards a FAIR ecosystem. Therefore, the standardisation of procedures and requirements to allow openness may facilitate the achievements of either GDPR or Open Data compliance. Combining technical safeguards with practical requirements and standards could facilitate the standardisation of some recurrent processes required for re-using data, like pseudonymization procedures.

For example, in the case of health data processed for research purposes, Belgian law establishes that pseudonymization could not be performed by the data controller, but by an independent body. That is subject to specific confidentiality obligations (i.e., professional secrecy). The "technical separation" between those who perform the two activities, and an explicit obligation of those who pseudonymise to avoid re-identification, might constitute a barrier in the case of cross-border partnerships.

To harmonise best practices of the fundamental conditions for processing personal datasets would also facilitate the interoperability and re-use of research data.

(ii) Harmonisation of Safeguards in specific research Sectors: Each Member State may decide to adopt general safeguards for personal data processed for research and statistics purposes. However, it could also decide to regulate several profiles, including the related data management of a specific sector (e.g Health, Genetics). Safeguards may at least be standardised under the parameter of data subjects' categories/vulnerabilities, whose fundamental rights shall be enhanced as a priority of Open Science policies.

Adopting similar measures for homogenous categories of data, considering the plurality of grounds of vulnerabilities stated under Articles 9 and 10 of GDPR, would facilitate the identification of common technical bases to make research data interoperable and re-usable beyond the specific means applied for data processing.

(iii) Development of an Organisational Structure: Organisational measures to process data for research purposes include a series of obligations to demonstrate compliance with the applicable legal framework. Roles and responsibilities are attributed to the top-level management of a body/entity even if – and this is particularly true for research activities – a more granular assignment could better represent the flow control.

To standardise roles and responsibilities within the research centre or funding body the principal investigator that develops research data could facilitate a responsible and legal attentive development of research data. This would confirm the responsibility of the principal investigator to take care of data management. For example, part of the data processing could be delegated parallel to the research life cycle to experts and advisors as a part of the research management, similar to other activities developed along with the project.

The data protection officer, the ethics advisor, IP and exploitation boards, etc. could facilitate the dialogue between different members of the research team/partnership/consortium to properly address Open Data and Open Science challenges. This need of shaping a standard organisation chart for research data management is particularly urgent in the case of AI-based technologies. R&D would have the obligation for the AI controllers/developers to perform an Impact Assessment, a policy envisaged by the most recent Resolutions of the EU Parliament.⁵

5. Cfr. European Parliament resolution of 20 January 2021 on artificial intelligence: questions of interpretation and application of international law in so far as the EU is affected in the areas of civil and military uses and of state authority outside the scope of criminal justice (2020/2013(INI)), available at this URL: https://www.europarl.europa.eu/doceo/document/TA-9-2021-0009_EN.html#def_1_10; The resolution of 12 February 2019 on a comprehensive European industrial policy on artificial intelligence and robotics, in OJ C 449, 23.12.2020, p. 37.


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