D4.6: Legal and Policy Framework and Federation Blueprint

second edition

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Deliverable Abstract

The document sketches a policy and legal framework by building upon the existing national policies, delivers recommendations, and considers the aspects that come with agreements on service delivery in a federated IT landscape. These can help to establish a governance structure for service providers and other organisations that handle scientific data. This is the second and revised edition of the original published in January 2021.

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TERMINOLOGY

https://eosc-portal.eu/glossary

Terminology/Acronym	Definition
AISA	Associazione italiana per la Scienza Aperta
ANVUR	Italian National Agency for the Evaluation of Universities and Research Institutes
API	Application Programming Interface
ARIADNEplus	International Data Infrastructure for Archaeology
BOAI	Budapest Open Access Initiative
CC BY	Creative Commons Attribution Licence
CERN	Centre Européen de Recherche Nucléaire
CINES	Centre Informatique National de l'Enseignement Supérieur
CDSM	Copyright in the Digital Single Market
CNRS	Centre National de la Recherche Scientifique

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CRUI	Conference of the Rectors of the Italian Universities and Italian Librarians
DKRZ	Deutsches Klimarechenzentrum
DPO	Data Protection Officer
E&L	Exceptions and Limitations
EDPS	European Data Protection Supervisor
EGI Federation	EGI Federation is an international e-Infrastructure providing computing and data analytics services for research and innovation
Elixir	European life sciences Infrastructure for biological Information
EU	European Union
FAIR	Findable, Accessible, Interoperable and Reusable
FitSM	An ITSM standard
GDPR	General Data Protection Regulation. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons about the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC
GPL	General Public License
ICDI	Italian Computing and Data Infrastructure
ICT	Information and Communications Technology
InfoSoc directive	Information Society Directive (Directive of the European Union enacted to implement the WIPO Copyright Treaty and to harmonize aspects of copyright law across Europe, such as copyright exceptions).
INFRAEOSC	A project call in the EU Horizon 2020 program
IOSSG	Italian Open Science Support Group
IPR	Intellectual Property Rights
IT	Information Technology
ITSM	Information Technology Service Management
KIT	Karlsruhe Institute of Technology
L&E	Exceptions and Limitations
OA	Open Access
OCRE	Open Clouds for Research Environments
OD	Open Data
OECD	Organization for Economic Cooperation and Development
OLA	Operational Level Agreement
OpenDOAR	Directory of Open Access Repositories
OS	Open Science
PPP	Public Private Partnership
PSI directive	Directive on open data and the reuse of **P**ublic **S**ector **I**nformation provides a common legal framework for a European market for government held data (public sector information)
PSI	Public Sector Information
RDA	Research Data Alliance
RDM	Research Data Management
RI	Research Infrastructure
ROARMAP	Registry of Open Access Repository Mandates and Policies
RoP	Rules of participation
SLA	Service Level Agreement
SLM	Service Level Management
SRIA	Strategic Research and Innovation agenda
TDM	Text and Data Mining
TTO	Technology Transfer Office

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Executive summary

Development of EOSC is influenced by the parallel development of data infrastructures at the national and regional levels. Requirements for open data, data protection and cross border data access rely on common understanding of existing regulations procedures in countries and their differences. The aim of EOSC-Pillar is to support the coordination and harmonization of national initiatives and help data/cloud providers through the development of common policies and tools. As part of this goal this deliverable presents the legal and organisational aspects of services delivery in a federated environment and recommends actions that enable service providers to position their services for improved interoperation in the context of the EOSC services landscape. The objectives of this deliverable are:

- a study of the legal and policy state of the art in the involved countries (Austria, Belgium, France, Germany, and Italy), highlighting commonalities to be leveraged and gaps or challenges to be tackled to help harmonise and improve the national policies and strategies related to FAIR data and Open Science,
- proposing recommendations for researchers on the rules and procedures with respect to legal issues regarding open access, open data, and cross border data access
- delivering a blueprint for EOSC which can be used by service providers as a guideline for legal aspects of service and data provisioning in a European and an international context

The document sketches a policy and legal framework by building upon the existing national policies, delivers recommendations, and considers the aspects that come with agreement on service delivery in a federated IT landscape. These can help individual researchers in their day-to-day work and equally help service providers and other organisations to establish a policy-based governance structure for the handling of scientific data.

Preface to the second edition

The second edition includes updates in line with the latest development of EOSC and the change of EOSC into an Association. It considers the comments from the project review in July 2021 with a focus on the improved accessibility of the presented guidelines on IPR and GDPR issues in the day-to-day practice of researchers (Blueprint/Guidelines in chapter 7). The structure and chapter naming were revised to clearly show the different aspects covered in this complex document.

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1 Introduction

This deliverable investigates the existence and relevance of selected policies that are required when service providers apply for participation in EOSC. The number of policies as well as the requirement of the existence of a certain policy depends on various factors, most prominently the ongoing preparation of the EOSC Rules of Participation and the Service Description Profile (SDP). The latter is a set of criteria that services must meet before being adopted in the EOSC services catalog. The SDP is currently being refined by the EOSC-Enhance project following collaboration with the EOSC-hub and the call 5b projects, including Task 7.1 of EOSC-Pillar.

Services that request to be part of the EOSC framework must comply with EOSC policies, ensure a high-level production quality, and adhere to agreed components of governance of services, of data and of persons. These components are prerequisite to offer services in EOSC and the following have been addressed in this document:

- **An interoperable policy framework for open data**: for ensuring openness and interoperability, privacy, and security (copyright status, disclosure limitations, patents pending, other IPR on the datasets or workflows, the existence of personal data, designation of data as PSI, etc.) [The Iron lady[1] document notes that although of high priority, the means to enable interoperable metadata by several key European service providers is not addressed]
- **Service management and access framework**: which role it is to provide a consistent and agreed upon understanding of open science services: what they offer, which problem they address, what is their operational capacity, how they are accessed, and who pays for them.

According to the Iron Lady document written under supervision of the former EOSC Executive Board, the demand for cross-border use of research services clearly does exist and is likely to grow, e.g., to address the OECD Sustainable Development Goals[2] from the UN 2030 sustainable development agenda. The EOSC-hub and OCRE project state that the main barriers to cross-border service provision are not technical but legal, financial, organisational, and regulatory.

The need for common policies to foster a healthy Open Science Environment policy is summarised in chapter 2 of the Strategic Research and Innovation Agenda (SRIA)[3] which reads: “Member States, associate countries and national funders will also develop policies that stimulate and support existing organisations in their countries to be as compliant as possible with EOSC and work towards sharing their research assets through EOSC. This will include policy changes that will allow services to be made available across national borders, as well as aligning and supporting requirements for researchers such as data management plans, metadata standards, and making data FAIR.”

The work presented in this deliverable zooms in at those areas in IPR and GDPR implementations that need changes to support FAIR data while at the same time touches on issues related to policies with respect to service delivery.

[1] The final version of the document “Solutions for a sustainable EOSC - Iron Lady” is published on the web site of EOSC secretariat. This footnote is based on the draft of 19 Oct 2020.

[2] http://www.oecd.org/dac/sustainable-development-goals.htm

[3] https://eosc.eu/sites/default/files/EOSC-SRIA-V1.0_15Feb2021.pdf

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1.1 Outline of the document

The rest of this document is outlined as follows. (The structure of the deliverable is depicted in Figure 1.) Chapter 2 gives an overview of the existing policy base in the countries represented in EOSC-Pillar including some historical background. Chapter 3 presents an analysis on the state of the legal interoperability of the EOSC-Pillar countries by mapping current regulations and conducting a gap analysis: this chapter was supported by the work of Scuola Superiore Sant'Anna. In chapter 4 the EOSC service level management structure is discussed, mainly based on agreements between providers and customers in relation to the cross-border access to services and data. Chapter 5 presents a Blueprint/Guidelines for researchers and research stakeholders and Policy recommendations for policymakers which is accompanied by an extensive checklist and phased analysis steps in chapter 7. A detailed comparison between implementations of IPR and GDPR can be found in chapter 6. Chapter 8 builds on the content of previous chapters, to draw some remarks and indicate viable ways to enhance the legislative and non-legislative environment for the flourishing of Open Access, Open Science, and FAIR research environments in the EU. Last, chapter 9 collects a few examples of data policies.

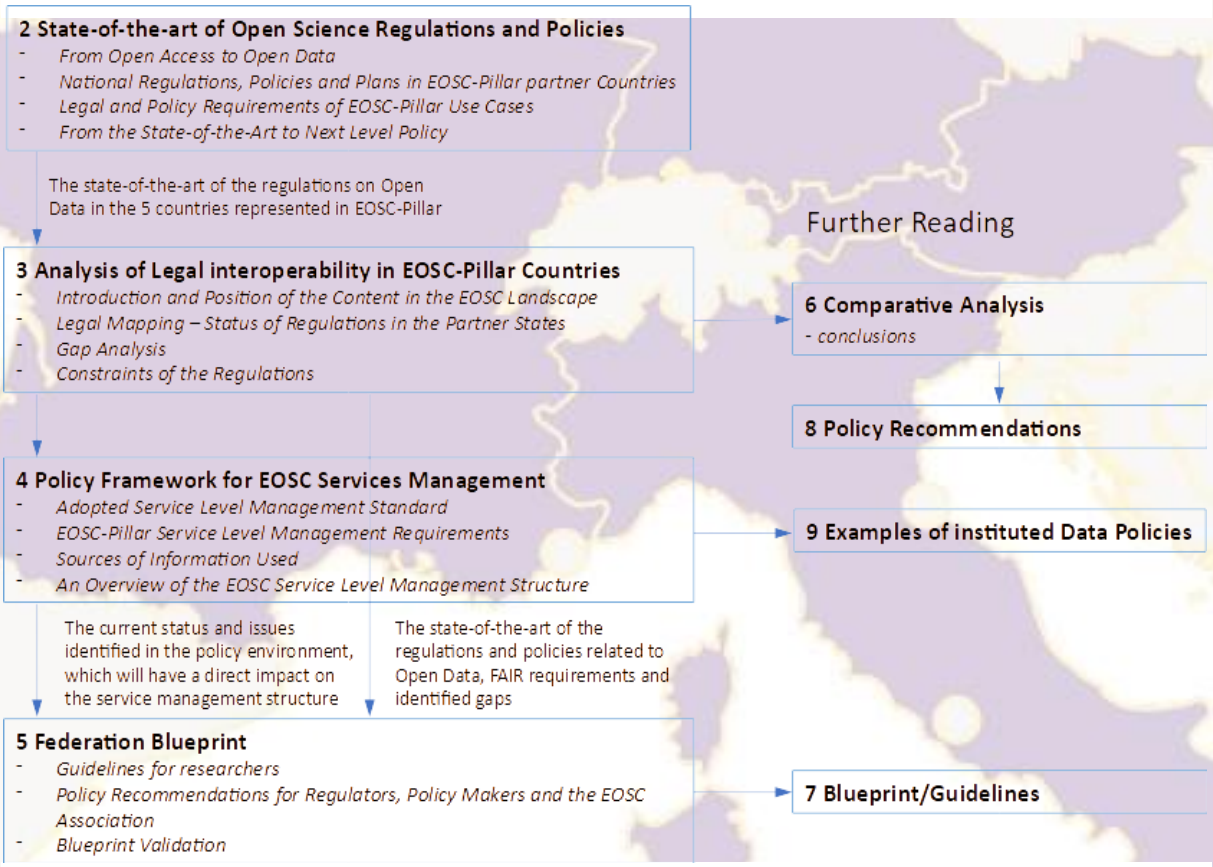

Figure 1 Document structure

1.2 Scope and Delivery

The ambition of the EOSC-Pillar project is very high and was inspired by the many activities including the shaping of new projects to drive development of the EOSC. At the time of inception of the project

an exhaustive list of tasks that could contribute to the future EOSC was assembled, irrespective of the activities to be deployed in sister projects from the EOSCINFRA calls. The work described in this deliverable zooms in on actual legal and policy requirements and gaps that are not of particular focus in other projects. These specialised topics surfaced during the first quarters of the project running time and have been analysed and evaluated as part of the work of T4.1. The document only covers the legal and policy environments of EOSC-Pillar participating countries Austria, Belgium, France, Germany, and Italy unless it is explicitly written otherwise.

1.3 Contracted Legal study

Significant contribution to the work in this deliverable was received from Prof. Dr. Catarina Sganga and her team at the Scuola Superiore Sant'Anna in Pisa. Scuola Superiore Sant'Anna was selected for its knowledge and experience on legal aspects of intellectual property rights (IPR) in a European research setting. The Funding was allocated by the EOSC-Pillar project and following a tender and procurement procedure carried out by KIT. The Scuola Superiore received a contract for the legal study for which a detailed work plan was drafted as part of this task. The authors of this deliverable and the project EOSC-Pillar acknowledge their participation and wish to thank Catarina Sganga, Denise Amram, Giulia Priora and Giovanni Comande of Scuola Superiore Sant'Anna for their excellent work done on the study, their contribution to the production of this delivery and their professional cooperation with members of task 4.1 of EOSC-Pillar.

2 State-of-the-Art of Open Science Regulations and Policies

The story of open access and its policies is foremost related to scientific publications of e.g., journals and the push to make these accessible, unrestricted, for a wide audience while at the same time reducing costs for access and publication. While less obvious in the beginning, the activities related to open access naturally led to requirements for open data and RDM because open access to publications involves long term archival of publications and their accompanying research products, as well as a push for a cultural change towards an open research lifecycle.

Important driver for the development of the Open Data concept were the European Commission's Open Research Data Pilot[4], which was carried out as part of Horizon 2020 from 2017 onwards, and the more recent EU Directive on Open Data and the reuse of Public Sector Information (PSI Directive)[5] in which specifically Article 10 calls upon all member states to adopt policies to make publicly funded research data openly available. Open Access, Open Data, FAIR Research Data Management and long-term access is now required for all funded Horizon Europe projects.

[4] https://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/open-access-data-management/data-management_en.htm

[5] Directive (EU) 2019/1024 of the European Parliament and of the Council of 20 June 2019 on open data and the re-use of public sector Information. https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1561563110433&uri=CELEX:32019L1024

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2.1 From Open Access to Open Data

The movement towards Open Science has started with activities that focus on Open Access to publications. First major event in that sense was the release in February 2002 of the Budapest Open Access Initiative (BOAI) declaration[6]. This declaration, which "call on all interested institutions and individuals to help open up access to [all scholarly journal literature] and remove the barriers, especially the price barriers, that stand in the way", proposed self-archiving and a new generation of open-access journals as strategies to achieve open access to peer-reviewed journal literature. Currently 6141 individuals and 976 organisations signed the declaration. The BOAI declaration was rapidly followed by the Berlin Declaration on Open Access[7] in 2003, which is the most prominent statement in use on the principles of Open Access to knowledge in Sciences and Humanities. Authors of this declaration clearly specify what is meant by open access contributions, namely original scientific research results, raw data and metadata, source materials, digital representations of pictorial and graphical materials and scholarly multimedia material, which is all much more than just journal literature. The declaration (translated in around 13 languages to date) is signed until now by 657 international research institutions/organizations including those from all countries participating in EOSC-Pillar. The first signatory on 22.10.2003 was Academia Europaea and the number of signatories is increasing every month.

Ten years after the release of their initial declaration, in 2012, the BOAI published a set of specific recommendations on i) policy development, ii) licensing and reuse, iii) infrastructure and sustainability, and iv) advocacy and coordination to achieve their goal of Open Access[8], which for sure also contributes to the current Open Access situation all over the world.

In the Amsterdam Call for Action on Open Science[9] published in 2016, a multi-actor approach to achieve both full open access for all scientific publications, as well as a fundamentally new approach towards optimal reuse of research data was proposed. This call set up a concrete plan with 12 action items to contribute to the transition towards Open Science until 2020. These action items were grouped in 5 cross cutting themes that follow the structure of the European Open Science Agenda as proposed by the EC. This was the basis for establishing the Open Science Policy Platform[10] in May 2016, a Group that advises the Commission on how to develop open science policy.

In 2016 the European Commission published the book 'Open Innovation, Open Science, Open to the World'[11] to present its vision on the three 'O's and ensure that research and innovation are essential elements across the European Commission's political priorities. The book clearly explains the transition from the concept of Open Access to Open Science and the impact that this new vision will have. Open Access to research results is an essential part of Open Science, which aims to make science more reliable, efficient, and responsive, and is therefore crucial for increased innovation opportunities, for instance by enabling more science-based start-ups to emerge. Although Open

[6] https://www.budapestopenaccessinitiative.org/
[7] Berlin declaration on Open Access to Knowledge in the Sciences and Humanities https://openaccess.mpg.de/Berlin-Declaration
[8] https://www.budapestopenaccessinitiative.org/boai-10-recommendations
[9] https://www.government.nl/topics/science/documents/reports/2016/04/04/amsterdam-call-for-action-on-open-science
[10] https://ec.europa.eu/research/openscience/index.cfm?pg=open-science-policy-platform
[11] https://op.europa.eu/en/publication-detail/-/publication/3213b335-1cbc-11e6-ba9a-01aa75ed71a1

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Access became primarily associated with a particular publishing or scientific dissemination practice, the broader Open Science practice includes the general re-use of all kinds of research products, not just publications or data, but open-source software, well described standards and research methods, available in a open virtual environment where researchers can share, re-use and co-create. The new concept of a transformed scientific practice shifted the focus of researchers' activity from 'publishing as fast as possible' to 'sharing knowledge as early as possible'.

In October 2017, several French researchers published the Jussieu Call for Open Science and Bibliodiversity [12] currently (more than 110 signatories – mostly French research organisations, associations, editors but also a few international signatories). This call is aimed at scientific communities, professional associations, and research institutions to promote a scientific publishing open-access model fostering "bibliodiversity" and innovation without involving the exclusive transfer of journal subscription budget to Article-processing charges (APC).

These declarations and calls were the start to further advance open science and open data policies. At present, Open Access policies are adopted by universities and research institutions/organisations level as well as by many research funding agencies (at European, national, regional levels). While some are restricted to Open Access to research publication,there are more and more specific policies related to/including rules for Open Access to research data (e.g. EC's H2020 mandate on open access to publications and extended Pilot on Open Access to Research Data). In the following section we briefly describe the situation regarding Open Data policies in the countries participating in the EOSC-Pillar project.

As was indicated in the FAIR Policy Landscape Analysis[13] and the State of Open Data 2019 report[14], the potential for open data is enormous, financially, in research and for society. Though the practice for making data open receives increasing incentives, e.g. the obligations related to Horizon Europe calls, the push needs the proper policy backing with adopted policies, as there is little room for research data in the open access model.

2.2 National Regulations, Policies and Plans in EOSC-Pillar countries

We have taken a snapshot of the situation regarding policies on Open Access to research products in the countries Austria, Belgium, France, Germany, and Italy, and indicated progressive developments or roadmaps when available.

[12] https://jussieucall.org/jussieu-call/
[13] https://doi.org/10.5281/zenodo.3558173
[14] The State of Open Data Report 2019. figshare. Report. https://doi.org/10.6084/m9.figshare.9980783.v2

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2.2.1 Austria

Austria has not implemented a national Open Access/Open Science policy yet but it is planned to establish such a national policy. General RDM policies were developed by several research performing institutions in the country, mainly universities.

Open access publications receive support from the highest level of the Austrian political landscape: The latest Austrian government programme[15] (January 2020) includes a commitment regarding Plan S. A cornerstone of Plan S is that publications relying on public funding have to be openly accessible.[16] In the government programme, the government states that also research performing organisations "should" implement Plan S. However, as a survey among universities and universities of applied science in 2019 shows, binding regulations on open access publications are not yet standard at Austrian research performing organisations: half of the twelve participating universities and universities of applied sciences indicated to have written regulations or policies on open access publications in place. Comparable regulations are much less common for other aspects related to open science (research data management, open research data, long-term availability of research data, compliance of data to the FAIR principles, publication of data in a (certified) repository).[17]

Development of RDM policies was supported by the e-Infrastructures Austria project [18]. Also, the Infrastructure Austria plus project had the goal to produce Research Data Management policies for each Austrian University. In August 2020 a policy was adopted by 5 universities out of 14 (a sixth one developed instead a "Regulation" on RDM).

Concerning open archives, Austria currently (as of July 2021) counts 46 national multidisciplinary and discipline-specific repositories, which are listed in OpenDOAR[19].

Even if no national policies are yet in place in Austria, the country counts several networks aiming for and working on the development of Open Science and its regulations.[20] Amongst those, the Open Science Network Austria (former called Open Access Network Austria OANA[21] and created in 2012) plays an important role especially through setting of recommendations by several thematic working groups as well as their strategic paper including recommendations for a national Open Science Policy - which is currently in planning. Another important national initiative is the Austrian Transition to Open Access (AT2OA) [22] project, aiming to contribute to the transformation from Closed to Open Access of scholarly publications.

[15] https://www.bundeskanzleramt.gv.at/bundeskanzleramt/die-bundesregierung/regierungsdokumente.html
[16] https://www.coalition-s.org/
[17] Bodlos, A., Hönegger, L., Kaczmirek, L., Beckmann, V., Breton, V., Romier, G., van Wezel, J., Streit, A., Stevanovic, U., Galeazzi, F., Tanlongo, F., van Nieuwerburgh, I. (2020a). "Summary report of the EOSC-Pillar 'National Initiatives' Survey". Version 1.1, Zenodo. doi: 10.5281/zenodo.3937318, p.A28-A31.
[18] https://e-infrastructures.univie.ac.at/das-projekt/
[19] Directory of Open Access Repositories http://www.opendoar.org/find.php
[20] https://www.bmbwf.gv.at/Themen/Hochschule-und-Universit%C3%A4t/Hochschulgovernance/Leitthemen/Digitalisierung/Open-Science.html
[21] https://oana.at/en/
[22] https://www.researchgate.net/project/Austrian-Transition-to-Open-Access-AT2OA

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2.2.2 Belgium

Many Belgian research organisations subscribed in 2007 to the Berlin Declaration on Open Access. This ambition was affirmed by the *Brussels Declaration on Open Access*, signed in 2012 by the Belgian, Flemish and French Community ministers of research at a conference organised by OpenAIRE. The declaration makes Open Access the default in circulating the results of Belgian academic and scientific research. It mentions the effort to support, set-up and maintenance of repositories and 'other innovative digital infrastructures to facilitate scientific communication'. It recognises that Open Access to scientific publications will be followed by Open Access to Data soon. Consequently, most Belgian universities have an Open Access mandate in place.

On a federal level, the "Code of Ethics for scientific research in Belgium"[23] has been in effect since 2009. With a focus on the verifiability of research, it states that "The primary data of a research project and the protocols must be kept and made accessible during a determined and sufficient period. When publications, especially review and summary articles, do not contain all the necessary data for verification, the data should nevertheless be available".

IPR in Belgium is regulated through the Wetboek van economisch recht / Code de droit économique (Code of Economic Law[24]) - book XI, which is a federal competence. The articles XI.189 to XI.192 of the Code contain the major statutory exceptions to copyright protection, including exceptions for use of copyright protected works for research and educational purposes.

An Open Access provision has been adopted in the Belgian law as of September 2018[25]. This law gives authors the right to make the final peer reviewed manuscript of peer reviewed scholarly articles available in Open Access if the publication is a result of research funded by public funds for at least 50%, with a maximum embargo period of 6 months for science technology and medicine and 12 months for social sciences and humanities.

In line with the European legislation, the EU PSI Directive[26] on open data and the re-use of public sector information is currently being implemented into federal and regional law according to the federated jurisdiction. The EU DSM directive[27] on copyright and related rights in the Digital Single Market is being implemented into federal law as well.

The three main governmental funders of Belgium (BELSPO - federal, FRS-FNRS -French Community, and FWO - Flanders) have adopted Open Access policies in line with the Belgium Open Access provision. Belgium follows the line to provide Open Access through mainly Open Access repositories with Open Access publishing as an option for immediate Open Access. Belspo and FWO also encourage good research data management practices and have a DMP requirement included in their mandates[28].

[23] https://www.belspo.be/belspo/organisation/publ/pub_ostc/Eth_code/ethcode_en.pdf

[24] http://www.ejustice.just.fgov.be/cgi_loi/loi_a1.pl?language=nl&la=N&cn=2013022819&table_name=wet&&caller=list&N&fromtab=wet&tri=dd+AS+RANK&rech=1&numero=1&sql=(text+contains+(%27%27))#LNK0335

[25] https://www.dekamer.be/FLWB/PDF/54/3143/54K3143006.pdf

[26] DIRECTIVE (EU) 2019/1024 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 20 June 2019 on open data and the re-use of public sector information

[27] DIRECTIVE (EU) 2019/790 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 17 April 2019 on copyright and related rights in the Digital Single Market and amending Directives 96/9/EC and 2001/29/EC

[28] An overview can be found here: https://openaccess.be/open-access-in-belgium/open-data/

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Because of the federated state, the federated entities developed additional and separate initiatives. The 'Open Access Decree' of the Wallonia-Brussels Federation[29] consolidates the deposit policy of the Universities, stipulating that all scientific articles subsidized by public funds must be deposited in an institutional repository. At least 3 universities of Belgium signed the (French) Jussieu Call[30] for Open Access publication made by several French researchers (more than 110 signatories in total until now).

The Flemish universities started working groups on Open Science and research data management in 2015 within the Flemish Interuniversity Council (VLIR) with the goal to discuss both Open Science practices and policy advice. A result of the activities was the white paper 'Research Data Management and the Flemish universities'[31] with recommendations to invest in infrastructure, training, copyright and incentivising the research process. Around the same time, the Flemish Council for Science and Innovation (VRWI)[32] urges the Flemish Government and relevant R&D stakeholders to make Open Science a top priority. The Flemish government included Open Science in its coalition agreement 2019-2024 and started the Flemish Open Science Board (FOSB) in 2020. FOSB unites Flemish stakeholders in a shared vision for the future with regard to Open Science and EOSC. The initiative is supported by the Flemish government with a budget, a guiding roadmap and KPI's to be achieved[33].

There are currently (September 2021) 15 Open Access institutional mandates in Belgium research institutes[34]. They follow an Immediate Deposit/Optional Open Access (ID/OA) Mandate[35]. Besides Open Access policies for publications, universities and research institutions have developed their own guidelines or policies on Open Access to data and research data management.

The DMPbelgium Consortium provides DMPOnline.be[36] to help write data management plans. KU Leuven has its own platform[37]. Furthermore, a dedicated website contains extensive information on Open Science in Belgium and information on activities related to Open Science and EOSC[38].

https://www.dekamer.be/FLWB/PDF/54/3143/54K3143006.pdf
[29] http://archive.pfwb.be/10000000208d0d1
[30] https://jussieucall.org/jussieu-call/
[31] https://vlir.be/publicaties/rdm-white-paper/
[32] https://www.vario.be/nl/publicaties/open-science-voor-een-betere-wetenschap-met-grotere-impact
[33] https://www.ewi-vlaanderen.be/nieuws/open-science-vlaanderen-uitgewerkte-roadmap
[34] http://roarmap.eprints.org/view/country/056.html
[35] More information can be found here: https://openaccess.be/open-access-in-belgium/brussels-declaration-on-open-access/
[36] https://dmponline.be/
[37] https://dmponline.kuleuven.be/
[38] https://openaccess.be

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2.2.3 France

In November 2000, prior to the various statements related to the Open Access movement, the French National Centre for Scientific Research (CNRS) created the Centre for Direct Scientific Communication (CCSD)[39] which can be considered as a major actor of the French national Open Access policy. In 2001, the Centre developed the Hyper Articles en Ligne (HAL)[40] platform, a national and centralised multi-disciplinary open archive chosen by the whole French scientific and university community for the dissemination of knowledge. In 2005, it launched the HAL-SHS[41], the specific open archive dedicated to humanities and social sciences. Five years later, in 2010, a novel open archive platform dedicated for deposition of visual and audio data produced as part of scientific research was created: MédiHAL[42]. Currently, there are 149 open archives running in the French academic environment (listed in OpenDOAR[43]), mostly institutional ones but also some disciplinary and governmental ones.

Concerning national policies, an important event concerns the publication in May 2016, of a French decree making the submission of the electronic thesis mandatory for all institutions as of September 2016[44]. This can be done by depositing the document in HAL or other national/institutional open archives.

Another key element is the entry into force in October 2016 of the French Law for a Digital Republic Act (LOI n° 2016-1321 du 7 octobre 2016 pour une République numérique[45]). This law introduces new provisions to regulate the digital economy, online cooperative economy, data protection and access to the internet. Two articles are of specific concern for scholarly communication, as they relate directly to open access/open data and text & data-mining (TDM). Article 30 is about Open Access and creates a new right for authors to archive an OA copy of their publication (related to publicly funded research outcomes) even if they have granted an exclusive right to a publisher. Article 30 also ensures the re-usability of open data deriving from public funding.

Article 38, meanwhile, creates a new exception for TDM and modifies the intellectual property law. Regarding TDM, it is expected that further decrees should soon be published to make explicit what this law allows. This new exception anticipates and supports the likely modification of the European Directive on Copyright in the Digital Single Market on this topic.[46]

On 4th July 2018 a national Open Science Plan[47] was officially published by the French Ministry of Higher Education, Research and Innovation. This plan is centred around three key commitments: Generalise Open Access to publications; Structure research data and make it available through Open Access; Be part of a sustainable European and international Open Science dynamic. This plan foresees specially to make open access mandatory for the dissemination of both research articles & books and

[39] https://www.ccsd.cnrs.fr/en/
[40] https://hal.archives-ouvertes.fr/
[41] https://halshs.archives-ouvertes.fr/
[42] https://medihal.archives-ouvertes.fr/
[43] Directory of Open Access Repositories http://www.opendoar.org/find.php
[44] https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000032587086
[45] https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000033202746&categorieLien=id
[46] OpenAIRE https://www.openaire.eu/blogs/new-french-digital-republic-law-boosts-support-for-oa-and-tdm-1
[47] https://cache.media.enseignementsup-recherche.gouv.fr/file/Recherche/50/1/SO_A4_2018_EN_01_leger_982501.pdf

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research data resulting from publicly funded projects, create the conditions for and promote the adoption of an Open Data policy for articles published by researchers, create an Open Science fund, support the national open repository HAL and simplify the publication filing procedures for researchers who publish through open access platforms around the world. With this plan, the French government explicitly mandates French research institutions and universities to develop their own OA policies. According to ROARMAP[48] around 21 French research institutions and 3 national Funders have until now open access mandates requiring authors to self-archive their papers.

On 6th July 2021 a second national Plan for Open Science[49] "Generalising open science in France 2021-2024" was officially published by the French Ministry of Higher Education, Research and Innovation. This plan is centred around four key themes: Generalizing open access to publications; Structuring, sharing and opening up research data; Opening up and promoting source code produced by research; Transforming practices to make open science the default principle. This plan takes effect until 2024. It extends the scope of the first plan to include source code from research, it structures actions promoting data sharing and openness through the creation of the Gov Data Research platform, it fosters the generalisation of practice of open science. It includes a European-wide vision, particularly to promote EOSC. This involves initiating a process of sustainable transformation in order to ensure that open science becomes a common and shared practice, encouraged by the whole international ecosystem of higher education, research and innovation.

IPR, with respect to copyright, are defined by the French Code de la Propriété Intellectuelle (CPI). It provides for a presumption of authorship which defines as author any person indicated as such, unless proven otherwise. It also defines the notion of co-authorship and the different types of co-owned work that result from it (collaborative work, composite work, and collective work), along with the notion of protected work (any intellectual work of any kind, form of expression, quality or purpose).

A number of national exceptions to copyright protection are introduced by the CPI, such as the impossibility for the author to prohibit, as long as the source and the author are cited, the reproduction, analysis or extract of his/her work for the purpose of illustration for teaching and scientific research and non-commercial use. The same type of exception applies for the electronic reproduction of scientific works, the dissemination of public speeches, the citation for purposes of criticism, review, education, science and information, the making of private copies for non-collective use, etc. Software and databases are subject to separate exceptions. All relevant exceptions and further information on French copyright regulations are detailed in Appendix 7.2.5.3.

With regard to open data repositories and research results, the French Code de la Recherche (Article L533-4) provides that data resulting from a research activity financed at least for 50% with public funding coming from the State, public institutions or the EU, may be freely reused once they have been made public, unless they are protected by specific rights.

In the context of research publications, this same article indicates that the author of a scientific work resulting from such a research activity and published in a journal publishing at least once a year,

[48] ROARMAP: Registry of Open Access Repository Mandates and Policies http://roarmap.eprints.org/view/country/250.html

[49] https://cache.media.enseignementsup-recherche.gouv.fr/file/science_ouverte/20/9/MEN_brochure_PNSO_web_1415209.pdf

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retains the right to a second publication in an electronic, open and freely accessible way, even when an exclusive license has been granted to the publisher, with a possible embargo period ranging from 6 months to 12 months.

The French legislative initiative, Act No. 78-17 of 6 January 1978 on Information Technology, Data files and Civil liberties, introduces national safeguards on data protection for research purposes. In particular, it specifies safeguards for sensitive data, genetic data or health data processing, that can relate to consent, professional secrecy, or control procedures through ethics or audit committees.

The same law also lays limitations on access, rectification or processing of data for archiving measures in the public interest for scientific research.

More detailed information on data protection regulation in France can be found in Appendix 7.3.5.4.

2.2.4 Germany

In Germany, there is currently no national policy or regulation on Open Access in place. However, efforts are being made in this direction. According to the latest work from the EOSC Landscape Working Group, Germany plans the creation of a publication policy, including a mandate for open access, as well as a policy regarding data/services, which includes an open access mandate and also a policy for open learning [50].

However, the German law already contains rights for authors of scientific contributions which result from research activities at least 50% of which were financed by public funds to publish in open repositories after one year embargo time even if they have granted an exclusive right to a publisher[51].

Back in January 2006, the Joint Committee of the German Research Council (DFG - the main national research funder) adopted a set of guidelines for the publication of results from DFG-funded projects on an open-access basis. These guidelines stipulate that, if possible, recipients of DFG research grants should make their results available online in digital format and free of charge, either instead of or in addition to traditional publication. The guidelines recommend publication in suitable open-access journals or the retroactive provision of previously published papers in open-access repositories [52].

In 2015, the DFG went a step further in its guidelines on the handling of research data („Leitlinien zum Umgang mit Forschungsdaten“) by highly recommending researchers of DFG-funded projects to make their research data freely accessible. The DFG policy focuses on research data, although it also addresses the software and methods necessary for validation and/or replication.[53]

At the beginning of 2021, the DFG launched its newly accentuated Infrastructures for Scientific Publishing program, whose main objectives include promoting the Open Access transformation by establishing and expanding suitable publication infrastructures and (further) developing structural frameworks.

In September 2016, the German Federal Ministry of Education and Research (BMBF) released its Open Access Strategy entitled "Open Access in Germany" which contains a clear commitment to the principles of open access and open science. The strategy includes 5 major action fields which should be worked on both at regional (“Länder”) and national level. Particular emphasis lies on developing guidelines concerning Open Access to outputs from publicly funded research projects, as well as on engagement of universities and research institutes to develop their own Open access policies. The BMBF is currently funding 20 innovative projects in Open Access.

Besides these two main national funders, several German research organisations, universities, and initiatives have developed their own Guidelines/policies on Open Access to publications and/or Data: as of 2020, 72 German universities and other higher education institutions had a published OA policy according to ROARMAP[54]. Also, all of the four large German research associations (Max Planck Society,

[50] Landscape of EOSC-related infrastructures and initiatives (EOSC Landscaping WG report) https://op.europa.eu/en/publication-detail/-/publication/cbb40bf3-f6fb-11ea-991b-01aa75ed71a1/language-en/format-PDF/source-156485650

[51] https://www.gesetze-im-internet.de/englisch_urhg/index.html

[52] https://www.dfg.de/formulare/2_00/index.jsp

[53] https://sparceurope.org/new-sparc-europe-report-analyses-open-data-open-science-policies-europe

[54] ROARMAP: Registry of Open Access Repository Mandates and Policies http://roarmap.eprints.org/view/country/040.html

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Fraunhofer-Gesellschaft, Helmholtz Association and Leibniz Association) have open access policies and actively support open data projects and initiatives.

These policies are based on the national guidelines. As an example, the Helmholtz Association (a union of 18 German scientific research Centres) adopted a position paper on the management of research data. This includes a commitment to "store research data from the Centres within suitable data Infrastructures and make them available openly and free of charge for subsequent use by Science and society."[55] The German rectors' conference (Hochschulrektorenkonferenz HRK) also developed at least 2 recommendations on Research Data Management.[56]

At regional level, many states have funded Research Data Management projects that resulted in recommendations and policies[57].

[55] https://www.helmholtz.de/fileadmin/user_upload/01_forschung/Open_Access/EN_AKOS_TG-Forschungsdatenleitlinie_Positionspapier.pdf

[56] https://www.hrk.de/uploads/tx_szconvention/HRK_Empfehlung_Forschungsdaten_13052014_01.pdf ; https://www.hrk.de/uploads/tx_szconvention/Empfehlung_Forschungsdatenmanagement__final_Stand_11.11.2015.pdf

[57] https://www.forschungsdaten.info/fdm-im-deutschsprachigen-raum/

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2.2.5 Italy

In 2004, in support of the Berlin Declaration[58], 31 Italian Universities signed the Messina Declaration[59]: the Italian road to Open Access. The Declaration was relaunched again on the occasion of the tenth anniversary with an event organized with the support of the Italian Librarian Association (AIB) and the Conference of the Rectors of the Italian Universities and (CRUI) attended by over 80 delegates from over 30 universities[60].

In 2006 the Conference of Italian Universities Rectors[61] established a Working Group on OA as part of the CRUI Library Committee. Since its founding it has released Guidelines and Recommendations for supporting Open data and Open access successively adopted by several universities, such as Guidelines on depositing Doctoral Dissertations in open access repositories, Recommendations on OA and Research Evaluation in 2009, Guidelines for OA Journals in 2009; and Guidelines for Institutional Repositories in 2009, Guidelines on the creation and management of OA metadata in 2012; Guidelines on drafting institutional policies and mandates for publications and data sets in 2013[62]. Over 91 Italian universities and research centres adopted regulations and policies on OA, registered in ROARMAP[63]

Furthermore, Italy as a member of the G8, together with France, Germany and the UK, participated in the G8 science ministers' summit, held in London on 12 June 2013. The meeting produced two important documents: the Open Data Charter[64], to reinforce the 'Open by default' concept and a statement that"proposes to the G8 for consideration new areas for collaboration and agreement on global challenges, global research infrastructure, open scientific research data, and increasing access to the peer reviewed, published results of scientific research"[65].

In Italy, Open Access (OA) to scientific articles has been adopted in the law no. 112/2013 art. 4[66] that states that publicly funded research shall be openly available to the public. At the same time, the Conference of Italian University Rectors (CRUI) has signed a position statement to encourage the creation of repositories.

A revision of the law is currently under discussion in the Senate for establishing shorter embargo periods and for allowing the right to re-publishing after 12 months.

In accordance with this law, the Italian National Agency for the Evaluation of Universities and Research Institutes (ANVUR) produced the Guidelines for the Evaluation of Research Quality for the period 2015-2019[67] to promote open access publication in the case of journal articles relating to research outputs financed for a share equal to or greater than 50% with public funds.

[58] Berlin declaration on Open Access to Knowledge in the Sciences and Humanities https://openaccess.mpg.de/Berlin-Declaration
[59] https://cab.unime.it/decennale/wp-content/uploads/2014/03/Dich_MessinaENG.pdf
[60] https://decennale.unime.it/?page_id=244
[61] CRUI, https://www.crui.it/crui-english.html
[62] See all the guidelines at https://www.crui.it/open-access.html
[63] ROARMAP: Registry of Open Access Repository Mandates and Policies - http://roarmap.eprints.org/
[64] https://opendatacharter.net/
[65] https://www.gov.uk/government/publications/g8-science-ministers-statement-london-12-june-2013
[66] http://www.normattiva.it/uri-res/N2Ls?urn:nir:stato:legge:2013;112
[67] https://www.anvur.it/wp-content/uploads/2020/02/VQR-Call_EN.pdf

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Currently the Italian Ministry of Education, Universities and Research (MIUR) has appointed a commission of national experts from different domains, to support the definition of national Open Science priorities; involved stakeholders include ICDI[68], ANVUR[69], CRUI[70], AISA[71] and IOSSG[72]. The commission is drafting a National Plan for Open Science (to be soon released, probably as a part of the National Plan for Research) according to EC recommendation 790/2018. The Plan will offer a common framework for Open Science main axes: texts, data, research evaluation and community engagement.

[68] https://www.icdi.it
[69] https://www.anvur.it
[70] https://www.crui.it
[71] https://www.aisa.sp.unipi.it
[72] https://sites.google.com/view/iossg

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2.3 From the State-of-the-Art to Next Level Policy

Concerning the legal framework for open data and the state of the art of open access in each member State, there are differences between national legislations. This situation is bound to create a significant gap in the free circulation of results of research activities and in the implementation of open science and open data.

In this context, the most important effort is defined by the EU legislation. In particular in the EU legal framework there is the Directive (EU) 2019/1024 on open data and the reuse of public sector information, which provides a common legal framework for an European market for government-held data (public sector information)[73].

In article 2, it defines a series of concepts. The following ones are particularly relevant to the scopes of Open Data:

- **document** as any content (or part of it) whatever its medium (paper or electronic form or as a sound, visual or audio-visual recording);
- **research data** as "documents in a digital form, other than scientific publications, which are collected or produced in the course of scientific research activities and are used as evidence in the research process, or are commonly accepted in the research community as necessary to validate research findings and results";
- **high-value datasets** as "documents the re-use of which is associated with important benefits for society, the environment and the economy, in particular because of their suitability for the creation of value-added services, applications and new, high-quality and decent jobs, and of the number of potential beneficiaries of the value-added services and applications based on those datasets". Key areas are represented by Geospatial, Earth Observation and Environment, Meteorological; Statistics; Companies and Company Ownership; Mobility.
- **re-use** as "the use by persons or legal entities of documents held by: (a) public sector bodies, for commercial or non-commercial purposes other than the initial purpose within the public task for which the documents were produced, except for the exchange of documents between public sector bodies purely in pursuit of their public tasks; or (b) public undertakings, for commercial or non- commercial purposes other than for the initial purpose of providing services in the general interest for which the documents were produced, except for the exchange of documents between public undertakings and public sector bodies purely in pursuit of the public tasks of public sector bodies".

These are key concepts to address the European Data Strategy towards Openness. In fact, article 4 describes the procedure that public sector bodies must follow to process requests of re-use in order to make documents available, managing the licenses, and possible time provisions. In case of refusal, the rightsholder/licensor shall be quoted. The decision shall be challenged. Re-use conditions are stated by article 5, it provides organizational as well as technical measures to ensure the interoperability requirement. The same provision is inspired by the openness by design and by default

[73] Cfr. Directive (EU) 2019/1024 of the European Parliament and of the Council of 20 June 2019 on open data and the re-use of public sector information PE/28/2019/REV/1, in *OJ L 172, 26.6.2019, p. 56–83* available at this URL: https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1561563110433&uri=CELEX:32019L1024

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formulas, identifying for the dynamic documents the means of “suitable APIs” and “bulk downloads”. Specific conditions for high value datasets are described under article 14 of the Directive (EU) 2019/1024.

Article 6 lists the principles that govern the re-use of documents. In this regard, the free of charge principle - a part of recovery of “marginal costs of reproduction, provision, and dissemination” - is the one that mostly encourages Open Data, making the re-use accessible despite any possible economic and social barriers. Possible exceptions are envisaged under the conditions that standard charges are pre-established in a transparent manner and, in any case, they do not include research data. Non-discrimination principle within any re-use activity and fair trading one, avoiding exclusive rights arrangements, are addressed in articles 11 and 12. In light of the fact that the new PSI Directive will replace the previous one and Member States are expected to implement it within a few months, this report has purposefully not covered national laws transposing the previous act. Member States are asked to implement possible standard licenses under article 8, practical arrangements to facilitate the engagement of FAIR ecosystems also for research data.

In the next section, we analyse the crucial aspects concerning the legal mapping, including the gap analysis in the first part. Based on the study of the legal framework we’ve elaborated the most important results of our research: the Blueprint/Guidelines for researchers and the Policy recommendations for the EOSC association. These documents are very important to facilitate the engagement of FAIR ecosystems for research data and to facilitate the diffusion of Open Access and Open Society.

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3 Analysis of Legal Interoperability in EOSC-Pillar Countries

Legal interoperability is about ensuring that organisations operating under different legal frameworks, policies and strategies are able to work together. This might require that legislation does not block the establishment of EOSC services within and between Member States and that there are clear agreements about how to deal with differences in legislation across borders, including the option of putting in place new legislation.

In this section we concentrate on the legal framework with impact of European and National regulations on data policies related to research with respect to IPR. One of the main obstacles to the free movement of transnational services is represented by the different legal approaches which, at national level, regulate intellectual property. As emerged in the context of the gap analysis, the differences in the protection of intellectual property represent a limit to the actual development of online services. For this reason, we have focused on defining the legal framework for IPR at the transnational and European level.

Because of the specialised nature of the topic, we cooperated with Scuola Superiore Sant'Anna in Pisa, In the following subsections the study is put into the perspective of the current EOSC landscape, and a summary is presented with the main conclusions. Finally, the importance of the findings for the development of EOSC is valued with a proposal for a blueprint.

3.1 Introduction and Position of the Content in the EOSC Landscape

The study conducted in the context of this deliverable on the legal framework is focused on the creation and promotion of a European cross-border open and inclusive environment for Open Science (OS), Open Access (OA) and FAIR research for research data management, and it has been notably a multifaceted endeavour.

The study has proved effective in converging a broad spectrum of relevant legal aspects and delivering a cohesive set of research outcomes. The study has covered a broad range of legislative and non-legislative aspects relating to both the EU and the national regulatory landscapes of the five EOSC-Pillar Countries (Austria, Belgium, France, Germany, Italy).

The main outcomes stemming from the study are the following:

- a legal mapping of the relevant provision, substantially thorough and methodologically sound qualitative and comparative legal analysis
- drafting of blueprint for stakeholders and for individual researchers of EOSC-Pillar Project
- recommendations for policymakers focusing on viable paths for effective reforms and a consistent implementation plan

All findings have been designed following a threefold focus on copyright, personal data protection, and non-personal data protection. The assumption that these three legal sectors and to a certain extent licensing, represent the regulatory pillars of OS and OA infrastructures, practices and envisioned future has, indeed, proved true by the significance of the data collected across the in-depth study.

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The legal analysis has been crucial to align the research activities with the specific needs of the project. The research has been twofold: the definition of a complete regulatory perspective on the topic of OA/OS; an informative tool for researchers, technologists, and the scientific community. The outcome of the study is composed of Legal mapping (see section 3.2 + Appendix A), Blueprint/Guidelines (Appendix B), and Policy recommendations for policy makers (Appendix C).

3.2 Legal Mapping - Status of Regulations in Partner States

The legal mapping has been divided into three parts.

In the first part the study focus is on Intellectual property law, starting from the territorial connotations of the regulatory framework to explain the international and EU Law regulatory framework. The analysis has been carried out also in the light of the EU and national laws. The study has investigated different aspects concerning IPR, and in particular: the Authorship, the subject matter, the term of protection, the exclusive rights, exceptions and limitations, and copyright contracts in the context of nationals and EU regulations prospective.

An analysis of the solutions implemented by the five Member States studied show a general convergence on the definitions of key concepts, rights, and exceptions. When EU Directives qualified an exception as mandatory, national legislators embedded them in their copyright laws using almost the same language used in the EU text. When exceptions were defined as optional and remitted in their implementation to the discretion of Member States, divergences among national solutions are much more frequent, as in the case of library and teaching & research exceptions. In some sectors relevant for EOSC, such as TDM activities, Member States such as Germany or France have provided interim exceptions, while a common regulatory solution adopted by the five national systems hereby analysed is a provision attributing a right to authors or an obligation for public funding institutions to ensure the open access publication of research outputs publicly funded for at least 50%, finalized (also) to build open repositories. The study concludes that the most recent copyright reform (CDSM Directive 2019/790/EU[74]) has introduced three new mandatory exceptions relevant to EOSC, Open Science and Open Access – digital preservation of library collection, TDM activities, and digital teaching. Implementation at national level is not expected before the third quarter of 2021.

Finally, on this topic the study shows that despite these positive developments, several areas relevant to EOSC, OA and OS purposes remain uncovered. The patchwork of national exceptions has a negative effect on the degree of legal certainty and self-confidence of researchers, research managers and institutional users when building, running, and populating research infrastructures, and when using and re-using materials produced by others.

The second part of the study has focused on personal data protection law. In this context different aspects have been investigated, the notions, principles, and obligation of EU Regulation 2016/679 in order to investigate the legal basis and safeguards to enable data processing for research purposes

[74] Cfr. Directive (EU) 2019/790 of the European Parliament and of the Council of 17 April 2019 on copyright and related rights in the Digital Single Market and amending Directives 96/9/EC and 2001/29/EC, in OJ L 130, 17.5.2019, p. 92–125, available at this URL: https://eur-lex.europa.eu/eli/dir/2019/790/oj

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and the secondary use and re-use of personal data flows for research purposes. Then the study has analyzed the national safeguards for research purposes.

The structure of the GDPR and national implementation under art. 89 represents the need to identify the basis to reduce the attention on the individual data subject and focusing on the vulnerabilities of the group of data subjects. In this regard, the study shows that national implementation confirms the structure of GDPR, by identifying limits to data subject rights, under the condition that otherwise the research could be compromised, and research data are at least pseudonymized. This approach is functional ensuring that raw data are collected and processed within a fair, transparent, lawful system. Once personal data processing has achieved its purposes, further processing shall use the least "personal" data as possible enabling personal data to become research data and being communicated, disseminated, and re-used for other research purposes without any risk of harm for the individual data subject. Indeed, the re-use framework is facilitated by the prior compliance procedures that allows an easily transposition of contexts (i.e. from the principle of minimization to open data policies) only if all the ethical and safety measures to segregate research data from that information that may identify data subjects along the entire data processing is met. Thus, it is possible to move towards the use of the processed data for further scientific research, also through data intermediaries, including international data sharing.

The third part of the study concerns non-personal data regulation, and it has the objective to investigate the scenario related to the combination of non-personal data (that are not covered by GDPR) that may infer or generate personal data. Considering that this scenario is particularly common within research activities, the analysis aims to provide specific recommendations for users and researchers. The study shows that the legislative framework is complex and still in progress, it shall in any case be combined with the legal framework concerning personal data, because the cross-processing of anonymous datasets could identify or make data subjects identifiable as described by art. 26 of GDPR. Moreover, the legal mapping describing the most recent EU legislative initiatives refer to EU Regulation 2018/1807 concerning the free flow of non-personal data in the EU[75]; the Directive 2019/1024 on open data and the re-use of public sector information (PSI Directive). According to the results of the study, open science is promoted through the principle of free movement of non-personal data and the boost of public sectors to make information available and re-usable, aligned with the scopes of FAIR Principles.

The aim of the study was to lay a groundwork for the drafting of a blueprint for European researchers and institutions, which may assist them in publishing, sharing, and integrating research data, thus guaranteeing the openness of research data with the goal of promoting the FAIR principles beyond their original scope. The conclusion of the study on this topic shows that as far as the personal data and non-personal data analysis is concerned, it emerged that the GDPR constitutes a compass for further legislative initiatives impacting the information society and already provides viable means to develop guidelines for opening the free flow of research data. Therefore, its risk-based approach, enabling the data protection by design and by default, is a system driven by the principle of accountability, whose structure ensures a responsible management of personal data while also

[75] Cfr. Regulation (EU) 2018/1807 of the European Parliament and of the Council of 14 November 2018 on a framework for the free flow of non-personal data in the European Union, in OJ L 303, 28.11.2018, p. 59–68, available at this URL: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32018R1807

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offering avenues to reduce the burdens for data controllers. The GDPR compliance of personal data and mixed datasets plays a paramount role in achieving the Open Science and Open Data purposes.

Concerning the IPR legal framework, the study concludes that despite the remarkable harmonization effort conducted by the EU, several legislative areas are in the legislative competence of EU member states and, for these reasons there is a very complex fragmentation of the legislative framework. The fragmentation of national solutions in a number of sectors that are of fundamental importance for the cross-border exchange of protected works and for the safe and legitimate use and re-use of copyright materials, such as the notion of authorship and co-ownership, copyright contracts, and the regulation of most of the exceptions to exclusive rights.

Concerning the second part of the study, related to the protection of personal data and non- personal data, the study has shown comparable outputs on data protection for research purposes. The comparative analysis shows that divergences among national implementations may refer to consistency mechanisms aimed at continuously assessing the impact of the data processing for research by a third independent body. This activity is allocated to the data protection authority, to the competent ethical committee, or to the institutionalized audit board. The role of control by an independent body and the consequent procedures of engagement might be considered as a barrier to cross border flows both in terms of data processing and dissemination aimed at further/secondary use, and opening possible strategies of forum shopping (i.e. the presence of legal constraints as parameter to share data). The full text of the legal mapping can be found in Appendix A.

3.3 Gap Analysis

The study by Sant'Anna defines the gaps in the regulation. It assesses the legal constraints hindering the full development of Open Access and Open Science principles and highlights the impact of such constraints on the successful participation of EU Member States in EOSC services enabling multinational FAIR data. This represents a crucial goal of the study. The identification and definition of legal gaps is an essential step towards the compilation of sound and effective recommendations at any level of decision-making, from the individual actor to the policymaker. The gap analysis and the legal constraints focus in particular on Copyright law and regulations, and the protection of personal and non-personal data.

3.3.1 Copyright law

Two flaws make EU copyright law incapable of supporting effectively the goals underlying the establishment of FAIR ecosystems and the implementation of Open Access and Open Science policies. One pertains to the system of exceptions and limitations (E&L). The second belongs to the area of copyright contracts.

On the side of E&L, the lack of a flexible and open balancing clause and the strict reading of exceptions make it impossible for the copyright system to respond to the changing needs of the research ecosystem and to the fast evolution of technologies. To have a new exception, a legislative intervention is always needed, and this entails long deliberative processes, and may lead to suboptimal results (too narrowly tailored, too rigid, born already outdated, etc). Waiting for the legislator, the area requiring a balancing intervention remains uncovered. Not unexpectedly, since

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FAIR principles and OA and OS policies are often in conflict with or constrained by the enforcement of author's rights, missing E&L represent one of the most frequent items in the related regulatory gap analysis. At the same time, areas where exceptions are not harmonized at the EU level, either because they are defined as optional by EU directives or because they have not been subject to an intervention of the EU legislator, have created national discrepancies, loopholes and consequent gaps impairing the smooth cross-border exchange, use and re-use of research products.

On the side of copyright contracts, national legal systems have a long tradition of regulating publishing contracts to ensure that the stronger bargaining power of publishers gets more balanced and does not disproportionately harm the interests and position of individual authors. Such rules, however, tend to be limited to traditional forms of publications, e.g., books, and are often not applicable to publishing contracts used in the research environment, e.g. license to publish agreements between researchers and journals. At the same time, national copyright acts are generally silent on license agreements, leaving the definition of their content to private parties. The missing legislative standardization of license agreements deprives national legal systems of clear references and rules of the game to regulate the commercialization and exchange of protected works, remitting them almost completely – save for some mandatory provisions - to the freedom of contract of the parties involved. Due to this regulatory gap, no legal system leverages on the instrument of open licenses when implementing OA/OS policies, despite the tools effectiveness to be used to pursue a wide range of balancing goals without altering the structure of copyright law. As in the case of E&L, the lack of EU harmonization in the field, except for very limited sectors, contributes to reinforcing the fragmentation of national solutions, with obvious impact on legal certainty and the smoothness of cross-border research operations and common activities.

The tables below show the main regulatory loopholes and gaps affecting the proper implementation of functions and objectives identified as essential for the realization of OA and OS policies and of FAIR data ecosystems.

Findable data	No (digital) rights management nor metadata obligation (compatible with Berne Convention) nor incentivizing provision
Accessible data	no additional constraints
Interoperable data	No interoperability exception nor interoperability obligation or standardization rule provided for metadata and data
Reusable data	Neither copyright law nor other related branches of law (see eg consumer protection law in general or in digital content contracts) contain provisions imposing information duties on provenance of data, and only limited information duties and safeguards to achieve clear usage licenses of data and collections
By design and by default standards	no additional constraints

Table 1 Gap Analysis FAIR Principles

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Open repositories	1.No EU harmonization on OA obligations (varying conditions; in some States it is the author's right, in others it is the obligation of public funding entity, etc.) 2.Limited or no provisions to rebalance author-publisher bargaining power in defining APC and OA routes, in preventing double-dipping etc.
Accessible metadata	no additional constraints
Interoperability	Need to verify effectiveness of interoperability exception under Software Directive II[76]
Integration of repositories	No exceptions, presumptions or other mechanisms allowing with certainty integration of repositories
Clear reusability	1.Only a handful of mandatory exception under Database Directive, not covering full range of conducts involving reusability 2.No full harmonization of database exceptions and gaps 3.Unclear case law and definitions in the field of database protection 4.Several non-harmonized exceptions across EU 5.Unclear application of Article 6 InfoSoc on relationship exceptions-TPMs
Balance author-publisher	1.No legislative standardization of license agreements 2.No legislative reference to open licenses 3.Traditional author-publisher rebalancing provisions not fully applicable to license-to-publish contracts or other agreements common in research environment 4.No harmonization of copyright contract safeguards in author-publisher relationship (safe for limited exceptions) 5.See point 2 under "open repositories"
Users with disabilities	1.No harmonization of disability exception under InfoSoc Directive 2. Marrakesh exception is good baseline, but too narrow and not covering all instances needed to ensure full access and accessibility to research products

Table 2 Gap Analysis Open Access

[76] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009L0024&from=EN

Open source	1.No legislative reference to open licenses, enforceability of GPL clauses etc. 2.No harmonization of copyright contract provisions in the EU
Open data	1.Good step forward with text and data mining exceptions in CDSM Directive, but Articles 3-4 present several flaws and trigger uncertainties. Effects yet to be seen after full implementation
Open educational resources	1.Article 6 CDSM Directive will help but effects yet to be seen after full implementation 2.Digital teaching exception narrowly tailored
Reusable data	See above under clear reusability, points 1-3

Table 3 Gap Analysis OS

3.3.2 Personal and non-personal data protection law

Combining the results of the comparative analysis, we notice that despite a new cultural approach has been embedded in the EU legislative initiatives oriented to boost Open Data and Open Science, the process towards the open data strategy has not completed yet.

In fact, the innovative principles introduced by the investigated legislative initiatives on personal and non-personal data (e.g. accountability, privacy/data protection/ethics/openness by design and by default), the useful definitions that enhance the role of ICT as innovation enabler (instead of simply being another sector of the data economy), and the consistency mechanisms introduced to sustain the multitude of research fields affected by the Open Science Revolution, shall still find a practical feedback.

This is due, as emerged by the national legislative initiatives on personal data processing for research purposes under article 89 of the GDPR, to a temporal factor (as they accumulated only few months of application) as well as to a huge number of practical issues that shall be addressed not only in terms of regulation, but also in terms of standardization, and compliance practices. Moreover, considering the cross-references between the GDPR and the legal framework impact on non-personal data (Open Data, PSI Directive and Non-Personal Data Flows Regulation[77]), whose national implementations have not been enacted yet, this gap analysis highlights the uncovered fields needed to complete the European Data Strategy in research activities and where it would be useful to intervene.

The tables below summarize limits of the legislative fragmentation to enhance research data within FAIR ecosystems.

[77] Regulation (EU) 2018/1807 of the European Parliament and of the Council of 14 November 2018 on a framework for the free flow of non-personal data in the European Union (Text with EEA relevance.), OJ L 303, 28.11.2018, p. 59–68, available to this URL https://eur-lex.europa.eu/eli/reg/2018/1807

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Findable data	Records are binding for personal data processing, but within the Data Management Plan all research data shall be described.
Accessible data	Access to research data is conditioned to the personal data governance, while for non-personal data shall be promoted free of charge, unless some exceptions occur.
Interoperable data	From the data protection impact assessment, technical safeguards may be identified prior and after the pseudonymization. Measures to ensure the interoperability after the pseudonymization do not emerge.
Reusable data	Conditions introduced by national legislators are not standardized nor do they always seem coherent with the GDPR.
By design and by default standards	These principles are applied both for "as close as necessary" formula and for "as open as possible" one, but consistency mechanisms are not provided.

Table 4 Gap Analysis GDPR vs. FAIR Principle

Open repositories	Still unarticulated reference and use to the exception of art 9(2)(e) "data made manifestly public" by the data subject.
Accessible metadata	The role of metadata for re-identification is still not clarified in legislation nor their role in defining the borderline between personal and Non-Personal data.
Interoperability	It is described as a principle, but no practical measures are defined.
Integration of repositories	GDPR compliance prevails on Non-Personal data regulatory framework.
Clear reusability	Conditions are not standardized
Balance author-publisher	no additional constraints

Table 5 Gap Analysis GDPR Open Access

Open source	no additional constraints
Open data	Conditions introduced by national legislators are not standardized.

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Open educational resources	no additional constraints
Reusable data	Conditions introduced by national legislators are not standardized.

Table 6 Gap Analysis GDPR Open Science

3.4 Constraints of the Regulations

After the gap analysis it is very important to assess legal constraints. This analysis has been divided in two sections: a) definition of the copyrights law, b) protection of personal data and non-personal data.

3.4.1 Copyright law

The main legal constraints for the implementation of FAIR principles and the realization of OA and OS policies stemming from national and EU copyright law are naturally linked with (i) the scope and enforcement of exclusive rights, (ii) the strict reading and lack of flexibilities of exceptions, and (iii) the ample room left to freedom of contract. The latter is often exercised in a manner conducive to the imposition of additional constraints to free use and to the enhancement of rights holders' control over protected works. Alongside these obvious barriers to openness, access, accessibility and reusability, the uncertainty surrounding specific areas, among other things, the breadth of the definition of protected works or the non-maximum harmonization of important areas e.g., E&L, all factors impacting on the scope of copyright law, thus have a constraining effect on the full development of FAIR data ecosystems and on the correct implementation of Open Access and Open Science.

The tables below show the main regulatory loopholes and gaps affecting the proper implementation of functions and objectives identified as essential for the realization of OA and OS policies and of FAIR data ecosystems.

Findable data	no additional constraints
Accessible data	no additional constraints
Interoperable data	Obstacles may be created by exclusive rights (copyright or patents) on technology and language used for knowledge representation.
Reusable data	Unconstrained freedom of contract – save for limited mandatory exceptions and information duties – cause the presence of a plethora of different usage licenses, often subject to different applicable laws due to copyright territoriality. This circumstance decreases the intelligibility and, in some instances, the transparency of usage licenses. This introduces significant constraints to cross-border use, and substantially weakens the confidence of researchers and operators in the reusability of data.

By design and by default standards	no additional constraints

Table 7 Constraints Fair Principles

Open repositories	1. Unconstrained freedom of contract leads to unbalanced author-publisher relationships, hampering development of OA policies and maintains or increases the financial burden on research institutions 2. Unclear and uneven/unharmonized application of exceptions has chilling effects on development of open repositories.
Accessible metadata	no additional constraints
Interoperability	1. Misuse in licensing clauses (hidden constraints and wrong notices on interoperability). 2. Unclear case law on interoperability exception triggering uncertainties and constraining effects.
Integration of repositories	1. Too broad interpretation of InfoSoc exclusive rights (particularly reproduction and communication to the public) 2. Unclear and uneven/unharmonized application of exceptions has a dampening effect on development of open repositories.
Clear reusability	1. Unclear breadth of notion of protected work creates uncertainty and dampening effects 2. Unclear definitions in database law (particularly sui generis right) and relationship with copyright law and public domain create uncertainty, dampening effects and ground for contractual misuses. 3. Not-fully harmonized EU copyright law (particularly exceptions) create uncertainties and as a result lead to delays in cross-border services settings and consequently creates delays in cross-border services settings.
Balance author-publisher	1. Too broad freedom of contracting, tilting the balance in authors-publisher relationship, particularly in the research journals arena. 2. Lack of EU harmonization hampers legal certainty and triggers race to the bottom in measures protecting authors.

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Table 8 Constraints Open Access

Open source	no additional constraints
Open data	1. See point 2 above under clear reusability 2. Constraints on text and data mining yet to be solved by implementation of Articles 3-4 of the Directive on Copyright in the Digital Single Market, which still carry several flaws and do not promise to remove all existing obstacles, particularly in case of multipurpose uses, public private partnership research ventures, etc.
Open educational resources	1. Fragmentation of national exceptions yet to be solved by implementation of Article 6 of the Directive on Copyright in the Digital Single Market.
Reusable data	See “clear reusability” above.

Table 9 Policy constraints for Open Science

3.4.2 Personal and non-personal data protection law

From the previous gap analysis, we are now able to extract three main barriers that prevent concrete harmonization of practices for enabling Open Science research data:

1) Despite the EU initiatives, the national regulatory frameworks are not enacted by equivalent legal sources, as national legislators introduced exceptions both by hard law and soft law instruments: therefore, the same provision may encounter a different level of efficacy and diversified enforcement tools among different countries.
2) Issues addressed in the national implementations deal with different profiles, sometimes connected to technical and organizational measures aimed at developing a detailed checklist to achieve a by-design compliant structure of the life cycle of the research, sometimes related to identify some boundaries under the general research purposes regime, sometimes to create a bridge between data protection laws and other sectoral legislations.
3) The relevant norms do not rely on technical standards that could facilitate the integration with the legal framework applicable to non-personal data and copyright and IP protections.

The following tables show which of the mentioned barriers affect the given function.

Findable data	(1) non-personal data flows shall not be recorded, (2) the Data Management Plan is not a binding procedure.

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Accessible data	(1),(2) compliance activities and conditions for accessibility are not harmonized in terms of means (hard and soft law regulations) and contents
Interoperable data	(3) technical standards are not mentioned.
Reusable data	(1), (2) compliance activities and conditions for reuse are not harmonized in terms of means (hard and soft law regulations) and contents.
By design and by default standards	(1), (2) compliance activities are not harmonized in terms of means (hard and soft law regulations) and contents.

Table 10 Barriers for enabling FAIR Principles

Open repositories	no additional constraints
Accessible metadata	no additional constraints
Interoperability	(3) technical standards are not mentioned.
Integration of repositories	(3) technical standards are not mentioned.
Clear reusability	(1), (2) compliance activities and conditions for reuse are not harmonized in terms of means (hard and soft law regulations) and contents.
Balance author-publisher	no additional constraints
Users with disabilities	(1), (2) compliance activities are not harmonized in terms of means (hard and soft law regulations) and contents.

Table 11 Barriers for enabling FAIR Principles

Open source	(3) technical standards are not mentioned.
Open data	(1), (2), (3) GDPR compliance is a requirement to enable open data policies, but compliance activities and conditions are not harmonized in terms of means (hard and soft law regulations) and contents. In addition, no cross reference is provided for technical standards and norms.
Open educational resources	no additional constraints

Reusable data	(1) (2) conditions for reuse are not harmonized in terms of means (hard and soft law regulations) and contents.

Table 12 Barriers for Open Science

4 Policy Framework for EOSC Services Management

The development of EOSC and its service ecosystem drives the requirement of a management policy structure for the service delivery. Such a structure includes mechanisms for the establishment of written and explicitly defined agreements between customers and providers. When (IT) services are offered and consumed because of a service delivery contract, the document that specifies the service, the targeted user, and the policies that govern the use of the service is a Service Level Agreement (SLA). Part of the SLA are documents describing the environment or the acceptable use of the service. For example, the Rules of Participation of the EOSC are implicitly part of any service entering EOSC. The process of delivery of a service involves service providers and consumers and both will need to agree on the content of the actual service and associated aspects that are part of the service. Especially in an international context and with widening 'distance' between provider and consumers, a written agreement will be required which includes regulations, policies, terms of use etc.

This chapter further focuses on the legal and policy requirements of activities within the service level management process in the context of EOSC-Pillar services. The information will be updated with the latest findings and developments of EOSC in the third quarter of 2021.

4.1 Adopted Service Level Management Standard

IT service management (ITSM) describes the processes that govern the delivery of IT services. Several standards exist for this. However, for the purpose of this document we refer to the FitSM standard[78] which can be considered a "lightweight" option for ITSM. FitSM is designed to help large and small providers to deliver, support, and manage their IT services. The experience and proliferation of the FitSM service management standard is well known in EOSC after its introduction in the EUDAT2020 project and following further recognition in the EOSC-Pilot project.

[78] https://www.fitsm.eu

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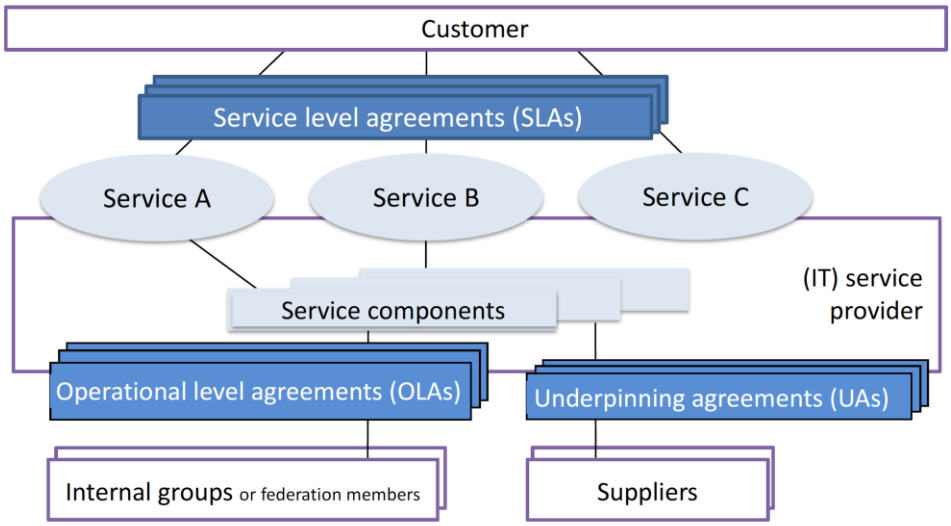

Figure 2 Service Level Management and the types of service agreements [79]

According to the FitSM service management standard, the Service Level Management process is employed for the purpose of maintaining a service catalogue and establishing an agreement on the terms of use with customers. It employs three types of agreements that differ depending on the involved parties. The Operational level agreement (OLA) and the Underpinning level agreement (ULA) are considered special cases of the SLA and are not specifically considered in this document.

In the context of FitSM, the term customer represents "Organisation or part of an organisation that commissions a service provider in order to receive one or more services; a customer usually represents a number of users"[80]. SLA is defined as: "Documented agreement between a customer and service provider that specifies the service to be provided and the service targets that define how it will be provided". Likewise, the EOSC glossary[81] defines SLA as: "service contract that defines measurable conditions of interactions between a service provider and an end-user." EOSC glossary also introduces a Service Level Specification which has the same content as an SLA but more clearly is not a service contract.

The SLA is a legally binding document underpinning the service and determines the service offering in detail, its expected and accepted use and more. Service offerings in the EOSC and any other context are consumed only after mutual agreement of both parties. Furthermore, an attractive service does not only require a description and a listing on a web page but a sound and trustworthy services management environment, plausible guarantees for sustainability and other attributes that ensure the service offering. All these are described in the SLA and in its appended documents.

This section of the deliverable centers on Service Level Agreement between the customer and the provider of a service or services, as a policy framework for EOSC services management.

[79] From: FitSM Foundation Training 2.11: https://www.fitsm.eu/download/360/

[80] https://www.fitsm.eu/downloads/#toggle-id-1

[81] https://repository.eosc-portal.eu/index.php/s/nEsxySAFMZJizwH

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4.2 EOSC-Pillar Service Level Management Requirements

EOSC-Pillar, being a project that will end in 2021, will not run its own services. Therefore, establishing a larger services management structure is not needed, particularly because most service management processes are run by the EOSC-Core and other EOSC associated service providers. The services management requirements and efforts of the EOSC-Pillar project focuses on maintaining national service catalogues, defining, agreeing and monitoring service levels with customers and with the EOSC federated ecosystem.

Efforts in EOSC-Pillar regarding services management aim to

- Support the use cases in EOSC-Pillar with the development of an initial SLA template
- Leverage the expertise and work done for the benefit of EOSC

The following components are parts of an SLA, according to the FitSM template.

- Scope and description of the service
- Service hours and exceptions
- Service components & dependencies
- Support
    - Incident handling
    - Fulfilment of service requests
- Service level targets
- Limitations & constraints
- Communication, reporting & escalation
    - General communication
    - Regular reporting
    - SLA violations
    - Escalation & complaints
- Information security & data protection
- Additional responsibilities of the service provider
- Customer responsibilities
- Review
- Glossary of terms

For the purpose of implementing a Service Level Management (SLM), it is useful for the project and for the EOSC at large to study the existing SLA's used by service providers in EOSC-Pillar to determine the validity of the respective SLA for service offerings within a national context and in an international context. The international context is that of the EOSC but also includes participation in European infrastructure provider organisations like EGI Federation and EUDAT as well as participation in the community specific infrastructures like ELIXIR.

The logic that underlies this SM policy framework is as follows. To participate in EOSC by offering a service in a national or international infrastructure an agreement needs to exist between:

- the customer and the provider directly delivering the service,

- the customer and the provider that offers the service on behalf of the actual service provider (a marketplace provider), and
- the provider of the actual service and the marketplace provider that offers the service to the customer (third party provisioning).

The EOSC-Enhance project studied the requirements with respect to the, operational, service delivery from the EOSC services perspective[82] and foresees four types of agreement.

- **Portal SLA**: (more specific: Exchange User Agreement). This would cover use of the Marketplace and portal by customers and users wishing to access services and other research related resources. It would describe the conditions under which the Marketplace platform could be used and what guarantees there would be for it.
- **Exchange Provider SLA:** to cover the provision of services from the Portal owner to the providers of services and other resources – with the service offered being the exposure of these resources through EOSC (both the portal and potentially linked other marketplaces and catalogues).
- **Core Provider SLA:** needed to keep EOSC running, and cover the functions offered to the operators or owners of EOSC and EOSC portal.
- **Research Service SLA:** SLA offered by providers of research resources for their services or other resources, which EOSC is not involved in though may support.

In the EOSC there are different customer and service types, based on which there need to be different agreements. Also, the role of the different actors, either customer or provider may change over time. EOSC Enhance validly argues that agreements i.e., the SLA, drive the different service management processes, e.g., the Service Reporting Management and, in other words, a reliable and dependable EOSC services infrastructure thus depends on the monitoring and reporting of indicators as agreed upon in the SLA.

4.3 Sources of Information Used

4.3.1 Interviews with Service Providers from EOSC-Pillar

A survey in the form of semi-structured interviews, was designed to gather information on the current and planned utilization of different agreements within the service provider community. The survey questions can be found on-line[83]: questions for survey of service providers

The interviews with service providers partnering in EOSC-Pillar, is targeted to gather insights on the following issues:

- Types of service providers, services offered, participation in EOSC and open data,
- Size and type of user community,

[82] EOSC-Enhance, "D1.4 EOSC Portal SLA, SRM, Privacy Policy ", https://repository.eosc-portal.eu/index.php/s/nEsxySAFMZJizwH

[83] https://docs.google.com/forms/d/e/1FAIpQLSdoi-isOKCs5SDuAEnjC5bmjA_Hz0hE2BfUnUiTSAAI56ZGVg

- Geographic scope of services,

- The existence and content of current and planned SLA with customers,
- The existence and use of operational level agreements with other service/component providers, such as the EOSC Association and other EOSC partners,
- The provider's current and foreseeable need for such agreements,
- Institutional, national policy and EOSC-level requirements for local and cross-border SLA/OLA creation, implementation and enforcement,
- Overall regulatory/policy barriers to compliance with EOSC RoP, FAIR principles.

In a series of interviews with four representatives of different stakeholders, the need for an SLA and its significance in the EOSC context was discussed. The interviewees are all representatives of partners of the EOSC-Pillar project. The transcripts of the interviews are available upon request and will be erased at the end of the project.

Organisation	Service Type
Deutsches Klimarechenzentrum - DKRZ[84]	Resource provider for climate research. Compute and data storage
ARIADNEplus[85] - International data infrastructure for archeology	Data aggregator of data sets from digital humanities, language studies, heritage science and archaeology.
CNRS-IPHC[86] Institut Pluridisciplinaire Hubert CURIEN.	e-Infrastructure, data storage
Centre Informatique National de l'Enseignement Supérieur - CINES[87]	Resource provider for higher education and research communities). Of the three main activities (simulations, long term preservation, hosting) the questions were answered specifically for the Archive storage

Table 13 IT Service providers participating in the survey

4.3.2 Inputs from review of related EOSC outputs, and legal study on data policies

The following documents have been used as references and to further build on existing EOSC accomplishments.

- EOSC-Enhance, "D1.4 EOSC Portal SLA, SRM, Privacy Policy", service management requirements identified, SLA types and templates provided (presented in section 4.2. above).
- European Open Science Cloud - Rules of Participation (presented in 4.4.2.)

[84] https://www.dkrz.de/
[85] https://ariadne-infrastructure.eu/
[86] http://www.iphc.cnrs.fr/
[87] https://www.cines.fr/

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- The FitSM Service Management Standard document (referenced for describing a standard service level management process adopted by EOSC, presented in section 4.1.)
- Policy recommendation from the legal study (presented in section 3.3)

4.4 An Overview of the EOSC Service Level Management Structure

In this section, the interviews with service providers and the study on the legal and policy framework of Open Science presented in the chapters above are considered to determine the legal opportunities and challenges that exist for EOSC to utilize SLAs with providers and customers in practical implementation of FAIR principles. Such as applying constraints on service use subject to compliance with: EOSC Rules of Participation, the EOSC Information security and Data Protection policy, and data sharing requirements.

4.4.1 Service management practices among EOSC-Pillar service providers

All organisations are familiar with SLAs. CNRS-IPHC and CINES have SLAs in place. DKRZ does not have written agreements and expects legal hurdles if these will be too complex. Their model is based on trust and best effort and has worked very well over many years in an international setting. This is like the international consortium of aggregators that go even a step further. Users are explicitly told that the service is free but regarding the content of the data they are on their own. This is similar for all respondents, as they host data that is stored by external users and cannot be held responsible for the content of the data, whether this relates to the quality of the data or whether the data contains elements that are not allowed e.g personal data which would be excluded because of GDPR. In the case of CINES its SLA states that only the data owner can be held responsible for the content.

Data of all respondents, except CINES, is entered from across the border. No regulations at CINES prevent international data input but there are no users requiring this until today. There are no legal or organisational issues with cross border data input and access except in the case of CNRS. At CNRS international access is covered by a higher-level SLA (CNRS-IPHC hosts data for CERN via EGI Federation) and access to the medical data stored is not allowed outside France.

Interviewees were asked if they expect benefits from written agreements with users (in the EOSC context), which may become more needed once services must be paid for. This was considered useful because the current tacit conditions are known but need to be made more explicit. In the case of the international consortium, it did not materialise yet because the service is under continuous improvement and not yet 100% ready. This shows a possible disadvantage of written statements because in that case one needs to describe the service while excluding some important features. This could possibly reduce the confidence in the service especially when you need to expand usage [funding of the international consortium depends on the number of customers or users]. In the end, it's necessary to prepare dependable written statements about the services. In general, all agree that written statements and signed agreements are needed, once EOSC picks up speed. The only question is to what detail the SLA should be written.

DKRZ has many international customers, and their services model is based only on trust and is exempt from legal contracts and regulations. At the same time a general framework must exist if services are entering the EOSC and there must be a mechanism that proves that the services are used. With large numbers of users there will be problems, but a complex SLA does not seem the right answer to any

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imageable problem. The SLA should not mean that delivering services will become complex. Beyond stating for whom the services are intended, which help planning for the operation of the service, and what the service is about, an SLA is less important. In this sense, a written statement on what the service delivers increases trust. Which is a good thing. Communities play a role in the SLA as well since it is derived from the community and shields for less reliable partners (DKRZ has experience with these). Providers could be excluded with respect to (data) quality issues. Within EOSC it does not help to have rules/penalties in case of problems (e.g., on the budget level).

The representative of the humanities data aggregator pointed to the fact that it is easy to allow access to data. Interoperability, at least in the technical sense, is easy as well. However, one thing that could be fixed in an agreement is "re-use" of data. Re-use can be expressed as the confidence the user has in the dataset. This can be done by indices connected to the dataset. Obliging users to do so establishes trust in the data based on their reactions.

4.4.2 Services management and the EOSC Rules Of Participation

Starting with the EOSC Pilot project and increasingly the past two years many documents have been written, some as the result of outsourced in depth studies, that can be considered high level guidelines for the implementation and execution of the EOSC. In 2020 the working groups (Sustainability, Architecture and Rules of Participation) of the Executive Board (EB) produced documents that must be considered with respect to services management.

What impact does the groundwork laid by the EB have at the SLM and what relationship exists between the EOSC framework and SLM? What follows is a preliminary analysis based on the latest revisions of non-final documents. The second revision of this Deliverable will further explore the impact and relationship mentioned.

In this paragraph we reflect on the “European Open Science Cloud - Rules of Participation” document from the Rules of Participation Working group which are high level rules that come into play upon becoming a participant of the EOSC infrastructure. This accounts not only for researchers or infrastructure providers but for their services as well.

In the RoP, rule 5 states: “EOSC users are expected to contribute to a successful EOSC and active EOSC community”. With respect to services and data there are two points to consider here.

- When researchers use EOSC services and access data within the EOSC framework, as a result new research products are possibly produced.
- What policy should EOSC adopt for derived works and should derived works be accessible through EOSC as well?

If these research products will be required to be shared, it must be made clear at the time of agreement. The reasons for this requirement may vary and depend on the conditions under which the new research was produced and on the materials used (e.g. European funding schemes may require the data to be accessible through EOSC, if external data is used in addition to data accessed via EOSC).

Another aspect relates to trust and confidence in the quality of the data and the reliability of the service. To ensure trust and confidence, there must be a feedback mechanism between EOSC and the customer community which is the collection of scientists, the users, and the service providers. In the

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latest version of the document, conditions and requirements are enforced on the users of data and services but not on EOSC either as an association or as a framework.

Trust in EOSC services and data is better served if mechanisms exist to allow the customer to send feedback to the EOSC technical and policy developers. This seems especially important for a federating system. Scientists are usually eager to propose new methods and are happy to share information and the members of the EOSC Association and its relevant boards may be too distant from the science community to allow efficient feedback.

Another aspect of interest is the validation of the rules. Who does the validation and what are the legal aspects if the validation does not pass?

4.4.3 Summary of Service Level Management Policy Issues in EOSC

The EOSC portal owner (i.e., EOSC Association AISBL) offers SLAs to providers of research services and other resources for exposure of their services through the EOSC marketplace and the use of EOSC core when required. A different SLA is offered to customers that represent end users of these services.

For cross-border users and providers to comply with the rules and requirements of participating in EOSC, the regulatory differences between their respective countries need to be narrowed. Interoperable policy frameworks are needed to create trust. In this regard, the following challenges and opportunities are identified in the current policy environments of the EOSC-Pillar countries, through the legal study presented above and interviews with service providers.

- Most research resources and services providers are publicly funded and their operational policies are influenced by their respective funding bodies, not by individual researchers or institutes.
- Compliance to and conditions for FAIRness need to be harmonized among countries.
- Conflicting data protection laws exist among countries.
- Rules on data sharing are not clear and standardized.
- Simple SLAs are preferred by EOSC customers and providers, additional constraints and responsibilities might create complexity.
- Proper documentation of research data for the purpose of reusability needs to be incentivised.
- There is a need to establish a common understanding on service provision conditions between users and providers such as re-use of data, if participants are expected to contribute to the success of EOSC.

5 Federation Blueprint

The Blueprint/Guidelines aims to assist researchers with publishing, sharing, and integrating research data, and pays particular attention to the challenges raised by IPR, data protection laws and regulations on non-personal data. The full version of the Blueprint/Guidelines is available in Appendix B and it represents an integral part of the deliverable.

The objective is to promote the implementation of FAIR principles beyond their original scope, and to lay the conditions for the effective realisation of Open Data and Open Science policies. The Blueprint allows regulatory flexibility and legitimate access restriction. The Blueprint helps to:

- guide researchers in the management of research data and research outputs
- promote best practices to achieve accessibility, findability, and interoperability of research data in view of reuse and open access of published research products
- facilitate the convergence of national solutions to remove unnecessary restrictions.

The Blueprint supports researchers to identify and understand the applicable legal framework to define their intellectual ownership and the applicable legal framework for personal and non-personal data. Moreover, the Blueprint will help the researchers understand and devise processes to define and declare the legal regime applicable to different research products, and to manage their access, use and re-use in subsequent stages of research including the dissemination of its results.

Also, the Blueprint aims to help researchers to understand how to deal with external data and protected intellectual assets to avoid liability and allow access via proper consent and licensing. Finally, the Blueprint offers data creators clear indication on how their works will be disseminated in the future, enables them to choose the best licensing forms, and highlights the importance of having a minimal set of data open by default. The Blueprint, which you can find in the Appendix B, assumes a three-step scientific lifecycle: (i) research proposal, (ii) research implementation and (iii) research review. For each of the phases the implication regarding IPR, and Data Protection is explained.

5.1 Guidelines for Researchers

The purpose of the guidelines is to promote the implementation of FAIR principles beyond their original scope, and to lay the conditions for the effective realization of Open Data and Open Science policies. By leveraging regulatory flexibilities and taking into account legitimate restrictions to access, the blueprint/guidelines aim at (a) guiding researchers in the management of research data and, more generally, research outputs, and (b) promoting best practices to achieve accessibility, findability and interoperability of research data in view of reuse, open access of published products, and the removal of unnecessary restrictions, facilitating the convergences of national solutions.

In the following table a high-level checklist of the recommended measures is presented. A detailed explanation of the guidelines and procedures are found in Chapter 8.

Research Phase	Issue	Recommendation
Research proposal	Intellectual Property	❑ Check whether there is background information, data and intellectual property rights brought into the project.
		❑ Be clear on ownership, legal regime and degree of openness or closeness of each asset.

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		❑ Liaise with your TTO and/or other support offices as soon as possible.
	Data Protection	❑ Assess each personal and non-personal data processing and the corresponding requirements to enable data flows.
		❑ Set up preparatory activities to ensure ethical-legal compliance.
		❑ Include compliance and data management activities in the general research risk-management.
Research implementation	Intellectual Property	❑ Make sure to develop an effective, comprehensive IP management plan.
		❑ Put in place clearance processes and systems that identify IP flexibilities and leverage them to afford re-use of protected materials without requesting rights holders' authorization.
	Data Protection	❑ Implement required safeguards to be compliant with legal obligations.
		❑ Implement technical safeguards.
		❑ Set up organizational measures for governance of data flows.
		❑ Be aware of vulnerable groups.
		❑ Protect data flows also in communication and dissemination activities.
Research review	Intellectual Property	❑ Identify maintenance mechanisms for IP management plan
		❑ Maintain and update clearance processes identifying IP flexibilities.
		❑ Run periodic checks on the expiration date of OA/OS embargos.

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		❑ Verify compliance with license agreements by your licensees, and particularly respect of FAIR, OA and OS clauses.
		❑ Run compliance checks of your status on institutional repositories
		❑ Help your institution be up-to-date with the state of the art in the implementation of FAIR principles and OA/OS policies.
	Data Protection	❑ Check data retention for personal data.
		❑ Check security policy.

Table 14 IT High-level checklist of the recommended measures to promote the implementation of FAIR principles

5.2 Policy Recommendations for Regulators, Policy Makers and the EOSC Association

The translation of the results of the legal analysis into solidly informed, methodologically sound, wide-ranging policy recommendations is a crucial step towards the effective building and practical improvement of the regulatory context surrounding research practices and infrastructures. The Policy recommendations addressed to policymakers and institutions that deal with the definition and application of soft law and binding regulations at national and European level. Further, they aim to involve public institutions at judicial and legislative level as well as at national and EU level, in order to improve the discussion on the most important gaps in the analysed regulatory framework. Policy recommendations also are the key means through which an impulse and solicitation can be done to policy decisions in most levels of government. They reflect an accurate selection of the most relevant identified shortcomings of the current regulation:

- The relevance of legal obstacles at comparative level (e.g., profound regulatory fragmentation and divergences across the fine analysed Member States)
- The relevance of legal obstacles vis-à-vis the guidelines issued to the benefit of individual stakeholders (e.g., specific needs to facilitate good practices);
- The urgency of intervention upon provision, whose modernization had been deemed to be long overdue.

The full text of the recommendation can be found in Appendix C and represents an integral part of this deliverable. It clearly shows the added value of considering both copyright and data protection laws thereby encompassing a multi-faceted account of the legislative and non-legislative reforms needed to pave the way towards an effective, open and inclusive research environment in EOSC and the EU.

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5.3 Blueprint Validation

A first version of the Guidelines and Recommendation has been presented in national and international conferences, in particular in the context of GARR Conference 2021 (https://www.eventi.garr.it/it/conf21) in the EOSC Symposium 2021 "Implementing an inclusive European Open Science Cloud" (https://www.eoscsecretariat.eu/eosc-symposium-2021) and at the OSFair2021 conference (https://www.opensciencefair.eu/2021).

After the implementation of the Blueprint Guidelines and the Policy recommendations a first step will be to ensure the validation of the Blueprint Guidelines. This helps to verify their practical usability, among research institutions and communities, and a certain degree of acceptance among policymakers and institutional stakeholders. A possibility is to present and explain the Blueprint/Guidelines and the Policy recommendations first to the use cases and services of the EOSC-Pillar project and subsequently in a webinar. The webinar can be structured either as independent training for research and administrative staff or as dedicated training in the context of specific research sectors/funding programs. Since this activity is not part of the planned effort in the project, the outcome and success depend on successful contribution and collaboration with other programs and projects.

Feedback can also be collected through a dedicated survey or through interviews which may cover multiple research communities. In order to analyze the possible solutions to the issues highlighted in the gap analysis, the guidelines need also be tested in the light of the best practices developed by the various research institutes and bodies involved in the Project and part of the EOSC landscape.

5.3.1 Validation through interviews

The EOSC-Pillar project has set up in December 2020 a Transversal Task Force (TTF) to coordinate a consultation process of national initiatives acting in the context of the EOSC. National representatives in this respect are the mandated organisations in the EOSC Association as well as national thematic infrastructures, national e-infrastructures federating national services, or the national nodes of ESFRI infrastructures. The list may slightly differ for each country.
During interviews it was tried to determine policy gaps and difficulties with respect to the application of the legislation on personal data and IPR. The interviews show that in order to overcome the gaps detected in the analysis of the legal framework of reference, some organisations have developed policies to guarantee open access and open science.

Some research institutes have developed policies and guidelines for the definition of standards to regulate the protection of intellectual property and aspects related to data protection. The results and analysis of the interviews are described in detail in the upcoming Deliverable 4.3 of the EOSC-Pillar project. It was found that many institutions lack specific guidelines and policies on GDPR and IPR.
In other cases, best practices have been developed to ensure the continuous adaptation of the policies. The aim of the majority of the institutes interviewed is to formulate policies as concisely and precisely as possible in order to be able to extract recommendations for action, especially in the area of data preservation.
A detailed report of the findings from the interviews will be published as "D4.3, Roadmap for consolidating National Initiatives", of the EOCS-Pillar project.

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6 Appendix A - Comparative Legal Analysis

6.1 Introduction, methodology and structure of the analysis

This report will provide a comparative analysis of the legal landscape relevant for the development of open access and open data research policies, and for the building and maintenance of open research infrastructures. The aim of the study, commissioned in the context of the activities of the H2020 project *EOSC-Pillar*, is to lay the groundwork for the drafting of blueprint/guidelines for European researchers and institutions, which may assist them in publishing, sharing, and integrating research data, thus guaranteeing the openness of research data with the goal of promoting the FAIR principles beyond their original scope.

The following pages will provide a comprehensive review of existing EU and national legal sources involved in the realization of FAIR research data, about the publication, sharing, access and reuse of research products. To this end, the study will focus mostly on IP laws, privacy and data protection law, security, regulations on the re-use and management of Public Services Information (PSI), regulations on the free flow of non-personal data, and other provisions for cross-border data access. More specifically, the task will highlight the legal barriers to and flexibilities for access and reusability of research data due to IPR, particularly in light of the most recent reforms (eg the Directive on Copyright in the Digital Single Market – CDSM Directive, 2019/790/EU), and will study the relevant implications of the new PSI Directive (Directive 2019/2014/EU) on open data and the reuse of public sector information as well as of the EU Regulation (EU) 2018/1807 on a framework for the free flow of non-personal data, and their relationships to the General Data Protection (GDPR, Regulation (EU) n.2016/679). The overview and analysis of EU legal sources will be complemented with a focus on their transposition in the legal systems of the five EOSC-Pillar Member States (Italy, Germany, France, Austria, Belgium) and with the study of eventual additional regulatory solutions developed at a national level.

The mapping of public regulatory sources is flanked by a concise overview of other contractual and technological constraints impacting on FAIR ecosystems and Open Access, such as meta-data governance and access, data pooling techniques functional to compliance, governance and data ownership for research data, interoperability including multinational and cross-border needs, anonymization and pseudonymization techniques, safeguards to re-use data, etc.

The task underlying this report has been conducted by means of desk research. In light of the territoriality and the incomplete harmonization of most of the bodies of law involved, the collection and analysis of legal sources have been carried out according to the principles and methods of comparative law. Convergences and divergences among legal systems are evaluated through a functional assessment, which privileges the focus on the effect of legal norms over their plain literal comparison. The study, now limited to hard and soft law sources, may constitute the platform for a subsequent follow-up analysis that may embed (i) the collection and analysis of national court decisions, if any, and (ii) a qualitative analysis of stakeholders' practices and perceptions of existing rules, to be conducted via analysis of policies and practices and via participatory research tools (eg survey, focus groups, semi-structured interviews), with the aim of evaluating the effectiveness and efficiency of regulatory solutions from an empirical user perspective.

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This report is structured in three parts. Part 1 focuses on IP law, and particularly on copyright and database regulations. Part 2 is centred on personal data protection, while Part 3 covers protection and use of non-personal data. Each part is articulated into sections devoted to single legal systems and elaborates on the provisions which were highlighted as relevant for EOSC purposes. The analysis offers a brief overview of the rights which may be held on different types of research outputs, followed by a more detailed description of exceptions, limitations, derogations, and other legislative flexibilities that allow open access and open uses.

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6.2 Part 1 – Intellectual property law

6.2.1 Introduction

IPR protects the moral and material interests of creators and inventors in enjoying the benefits arising from the exploitation of their inventions and intellectual creations. Subject matters, requirements for protection, rights granted, duration and exceptions vary depending on the IPRs involved. Almost all research products are potential subject matters of patents or of copyright.

Patents protect inventions - defined as technical solutions to technical problems - in all fields of technologies, with limited exclusions (e.g. laws of nature, diagnostic and therapeutic methods, plants and animals, etc.). They are granted upon the filing of an application before a national or regional patent office, which verifies that the invention is new, entails an inventive step or is non-obvious, and has an industrial application. A patent lasts for 20 years from the filing date and grants the rights to use, produce, sell, import the patented product, or to implement and use the patented process. National laws provide limited exceptions for, e.g., private non-commercial uses, experimental uses, prior uses and the like. Compulsory license schemes are in place to pursue public interest goals and block anti-competitive practices.

Copyright protects creative works in the field of literature, art, music, science, and covers not underlying ideas but their original, individual expression. Its scope was recently expanded to also cover software codes and databases. Copyright is granted for the mere fact of the creation, with no formalities needed to obtain protection. It lasts for 70 years after the death of the author, with shorter terms provided for specific works.[88] The bundle of rights granted to authors can be divided in two groups: moral rights, protecting the recognition of paternity and integrity of the work; and economic rights, granting exclusivity over, *inter alia,* the reproduction, distribution, communication to the public, display, performance, making available online of the work. National laws provide for a range of exceptions to exclusive rights, with the aim to balance copyright against conflicting public interests and private rights. The most common examples are exceptions for teaching and research, for quotation, parody, criticism and pastiche, for public lending, for news of public interest.

All IPRs are territorial. This entails that their validity is limited to the territory of the country granting or recognizing them, a country which will apply its own laws within its own courts. The territoriality of IPRs has a number of additional implications. For inventors and creators, it requires to secure protection in as many national markets as they intend to target. For users, it means uncertainty as to whether or not a specific product or work is protected, and according to which national law(s). In case of collaborative projects and activities having a transnational nature and/or taking place online, the territoriality of IPRs represents a constant source of doubts and challenges.

To tackle the differences in national laws, from 1883 on an increasing number of countries have stipulated international treaties and conventions setting common procedures for the granting of IPRs,

[88] For instance, in some jurisdictions non-original photographs are protected for up to 50 years after their creation; sui generis database rights last for 15 years after the creation; pseudonymous or anonymous works are protected for shorter terms, and always from the date of publication.

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and minimum common definitions and rules.[89] Since the 1980s also the European Union has engaged in a pervasive harmonization process, with the aim of eliminating the barriers that fragmented national IP laws were creating for the smooth functioning of the internal market. The standardization of national trademark laws has been coupled with the introduction of a unitary Community trademark.[90] Sensitive areas of patent law have been subject to *ad hoc i*nterventions (e.g. biotechnology), and the Unitary EU Patent is now on its way.[91] Copyright law has been by far the most intensively harmonized, with sectorial and horizontal directives and regulations from 1991 on. Notwithstanding the efforts, the EU copyright landscape is still fragmented, flawed with loopholes, and far from reaching the goal of a full convergence. At the same time, the introduction of a unitary copyright title is still not in the agenda of the EU legislator.

6.2.2 Focus of this part

Although patents are often used to protect the output of research activities, they play a minor role in the current FAIR Principles, Open Access and Open Science debate. In fact, repositories and research infrastructures handle information, data and works the great majority of which is protected – if at all – by copyright or related rights. The focus of this comparative assessment is thus limited to copyright law, with occasional references to patent law to the extent needed for the overall analysis.

6.2.3 Copyright: between EU and national laws

As mentioned above, since 1991 – the year of the first copyright Directive on the protection of computer programs – national copyright laws have been subject to numerous interventions of the EU legislator, directed to harmonize specific sectors, which were recognized as key for the functioning of the internal market.

As of today, EU copyright law provides for a common level playing field in the areas of software protection, database protection, rental and lending rights, duration of copyright, release right, neighboring rights, orphan works, exceptions for the production of accessible works for visually impaired individuals, satellite and cable transmissions, collective management of rights. Alongside these "vertical" interventions, the EU legislator has twice attempted to move towards a horizontal harmonization of copyright law, first in 2001 with the InfoSoc Directive (2001/29/EC),[92] and then in

[89] Almost all of them are administered by WIPO. See https://www.wipo.int/treaties/en/, last accessed 28 November 2020.
[90] Recently amended and recodified by Directive (EU) 2015/2436 to approximate the laws of the Member States relating to trade marks [2015] L336/1 and Regulation (EU) 2017/1001 on the European Union trade mark [2017] OJ L154/1.
[91] Directive 98/44/EC on the legal protection of biotechnological inventions [1998] OJ L213/13 and Regulation (EU) No 1257/2012 implementing enhanced cooperation in the area of the creation of unitary patent protection [2012] OJ L361/1, on which two subsequent acts were based: Council regulation (EU) No 1260/2012 implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements [2012] OJ L361/89, and the International Cooperation Agreement on the Unified Patent Court [2013] OJ C175/1.
[92] Directive 2001/29/EC on the harmonization of certain aspects of copyright and related rights in the information society [2001] OJ L167/10

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2004 with the Enforcement Directive (2004/48/EC),[93] the latter covering all IPRs. The InfoSoc Directive marked a turning point in the construction of EU copyright law. Born to address the challenges of digitisation, it standardized main exclusive rights, and provided a full list of optional exceptions, opening the gate for the even deeper harmonization led by the decisions of the Court of Justice of the European Union (CJEU).

This does not mean that national laws play no role in the copyright arena. On the contrary, they are still the main source of reference for non-harmonized areas such as authorship and co-ownership, or some exclusive rights such as adaptation. In addition, for long national legislators could enjoy a relatively broad discretion in setting the basic rules determining the copyright balance. In the past two decades, exclusive rights have moved towards an almost complete convergence, mostly due to the EU-level introduction of new "digital" rights and the consequent rearrangement of more "traditional" rights to align to the new classification of conducts under the scope of this or that entitlement.

Against this background, the following pages will analyze EU and national copyright exclusive rights and exceptions, putting greater emphasis on the flexibilities offered by the system to build a FAIR ecosystem and foster Open Access and Open Science principles and practices, particularly in light of the most recent reforms, which have significantly intervened on the matter. The overview of the five national copyright laws considered of this study will be limited to exceptions, and particularly to those elements of divergence from the EU model which may be relevant for cross-border research activities.

6.2.4 EU Copyright Law

6.2.4.1 Authorship

EU law does not offer a general definition of "author". References to the notion may be found only in the Software Directives I and II, Article 2, and in the Database Directive, Article 4, which use the same language to define the author of the program or the database as "the natural person or group of natural persons who created" the software or base "or, where the legislation of the Member States so permits, the legal person designated as the rights holder by that legislation".

Similarly, the two Directives regulate the ownership of economic rights over collective works, attributing them to the person considered by the national legislation as the author-coordinator (Article 2(2) Software II) or to the person holding the copyright over the base (Article 4(2) Database). In case of a database or program created "by a group of natural persons jointly", the exclusive rights shall be owned jointly (Article 2(3) Software II; Article 4(3) Database). Along the same line, Article 1(1) Directive 2011/77/EU qualifies as co-authors composer and lyricist of music works.

EU copyright law does not feature, instead, general rules applicable to collective or joint authorship. The matter is completely remitted to Member States' discretion – a circumstance that triggers fragmentation and substantial uncertainties in collaborative transnational projects and endeavors.

[93] Corrigendum to Directive 2004/48/EC on the enforcement of intellectual property rights (OJ L 157, 30.4.2004) [2004] OJ L195/16.

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6.2.4.2 Subject matter

EU Directives do not offer a general definition of protected works as most national laws do. References to the notion can be found only in the Database and Software Directives. Article 3(1) Database states that "databases which, by reason of the selection or arrangement of their contents, constitute the author's own intellectual creation, shall be protected as such by copyright. No other criteria shall be applied to determine their eligibility for that protection". Similarly, Article 1(3) Software II requests Member States to protect a computer program "if it is original in the sense that it is the author's own intellectual creation", adding that no other eligibility criteria may be added by Member States. Term Directives I and II[94] solved a long dispute on the copyright protectability of photographs by ruling that "photographs which are original in the sense that they are the author's own intellectual creation shall be protected" (Article 6).

Despite the silence of the InfoSoc Directive, a number of CJEU decisions[95] have used the definitions provided by these sector-specific directives to qualify as protected work any intellectual product which is original, for it constitutes its "author's own intellectual creation". This specification excludes, *inter alia*, mere ideas, facts and non-original objects (such as, eg, graphic-user interfaces[96] or sport moves[97]) from the subject matter of EU copyright.

Later on, in order to exclude from protection objects lacking definiteness and triggering legal uncertainty, the CJEU introduced another requirement, that is the nature of "expression" of the creation.[98] To be protected by copyright under EU law, a work should not only be original but also "expressed in a manner which makes it identifiable with sufficient precision and objectivity, even though that expression is not necessarily in permanent form".[99]

6.2.4.3 Duration (term of protection)

First in 1993, and then in 2006 and 2011, three Term Directives have almost fully harmonized the duration of copyright and related rights.[100]

General economic rights last for 70 years after the death of the author. Rights attributed to performers, producers of phonograms and broadcasters last for 50 years after the first fixation or broadcasting. Pseudonymous and anonymous works are protected for 70 years after they are first

[94] Council Directive 93/98/EEC harmonizing the term of protection of copyright and certain related rights [1993] OJ L290/9 (Term Directive I); Directive 2006/116/EC on the term of protection of copyright and certain related rights (codified version) [2006] OJ L372/12 (Term Directive II).
[95] The reference goes to the lines of cases stemming from the landmark decision Case C-5/08, *Infopaq International A/S v Danske Dagblades Forening* [2009] ECR I-06569.
[96] Case C-393/09, Bezpečnostní softwarová asociace - Svaz softwarové ochrany v Ministerstvo kultury [2010] ECR I-13971.
[97] Joined cases Football Association Premier League Ltd et al v QC Leisure et al (C-403/08) and Karen Murphy v Media Protection Services Ltd (C-429/08) [2011] ECR I-09083.
[98] Case C-310/17, Levola Hengelo BV v Smilde Foods BV, EU:C:2018:899, followed by Case C-683/17, Cofemel – Sociedade de Vestuário SA v G-Star Raw CV, EU:C:2019:721, and by Case C-833/18, SI and Brompton Bicycle Ltd v Chedech / Get2Get, EU:C:2020:461.
[99] Case C-310/17, *Levola Hengelo BV v Smilde Foods BV*, EU:C:2018:899, para 40.
[100] After Term Directives I and II, see also Directive 2011/77/EU amending Directive 2006/116/EC on the term of protection of copyright and certain related rights [2011] OJ L265/1.

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made available to the public, while previously unpublished works which are published after copyright expired gain back protection for 25 years. Special rules of calculation are introduced to regulate the expiry of copyright over collective works, collections, cinematographic or audio-visual works. The newly introduced press publisher right (Article 15 CDSM Directive[101]), which belongs to the category of neighboring rights, expires 2 years after publication.

6.2.4.4 Exclusive rights

The first exclusive rights harmonized by the EU legislator were those granted on software programs and databases.

The Software Directives[102] attributed to rights holders the right to do or to authorize (i) the permanent or temporary reproduction of the program, by any means and in any form, in part of in whole, including also reproduction necessary for loading, displaying, running, transmitting or storing the computer program; (ii) the translation, adaptation, arrangement and any other alteration of the program, and (iii) any form of distribution to the public of the program or its copies, rental included (Article 4).

The Database Directive[103] introduced two groups of rights. The first one is the copyright over the original selection and arrangement of the database content and includes the right to carry out or to authorize, as in the Software Directive, reproduction, adaptation and distribution (Article 5). The second is the *sui generis* right. It is granted upon evidence of a qualitatively and/or quantitatively substantial investment in obtaining, verifying or presenting the database content, and entails the right to prevent extraction and re-utilization of the whole or of a substantial part of the database (Article 7).

In 2001, in response to the digital and Internet revolution, and to the input coming from the World Intellectual Property Organization (WIPO) with the WIPO Internet Treaties,[104] the EU legislator enacted the InfoSoc Directive, which constituted the first attempt of horizontal harmonization of EU copyright law. The InfoSoc Directive introduced three main exclusive economic rights: (i) the right of direct and indirect, temporary or permanent reproduction, in whole or in part, for authors, performers, phonogram producers, producers of first fixations of films and broadcasting organizations (Article 2); (ii) the right of communication to the public and the right of making available to the public, by wire or wireless mean, the second in such a way that members of the public may access them from a place and at a time individually chosen by them (Article 3);[105] (iii) the right of distribution of original

[101]Directive EU 2019/790 on copyright and related rights in the Digital Single Market and amending Directives 96/9/EC and 2001/29/EC [2019] OJ L130/92

[102] Directive 91/250/EEC on the legal protection of computer programs [1991] OJ L122/42, codified by Directive 2009/24/EC on the legal protection of computer programs [2009] OJ L111/16 (hereinafter Software Directive I and Software Directive II).

[103] Directive 96/9/EC on the legal protection of databases [1996] OJ L77/20.

[104] WIPO Copyright Treaty, Dec. 20, 1996, S. Treaty Doc. No. 105-17 (1997); 2186 U.N.T.S. 121; 36 I.L.M. 65 (1997) WIPO Performances and Phonograms Treaty, Dec. 20, 1996, S. Treaty Doc. No. 105-17 (1997); 2186 U.N.T.S. 203; 36 I.L.M. 76 (1997)

[105] The making available right is extended also to performers, phonogram producers, producers of first fixations of films and broadcasting organisations, while the right of communication to the public for the same neighboring rights holders is regulated by the Rental and Lending Directive (Directive 2006/115/EC on rental right and lending right and on certain rights related to copyright in the field of intellectual property [2006] OJ

or copies, by sale of otherwise, subject to exhaustion after the first lawful sale or other transfer of ownership.

Aside from the related rights of performers, producers of phonograms, producers of first fixation of films and broadcasting organizations, harmonized (also) by the Rental Directives,[106] the Term Directives introduced two further optional related rights for critical and scientific publications of public domain works, and for previously unpublished works of authorship in public domain (Article 8). The ambitious, recent Directive on Copyright in the Digital Single Market (CDSM Directive, 2019/790/EU) added yet another related right – or ancillary copyright -, this time for press publisher, consisting in the right of reproduction and making available for the online use of their press publications by information society service providers (Article 15).

6.2.4.5 Exceptions and limitations

The area of copyright exceptions and limitations deserves the most attentive analysis, due to the crucial role they play in realizing the copyright balance and creating the condition for the establishment and promotion of open research environments.

The EU system of copyright exceptions is based on a closed list of provisions, which are subject to strict interpretation. Since we miss general open clauses that can be used as flexible tools by courts to adapt existing laws to new phenomena, every time a new balancing need emerges due to technological, social or economic evolutions, the EU legislator is compelled to intervene and introduce new ad hoc limitations. Some of them are mandatory, that is they should be implemented by Member States in their own national laws. Others are optional, *id est* Member States are free to adopt them or not depending on their policy choices and needs. This has led to the incremental creation of a patchwork of exceptions disseminated in various Directives, transposed in a possibly more fragmented manner at a national level. The situation appears rather peculiar, especially if compared to the maximum harmonization of exclusive rights.

For the sake of conciseness, this report focuses only on exceptions that are considered relevant for the fostering of FAIR ecosystems and for the development of reliable and resilient open access and open science policies in the EU research environment.

The exceptions feature in three different Directives:

- In **Article 5(3)(a) InfoSoc,** it allows the reproduction and communication to the public of any protected work “for the sole purpose of illustration for teaching and scientific research”, to the extent justified by the non-commercial purpose of the use. It is mandatory to indicate the source and the author, unless impossible. The exception has an optional nature.
- In **Article 10(1)(d) Rental II**, it provides for a limitation to the rental and lending rights for uses “solely for the purposes of teaching and scientific research”. The exception has an optional nature.
- In **Article 5 CDSM,** it provides for a limitation to the right of reproduction, communication to public, sui generis database rights, press publisher’s right, to allow the **digital use** of works or

L376/28, codifying and repealing Directive 92/100/EEC, on rental right and lending right and on certain rights related to copyright in the field of intellectual property [1992] OJ L346/61)

[106] Ibid.

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other subject matter "for the sole purpose of illustration for teaching", to the extent justified by the non-commercial purpose. It is mandatory to indicate the source and the author, unless impossible. The use should be carried out under the responsibility of an educational institution based in the EU, which makes content accessible only to its students. The exception has a mandatory nature, but Member States can exclude some uses or some works from its scope, and/or subordinate its exercise to the payment of fair compensation to rights holders. In order to avoid the problems arising from differences in national laws in case of cross-border activities, as it is the case for digital teaching activities, the provision introduces a country-of-origin principle, ruling that the applicable law is the one of the State where the educational establishment is located.

Private use for non-commercial purposes. Article 5(2)(b) InfoSoc authorizes natural persons to make private copies of protected works, "for ends that are neither directly nor indirectly commercial". The exercise of the exception is subordinated to the payment of a fair compensation to rights holders, usually collected at a national level by collecting societies through private levies schemes. The exception has an optional nature, and it has been elaborated in detail by numerous CJEU decisions.

Text and data mining exceptions. The exceptions have been introduced in the CDSM Directive after years of heated debate on the constraints copyright enforcement imposed on TDM activities and the development of artificial intelligence and machine learning research. The Directive distinguishes two cases, depending on the purpose of the TDM activity. Both exceptions have a mandatory nature, and refer to the right of reproduction, sui generis database right and press publisher's right, with the exclusion of the right of communication to the public.

- **TDM for research (Article 3 CDSM Directive)** - The exception covers "reproduction and extractions made by research organizations and cultural heritage institutions in order to carry out, for the purposes of scientific research, text and data mining of works or other subject matter to which they have lawful access". Its users should ensure the adoption of an appropriate level of security in the storage and retention of works for subsequent verifications. At the same time, rights holders are allowed to apply measures to ensure the security and integrity of the networks and databases where the work or other subject matter are hosted.
- **TDM in general (Article 4 CDSMD)** - The exception covers "reproductions and extractions of lawfully accessible works and other subject matter for the purposes of text and data mining", with no limitation as to the beneficiaries. However, its exercise may be expressly excluded by rights holders, and the storage of copies may be limited.

Public lecture exception. Article 5(3)(f) InfoSoc allows the reproduction and communication to the public of "extracts of public lectures or similar works or subject-matter to the extent justified by the informatory purpose". It is mandatory to indicate the source and the author, unless it is proven impossible. The exception has an optional nature.

Quotation exception. Article 5(3)(d) InfoSoc allows the reproduction and communication to the public of "quotations for purposes such as criticism or review, provided that they relate to a work or other subject-matter which has already been lawfully made available to the public". The use shall respect fair practices and be up to the extent necessary for the purpose, with the mandatory indication of

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source and author unless it is proven impossible. The exception has an optional nature (but mandatory in the Berne Convention).

Library/CHI uses exceptions. A number of exceptions are provided for the benefit of libraries and other cultural heritage/educational institutions e.g.

- **Reproduction.** Article 5(2)(C) InfoSoc allows publicly accessible libraries, educational establishments, museums and archives to perform reproductions of protected works "which are not for direct or indirect economic or commercial advantage". The exception has an optional nature.
- **Digitisation and transmission on terminals.** Article 5(3)(n) InfoSoc allows libraries to perform acts of reproduction and communication to the public of protected works for uses "for the purpose of research or private study, to individual members of the public by dedicated terminals on the premises of [cultural] establishments". The exception, which has an optional nature, is applicable only to works and other subject matters contained in their collections which are not subject to purchase or licensing terms.
- **Public lending.** Article 6(1) Rental allows library to freely lend to the public works from their collection, subject to the payment of fair compensation to authors determined by Member States. The exception has an optional nature.
- **Preservation of collections (digitisation).** Article 6 CDSM Directive introduces an exception to the right of reproduction, the sui generis database right, the exclusive rights on software, and the press publisher's right in favor of cultural heritage institutions. The aim is to allow them "to make copies of any works or other subject matter that are permanently in their collections, in any format or medium, for purposes of preservation […] to the extent necessary for such preservation". The exception has a mandatory nature.

Marrakesh (accessibility for visually impaired individuals). To implement the WIPO Marrakesh Treaty, the EU enacted a Directive[107] and a Regulation,[108] the latter devoted to the import/export of works from and to extra-EU countries. Directive 2017/1564/EU introduces a mandatory exception, covering all copyright exclusive rights, related rights, and exclusive rights on software and database, in favour of visually impaired individuals and authorized entities, directed to allow the production (both individual and entities) and distribution/communication to the public of works (only entities) in accessible format. The Directive provides an ample definition of reading disabilities, gives the possibility to Member States to introduce mechanisms of fair compensation, and allows authorized entities to carry out the transformation of works in accessible format also on behalf of beneficiaries

[107] Directive (EU) 2017/1564 of the European Parliament and of the Council of 13 September 2017 on certain permitted uses of certain works and other subject matter protected by copyright and related rights for the benefit of persons who are blind, visually impaired or otherwise print-disabled and amending Directive 2001/29/EC on the harmonisation of certain aspects of copyright and related rights in the information society [2017] OJ L242/6.

[108] Regulation (EU) 2017/1563 of the European Parliament and of the Council of 13 September 2017 on the cross-border exchange between the Union and third countries of accessible format copies of certain works and other subject matter protected by copyright and related rights for the benefit of persons who are blind, visually impaired or otherwise print-disabled [2017] OJ L242/1.

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and entities from other Member States. Entities are authorized and recognized by each Member State, should be non-profit, and comply with a detailed list of obligations to control piracy risks.

Orphan works exception. Article 6 of the Orphan Works Directive[109] provides for an exception to the rights of reproduction and communication to the public of protected literary works in favour of cultural heritage institutions. It applies to works that are declared "orphan", i.e. without a traceable author, after a diligent search performed by a potential beneficiary of the exception and notified to the EUIPO, which manages the orphan works database. CHI may "use orphan works contained in their collections in the following ways: (a) by making the orphan work available to the public, […] [and] for the purposes of digitisation, making available, indexing, cataloguing, preservation or restoration". Fair compensation should be provided to rights holders who put an end to the orphan work status of the used content. The exception has a mandatory nature.

Out-of-commerce works exception. Article 8(2) CDSMD provides an exception to the right of reproduction, communication to the public, sui generis database right, exclusive rights on software, press publisher's right in favor of cultural heritage institutions, for them "to make available, for non-commercial purposes, out-of-commerce works or other subject matter that are permanently in their collections''. The author or other rights holders should be indicated unless it is proven impossible, and the communication of the works should take place on non-commercial websites. The exception has a mandatory nature, and it is flanked by parallel mandatory collective management schemes.

Other database exceptions. The Database Directive provides for specific exceptions to restricted acts under copyright and to the sui generis rights.

- As to **copyright**, the Directive allows the lawful user of a database to perform any restricted act if necessary to access the content of the database or to engage in its normal use. Article 6 also introduces three optional exceptions for reproduction for private purposes of a non-electronic database, for use of illustration for teaching and scientific research, for purposes of public security, and where other exceptions to copyright are extended to databases under national law.
- As to the **sui generis right**, Article 9 Database allows the extraction and re-utilization of a substantial part of the database for private purposes (in case of non-electronic databases), for teaching and scientific research, and for purposes of public security.

Other software exceptions. The Software II Directive provides specific exceptions to restricted acts, allowing:

- the reproduction, translation, adaptation, arrangement and other alteration of the program if necessary for its use by the lawful acquirer in accordance with its intended purpose, including for error correction.
- the making of backup copies by a person having the right to use the program.
- the observation, study and test of the functioning of the program in order to determine the ideas and principles underlying its elements

[109] Directive 2012/28/EU on certain permitted uses of orphan works [2012] OJ L299/5.

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- the reproduction of the code and translation of its forms when indispensable to obtain the information necessary to achieve the interoperability of an independently created program, upon specific conditions and within the limits listed in Article 6.

***De minimis* analogue use exceptions.** Article 5(3)(o) leaves Member States free to provide national exceptions to the right of reproduction, devoted to analogue uses having minor importance and no relevance for the internal market.

6.2.4.6 Copyright contracts

Despite the factual centrality of license agreements for the exploitation of works protected by copyright, relevant contract law rules remain mostly unharmonized in the EU. The interventions of the EU legislator have been limited to the provision of mechanisms of protection for individual authors and performers in specific cases, such as the transfer of copyright in return of a lump sum payment (Art. 1(2) Term Directive III), or the impossibility to waive the right to an equitable remuneration for performers transferring their rental right to producers (Art. 6 Rental Directive II). More recently, the CDMS Directive has substantially intervened on the asymmetries in the bargaining power of authors and publishers by introducing a general principle of fairness in the remuneration contractually offered to authors, best-seller clauses and renegotiation of royalties in case of market success of the work, new rules on termination of contract and alternative dispute resolution schemes in case of conflicts, and provisions on purpose-limited exploitations. Other interventions on freedom of contract are the declaration of non-overridability of certain exceptions in license agreements, as it has been the case for the interoperability exception in the Software Directive, for the Marrakesh and orphan works exception, and for almost all the exceptions introduced by the CDSM Directive.

Because license agreements are usually not among the contracts typified by national laws, the lack of harmonized norms regulating copyright licensing practices has led to a significant fragmentation in market practices, impacting on the EU copyright harmonization. Against this background, a basic EU intervention would have been strongly needed but has never materialized beyond scattered steps directed to declare the mandatory nature of copyright exceptions or other balancing norms. And while recently the attention of legislators seems to have turned towards the author-publisher relationship, no effort has been made, neither at an EU nor at a national level, to operate a long-due reordering of the plethora of license agreement schemes developed in the private practice. In fact, open licenses such as Creative Commons and GPL would have benefitted from a legislative recognition, and legislators could have incentivized or imposed their use in particular areas where the all-rights-reserved approach may be detrimental to the copyright balance.

6.2.5 National copyright laws

The analysis of national copyright laws will be limited to areas not covered by the EU harmonization and to the sector of exceptions and limitations, due to their relevance for the project.

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6.2.5.1 Austria

6.2.5.1.1 Authorship

According to the Austrian *Urheberrechtsgesetz* (öUrhG),[110] the author is who creates the original work. The definition applies also to heirs and legatees unless proved otherwise (§10 öUrhG). Also the Austrian act contains a presumption of authorship, which attributes the qualification of author to the natural person who is indicated as such, unless proven otherwise (§12 öUrhG). In case of missing indication of the author, the editor or, if missing, the publisher is to be considered as an authorized representative of the author (§13 öUrhG).

As to co-authorship, all co-authors hold copyright jointly, if their contributions are indistinguishable contributions. If contributions are of different nature (e.g. literary, audio, visual works) no co-authorship can exist (§11 öUrhG).

6.2.5.1.2 Subject matter

The Austrian Copyright Act contains a long list of protected works (§§1 to 6 öUrhG), which is still deemed to be only exemplificative. It excludes from protection legislative acts, ordinances, government reports, court decisions, with the exception of geographical maps issued by government institutions, which enjoy copyright protection (§7 öUrhG).

6.2.5.1.3 Exceptions

Illustration for teaching and scientific research. While Article 5 CDSM Directive on the exception for digital teaching has yet to be implemented, Austrian law provides a number of exceptions in the field of illustration for teaching and scientific research. § 42g öUrhG allows schools, universities and education institutions to reproduce and communicate public works to a certain closed-number audience of students or participants for the purpose of teaching and education, within extent necessary and for non-commercial purposes. Works specifically intended for education markets are excluded from the provision, while audio-visual works can be used only starting from 2 years after their first publication. The exception is subordinated to the payment of fair compensation. A similar exception is provided for reproduction and material distribution, having identical constraints but for the lack of fair compensation. (§42(6) öUrhG). Schools, universities and other education institutions are also allowed to display music and audio-visual works for teaching purposes, and with the exclusion of certain movies that are specifically intended for education. Also in this case the exception is subordinated to the payment of fair compensation (§56c öUrhG). §71(3) öUrhG authorizes the use of a performance for non-commercial research or teaching purposes, requesting the indication of source unless it is proven impossible.

[110] Bundesgesetz über das Urheberrecht an Werken der Literatur und der Kunst und über verwandte Schutzrechte (Urheberrechtsgesetz). StF: BGBl. Nr. 111/1936 (StR: 39/Gu. BT: 64/Ge S. 19.) as last amended by BGBl. I Nr. 105/2018 (VfGH) (hereinafter öUrhG).

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Private use for non-commercial purposes. Under §42(2) öUrhG, anyone can reproduce a private copy on paper or other similar support for purpose of research and with non-commercial aim, with the exclusion of books and journals in full version and music sheets (§42(8) öUrhG).

Text and data mining. Austrian law does not contain any provision adequate to address TDM needs. Articles 3 and 4 CDSMD are yet to be implemented.

Public lecture. Under § 43 öUrhG, public speeches delivered in public or in public institutional settings or political assemblies can be reproduced, communicated, distributed for the purpose of information without the authorization of the rightsholder. If the speech has been fixed by means of an audio-recorder, the distribution requires consent of the author. The provision does not make any specific mentioning of public lectures/academic speeches.

Quotation. According to § 42f öUrhG, a published work can be used for quotation in the extent justified by the purpose. The provision mentions in particular the quotation of a work in a scientific work, but it is not limited to that. § 71(3) öUrhG adds to the general clause that performances can be freely used for non-commercial quotation purposes.

Uses in libraries and other CHIs. Cultural institutions can reproduce copies of the works in their collection for the non-commercial purpose of archiving, and also use such reproduced copies for the purpose of making available, lending, displaying the works in their collections (§42(7)(1) öUrhG). Under §56b öUrhG, libraries and cultural institutions can make available a maximum of two terminals per establishment to enable the access to works via screen or audio, for non-commercial purposes, and upon payment of fair compensation. The exception for digitisation of library collection provided by Article 6 CDSM Directive has yet to be implemented.

Marrakesh (accessibility for visually impaired individuals). §42d öUrhG implements the Marrakesh Directive by following consistently definitions and regulatory options of the EU text, particularly with regard to obligations imposed on entities (§6) and the scope of the exceptions for entities and beneficiaries (§7). Compared to the EU text, the Austrian act articulates in more details the description of “authorized entities” (§2) and copy in accessible format (§3), and decides to opt for the provision of financial compensation of authors “for the reproduction, distribution, broadcasting, making available to the public, public communication in accordance with § 40g as well as use for lectures, performances and presentations by an authorized entity for visual and reading disabilities with its registered office in Austria”, to be managed only by collecting society. The compensation should be calculated on the basis of “the special circumstances of the individual case and the fact that the activities of authorized entities for visual and reading disabilities are not for profit (…), as well as the objectives pursued by this provision which are in the public interest, the interests of people with visual or reading disabilities, the possible damage to authors and the need to ensure the cross-border distribution of reproductions in barrier-free formats.” The exception cannot be overridden by contract (§9).

Orphan works. The provisions (§56e öUrhG) are fully in line with EU law, with the specification of the purpose of access to cultural and political content, preservation and restoration.

Out-of commerce works. Although Article 8(2) CDSMD has yet to be implemented, §42(7)(2) öUrhG already states that cultural institutions can reproduce and make available copies of the out-of-commerce works.

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Other software exceptions. §40d öUrhG excludes the applicability to computer programs of the private copy exception, and it implements the Software Directive's exceptions - not overriddable by contract - of backup, study and test of the program functioning and lawful use. §40e öUrhG is devoted to decompilation and follows closely the text of the EU Directive.

Other database exceptions. §40h excludes the applicability of the private copy exception to database works, and it implements the Database Directive's exceptions for private use and lawful uses, excluding their waiver, but admitting agreements on the scope of the intended use.

Open repository right. Author of a scientific work who is affiliated to a research institute financed at least 50% by public funding, which appeared in a journal with at least 2 issues a year, who has licensed the rights to the publisher, retains the right to a second publication of the final accepted version for non-commercial purposes, after an embargo of 12 months for every scientific field. The provision cannot be overridden by contract and requires the mandatory indication of source of first publication (§37a öUrhG).

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6.2.5.2 Belgium

6.2.5.2.1 Authorship

The Belgian *Code de droit économique* (CDE)[111] defines as author the natural person who creates the work, and introduces a presumption of authorship, according to which it has to be considered as the author who is indicated as such, unless proven otherwise. The editor of an anonymous or pseudonymous work is to be considered as the author *vis-à-vis* third parties (Art. XI.170 CDE).

As to co-authorship, Art. XI.169 CDE provides that for works of collaboration in which the contributions of each author can be singularly identified, co-authors cannot use their own contributions for new collaborations, unless agreed otherwise, while they can use their own contributions in isolation without prejudice to the exploitation of the collaborative work.

6.2.5.2.2 Subject matter

The CDE offers a general definition of protected works, followed by a broad definition of protected literary works, including oral speeches. Official acts are excluded from protection (Art. XI.172 CDE).

6.2.5.2.3 Exceptions

Illustration for teaching and scientific research. Adding several specifications to the exception provided by the InfoSoc Directive, article XI.191/1 CDE, authors cannot prohibit (i) the use of the published work for citation for teaching or scientific research purpose within the extent necessary and complaint with fair practices; (ii) its free use in teaching activities (including for exams) inside or outside the educational establishment buildings; (iii) its non-commercial reproduction and communication to public for illustration for teaching within the extent necessary; (iv) the use of works by deceased authors for the compilation of textbooks ("anthologies") pursuing no direct or indirect economic profit and under the conditions of respect of the moral rights of the authors and of payment of fair compensation; (v) the reproduction and communication of the work by kindergartens/daycare centres ("établissements d'accueil de la petite enfance") for pedagogical purposes. It is mandatory to indicate sources and author, unless it is proven impossible. The exception for digital teaching provided by Article 5 CDSM Directive has yet to be implemented.

Private use for non-commercial purposes. Article XI.190(9) CDE provides a very broad private copying exception for copies of lawfully accessed works – music sheets excluded – by natural persons for non-commercial purposes, with no qualifying constraints but only the requirement of fair compensation.

Text and data mining. Belgian law does not contain any provision adequate to address TDM needs. Articles 3 and 4 CDSM Directive are yet to be implemented.

Public lecture. Under Article XI.172(1) CDE, public speeches delivered in legislative, judicial or political assemblies can be freely reproduced and communicated to the public, under the condition that only the author can withdraw them from the market. Differently than in other national laws, no specific

[111] Code de droit économique, 11-13, 077, 28 Fevrier 2013, as last amended by L 2019-05-02/28.

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reference is made to lecture or speeches in academic events, nor the provision fixes any quantitative limitation of use.

Quotation. In line with the Berne Convention and the InfoSoc Directive, Article XI.189(1) CDE states that authors cannot prohibit quotations of published works for purposes of criticism and review, to the extent justified by the purpose, and respecting fair practices. Author and sources should be mentioned unless proven impossible.

Uses in libraries and other CHIs. While Article 6 CDSM Directive on digital preservation has yet to be implemented, in line with the InfoSoc Directive, Article XI.190(12) CDE allows public libraries and other cultural institutions to reproduce a certain number of copies of works in their collection for purposes of preservation of the cultural and scientific heritage, with no commercial purposes. Fair compensation schemes apply. The public lending exception is provided for study and cultural purposes and it is not subject to fair compensation. It covers literary, musical and audiovisual works, for the latter two categories only 2 months after their first publication (Article XI.192 CDE).

Marrakesh (accessibility for visually impaired individuals). Under Belgian law, as long as the work is lawfully accessible, the author cannot prohibit any act necessary to make accessible format copies of the work or performance and to the exclusive use of the beneficiary, or any act carried out by authorized national entities necessary to make available accessible format copies to beneficiaries and other authorized entities across EU. (Artt.XI.190(15) CDE). Subsequent paragraphs specify technical elements of the functioning of the mechanisms, while paras 18 and 19 refer to the cross-border exchange of accessible works. Art.XI 299(2)(4) CDE and Art.XI.310(1)(1ter) CDE extend the Marrakesh exception to the realization of programs in accessible format and to the extraction, reproduction, communication to the public of part of a database to make that material accessible for visually impaired individuals. Ar

Orphan works. The provisions (Articles XI.129/1 and XI.218/1 CDE) are fully in line with EU law.

Out-of commerce works. While Article 8(2) CDSM Directive has yet to be implemented, Article XI.190(13) CDE allows libraries and other cultural institutions to communicate to the public from the terminals provided in their establishments, for the purpose of private study or research, out-of-commerce works included in their collections.

Other software exceptions. As in the EU text, Art.XI 299 CDE excludes the need for rightholder's authorization, absent specific contractual determinations, for acts necessary to use the program in conformity with its functions, including for the correction of errors (§1). Backup copies and study of functioning of the program are not subordinated to the absence of a different contractual specification (§2), and the same can be said of the interoperability exception under Art.XI.300(1), subject to the three-step test. All limitations are regulated using a language that is fully in line with the text of the Software Directive.

Other database exceptions. In line with EU law, the CDE includes an exception to the right of reproduction and communication to the public (copyright) and to the sui generis right on a lawfully accessed database, lawfully accessed, for lawful use personal use, public security, and non-profit teaching or research purposes (Art.XI.310(1)) The exception to the right of communication to the public is limited to educational establishments that are officially recognized, in the context of their

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activities, and upon implementation of appropriate safety measures, to the extent this does not prejudice the normal exploitation of the work (Art.XI.191/2 CDE).

Open repository right. According to Article XI.196(2/1) CDE, authors of scientific works stemming from research funded at least for 50% from public sources, who have granted an exclusive or non-exclusive license to a publisher, retain the right to make the work available in a free, open format, after an embargo period of 12 months in the field of social science and 6 months for other science. The provision applies also retroactively on scientific works published before the entry into force of the provision.

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6.2.5.3 France

6.2.5.3.1 Authorship

The French *Code de la Propriété Intellectuelle* (CPI)[112] provides for a presumption of authorship which defines as author everyone who is indicated as such, unless proven otherwise (Article L113-1 CPI). It also specifies that the editor or the publisher of an anonymous or pseudonymous work represents the author in the exercise of copyright (Article L113-6 CPI).

As to co-authorship, Article L113 CPI provides detailed definition of work of collaboration, composite work, collective work. A work of collaboration is co-owned by co-authors ("propriété commune"), and copyright shall be exercised on the basis of mutual agreement. In case of disagreement, a judge will decide. Contributions of different types can be exploited singularly by each respective co-author without prejudice to the work of collaboration. A composite work is owned by the author who created it without prejudice to the copyright of the author of the pre-existing work. A collective work is owned, unless proven otherwise, by the person indicated as the author. All contributors to audio-visual and radiophonic works are considered co-authors.

6.2.5.3.2 Subject matter

In line with the continental tradition and the Berne Convention, the CPI qualifies as protected work "any intellectual work of any genre, form of expression, quality or destination". The general definition is followed by a list of works traditionally classified as subject matters of author's rights. Titles of works are also included (arts. L112-1,-2,-3,-4 CPI).

6.2.5.3.3 Exceptions

Illustration for teaching and scientific research. Article L122-5(3°)(a),(e) CPI provides that authors cannot prohibit the inclusion of lawfully accessed works nor the reproduction and communication to the public of excerpts of the work for illustration for teaching or scientific research, under the condition that such uses do not have any commercial purpose and address an audience mostly consisting of students, teachers or researchers. The exception includes also uses for exams and tenders in educational environments, but excludes works specifically intended for educational uses and music sheets. It is mandatory to indicate the source and author, and a fair compensation system is envisioned based on lump-sum schemes. Article 5 CDSM Directive on digital teaching exception has not been implemented yet.

Private use for non-commercial purposes. With a text that partially differs from the related EU InfoSoc exceptions, according to Article L122-5(1) and (2) CPI, authors cannot prohibit the making of private copies of lawfully acquired works if they are not intended for a collective use. Artworks, software and databases are excluded from the provision, while fair compensation is due only when the use is not proportionate or does not relate to the exceptional informational purpose pursued by the exception.

[112] Code de la propriété intellectuelle, Partie législative, JO no 0153 du 03/07/1992, as last amended by Décret n°2020-946 du 30 juillet 2020.

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Text and data mining. While Articles 3 and 4 CDSM Directive are yet to be implemented, Art. L122-5(10) CPI already provides that authors cannot prohibit the electronic reproduction of lawfully accessed works for the extraction of data from scientific works having research and non-commercial purposes.

Public lecture. Under Article L122-5(3°)(c) CPI, authors cannot prohibit the distribution of public speeches at academic events, even in full, by the press or television for the purpose of information. It is mandatory to indicate the source and author of the work.

Quotation. In line with the Berne Convention, Article L122-5(3)(a) CPI provides that authors cannot prohibit quotation – albeit only short – of lawfully accessed works for the purpose of criticism, review, education, science and information, with the mandatory indication of source and author.

Uses in libraries and other CHIs. While Article 6 CDSM Directive has yet to be implemented, France already features a provision allowing libraries and other non-profit cultural institutions to reproduce and communicate to the public published works for purposes of preservation, access, private study and research (Article L122-5(8) CPI). Article L133-1 to –4 CPI allows the public lending of a work if subject to a publishing contract, subject to a fair compensation scheme managed by collecting societies.

Marrakesh (accessibility for visually impaired individuals). Arts. L122-5(1)-(2)-(7) CPI introduce the Marrakesh exception departing very limitedly from the text of the EU Directive, referring for the regulatory implementation of the details of the legislative mechanism to the Conseil d'Etat.

Orphan works. The orphan work exception follows the EU scheme, adding a legal presumption that authors do not oppose their reproduction and making it available to the public by cultural institutions.

Out-of commerce works. While Article 8(2) CDSM Directive has yet to be implemented, at the moment the French system provides for a mandatory collective management schemes of out-of-commerce works managed by collecting societies and having as object the right of reproduction and communication to the public of works that have not been commercialized for a certain period of time. The original scheme provided by French law was quashed by the CJEU in the *Soulier and Doke*[113] decision, and partially revisited while waiting for the implementation of the CDSM Directive.

Other software exceptions. Aside from the possibility granted to the author of a software program to oppose modifications of the code which would prejudice his honor or reputation (Article L121-7 CPI), the French CPI provides the EU-based mandatory exception of reproduction for lawful uses, backup copy, study of functioning and the mandatory interoperability exception (Article L122-6-1 CPI), all subordinated to the three-step test. Article L122-5(6) excludes the applicability of the private copying exception beyond backups.

Other database exceptions. Article L122-5(6) excludes the applicability of the private copying exception to databases, while Art. L122-5(2)-(5) covers the lawful use, private copy and teaching and research exception of the sui generis right.

[113] Case C-301/15, Marc Soulier and Sara Doke v Premier ministre and Ministre de la Culture et de la Communication, EU:C:2016:878

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Open repository right. Article L533-4 of the *Code de la Recherche*[114] provides that the author of scientific works funded at least for 50% with public funding coming from the State, public institutions or the EU, and resulting in contributions on journals publishing at least one issue a year, retains the right to a second publication in an electronic, open and freely accessible way of the final version of the manuscript, even when an exclusive license has been granted to the publisher. The embargo period can be maximum 6 months in the field of natural sciences and 12 months in the field of social sciences. The consent of co-authors, if any, is needed. The re-use of such works, once published in open access, is free and cannot be prohibited by rights holders, unless they are protected by specific rights or a particular regulation.

[114] https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000038588829

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6.2.5.4 Germany

6.2.5.4.1 Authorship

Under the German *Urheberrechtsgesetz* (UrhG),[115] the author is the creator of the work (§7 UrhG). Also here the act provides for a presumption of authorship, according to which the author is who is indicated as such, unless it is proven otherwise. In case of missing indication of the author, the editor or, if missing, the publisher is considered as authorized to assert the author's rights (§10 UrhG).

As to co-authorship, all co-authors jointly hold copyright if their contributions to the work are indistinguishable, and they are supposed to jointly exercise their rights of publication and exploitation (§8 UrhG). The author of a compound work needs the authorization of other authors to publish, exploit or alter the work, for no joint exercise of rights over the single contribution is allowed (§9 UrhG).

6.2.5.4.2 Subject matter

According to §§2-5 UrhG, the subject matter of copyright includes only author's own intellectual creations, which are exemplified in a list containing works traditionally included under the umbrella of author's rights. Official works and acts are excluded from the subject matter.

6.2.5.4.3 Exceptions

Illustration for teaching and scientific research. §60 UrhG identifies three exceptions for teaching and scientific research, all very narrowly tailored and very detailed. Paragraph A provides that up to 15% of a published work can be reproduced, communicated, distributed on a non-commercial basis for teachers, examiners, third party participants to education institutions and education activities. Full works can be used for the same purpose only if they are illustrations, singled-out articles of a professional or scientific journal, small-scale works and out-of-commerce works. Recording of a public presentation of a work, content specifically intended for education markets are excluded from the scope of this exception. Paragraph B states that up to 10% of a published work can be reproduced, communicated and distributed for media collections for teaching purposes. Paragraph C allows the reproduction, distribution and making available to the public of up to 15% of a work for the purpose of non-commercial scientific research (i) for a specifically limited circle of persons for their personal scientific research and (ii) for individual third persons insofar as this serves the monitoring of the quality of scientific research". It adds that up to 75% of a work may be reproduced for personal scientific research, and that full use may be made only of illustrations, isolated articles from the same professional or scientific journal, other small-scale works and out-of-commerce works. The entire provision cannot be overridden by contract (§60g(1) UrhG). § 47 UrhG contains the traditional teaching exception, stating that schools, teacher training and further training institutions may make individual copies of works to be used as part of a school broadcast by transferring the works to video

[115] Urheberrechtsgesetz vom 9. September 1965 (BGBl. I S. 1273), as last amended by Artikel 1 des Gesetzes vom 28. November 2018 (BGBl. I S. 2014) (hereinafter UrhG).

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or audio recording mediums exclusively for teaching purposes. The digital teaching exception under Article 5 CDSM Directive has yet to be implemented.

Private use for non-commercial purposes. With some additional specification compared to the text of the InfoSoc Directive, §53(2)(2) UrhG permits to make single copies of a work or to have these made for inclusion in a personal archive if and insofar as the reproduction is necessary for this purpose, and one's own personal copy of the work is used as the model from which the copy is made.

Text and data mining. Although Germany still has to implement the TDM exceptions provided by Articles 3 and 4 CDSM Directive, the German Copyright Act already features mechanisms allowing TDM activities. In order to enable the automatic analysis of large numbers of works for scientific research, §60d UrhG allows (I) the reproduction of the source material in order to create, particularly by means of normalisation, structuring and categorisation, a corpus which can be analysed and (ii) the making available of the corpus to a specifically limited circle of persons for their joint scientific research, as well as to individual third persons for the purpose of monitoring the quality of scientific research. Such uses are admitted only if for non-commercial purposes. Once the research work has been completed, the corpus and the reproductions of the source material shall be deleted. They may no longer be made available to the public. It is, however, permitted to transmit the corpus and the reproductions of the source material to specific institutions for the purpose of long-term storage. The provision cannot be overridden by contract.

Public lectures. Under §48 UrhG, it is permissible to reproduce and distribute public speeches for informative purposes, with no quantitative limitation. No specific mention is made to lectures or academic speeches. The exception does not cover the reproduction and distribution of public speeches in the form of a collection predominantly containing speeches by the same author. Similarly, §53(7) UrhG always requires consent of the rights holder for "the recording of public lectures, productions or performances of a work on video or audio recording mediums, the realisation of plans and drafts of artistic works and the reconstruction of architectural works".

Quotation. Adding more specification to the provision of the Berne Convention and the InfoSoc Directive, §51 UrhG permits the reproduction, distribution and communication to the public of a published work for the purpose of quotation so far as such use is justified to that extent by the particular purpose. The provision specifies that this should be particularly the case where after publication individual works are included in an independent scientific work for the purpose of explaining their content.

Uses in libraries and other CHIs. Although Article 6 CDSM Directive has yet to be implemented, German law already contains a number of provisions pursuing similar goals. Very punctually, §60e UrhG allows publicly accessible libraries, which neither directly nor indirectly serve commercial purposes, to reproduce a work from their collections or exhibitions, or have such a work reproduced, for the purpose of making available, indexing, cataloguing, preservation and restoration, including more than once and with technically required alterations. For restoration purposes, libraries may also distribute reproductions of a work to other libraries or to institutions, and lend restored works and copies of newspapers, out-of-commerce works or damaged works. Under §60f UrhG, archives which also act in the public interest may reproduce a work or have a work reproduced in order to include it as archival material in their collection. §60e UrhG also reports the InfoSoc exception that allows libraries to make works from their collections available to their users for personal research or private

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studies at terminals on their premises. The provision adds, however, a specification: patrons may reproduce for non-commercial purposes, to reproduce up to 10% of a work per session and to make reproductions of isolated illustrations, articles from the same professional or scientific journal, other small-scale works and out-of-commerce works. In addition, and in response to individual orders for non-commercial purposes, libraries may transmit to users reproductions of up to 10% of a published work or of isolated articles which have appeared in professional or scientific journals. None of these provisions is overridable by contract, except for the case of access from terminals in libraries and other institutions, where contractual agreements prevail.

Marrakesh (accessibility for visually impaired individuals). §45a(1) UrhG already provided for an exception to reproduction and distributions rights in order to facilitate access to protected works for people with disabilities "whose access to the work is, due to a disability, not possible or is made considerably more difficult by the already available means of sensual perception. The Marrakesh Directive has been implemented by §45b and §45c UrhG, which closely follow the EU text, and request equitable remuneration to be paid by authors via collecting societies. Authorized entities are regulated through acts emanated by the Federal Ministry of Justice and Consumer Protection.

Orphan works. Compared to the UE text, §61(4) UrhG adds a legal presumption according to which if the orphan works have already been made available to the public with the permission of the rights holder, it can be assumed in good faith that the rightholder would agree to the use" in libraries or other cultural institutions. Furthermore, the same exception is extended to the use of orphan works by public broadcasting organisations (§61c UrhG).

Out-of commerce works. Article 8(3) CDSMD has yet to be implemented. However, German law already contains provisions devoted to out-of-commerce works. §§53(2)(4)(b) makes it possible to make single copies of a work or to have these made for other personal use in the case of a work which has been out of print for at least two years. §53(4) UrhG specifies, instead, that the consent of the rights holder is always required for the reproduction of graphic recordings of musical works, a book or a periodical, in the case of an essentially complete reproduction, insofar as this does not occur by means of manual transcription, unless it is for personal use and the work has been out-of-commerce for at least two years. §53(6) UrhG specifies that the copies so made may neither be distributed nor communicated to the public, but it should be possible to lend lawfully produced copies of newspapers and out-of-commerce works.

Other software exceptions. The UrhG follows the Software Directive and includes exceptions for lawful uses, unless otherwise provided by contracts (§69d), making of backup copies and study or test of functioning of the program. §60e UrhG contains a faithful reproduction of the Directive's interoperability exception.

Other database exceptions. Apart from the text and data mining exception (§60d), §87c UrhG allows the reproduction of a qualitatively or quantitatively substantial part of a database in case of private use (but not for databases whose elements are accessible individually by electronic means), purposes of scientific research and illustration in teaching, court proceedings and purposes of public safety.

Open repository right. According to §38(4) UrhG, the author of a scientific contribution which results from research activities at least 50% of which were financed by public funds, and which was reprinted in a collection which is published periodically at least twice per year, has the right, if he has granted the publisher or editor an exclusive right of use, to make the contribution available to the public upon

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expiry of 12 months after first publication in the accepted manuscript version, unless this serves a commercial purpose. The source of the first publication must be cited. The provision is deemed mandatory and cannot be overridden by contract.

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6.2.5.5 Italy

6.2.5.5.1 Authorship

The Italian "Legge sul diritto d'autore" (l.aut.)[116] introduces a presumption of authorship, which identifies as author who is indicated as such, unless proven otherwise (art. 8 l.aut.). Whoever has performed ("rappresentato, eseguito") or published in any manner an anonymous or pseudonymous work is authorized to assert author's rights, until the author reveals him/herself (art.9 l.aut.). State, Provinces, Municipalities, non-profit private entities, universities, and cultural institutions hold the copyright of the works created and published on their behalf and under their financial sponsorship (art.11 l.aut.). Titles of works are covered by a neighboring right.

As to co-authorship, the author of a collective work is the natural person who organizes and coordinates its creation (art.7 l.aut.). If a created work sees the indistinguishable contributions by co-authors, joint ownership of copyright, civil code rules on joint ownership apply (art.10 l.aut.).

6.2.5.5.2 Subject matter

Art.2 l.aut. offers a general definition of protected works as creative intellectual works of literary, musical, figurative art, architectural, theatral, cinematographic nature, and couples it with an exemplificative list of works traditionally included within the subject matter of author's right (arts. 1 and 2 l.aut.). Among the exclusion from protection, it is worth mentioning official acts by the State and public administration of Italy and other national States (art.5 l.aut.).

6.2.5.5.3 Exceptions

The Italian legislator has implemented most of the optional exceptions provided by the InfoSoc Directive and fully aligned to the mandatory exceptions introduced by subsequent EU acts, adding some specifications.

Illustration for teaching and scientific research. While Article 5 CDSM Directive on the exception for digital teaching is expected to be implemented by the deadline of 7 June 2021, Article 70 l.aut. provides, in line with EU law, for an exception that covers reproduction and communication to the public ONLY of parts of works for teaching and scientific research purposes, without commercial aim. Italian law adds, however, also the possibility to publish via the Internet, for the same purposes and non-commercial aim, pictures and music works of lower resolution and quality (art.70bis), and provides for an ad hoc levy system to allow the unauthorized inclusion of works in textbooks ("anthology", art.70(3)). In any case, the indication of author, publisher, and translator if any is always mandatory.

Private use for non-commercial purposes. According to art.68(3) l.aut., modified to align with the InfoSoc Directive, the reproduction of a book or journal by photocopying or similar technique is allowed up to 15% of the work. Levy systems are introduced via Ministerial Decree to provide fair

[116] Law 22 April 1941 no. 66, Protezione del diritto d'autore e di altri diritti connessi al suo esercizio, in GU 16 July 1941, no.166.

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compensation. Music sheets are excluded from the scope of the exception. Art.68(4) provides for a similar *ad hoc* levy system for copy shops or shops making copy equipment available to the public.

Text and data mining. Articles 3 and 4 CDSM Directive are yet to be implemented. No other provisions can be used for the purpose.

Public lecture. Art. 66 l.aut. provides for an exception to the right of reproduction and communication to the public of public speeches and excerpts of public conferences in newspapers, news programs and information materials, to the extent necessary for the informatorily purpose, and with the mandatory indication of author, source, date and place.

Quotation. In line with the Berne Convention and the InfoSoc Directive, art.70 l.aut. authorizes the reproduction and communication to the public of protected works for quotation purposes aiming at criticism or review, to the extent justified by the purpose, and provided that it does not interfere with the economic exploitation of the work. Also in this case it is mandatory to indicate author, publisher and translator if any, unless it is proven impossible.

Uses in libraries and other CHIs. Italian law has not followed suit the evolution of EU law in this area. While the CDSM Directive art.6 exception has yet to be implemented, the Italian legislator has not implemented the exception on digitisation and communication via dedicated terminal (art.5(3)(n) InfoSoc). As a consequence, the Italian system provides only for the possibility to photocopy books available in libraries or archives if there is no direct or indirect economic purpose (art.68(2) l.aut.), subordinated to a levy system (art.68(5) l.aut.), and for the public lending of literary works, musical (music sheets excluded) and audio-visual works, the latter only after 18 months from distribution or, if not distributed, after 24 months from fixation.

Marrakesh (accessibility for visually impaired individuals). Article 71bis l.aut. mirrors the exception provided by the Marrakesh Directive with no substantial addition. Entities can claim from beneficiaries only the reimbursement of the cost for making the work accessible.

Orphan works. Art.69*bis* l.aut. provides that orphan works in libraries' collections can be used for digitization, indexing, cataloguing, preservation and for making them accessible to the public at any time from any place chosen by users. While libraries can stipulate contracts with third parties to further promote orphan works, this should not limit the scope of the exception (art.69*bis*(5)). I line with EU law, art.69*quinquies*(2) l.aut. introduces a mandatory fair compensation scheme for rights holders who put an end to the orphan status of their works, proportional to the use made of the latter.

Out-of commerce works. While art.8(2) CDSMD has yet to be implemented, art.68(5) l.aut. gives the possibility to reproduce for private non-commercial uses out-of-commerce works beyond the 15% limit set by art.68(3) l.aut.

Other software exceptions. Articles 64-ter l.aut. reports the exception to the right of reproduction for lawful uses, backup copies and study of the functioning of the program, as in the Software Directive. Also similar is the exception on interoperability (Art.64quater l.aut.). Both provisions are mandatory and cannot be overridden by contract, while the interoperability exception is subject to the three-step test.

Other database exceptions. The Italian copyright act includes the exception for lawful use, for private uses and for teaching and research purposes, with the same language used by the EU Directive and the same mandatory nature (Arts. 102ter(3) and 64-sexies(1)(a) l.aut).

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Open repository right. A very important provision for EOSC purposes is art.4 law no.112 of 7 October 2013, [117]which requests public institutions funding research to adopt measures to establish and promote the open access of the outcomes stemming from the research financed by them at least at 50%, if those outcomes come in the form of published articles in journals of at least 2 issues a year. Open access can be established by the published at first publication, or by way of second non-profit publication on public institutional repositories by 18 months (for natural sciences) or by 24 months (for social sciences) after first publication. Best effort shall be promoted among public institutions to merge the respective research databases. It has to be noted that the provision introduces an obligation for public funding institutions, not a right for authors, and that it excludes its application on research products which are protected by the Industrial Property Code (id est by patents and other IPRs except copyright).

[117] Law 7 October 2013, n.112, Disposizioni urgenti per la tutela, la valorizzazione e il rilancio dei beni e delle attività culturali e del turismo, in GU no.236 of 8 October 2013.

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6.3 Part 2 – Personal data protection law

6.3.1 Introduction

The EU Regulation 2016/679 (General Regulation on the Protection of Personal Data, hereinafter also "GDPR")[118] entered into application on 25 May 2018. It increased the general attention placed on the so-called protection of privacy in all activities, public or private, by introducing certain principles aimed, on the one hand, at regulating data flows, in the awareness of the indispensable role played by the information society today and, on the other one, at obliging the data controllers (i.e. who determines the means and purposes of the processing) to put in place a series of technical-organizational measures aimed at protecting fundamental rights and freedoms of the data subjects (i.e. who can be identified, directly or indirectly, as a consequence of the data processing).

For these reasons, notions, principles, and the obligations set by the GDPR strongly impact on research activities processing personal data and their main regulatory framework aimed at developing FAIR ecosystems.[119]

Privacy prevention, in fact, constitutes one of the barriers to open data pilots because personal data flows might be enabled only if necessary under a specific purpose (*infra*).[120] Nevertheless, the GDPR compliance process ensures the implementation of those technical measures aiming at processing data in a safe environment. Therefore, the robustness of a whole FAIR ecosystem that includes personal (we will see at least pseudonymized data) is boosted by the GDPR boundaries. From a practical perspective, indeed, the data controller who has to protect personal data in terms of availability, integrity, and confidentiality, will design a robust infrastructure that could be used also to process non-personal data. In this regard, GDPR compliance is one of the requirements that support FAIR principles and Open Science in terms of accountability, ethics, safety, and integrity.[121]

6.3.2 Notions, principles, and obligations

According to article 4 GDPR, personal data is any information concerning a data subject. Due to their nature, two broad classifications are identified: data of a general nature (such as personal data, mobility data, etc.) and data belonging to particular categories that can reveal the so-called sensitive information. The latter category includes genetic data, biometric data, those that reveal a vulnerability

[118] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) [2016] OJ L119/1

[119] European Commission. Turning FAIR Data into Reality: Final Report and Action Plan from the European Commission Expert Group on FAIR Data.; 2018. https://publications.europa.eu/en/publication-detail/-/publication/7769a148-f1f6-11e8-9982-01aa75ed71a1/language-en/format-PDF Accessed December 6, 2018

[120] Article 29 WP, Guidelines on consent under Regulation 2016/679, adopted in November 2017 and revised in April 2018, in https://ec.europa.eu/newsroom/article29/item-detail.cfm?item_id=623051 e EDPB, A Preliminary Opinion on data protection and scientific research, https://edps.europa.eu/sites/edp/files/publication/20-01-06_opinion_research_en.pdf EDPB, Guidelines 03/2020 on the processing of data concerning health for the purpose of scientific research in the context of the COVID-19 outbreak, in https://edpb.europa.eu/sites/edpb/files/files/file1/edpb_guidelines_202003_healthdatascientificresearchcovid19_en.pdf

[121] Sparc Europe, Research Integrity through Open Science and FAIR Data, March 2019, https://sparceurope.org/download/7380/

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or provide a possible ground for discrimination - political opinions, philosophical opinions, religious belief, race, sexual orientation, etc. - as well as personal data relating to the physical or mental health of a person.

Personal data processing can be **pseudonymized** through obscuring techniques or by associating codes with identifiers through tokens in order to make the data subjects re-identifiable only through a re-association of the key by the data controller. In case of destruction of the re-association key, the data are considered to be made anonymous.[122] Pseudonymization is also recalled by article 89 GDPR to enable data processing for research and statistics purposes (see *infra*).[123]

Personal data processing consists of any operation, or set of operations, either with automated processes or manually carried out such as "*the collection, registration, organization, structuring, storage, adaptation or modification, extraction, consultation, use, communication by transmission, dissemination or any other form of making available, comparison or interconnection, limitation, cancellation or destruction*". In the life-cycle of a given research, researchers might control any of the mentioned activities to produce their outputs. This is true both within social and hard sciences.

Article 5 GDPR sets out the principles applicable to all personal data processing: lawfulness, correctness, transparency that are implemented through the technical-organizational measures, adopted by the data controller for each processing in order to justify it in terms of purposes limitation, minimization, and proportionality. Each processing operation must be either justified on a legal basis described under articles 6, 9, and 10 of the GDPR or functional as well as limited to the accomplishment of a purpose through methods that allow not to exceed in terms of quality, quantity of personal information, or methods of the data processing.

The data subjects must be aware of the characteristics of each data flow in order to exercise their rights. Under articles 15 ff. of the GDPR, among the rights that the data subjects can exercise, there is the right to access their personal data, to rectify those data that are inaccurate and to integrate those that are incomplete, to cancel (to be forgotten), unless there is a legitimate overriding reason for proceeding in any case to the processing, to the limitation of the same processing in the cases provided for by article 18 GDPR and national implementations. The data subject has also the right to object to the processing of their personal data, to revoke any consent given for non-mandatory processing of the data, without thereby compromising the lawfulness of the processing based on the consent given before the revocation, to exercise portability, or to make the flow of data interoperable, and allow its transfer to third parties. Moreover, the data subject has the right not to be subjected to a decision based solely on automated processing that produces legal effects concerning him/her or that significantly affects his/her person, unless some conditions are met. Finally, the data subject may lodge a complaint before the Data Protection Authority under article 77 of EU Reg. 679/2016. These rights might be limited under article 89 GDPR in case of data processing for research and statistics purposes.

[122] Irish Data Protection Authority, Guidance note: Guidance on Anonymization and Pseudonymization, 2019, https://www.dataprotection.ie/sites/default/files/uploads/2019-06/190614%20Anonymisation%20and%20Pseudonymisation.pdf

[123] ENISA, Pseudonymisation techniques and best practices Recommendations on shaping technology according to data protection and privacy provisions, https://www.enisa.europa.eu/publications/pseudonymisation-techniques-and-best-practices/at_download/fullReport

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This system of general principles and rights of the data subject falls within a paradigm of obligations and responsibilities of those who carry out the data processing who must implement technical measures (connected to the protection of the data in terms of availability, integrity and confidentiality) and organizational ones (connected to mapping activities under article 30 GDPR, as well as designing the internal and external governance), aimed at demonstrating the so-called GDPR compliance with respect to the carried-out activities.

Personal data, both general and belonging to special categories, can be processed where there is a legal basis that makes the processing operation lawful in compliance with the aforementioned principles and allowing the exercise of the illustrated rights.

In particular, pursuant to art. 6 GDPR, common data can be processed if the data subject has given his/her consent, or there is a contractual relationship between the parties, or the processing is carried out in compliance with a legal obligation, or if it is set for the protection of vital interests of the person concerned or a third party, is necessary for the execution of an institutional activity (public interest or connected to the exercise of public authority), or it is necessary for the pursuit of a legitimate interest of the data controller or third parties after balancing rights of the data subjects.

Under article 9, paragraph 1, GDPR, however, personal data belonging to special categories cannot be processed unless the conditions of lawfulness provided for by paragraph 2 of the same article apply. As for general data, the consent, the protection of a vital interest of the data subject or of a third party and the relevant public interest on the basis of an EU or national regulatory source could justify the processing. In addition to these legal bases, other conditions applicable in various contexts may find application: such as the fulfilment of obligations or the exercise of rights in the field of labour law, social security and social protection as provided for by European, national or collective agreements, such as activities of associations or non-profit organizations that pursue political, philosophical or religious or trade union purposes in relation to the data of members and former members; such as the data made manifestly public by the data subject and, finally, the ascertainment, exercise or defence of a right before the court. It is noteworthy for this report a specific provision technically not devoted to research, but highly relevant in the framework of open and FAIR data. Beyond the possibility of leveraging consent, it is useful to recall the legitimate basis under art. 9(2) lett. e) GDPR, regarding the processing of sensitive data that are “manifestly made public by the data subject” since it equally implies the release of personal data based on the data subject’s will. It however appears to be particularly problematic, since it could be applied to all the data that are “made public” online, in social networks or in specific online communities, without the need of a consent, be it of specific or of broad nature, or the enactment of safeguards offering the outer limits of the perimeter of a lawful data processing of sensitive data. This basis could thus potentially legitimate free flows of sensitive data as a result of their publicity. Nonetheless, the applicability of general data subjects’ rights under Chapter III GDPR still assures the preservation of a certain degree of individual control over such data flows and ability to contest the requirement of being “manifestly made public”. Yet, the circulation regime would remain in the hands of data subjects.

Conversely, as we will analyse in the next paragraph, Article 9, sub j) justifies the data processing is “necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide

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for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject".

Among the innovations introduced under the new regulation there is the professional figure of the data protection officer (DPO) made mandatory in public bodies and organizations that process data belonging to particular categories on a large scale. Article 39 GDPR states the tasks that the DPO has to undertake: to inform and provide advice to the data controller or data processor as well as to the employees who carry out the data processing regarding the obligations deriving from the GDPR, to monitor compliance with them, to provide, if requested, an opinion on the impact assessment under article 35 GDPR – that is the operation aimed at identifying the technical-organizational measures aimed at mitigating the risk of processing on the fundamental rights and freedoms of the data subject in order to make the latter acceptable and compliant with the legislation according to the applicable standards and knowledge, to cooperate with the data protection authority and to act as a contact point. The DPO is often supported by boards or committees that interact with the structures dedicated to the multiple activities (and consequent processing purposes). Tailored skills and competence of the DPO aligned to the activities performed by the data controller could facilitate the compliance process, especially where sensitive data are processed.[124]

Under article 24 GDPR, the data controller has a series of obligations and responsibilities that require the need to demonstrate that it has adopted adequate technical-organizational measures to guarantee the protection of the rights and freedoms of individuals in consideration of the nature and scope of the given application, of the context and purposes of the processing, and of the outcome of any impact assessment carried out under 35 GDPR. In this framework, oriented to the prevention and mitigation of risks with the interplay of several roles, the implementation of a complex system of checks and balances and the allocation of responsibilities are required to let the data subject maintain control over his/her own personal data. The data controller shall guarantee it.

It is not a coincidence that the GDPR provides under articles 32-34 GDPR a series of obligations, including the adoption of adequate security measures and specific communication protocols of any security incidents: the so-called data breach. The latter is defined as any loss or unauthorized access, even accidental, to personal data, so only in the case in which the accident has not caused a possible harm to the freedoms of the data subjects it shall not notify the breach to the Authority. The risks associated with a data breach range from human / organizational error to external threats (e.g. hacker attacks on information systems).

Not every data breach corresponds to the identification of a reprehensible conduct by the data controller: however, it is up to the latter to prove, pursuant to the principle of accountability, that he/she has mapped the type of data processing and based on its characteristics, have identified, and implemented the appropriate measures to ensure the rights and freedoms of the data subject. Monitoring, auditing, and internal inspections are, in this perspective, good practices generally applied also in the research contexts.

Despite many references to technical and "security measures" in order to meet the compliance requirements, the GDPR does not introduce specific standards, but it recalls only pseudonymization

[124] Douwe Korff and Marie Georges, The DPO Handbook, 2019, https://www.garanteprivacy.it/documents/10160/0/T4DATA-The+DPO+Handbook.pdf

and encryption techniques as possible examples of technical safeguards. Any peculiar safeguard is assigned as a consequence of the impact assessment under article 35 GDPR.

6.3.3 Legal basis and safeguards to enable data processing for research purposes

The harmonization provided by GDPR at EU level has some exceptions that impact on the purposes of open data. In fact, as anticipated, article 89 GDPR establishes a favour for research and statistics purposes, opening to an exceptional regime aimed at facilitating data controllers.[125] At the same time, however, it creates possible conflicts of laws as it allows States Members to introduce national safeguards to better protect data subjects in case of personal research data.

According to the article 89 GDPR, data processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes, in fact, shall be subject to appropriate safeguards. The same article refers to pseudonymization as the first measure aimed at achieving the minimization purposes. For further processing, it states that a further level "which does not permit or no longer permits the identification of data subjects" should be gained. However, technically, it does not exist a unique criterion of anonymization. Data can be considered anonymized having regard to any methods reasonably likely to be used by the data controller (or any third party) to reverse the process and allow the re-linking of the data subject. The assessment is based on the risk of re-identification through a rational effort.

Therefore, the pseudonymization standard could be always obtained through technical separation of information, considering several levels (e.g., scrambling, encryption, masking, tokenization, data blurring, etc.) while the anonymization could be achieved by the combination of technical and organizational measures as well, considering the features of the data controller. Art 89 GDPR obligation\indication to use "further processing which does not permit or no longer permits the identification of data subjects" (**anonymous data**) if the purposes of processing can be fulfilled with these data. This is in line with art. 2 GDPR and referral 26 and with art. 6(4) at least as a safeguard for further processing. Note, however, that such a notion can be fine-tuned for the interest of the data controller as well by pairing the choice of selecting processing modalities which do not require identification (art. 11 GDPR). If the controller is able to demonstrate that it is not in a position to identify the data subject, and upon informing the data subject, if possible, articles 15 to 20 shall not apply (except where the data subject, for the purpose of exercising his or her rights under those articles, provides additional information enabling his or her identification). For example, separating permanently a pseudonymized dataset from the dataset of the corresponding identifiers can easily fulfil this anonymity safeguard discharging the data controller by several burdens. Note, however, that art. 89 GDPR **imposes a principle of segregation** of data processing since derogations are strictly connected to research purposes and cannot spillover other data processing purposes (art. 89(4)).

National implementations of the article 89 GDPR focused on these profiles (*infra*). However, none of them deals with specific technical standards neither for identifying pseudonymization levels nor for specifying encryption methods. In addition, the GDPR does not list any security (physical or digital) measure to design a robust security system. In this regard, the ENISA Agency has developed some

[125] EDPS, A Preliminary Opinion on data protection and scientific research, 6.11.2020, https://edps.europa.eu/sites/edp/files/publication/20-01-06_opinion_research_en.pdf

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guidelines and standards that are generally shared in terms of best practices, addressing how to manage cybersecurity and possible breaches in specific sectors, like manufacturing, IoT, etc[126]. These reports could play a useful role during the data protection impact assessment under article 35 GDPR as they identify practical physical as well as digital measures that can be either applied as a parameter to assess the risk or as a possible measure to be implemented to mitigate it. However, they are not enforceable. They may contribute to meet a higher accountability standard.

6.3.4 Secondary use and re-use of personal data flows for research purposes

Article 5 GDPR opted for the presumption of compatibility of research purposes with any initial purpose of data collection. This presumption is conditioned to the need that the requirements provided under Article 89 GDPR are met and therefore appropriate technical and organizational safeguards, such as pseudonymization and access limitations are ensured.[127] Considering this presumption whereas the initial purpose of collection already deals with research purposes, any other re-use of research data shall be presumed lawful.

From this perspective, the EU data protection framework contributes to the purposes of open science and open data laying down a solid legal basis to enable further data processing for research purposes. However, the interplay of national implementations insisting both on technical and organizational measures aimed at defining the accountability model to collect, cure, and share data. In addition, considering that the different fields of application of research activities arise a plurality of needs to protect individuals and groups of stakeholders that may be involved in the life-cycle of the research, a complex system of legal constraints shall be analyzed to ensuring a fully and tailored compliant approach towards the development of FAIR ecosystems. Therefore, a general overview could be useful to raise awareness and develop a legal attentive methodology towards research.

6.3.5 National safeguards for research purposes

As stated, the flexible approach provided by article 89 GDPR brought many EU countries, and in particular the ones we are going to analyze – Austria, Germany, Italy, France, and Belgium – to introduce possible safeguards.

From the mapping of the national legislative initiatives on the topic, we remark three main elements that affect the harmonization and shall be properly addressed to possibly extract guidelines: I) the national regulatory frameworks are not enacted by equivalent legal sources, as national legislators introduced exceptions both by hard law and soft law instruments; II) where introduced, they deal with different profiles, therefore a common core on a given issue is difficult to identify; III) provisions do

[126] ENISA, Guidelines for Securing the Internet of Things, 2020, https://www.enisa.europa.eu/publications/guidelines-for-securing-the-internet-of-things; ENISA, Good Practices for Security of Internet of Things in the context of Smart Manufacturing, 2018, https://www.enisa.europa.eu/publications/good-practices-for-security-of-iot/at_download/fullReport; ENISA, Privacy and data protection in mobile applications A study on the app development ecosystem and the technical implementation of GDPR, 2017, https://www.enisa.europa.eu/publications/privacy-and-data-protection-in-mobile-applications/at_download/fullReport

[127] EDPS, European Data Protection Board, Opinion 3/2019 concerning the Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection regulation (GDPR), 23 January 2019, https://edps.europa.eu/sites/edp/files/publication/20-01-06_opinion_research_en.pdf

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not rely with technical standards. From this perspective, the efforts emerging from specific issues are a good basis for a general assessment of legal constraints to open science and open data.

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6.3.5.1 Austria

Relevant legislative initiatives

- Federal law on general matters according to Art. 89 GDPR and the research organization (Research Organization Act - FOG) StF: BGBl. No. 341/1981 as amended by BGBl. No. 448/1981 (DFB) (NR: GP XV RV 214 AB 778 p. 81. BR: p. 413).
- Federal law for the protection of natural persons in the processing of personal data (Data Protection Act - DSG) StF: Federal Law Gazette I No. 165/1999 (NR: GP XX RV 1613 AB 2028 S. 179. BR: 5992 AB 6034 S. 657).

Issues

- Field of application Art. 2b: it includes private and public universities and other research institutes.
- Confidentiality obligations and data secrecy are required under Art. 2d: “Verantwortliche und Auftragsverarbeiter, die personenbezogene Daten auf Grundlage dieses Abschnitts verarbeiten und ihre Mitarbeiterinnen und Mitarbeiter - das sind Arbeitnehmerinnen und Arbeitnehmer (Dienstnehmerinnen und Dienstnehmer) und persons in einem arbeitnehmerähnlichen (dienstnehmerähnlichen) Verhältnis - haben personenbezogene Daten, die ihnen ausschließlich auf Grundlage dieses Abschnitts anvertraut wurden oder zugänglich geworden sind, unbeschadet sonstiger gesetzlicher Verschwiegenheitspflichten, geheim zu halten, soweit kein rechtlich zulässiger Grund für eine Übermittlung der anvertrauten oder zugänglich geogeniswordenen”.
- Organizational safeguards under Art. 2d include:
    - Use and legal basis of the data processing shall be available on internet.
    - Pseudonymization or data publicly are information that shall be available (section 2 §7 DSG).
    - DPO appointment is required.
    - Internal and external governance shall be designed and implemented.
    - Training, instructions before authorizing the access to data shall be performed.
    - DPIA under article 35 shall be performed.
- Legal basis section 2 §7 DSG
    - Personal data can be processed for research purposes if data are publicly accessible, the data controller has legitimately determined means and purposes for previous research and data are pseudonymized.
    - Special regulations may provide a legal basis, with the consent of data subject, otherwise under the approval of data protection authority after DPIA has been performed. Before the authority, the data controller shall prove to be credible, obliged to confidentiality, and reasons why the data subject’s consent cannot be collected.

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- In the context of big data, personalized medicine, biomedical research, biobanks, art. 2d specifies that:
    - Pseudonymization is required.
    - Results publication shall exclude any pictures, names, addresses.
    - No disclosure agreement to any third party.
    - Re-use under article 89 GDPR art. 2d does not envisage any temporal limits for data retention.
- Data subjects' rights under art. 2d, can be limited as far as the rights to access, correction, erasure/be forgotten, restriction of processing, portability, and objection are concerned.
- Biological sample and data collections for reasons of public interest in the area of public health under art. 2f can be processed implementing the following safeguards:
    - the fastest possible pseudonymization, if purposes of the research allow it.
    - compliance with the data security measures required in accordance with article 32 GDPR.
- In the context of knowledge technology transfer art. 2i in case of open science and citizenship science projects specifies that:
    - Data shall be based on observations or measurements in public space or they shall be pseudonymized;
    - Deletion could be provided only if it meets goals, methodology, and purposes of the project.

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6.3.5.2 Germany

Relevant legislative initiative

- Bundesdatenschutzgesetz (BSDG) Federal Data Protection Law

Issues:

- Legal basis for processing sensitive data for research purposes are described by Section 27
    - Consent is considered as a general rule.
    - Consent is not necessary under conditions described under section 22(2), namely:

1. the implementation of technical organizational measures to ensure that processing complies with Regulation (EU) 2016/679;

2. measures to ensure that it is subsequently possible to verify and establish whether and by whom personal data were input, altered or removed;

3. measures to increase awareness of staff involved in processing operations;

4. designation of a data protection officer;

5. restrictions on access to personal data within the controller and by processors;

6. the pseudonymization of personal data;

7. the encryption of personal data;

8. measures to ensure the ability, confidentiality, integrity, availability, and resilience of processing systems and services related to the processing of personal data, including the ability to rapidly restore availability and access in the event of a physical or technical incident;

9. a process for regularly testing, assessing and evaluating the effectiveness of technical, and organizational measures for ensuring the security of the processing;

10. specific rules of procedure to ensure compliance with this Act and with Regulation (EU) 2016/679 in the event of transfer or processing for other purposes.

- Organizational and technical measures
    - Special categories of data shall be rendered anonymous as soon as the research or statistical purpose allows, unless this conflicts with legitimate interests of the data subject.
    - Token and data shall be separately stored.
    - Data can be published only if data subject has given consent, or it is indispensable for the purposes of the research.

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- Data subjects' rights limitations are described under Section 27.
    - Limitation refers to rights to access, correction, erasure/be forgotten, objection.
    - Regarding data processing for archiving purposes in the public interest Section 28 specifies:
        - that if the data subject disputes the accuracy of the personal data, he or she shall have the opportunity to present his or her version. The archive responsible shall be obligated to add this version to the files.
        - Article 15 GDPR is not applicable.

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6.3.5.3 Italy

Relevant legislative initiatives

- Decreto Legislativo, 30 giugno 2003, n.196 recante il "Codice in materia di protezione dei dati personali" - also Privacy Code.
- Regole deontologiche per trattamenti a fini statistici o di ricerca scientifica pubblicate ai sensi dell'art. 20, comma 4, del d.lgs. 10 agosto 2018, n. 101 - 19 dicembre 2018" issued by the Italian Data Protection Authority.

Issues

- Legal basis for sensitive data in research is included in art. 7 of the Ethics Code:
  - Freely given written consent after having read the privacy notice is the main rule.
- Specific safeguards have been introduced for the medical-biomedical-epidemiological research under the main Privacy Code and the Ethics Code.
  - Art. 110 Dlgs196/03 states when Consent is not required:
    - When the research in undertaken under a legislative provision, including a research programme established under a specific regulatory framework for clinics (art. 12-bis del decreto legislativo 30 dicembre 1992, n. 502) and the DPIA is publicly available.
    - When, considering specific reasons, to inform data subjects is not possible or it requires an unproportioned effort, or it could seriously undermine the research purposes. In these cases, the data controller adopts appropriate safeguards to protect the data subjects' rights and interests, the research has obtained an approval from the competent ethics committee and the Data Protection Authority provided a prior consultation under article 36 GDPR.
  - Art 8 Ethics Code provides the following safeguards to bridge data protection compliance and ethics in the field.
    - A general obligation of compliance with the applicable ethics framework is recalled also in the context of data protection.
    - Healthcare and research purposes shall be distinguished in the privacy information.
    - Incidental findings policy is required.
- Monitoring and enforcement mechanisms for research are stated under art. 9 Ethics Code:
  - Universities shall share awareness and information on the provisions established in this ethics code.
  - Universities shall report to the data protection authority any violation.
- Data collection
  - The authorized person introduces him/herself, inform the participant and does not collect data for other data controllers.
- Data retention for research purposes could be extended beyond the needed duration in order to pursuing the several scopes that enabled the previous collection and processing according to art. 99 Dlgs 196/2003.

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- Communication of general data of research staff under art. 100 Dlgs 196/2003 is allowed. Data subjects can in any case exercise their rights.
- Privacy notice: art. 105 recalls the general principle of information under article 13 and 14 GDPR unless the effort to inform is unproportionate.
- Re-using: The article 110bis of the Italian Privacy Code refers to the re-using of data by third parties. The first condition for it is that data subjects must be informed. Otherwise, a prior authorization from the data protection authority is needed. This approach is not applicable when personal data are collected for healthcare purposes and used for research ones by the same (private or public) scientific hospitalization and care clinics, considering the functional link between the two purposes. The provision seems to refer to patients' personal data before being pseudonymized or anonymized for research purposes, as stated under article 89 GDPR.

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6.3.5.4 France

Relevant legislative initiative

- Act No. 78-17 of 6 January 1978 on Information Technology, Data Files and Civil Liberties.

Issues

- Legal bases are specified by art. 44 for sensitive data processed by public research, under the condition that the processing is necessary for reasons of public interests.
- For genetics data, the data subject consent is required under article 75.

- Technical and organizational measures for health data processing for research purposes are listed below:
  - Article 72 The ethics committee analyses whether or not the data processing meets the public interest.
  - Article 74 Professional confidentiality is required for the data processing.
  - Article 73 established the requirement that the research shall provide its adherence to the “méthodologie de référence” established by the CNIL, otherwise a specific authorization is required under article 76. The procedure distinguishes the research including human beings from the one that enables personal data flows without involving human beings.
  - Monitoring and enforcement activities: the article 77 establishes an audit board “comité d’audit” promoting a system of auditing activities aimed at harmonizing the compliance level of all research activities processing health data.
- Technical and organizational measures for archiving in the public interests' purposes for scientific, historical, and statistics research include:
  - Data subjects’ rights can be limited as far as the rights to access, correction, restriction of processing, and objection are concerned
  - Article 14 is not applicable neither to initial nor to secondary purposes.

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6.3.5.5 Belgium

Relevant legislative initiatives

- The Act of 30 July 2018 on the protection of natural persons with regard to the processing of personal data, TITLE 4. - Processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes referred to in article 89, §§ 2 and 3, of the Regulation.

Issues

- General clause article 186: Data subjects' rights can be limited if necessary to achieve the research purpose.
- Organizational measures:
    - General clause article 187: a possible Code of conduct on a specific field prevails on the following organizational measures.
    - Art. 190 states that in case a DPIA highlights a high risk, a DPO shall be appointed.
    - Art. 204 states that the DPO shall issue opinions on the use of the various pseudonymization and anonymization methods, in particular on their effectiveness in terms of data protection.
    - Art 191 concerns the record activities that shall introduce new items:
        - 1° the justification for the use of the data, whether pseudonymized or not;
        - 2° the reasons why the exercise of the rights by the data subject is likely to make the achievement of the purposes impossible or to seriously hinder it;
        - 3° where appropriate, the data protection impact assessment if the controller processes sensitive data, within the meaning of article 9.1 of the Regulation, for scientific or historical research or statistical purposes.
        - According to art. 196, the agreement or notification concerning the data collection shall be appended to the record of processing activities.
    - Art. 191 establishes that the record activities for data processing for archiving purposes in the public interest shall introduce new items:
        - 1° the justification for the public interest of the stored archives.
        - 2° the reasons why the exercise of the rights by the data subject is likely to make the achievement of the purposes impossible or to seriously hinder it.
- Re-use and further processing of collected personal data is analyzed under article 194:
    - Where personal data are not collected from the data subject, the controller shall conclude an agreement with the original controller. Unless :
        - 1° the processing relates to personal data that were made public;
        - 2° European Union law, a law, a decree or an ordinance: a) gives the controller as a mandate to process personal data for archiving purposes in the public interest, scientific or historical research or statistical purposes; and b) prohibits the reuse of the data collected for other purposes.

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- Where exempted from concluding an agreement, the controller shall notify the original controller of the data collection.
- The controller of the further processing shall not have any access to the pseudonymization keys.

- Anonymization and pseudonymization techniques are described by article 197ff:
  - Articles 198-199 state that when the data processing is based on data collected from the data subject, the controller shall anonymize or pseudonymise the data once they have been collected or before the further processing.
  - Article 200 specifies that the de-pseudonymization is allowed only to the data controller after consulting the DPO.
  - Article 204 states the prohibition to disseminate any non-pseudonymized data, unless:
    - 1° the data subject has given his consent; or
    - 2° the data were made public by the data subject in person; or
    - 3° the data are closely linked to the public or historical nature of the data subject; or
    - 4° the data are closely linked to the public or historical nature of facts in which the data subject was involved.
  - Article 205 provides a general rule, unless it has been different established, by which the controller can disseminate pseudonymized data, with the exception of the personal data referred to in article 9.1 of the Regulation, while, according to article 206 non-pseudonymized data can be communicated to an identified third party only if he/she is unable to reproduce the data communicated. This condition is not necessary if:
    - 1° the data subject has given his consent; or
    - 2° the data were made public by the data subject in person; or
    - 3° the data are closely linked to the public or historical nature of the data subject; or
    - 4° the data are closely linked to the public or historical nature of facts in which the data subject was involved.

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6.3.6 Comparative notes on data protection for research purposes

From the illustrated frameworks on data protection regarding the safeguards implemented to enable personal data processing for scientific research and statistics, we could identify further convergences that could be addressed as enablers to facilitate open data and open science.

In this regard, the allocation of roles and responsibilities within the data processing for research purposes is a common organizational measure introduced to distinguish sensitive research fields (for instance using health data) from the regular ones. Furthermore, the organizational and technical measures that each mentioned legal system has introduced to ensure the pseudonymization of data flows for research purposes are functional not only to the compliance purposes, but also to openly disseminate, communicate, and share data in robust and compliant infrastructures. Furthermore, they enable an extensive use of art. 11 alleviating the compliance burden of data controllers.

Divergences within national implementations may refer to the consistency mechanisms aimed at continuously assessing the impact of the data processing for research by a third independent body. This activity is sometimes allocated to the data protection authority, sometimes to the competent ethical committee, sometimes to institutionalized audit boards. The role of control by an independent body and the consequent procedures of engagement might be considered as a barrier to enable cross-border flows both in terms of data processing and dissemination aimed at further / secondary uses, opening possible strategies of “forum shopping” (i.e. the presence of legal constraints as a parameter to share data).

The structure of the GDPR and national implementations under article 89 represents the need to identify the basis to reduce the attention on the individual data subject and focusing on the vulnerabilities of the group of data subjects. In this regard, national implementations confirm the structure of the GDPR, by identifying limits to data subjects’ rights, under the condition that otherwise the research could be compromised, and research data are at least pseudonymized. This approach is functional to ensuring that raw data are collected and processed within a fair, transparent, lawful system. Once personal data processing has achieved its purposes, further processing shall use the least “personal” data as possible enabling personal data to become research data and being communicated, disseminated, and re-used for other research purposes without any risk of harm for the individual data subject. Indeed, the re-use framework is facilitated by the prior compliance procedures that allows an easily transposition of contexts (i.e. from the principle of minimization to open data policies) only if all the ethical and safety measures to segregate research data from that information that may identify data subjects along the entire data processing is met. Thus, it is possible to move towards the use of the processed data for further scientific research, also through data intermediaries, including international data sharing.

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6.4 Part 3 – Non-personal data regulation

6.4.1 Principles and purposes

According to the EDPS Opinion on EU Data Strategy three are the categories of data: namely non-personal, personal, and mixed data sets. Nevertheless, as the combination of non-personal data may infer or generate personal data, specific recommendations are provided. This scenario is particularly common within research activities.[128]

To this end, the complex and still in progress legislative framework shall in any case be combined with the previously described regulatory frameworks in which the cross-processing of anonymous datasets could identify or make data subjects identifiable as described by recital 26 GDPR: "…To determine whether a natural person is identifiable, account should be taken of all the means reasonably likely to be used, such as singling out, either by the controller or by another person to identify the natural person directly or indirectly. To ascertain whether means are reasonably likely to be used to identify the natural person, account should be taken of all objective factors, such as the costs of and the amount of time required for identification, taking into consideration the available technology at the time of the processing and technological developments…".

The most recent EU legislative initiatives refer to:

I. the EU Regulation (EU) 2018/1807 of the European Parliament and of the Council of 14 November 2018 on a framework for the free flow of non-personal data in the European Union, that entered into force on 28 May 2019.[129] However, it includes provisions that request Member States to regulate some requirements by a national law, to be introduced by May 2021.
II. the Directive (EU) 2019/1024 of the European Parliament and of the Council of 20 June 2019 on open data and the re-use of public sector information (Open Data and PSI Directive[130]). According to its article 17, Member States shall transpose it into national laws, regulations and administrative provisions necessary to comply with this Directive by 17 July 2021. It sets principles to achieve a common legal framework for a European market for government-held data (public sector information) in a transparent and fair competition manner.

According to these two EU initiatives, open science is promoted through the following principles, aligned with the scopes of the FAIR principles:

- Free movement of non-personal data across borders, by facilitating the access and storage both from a regulatory (enabling also soft-law mechanisms) and technical viewpoint (interoperability).

[128] National Academies of Sciences E. Open Science by Design: Realizing a Vision for 21st Century Research.; 2018. doi:10.17226/25116

[129] Regulation (EU) 2018/1807 of the European Parliament and of the Council of 14 November 2018 on a framework for the free flow of non-personal data in the European Union [2018] OJ L303/59

[130] Directive (EU) 2019/1024 of the European Parliament and of the Council of 20 June 2019 on open data and the re-use of public sector information [2019] L172/56.

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- To boost public sectors to make information available and re-usable in public sectors.

However, the interplay with the previous legislative frameworks on IP and Data Protection might be affected by the following issues.

I. Firstly, according to article 1 and recital 54, the IPR of third parties are not affected by the Open Data PSI Directive. The term 'intellectual property rights', defined as "copyright and related rights only, including sui generis forms of protection", does not apply to documents covered by industrial property rights (i.e., patents and registered designs and trademarks).
II. According to article 2 and recital 52, rendering information anonymously is a means of reconciling the interests in making public sector information as re-usable as possible with the obligations under data protection law. In any case, it shall be specified that the combination of anonymous datasets may bring to pseudonymized information that are back included in the field of application of GDPR.[131] Cost allocation could affect the decision.
III. Thirdly, possible new regulation on AI could impact either to the free movement of non-personal data flows while they are used for automated decision making or to the accessibility and availability of information in the re-use favour perspective.

6.4.2 The Regulation on the free flow of personal data

The EU Regulation 2018/1807 starts from the premises that ICT is not a sector anymore, but "the foundation of all modern innovative economic systems and societies" (recital 1) to boost the free movement of data processing services and the right of establishment of service providers across Europe to achieve the data-driven growth and innovation.

This Regulation is applicable to "electronic data other than personal data" in the EU. It aims at removing obstacles to the free movement of non-personal data across Member States and IT systems in Europe, "by laying down rules relating to data localisation requirements, the availability of data to competent authorities and the porting of data for professional users" (art. 1).

The first issue addressed is the relationship with the GDPR in case of personal and non-personal datasets: according to art. 2 § 2, the latter prevails as "this Regulation shall not prejudice the application of Regulation (EU) 2016/679" in case the non-personal part of the dataset could not be isolated.

Article 3 provides a series of definitions, mostly aligned with the ones provided by the GDPR unless for the "processing" that slightly diverges as it includes "any operation or set of operations which is performed on data or on sets of data in electronic format, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction"

[131] M. Nanni et. Al, Give more data, awareness and control to individual citizens, and they will help COVID-19 containment Transactions on data privacy, 2020, 13, 61 ff.

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Article 4 is addressed to Member States, stating that they must delete any data localisation requirement, unless they are justified under the grounds of public security following the principle of proportionality from any existing legislative framework by 30 May 2021.

Article 6 encourages the development of codes of conducts to enable the portability of data flows considering the principle of transparency and interoperability, to cover – above all - the development of best practices "for facilitating the switching of service providers and the porting of data in a structured, commonly used and machine-readable format including open standard formats where required or requested by the service provider receiving the data". The role of stakeholders and their awareness is stressed as well.

It's impact on national frameworks could be assessed in terms of policymaking from June 2021.

6.4.3 The new Open Data and PSI Directive

To stress the role of the new PSI directive on the Open Data strategy it has been renamed as the Open Data and Public Sector Information Directive.

In article 2, it defines a series of concepts. The following ones are particularly relevant to the scopes of Open Data:

- document as any content (or part of it) whatever its medium (paper or electronic form or as a sound, visual or audio-visual recording)
- research data as "documents in a digital form, other than scientific publications, which are collected or produced in the course of scientific research activities and are used as evidence in the research process, or are commonly accepted in the research community as necessary to validate research findings and results"
- high-value datasets as "documents the re-use of which is associated with important benefits for society, the environment and the economy, in particular because of their suitability for the creation of value-added services, applications and new, high-quality and decent jobs, and of the number of potential beneficiaries of the value-added services and applications based on those datasets". Key areas are represented by Geospatial, Earth Observation and Environment, Meteorological; Statistics; Companies and Company Ownership; Mobility
- re-use as "the use by persons or legal entities of documents held by: (a) public sector bodies, for commercial or non-commercial purposes other than the initial purpose within the public task for which the documents were produced, except for the exchange of documents between public sector bodies purely in pursuit of their public tasks; or (b) public undertakings, for commercial or non-commercial purposes other than for the initial purpose of providing services in the general interest for which the documents were produced, except for the exchange of documents between public undertakings and public sector bodies purely in pursuit of the public tasks of public sector bodies"

These are key concepts to address the European Data Strategy towards Openness. In fact, article 4 describes the procedure that public sector bodies must follow to process requests of re-use to make documents available, managing the licenses, and possible time provisions. In case of refusal, the rightsholder/licensor shall be quoted. The decision shall be challenged.

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Re-use conditions are stated by article 5 that provides organizational as well as technical measures to ensure the interoperability requirement. The same provision is inspired to the *openness by design* and *by default* formulas, identifying for the dynamic documents the means of "suitable APIs" and "bulk downloads". Specific conditions for high value datasets are described under article 14.

Article 6 lists the principles that govern the re-use of documents. In this regard, the free of charge, unless *"marginal costs of reproduction, provision, and dissemination*" is the one that mostly encourages Open Data, making the re-use accessible despite any possible economics and social barriers. Possible exceptions are envisaged under the conditions that standard charges are pre-established in a transparent manner and, in any case, they do not include research data. Non-discrimination principle within any re-use activity and fair trading one, avoiding exclusive rights arrangements, are addressed in articles 11 and 12.

In light of the fact that the new PSI Directive will replace the previous one and Member States are expected to implement it within a few months, this report has purposefully not covered national laws transposing the previous act. In particular, Member States are asked to implement possible standard licenses under article 8, practical arrangements to facilitate the engagement of FAIR ecosystems also for research data. A follow-up with a comparative analysis of national implementations will be provided to the EOSC-Pillar consortium if needed.

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6.5 Conclusions

This chapter aims to provide an exhaustive comparative analysis of the legal landscape relevant for the development of open access and open data research policies, and for the building and maintenance of open research infrastructures. To this end, the study focused mostly on IP laws – and particularly on copyright -, privacy and data protection law, security, regulations on the re-use and management of Public Services Information (PSI), regulations on the free flow of non-personal data, and other provisions for cross-border data access. The overview and analysis of EU legal sources was complemented with a focus on their transposition in the legal systems of the five EOSC-Pillar Member States (Austria, Belgium, France, Germany, Italy) and with the study of additional regulatory solutions developed at a national level. The aim of the study was to lay the groundwork for the drafting of blueprint/guidelines for European researchers and institutions, which may assist them in publishing, sharing and integrating research data, thus guaranteeing the openness of research data with the goal of promoting the FAIR principles beyond their original scope.

In the field of copyright, despite the remarkable harmonization effort conducted by the EC, several areas remain subject to the legislative discretion of Member States. This has created fragmentation of national solutions in a number of sectors that are of fundamental importance for the cross-border exchange of protected works and for the safe and legitimate use and re-use of copyright materials, such as the notion of authorship and co-ownership, copyright contracts, and the regulation of most of the exceptions to exclusive rights.

An analysis of the solutions implemented by the five Member States studied show a general convergence on the definitions of key concepts, rights and exceptions. When EU Directives qualified an exception as mandatory, national legislators embedded them in their copyright laws using almost the same language used in the EU text. When exceptions were defined as optional and remitted in their implementation to the discretion of Member States, divergences among national solutions are much more frequent, as in the case of library and teaching & research exceptions. In some sectors relevant for EOSC, such as TDM activities, Member States such as Germany or France have provided interim exceptions, while a common regulatory solution adopted by the five national systems hereby analyzed is a provision attributing a right to authors or an obligation for public funding institutions to ensure the open access publication of research outputs publicly funded for at least 50%, finalized (also) to build open repositories. The most recent copyright reform (CDSM Directive) has introduced three new mandatory exceptions relevant for EOSC, Open Science and Open Access – digital preservation of library collection, TDM activities, digital teaching -, but we will need to wait until at least mid-2021 to see them implemented at a national level.

Despite these positive developments, several areas relevant for EOSC, OA and OS purposes remain still uncovered, while the patchwork of national exceptions has negative effect on the degree of legal certainty and self-confidence of researchers, research managers and institutional users when building, running, and populating research infrastructures, and when using and re-using materials produced by others.

As far as the personal data and non-personal data analysis is concerned, it emerged that the GDPR constitutes a compass for further legislative initiatives impacting on information society and already provides viable means to develop guidelines for opening the free flow of research data. Therefore, its risk-based approach, enabling the data protection by design and by default, is a system driven by the

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principle of accountability, whose structure ensures a responsible management of personal data while also offering avenues to reduce the burdens for data controllers. The GDPR compliance of personal data and mixed datasets plays a paramount role to achieve the Open Science and Open Data purposes.

For this reason, a similar structure is reproduced within the most recent non-personal data relevant EU initiatives, whose impact within Member States national framework will be disruptive, boosting even the implementation of the principles of openness by design and by default of documents and non-personal information.

These remarks allow to build up the boundaries of any FAIR ecosystem. How to make research data findable, accessible, interoperable, and re-usable is the *fil rouge* between the legal constraints emerging from the analysed frameworks.

From the analysis of the EOSC Pillar Countries national implementations of the safeguards under article 89 GDPR, in fact, it emerged that any action point adopted by the analysed Member States is governed by the general principle of accountability. They all aim at enhancing the role of the impact assessment performed under article 35 along all the life cycle of the research.

In this context, therefore, the balance between data protection by design and data protection by default with the strategy of open research data is identified by those technical and organizational measures that are introduced to facilitate a positive outcome from the DPIA as “acceptable”. Thus, the involvement (and in certain cases the appointment) of the data protection officer, the separation of roles between those who pseudonymized data and those who processes them, the identification of consistency mechanisms between the ethical framework highlights the need to identify possible harmonized best practices to enable a fair, transparent, and compliant data management for research purposes.

As a follow up of this report will articulate in a structured and schematic fashion the provisions which support and hinder the expression of the entire potential of EOSC and the implementation of successful OA and OS policies.

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7 Appendix B - Blueprint / guidelines

7.1 Introduction

This document aims at providing a blueprint/guidelines to facilitate researchers' work when publishing, sharing and integrating research data, with particular regard to the challenges raised by IPR, data protection laws and regulations on non-personal data.

The guidelines will help researchers:

1. identifying and understanding
    a. the legal regime applicable to research products in order to define their intellectual ownership. More specifically, they will guide researchers in the definition of the type of exclusivity applicable to the given subject matter, the rights conferred, how to acquire them, and eventual exceptions and limitations. Attention will be devoted to differences among Member States and the implication of IPRs territoriality on cross-border access and re-use of intellectual products and other data.
    b. the legal regime applicable to personal and non-personal data for research purposes, providing a useful instrument to address both ethical-legal issues and security ones, highlighting how to deal with cross-border data flows, re-use for further research purposes by design and by default, and considering the differences emerging from the analysed scenarios (nature of data like sensitive ones, ground of data subject's vulnerability, etc.) as well as the impact of public / private nature of the users.
2. understanding and devising processes to define and declare the legal regime applicable to different research products, and to manage their access, use and re-use in subsequent stages of the research project and of the dissemination of its results.
    a. The Guidelines will include best practices to design the Data Management Plan (DMP), which translates a compliance task into an opportunity to design an efficient strategy for the life-cycle of the research and its future use. The aim of the DMP is to balance freedom of research, knowledge sharing and the need to protect content, people or products. To this end, the DMP devotes specific attention to (i) the tailoring of open licenses for reuse; (ii) the identification of possible progressive levels of insights to distinguish means, purposes, and end-users of a given dataset considering the nature of data; (iii) the provision of the requirements to get access highlighting the legal basis to maintain the compatibility standard under article 5 GDPR; (iv) the identification of technical and organizational measures to make sensitive data accessible; (v) the granting of an embargo, if required or needed, for the dissemination of sensitive data, limited to the study phase.
    b. Best practices on DMP design will be flanked by basic suggestions on how to lay the basis for the implementation of successful Open Access and Open Science policies.

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3. Understanding how to deal with external data and protected intellectual assets, in order to avoid liability and reach access via proper consent and licensing, or by leveraging regulatory flexibility.

Such processes will give the possibility for researchers to get acquainted with the ways how research products may be protected, collected, and shared with the public since the early stages of a research project or endeavour. Our blueprint/guidelines will offer data creators clear indications on how their works will be disseminated in the future, empower them to choose the best licensing forms, highlight the importance of having a minimal set of data open by default. In order to ensure a correct application of FAIR principles, the guidelines will be articulated in two phases, i.e. the phase of data production and/or gathering, and the phase of conclusion of research activities, involving data archiving, storage and re-use.

7.2 3-Phased Checklists

Blueprint guidelines for research infrastructures accompany researchers along a research project or research endeavour life cycle and help them deal with legal constraints while adopting an efficient approach to leverage regulatory enablers.

The guidelines may be translated into practical checklists, articulated into 3 phases: (a) research proposal, (b) research implementation and (c) research review.

7.3 Phase 1 - Research Proposal

The “research proposal” phase covers the early conception of a research project or endeavour. It generally refers to the preparation of a research proposal, but this checklist may also be applied to any initial planning that precede the actual start of research activities.

7.3.1 Intellectual property rights

When drafting a proposal or planning joint research

1. Check whether there are background information, data and IPR brought into the project
    a. Clarify who brings what
    b. Identify the legal regime applicable to each background material. Pay particular attention to territorial applicability of each right
    c. Make sure to obtain clearance for each use. Aim at avoiding secrecy and allow re-use
2. Define in a clear manner
    a. The ownership and/or co-ownership of each research output stemming from
        i. The use and re-use of pre-existing background information, data and IPRs
        ii. Single or joint research activities within the framework of the project
        iii. Single or joint research activities partially within OR outside the framework of the project, if building or depending on project activities
    b. The legal regime applicable to each research output, with particular regard to territoriality and cross-border activities

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c. The forms of exploitation and degree of openness vs closeness envisioned, in light of OA and OS goals
    i. Make sure to secure sufficient funding for OA/OS or to identify reliable free outlets and channels where to disseminate

3. Liaise with your Technology Transfer Office (TTO), or offices in charge for legal matters, to lay down internal processes for the protection and management of intellectual capital stemming from the project
    a. Make sure that your TTO or other office is aware of FAIR principles, and OA/OS best practices.

7.3.2 Data Protection

If you process any information that identifies a human person, please be aware to follow this checklist.

a. If you cannot answer one (or any) of these questions, please, deal with your DPO or consider that it could be useful to appoint an ethics advisor or to include an ethical-legal unity.
b. If you are going to process either general or special categories of data be aware to organize your data flows as follows. Please, be aware to
    a. select which categories of data are you going to process
        i. If you are processing special categories of data please check whether or not you will need the following safeguards:
            1. To appoint a DPO and/or an ethical advisor.
            2. To receive the approval of the competent ethics committee.
            3. To collect the consent to process data in addition to the informed consent (infra) and to store it for a specific delay.
            4. To appoint a technician to pseudonymise data.
            5. To commit yourself and your collaborators to specific confidential obligations.
            6. To perform and publish a DPIA.
            7. To provide a specific publicly visible privacy.
            8. If special conditions are applicable considering the private/public nature of your entity.
    b. Identify whether or not there are any codes of conducts applicable for your data processing.
    c. identify specific means of the data processing.
    d. Identify the external governance of the data processing.
    e. Identify the internal governance of the data processing.
    f. Identify which data are necessary for each step of the research and define how you will pseudonymise personal data.
    g. Identify where you are going to store your data.
    h. Identify if other uses than the initial ones are envisaged.
    i. Identify how you are compliant with the principle of minimization and proportionality.

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c. If you are going to process personal and non-personal data through AI-based technologies or machine learning techniques. Please, be aware (according to the expected level of risk) to:
    a. Verify the applicable ethical-legal framework.
    b. Perform an initial stage AI, if applicable, otherwise address how you will be compliant with the pillars of ethics, lawful, and robust AI, namely:
        i. be able to explain how the developed/used AI meets the criteria for trustworthiness;
        ii. define the measures set in place to avoid potential bias, discrimination and stigmatization;
        iii. define the measures set in place to ensure safety and prevention of harms (to humans, animals, environment);
        iv. prepare detailed explanation on how the respect of fundamental human rights and freedoms (e.g. human autonomy, privacy and data protection) will be ensured;
        v. define measures to ensure fairness and explicability (paying particular attention to situations involving more vulnerable groups);
        vi. explain how humans will maintain meaningful control over the most important aspects of decision-making process (especially in those instances in which the AI systems/techniques to be developed/used may interact, replace or influence human decision-making processes);
        vii. evaluate the ethics risks related to the development/deployment of the AI systems/techniques and explain how the potential negative social impacts will be mitigated (this especially when the AI to be developed/used in the project may lead to significant negative social impacts -e.g. on democracy, media, labour market, freedoms, educational choices, mass surveillance- either through intended applications or plausible alternative uses).
d. If you are going to process either personal or non-personal data extra-EU, be aware to:
    a. Check conditions to share them;
    b. Verify whether or not specific conditions apply for private/public institutions.
e. If you are going to process non personal data, be aware to:
    a. Allocate costs for data management;
    b. Identify safety requirements to process data;
    c. Identify proper format to facilitate their interoperability and the re-use;
    d. Identify a proper repository;
f. If you are required to submit a protocol to the competent ethical committee, be aware to:
    a. Allocate time and resources;
    b. Identify the competent ethical committee;
    c. Identify all the required documents and information.

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7.4 Phase 2 - Research Implementation

Along with the conditions to be verified in the proposal phase, which must be monitored and updated also during the research implementation, the second phase also requires compliance with other requirements.

7.4.1 Intellectual property rights

1. As soon as the funding is awarded and/or the research consortium is established and/or the research project/endeavor is about to start
    a. Make sure to develop an IP management plan, containing
        i. An innovation/creation disclosure mechanism
        ii. The identification of the internal office in charge of assisting with patent applications and other registrations required to achieve IP protection
        iii. IP acquisition principles and policies, including at least
            1. Decisions on territoriality (where to apply and why)
            2. Ownership matters, ie how to regulate cases of joint development and co-ownership
            3. Clearance matters, ie how to deal with cases where access to external IPRs is necessary to protect your own intellectual capital
        iv. IP management matters, including at least
            1. Monitoring of fee payments and other maintenance issues
            2. Cost-cutting measures if protection not needed anymore
            3. Clear public disclosure of IPRs, applicable legal regime and re-use conditions
        v. IP exploitation processes, including at least
            1. The definition of common consortium policies and internal policies identifying the principles and goals to be pursued in exploitation activities
                a. Eg balance between proprietary approach necessary to reach adoption/commercial exploitation and OA/OS policies allowing free re-use (as open as possible, as closed as necessary)
                b. Definition of cases when to adopt cross-licensing agreements between partners (on background IPRs or intellectual capital developed jointly but attributed in single ownership), possibly on a non-exclusive and gratuitous basis.
            2. The selection of a set of licensing templates ranging from traditional commercial exploitation to open access and open science formats (eg Creative Commons, GNU/GPL or EUPL free non-exclusive patent licenses etc)

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3. The implementation of processes of periodic checks to allow the OA/OS dissemination of materials covered by embargos, once embargo periods expire

2. Put in place clearance processes and systems that identify IP flexibilities and leverage them to afford re-use of protected materials without requesting rights holders' authorization.

7.4.2 Data Protection

If you process any information that identifies - directly or indirectly – a human person, please be aware to follow this checklist.

1. If you have appointed one(s) please engage the DPO or the ethics advisor or the ethical-legal unit to provide the compliance activities.
2. If you are going to process either general or special categories of data be aware to implement the technical and organizational measures required to protect your data flows in terms of availability, confidentiality, and integrity. Please, be aware to:
    a. Have filled the records of the processing under article 30 GDPR;
    b. Have assessed the impact under article 35 GDPR;
    c. Have regulated the governance under articles 26 and/or 28 GDPR if third parties are involved in the processing (so-called external governance);
    d. Have informed data subjects;
    e. Have received the approval of the competent ethical committee (if required);
    f. Have trained collaborators, instructed and therefore authorized them under article 29 GDPR (so-called internal governance);
    g. Have obtained a commitment for confidential obligations (if required);
    h. Have established procedures to ensure data subjects to exercise their rights;
    i. Have established procedures for data breach;
    j. Have identified proper technique of pseudonymization;
    k. Have identified how to encrypt your data;
    l. Have planned stress tests to identify infrastructural vulnerabilities;
    m. Have planned auditing activities;
3. A data management plan (DMP) shall be provided and implemented.
    a. A repository shall be chosen in order to collect research data, check the most common one used in your research community.
    b. Create a general chart where you provide all the data curation information for each data flow.
    c. Identify convergences and divergences in the described categories of research data.
    d. Decide how you plan to make similar categories of research data as open as possible, as close as necessary.
        i. The ethical-legal, IPRs, and commercial constraints shall be identified.
        ii. Identify how you will describe your research data (findable).
        iii. Identify how you will make your research data accessible.
        iv. Identify which is the format that will make your data interoperable.
        v. Identify how your data could be re-usable.

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e. In case of archive services, identify conditions to reverse pseudonymization to not endanger the evidential value of the records (e.g. a procedure of requests by the researcher).

4. Any innovative feature (new data processing, new means, new purposes, new target groups) shall be re- assessed under sub Section 1.2 a)-g) and sub Section 2.2. a)-e).
5. If you are analyzing data, verify the threshold of aggregation required to publish and disseminate your personal data.

7.5 Phase 3 - Research review

After the conclusion of a funded research project or any other form of research endeavor, additional issues should be checked, and some of the processes should remain in place to ensure persisting compliance and the rolling implementation of FAIR principles and OA/OS policies.

7.5.1 Intellectual property rights

a. Identify, with your TTO or legal office, maintenance mechanisms to ensure that your IP management plan keeps on running and is subject to periodic checks also after the conclusion of the research project.
b. Maintain and update clearance processes and systems that identify IP flexibilities and leverage them to afford re-use of protected materials without requesting rights holders' authorization.
c. Run periodic checks to allow the OA/OS dissemination of materials covered by embargos, once embargo periods expire.
d. Verify compliance with license agreements by your licensees, and particularly respect of FAIR, OA and OS clauses. e.g.
    i. Run compliance checks of your status on institutional repositories.
    ii. Have I uploaded all the materials (papers, background data etc) which I can freely disseminate?
    iii. Am I using interoperable and accessible formats?
    iv. Have I provided correct metadata?
e. Help your institution being up-to-date with the state of the art in the implementation of FAIR principles and OA/OS policies

7.5.2 Data Protection

Check the data retention limit and verify if you have anonymized data or deleted them accordingly or plan the necessary actions.

a. Determine how long you shall store informed consent from research subjects and act accordingly.
b. Access by no longer authorized entities/bodies/collaborators shall be removed.
c. Check if you have pursued all the instructions you provided within the data management plan.
d. Re-use policy shall be clearly identified.
e. Proper retention location and access privileges for data whose further use is enabled should be identified and consequent actions adopted.

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7.6 Guidelines in Detail

7.6.1 In general

7.6.1.1 Who do you need

These guidelines are directed to individual researchers dealing with data and innovation/creations which may be protected via IPRs. Researchers usually operate in institutional contexts such as universities and research centers which offer integrated services to support research activities. Among those, grant offices, legal offices, and data protection officers (DPOs), academic cooperation and research offices and technologies transfer offices could be in charge of providing assistance in the key-phases of the project or research endeavour life-cycle, and particularly with IP- and data-related issues.

While personal awareness and do-it-yourself are always useful skills to navigate legal and ethical issues related to research, it is always advisable to (a) identify competent offices and (b) revert to them sooner than later in order to implement all necessary processes and steps as early as possible in the project life-cycle. Institutional DPOs could give advice on personal data flows, along with grant and/or research offices, while TTOs are in charge of intellectual property protection and exploitation, trade secret protection et al. However, due to the complexity of certain research activities and topics, it is advisable to be considered as an accountable approach to engage in a given research specific boards and / or advisors and/or ethical-legal units fully dedicated to deal with the complex and multilevel system of enablers and constraints impacting on the specific data strategy of the project and translate it into a tailored and accurate DMP.

7.6.1.2 What do you need

Along with these guidelines, we suggest consulting the following documents.

- EU Commission, Data governance and data policies at the European Commission, 2020, https://ec.europa.eu/info/sites/info/files/summary-data-governance-data-policies_en.pdf
- EU Commission, European Data Strategy, https://ec.europa.eu/commission/presscorner/api/files/attachment/862109/European_data_strategy_en.pdf.pdf
- EU Commission, Reproducibility of scientific results in the EU, https://op.europa.eu/en/publication-detail/-/publication/6bc538ad-344f-11eb-b27b-01aa75ed71a1#
- Research Data Lifecycle by the UK Data Service (2017) (https://www.ukdataservice.ac.uk/manage-data/lifecycle)
- EU Commission, Guide on Open Access to Scientific Publications and Research Data in Horizon2020 (http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-pilot-guide_en.pdf)

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- EU Commission, Open Access Factsheet (https://www.openaire.eu/openaire-h2020-factsheets)
- FAIR Checklist (https://www.force11.org/fairprinciples)
- S. Hodson et al., FAIR Data Action Plan Interim recommendations and actions from the European Commission Expert Group on FAIR data (https://zenodo.org/record/1285290#.XBEjSi8VRKM)
- S. Hodson et al. Report of the Commission FAIR Data Expert Group (FAIR Data EG): Turning FAIR into reality (https://zenodo.org/record/1285272#.XBEjri8VRKM)
- Creative Commons License https://creativecommons.org
- Guidance on the Regulation on a framework for the free flow of non-personal data in the European Union, COM/2019/250 final, https://ec.europa.eu/digital-single-market/en/news/practical-guidance-businesses-how-process-mixed-datasets

7.6.1.3 What to look at

It is crucial to keep in mind that cross-border research activities entail the possible application of a range of national laws, and that national laws are harmonized only to a limited extent within the EU. IPR are territorial, which means that they are valid only within the borders of the state where they have been granted (if registered), or that in any case they follow the law of the "country of origin" of the protected work. By the same token, jurisdiction over infringements, validity matters et al is usually exercised by the courts of the country where the right was granted.

In the field of data protection, against a uniform backdrop offered by the GDPR, the current legal framework is mostly shaped by national legislative initiatives implementing specific safeguards for personal data processing for research purposes under article 89 GDPR. This flexibility offered to Member States has resulted in the development of large sets of practical measures, which could be addressed either as best practices to be followed in line with the principle of accountability, leading to an efficient process standardization; or as regulatory binding constraints that have to be abided by in order to avoid fines and penalties. For example, the measure to appoint a data protection officer for a given research is binding in some legal systems, like Austria and Belgium, but it could be introduced as an additional organizational measure in other ones. The patchwork of national implementations is now flanked by the cross-references between the GDPR and the new pieces of EU legislation intervening on non-personal data, such as the Open Data and PSI Directive and the Non-Personal Data Flows Regulation, which have yet to be fully transposed at a national level and will increase the degree of complexity of the European Data Strategy in research activities.

As a consequence, it is always advisable to look at regulations and practices of all the States involved in the research consortiums and – possibly more important - to draft internal policies that take into account possibilities, uncertainties and challenges raised by regulatory territoriality, in order to minimize their disruptive effects.

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7.6.2 Phase 1 - Research proposal

As mentioned above, the "research proposal" phase covers the early conception of a research project or endeavor. It generally refers to the preparation of a research proposal, but these guidelines may also be applied to any initial planning that precede the actual start of research activities.

7.6.2.1 Intellectual property

When drafting a proposal or planning a joint research endeavor, make sure to go through the following three steps.

- ✔ Check whether there are background information, data and intellectual property rights brought into the project

Each research activity builds on pre-existing knowledge. By the same token, a research project or common research endeavour may assume the contribution, by each or only some of the partners, of pre-existing background information, data and IPRs. Best practices used in framework EU projects, which request the identification of background intellectual assets brought into the project by each partner and the identification of ownership and legal regime applicable to each of them, should be generalized and used in any research project.

To the extent possible, background materials should be made compliant with FAIR principles.

It is advisable to pay attention to the territorial scope of each right, and to make sure that the consortium has clearance and all the necessary authorization to operate on each pre-existing background material. Researchers should aim at avoiding that partners impose non-disclosure clauses, and at reaching full re-usability of background data, information and IPRs within the consortium, together with the greatest openness possible of derived research outputs.

- ✔ Be clear on ownership, legal regime and degree of openness or closeness of each asset

In the research proposal and/or in any other agreement stipulated at the onset of a common research endeavour, it is of key importance to define in a clear manner a number of issues that are always prone to trigger uncertainties and problems when research activities are carried out.

First, it is fundamental to agree on rules to attribute the ownership or co-ownership of research outputs. Particular attention should be devoted to cases where data or other outputs that may be protected via IP derive from the use and re-use of pre-existing background information, data and IPRs owned by other consortium members or by third parties. In that case, researchers should make sure to (i) secure clearance of pre-existing rights by obtaining any authorization needed for re-use and protection of derived data and other intellectual outputs and (ii) agree on rules of ownership attribution on derived data and other intellectual outputs.

Attention should be also paid to the definition of ownership attribution for outputs stemming from single or joint research activities carried out (i) within the framework of the project or (ii) outside the framework of the project, if the output builds or depends on project activities. This is particularly

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important in case of cross-border activities, in order to avoid uncertainties triggered by possible differences in national rules on co-ownership of IPRs.

Second, researchers should **understand and define the legal regime applicable to each research output**. On this basis, they should agree on basic principles to determine whether, what and where to protect (i.e. whether or not to patent, what, in which countries(s)). This will constitute the basis to p**redetermine basic guidelines on the forms of exploitation of research outputs** envisioned by the consortium, and particularly on the degree of openness and closeness to be set in order to align the project activities and results to the requirements of FAIR principles, and to OA and OS goals.

When preparing the project budget, researchers should make sure to **secure sufficient funding** to disseminate research outputs on OA and OS channels. Alternatively, they should identify reliable outlets and channels where dissemination is open and free of charge (e.g. DOAJ journals, ORE and the like).

- ✔ Liaise with your TTO and/or other support offices as soon as possible

Researchers should make sure to liaise as early as possible with their **TTO,** or offices in charge for legal matters, to **lay down internal processes** for the protection and management of intellectual capital stemming from the project.

When discussing project-related matters with competent offices and their plans on the management of data and intellectual capital, researchers should make sure that their support staff is aware of FAIR principles and of the state of the art of OA and OS best practices.

7.6.2.2 Data Protection

- ✔ Assess each personal and non-personal data processing and the corresponding requirements to enable data flows

Data protection issues shall be addressed through a risk-based approach aimed at ensuring the enhancement of principles of data protection by design and data protection by default as a condition to reach openness by design and openness by default standards. On this basis, since the very beginning of the research, the principal investigator shall identify the main features of personal and non-personal data flows (who is processing, what data, whose data, how they shall be processed, how long, where and which means of the processing are envisaged, etc.). This is functional to assess how to exploit the existing enablers emerging from the given research field and, at the same time, to determine which strategies to implement in order to tackle and overcome technical, organizational, legal and ethical constraints during the entire life cycle of the research.

In this respect, the checklist poses questions that facilitate the identification of the main risks, constraints, and opportunities emerging from the planned research. This pre-compliance assessment should be inspired by the goal of transposing the future research data into a FAIR ecosystem. To this end, possible organizational and technical safeguards required in the following steps of the project shall be pre-determined by the researcher in order to lay the groundwork for the fulfillment of such objectives when carrying out the research project.

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✔ Set up preparatory activities to ensure ethical-legal compliance

For each critical profile emerged in the previous assessment, the checklist brings to the attention of the researcher all the main ethical-legal and technical requirements which must be taken into account to orient decisions during the project/research development. The two main dimensions that affect personal and non-personal data flows are the GDPR compliance and other ethical issues.

GDPR compliance activities require mapping personal data flows; providing an impact assessment on the **availability, confidentiality, and integrity of data;** designing internal and external **governance**, including the identification of **roles and responsibilities** aligned with the different skills and competence required to develop the envisaged research activities.

Other ethical-legal issues to be addressed in the early stages of the life cycle of the research concern the involvement of human beings, animals, the possible misuse or dual use of the data flows, the use of AI-based technologies. In this regard, the checklist helps the researcher to consider since the very beginning of the activities the requirements needed for a responsible development of the research. These to responsibly develop research. These may include the necessity to submit protocols to competent ethics committees.

✔ Include compliance and data management activities in the general research risk-management

Questions related to the identification of roles, responsibilities, and assessment of technical safeguards will allow the researcher to **properly allocate time, costs, and efforts** required for the performance of such tasks in the development of the project/research, optimizing an efficient management of the related activities.

When deciding on the safety and security of information for compliance purposes, the researcher should also take into account the need to boost the development of FAIR ecosystems. Specific skills and competences which are not covered by research team members should be covered by recruiting or outsourcing in order to ensure a proper assessment of risks and opportunities in the management of personal and non-personal data.

7.6.3 Phase 2 - Research implementation

Along with the conditions to be verified in the proposal phase, which must be monitored and updated also during the research implementation, the second phase also requires compliance with other requirements.

7.6.3.1 Intellectual Property

As soon as the grant is awarded and the research consortium is established, or in any case as soon as research activities are about to start, researchers should perform at least the following basic steps.

✔ Make sure to develop an effective, comprehensive IP management plan

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With the help of competent offices and together with the data management plan, researchers should make sure to draft and have in place an articulated IP management plan, which reflects both the need for proprietary rights in view of exploitation and the OA and OS goals inspiring EOSC.

A basic IP management plan should envision and articulate a number of key mechanisms and processes accompanying researchers through the entire life cycle of a potential IP asset. More specifically, it should:

(i) identify the internal office in charge of assisting with patent applications and other registrations required to achieve IP protection;
(ii) establish an innovation disclosure mechanism, which may facilitate the identification and description of research outcomes that may be eligible for IP protection;
(iii) provide basic rules and guidelines on IP acquisitions, including but not limited to territoriality policies (ie where to apply for protection and why), ownership attribution rules (ie how to regulate cases of joint development and co-ownership), and clearance matters (ie how to deal with cases where access to external IPRs is needed to protect your own intellectual capital);
(iv) establish IP management processes, including at least the monitoring of fee payments and other maintenance activities, the implementation of cost-cutting measures, such as abandonment of unexploited IPRs, and the disclosure of the existence of IPRs, their legal regime and the licensing/re-use conditions;
(v) establish IP exploitation processes and rules, including at least (a) the definition of common consortium policies identifying principles and goals to be pursued in exploitation activities, with particular regard to the balance between proprietary rights needed for commercial exploitation and OA/OS policies allowing free re-use (as open as possible, as closed as necessary), and (b) the definition of cases when to adopt cross-licensing agreements between parties, e.g. on background IPRs, or IPRs developed jointly but attributed in singe ownership, possible on a non-exclusive and gratuitous basis. The IP management plan should also identify and provide licensing templates for all needs, ranging from traditional commercial exploitation to open access and open science formats, such as Creative Commons, GNU/GPL, patent licenses on a free, non-exclusive basis etc.
(vi) implement periodic checks to allow the dissemination of materials covered by embargos in OA/OS, once the embargo period expires.
(vii) put in place clearance processes and systems that identify IP flexibilities and leverage them to afford re-use of protected materials without requesting rights holders' authorization

National and EU IP laws, particularly in the field of copyright, provide for a set of exceptions, limitations and other forms of flexibility enabling free unauthorized uses of protected works. Knowing them and being able to efficiently leverage them helps to achieve clearance and re-use by saving time and money. Researchers should either train themselves on such flexibilities (see, in this respect, the charts and reports developed in the context of this study) or ask competent offices to prepare infographics or other tools to get acquainted with them. Associations such as EOSC and Sparc Europe provide support materials to this end, and so do platforms such as, eg, copyrightusers.org.

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7.6.3.2 Data Protection

Thanks to resources allocated and the risk assessment undertaken in the preparatory activities, the researcher shall start their activities being aware that by design standards are properly arranged.

The second section of the checklist is dedicated to the implementation of the research. It identifies the required technical and organizational measures to fulfill existing legal obligations under the applicable legal frameworks.

✔ Implement required safeguards to be compliant with legal obligations

Ethical-legal compliance is a pre-condition to ensure openness of research data. To properly approach research activities in compliance with the applicable ethical-legal framework requires ensuring for each step of the research an efficient management of raw and research data. In fact, planning an efficient strategy of data management designed to reach the standard of "as open as possible, as close as necessary" is part of the compliance process as it engages the ethical, legal, and technical dimensions of each processed information.

Data intensive research includes the collection of data, their processing, and the analysis of research results. During these activities, the researcher has to provide **a robust plan illustrating how raw and research data shall be collected, curated, processed, stored possibly within a FAIR ecosystem**. In addition, the researcher has to deal with GDPR compliance activities identified by design, in order to process personal data by adopting the required technical and organizational safeguards, which will ensure a lawful, fair, and accountable approach.

The proposed checklist helps the researcher fulfill legal obligations while providing efficient data management both in the technical and in the organizational dimensions.

✔ Implement technical safeguards

Compliance activities related to data protection shall be assessed for each data flow. Data processing for research and statistics purposes are covered by two main technical safeguards: **pseudonymization** and **encryption of data flows**. The researcher has, therefore, to identify how to protect the enabled data flows **before and after the pseudonymization,** who is responsible to separate information, store the re-association key, and when to destroy it. The procedure shall consider that the data flow shall be processed by pre-determined means according to the objectives of the research. These remarks will affect the decisions on the infrastructure that could host data and the format of the research data, considering the opportunity to make them **interoperable,** in order to accomplish data openness by design. All this information shall be clearly stated in the Data Management Plan.

✔ Set up organizational measures

Organizational measures shall be set up since preparatory activities and implemented as soon as research activities kick off. They refer to the **governance of data flows,** which shall be managed along the temporal dimension (how long a data processing shall be enabled? Is the applied framework still into force?) and the geographical dimension, in case of cross-border data flows. This requires a

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continuous assessment of the applicable legal framework. To draft the DMP constitutes an organizational measure and represents a key tool to ensure that research data are findable, accessible, interoperable, and reusable (FAIR) and comply with the applicable framework.

✔ Be aware of vulnerable groups

If the research engages vulnerable research subjects (children, patients, etc.), considers them as final end-users/stakeholders, or processes their pseudonymized data, proper organizational measures shall be implemented in the development of the research to take into account their vulnerabilities. The same applies to health-related data, and/or genetic ones, and/or biometric ones, which are subject to a higher degree of protection and could present **specific national constraints and/or derogations**. In such cases, it may be required to **submit a protocol** to the competent **ethical committee** to obtain approval on the entire research management plan, DMP included.

✔ Protect data flows also in communication and dissemination activities

Researchers should be aware of any obligation of confidentiality they are subject to and verify their compliance with the applicable legal framework also in the context of their communication and dissemination activities. Some national legal safeguards, for example, provide specific thresholds to communicate and disseminate results which include personal data, as aggregated ones. If the creation of an archive is part of the dissemination, the researcher shall supervise the related activities in order to ensure the compliance of such a further ecosystem.

7.6.4 Phase 3- Research review

After the conclusion of a funded research project or any other form of research endeavor, additional issues should be checked, and some of the processes should remain in place to ensure persisting compliance and the rolling implementation of FAIR principles and OA/OS policies.

7.6.4.1 Intellectual Property

Both at the end of a research project and, more generally, when dealing with research outputs, researchers should make sure to comply at least with the following five guidelines.

✔ Identify maintenance mechanisms for IP management plan

Researchers should identify, with their TTO or legal office, **maintenance mechanisms** to ensure that **IP management plans** keep on running and are subject to periodic checks also after the conclusion of the research projects, in line with what is specified under Phase 2 guidelines.

✔ Maintain and update clearance processes identifying IP flexibilities

Researchers should maintain and update **clearance processes and systems that identify IP flexibilities** and leverage them to afford re-use of protected materials without requesting rights holders' authorization, in line with what specified under Phase 2 guidelines.

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✔ Run periodic checks on expiration date of OA/OS embargos

Researchers should run **periodic checks** to allow the OA/OS dissemination of materials covered by embargos, once embargo periods expire.

✔ Verify compliance with license agreements

Researchers should do their best to verify, directly or with the help of supporting offices, the **compliance with license agreements by their licensees**, and particularly respect of FAIR, OA and OS clauses, in order to avoid privatization of derived results and imposition of obstacles to open dissemination and re-use.

✔ Run compliance checks of your status on institutional repositories

Researchers should run compliance checks of their **status on institutional repositories.** They should make sure to have uploaded all the materials (papers, background data etc) which they can freely disseminate, to use interoperable and accessible formats, and to provide correct metadata. Sherpa-Romeo systems may be used to learn about journal policies as to conditions for the upload of full text versions of articles. Ask yourself:

✔ Help your institution being up-to-date with the state of the art in the implementation of FAIR principles and OA/OS policies

Research communities develop thanks to the commitment of all their members. Each researcher should feel entitled and have the duty to help their institutions keeping the pace of developments in the field of FAIR principles and OA/OS policies. This will facilitate the adoption of state-of-the-art solutions and the leverage of any opportunity to increase the degree of openness and accessibility of research outputs across the EU.

7.6.4.2 Data Protection

At the end of the research, issues related to personal and non-personal data flows shall be addressed in order to make research data as open as possible and maximize the reuse of data. At the same time, the researcher must disable the unnecessary data flows in a compliant manner and store all the documents in order to be ready in case of audits and other monitoring activities.

✔ Check data retention for personal data

The researcher has to verify **data retention** terms for each enabled personal data flow in order to schedule their anonymization and / or erasure in compliance with the applicable legal framework.

✔ Check security policy

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Once the research is concluded, access and authorizations to the research infrastructure, data flows, etc. shall be **removed** according to the Data Management Plan, unless they are still needed for the purpose of reuse.

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8 Appendix C - Policy recommendations

8.1 Introduction

The aim of this part of the document is to draw conclusive remarks from the various assessments of the regulatory framework and indicate viable ways to enhance the legislative and non-legislative environment for the flourishing of Open Access, Open Science, and FAIR research environments in the EU. To this end, the report illustrates the lessons to be learnt from a policymaking perspective, substantially builds on the comprehensive legal mapping, comparative legal analysis, and gap analysis, and elaborates consistent policy recommendations, addressing both legal disciplines that are protagonists of the entire study, i.e., copyright law, and personal and non-personal data protection law.

The translation of the results of the legal analysis into solidly informed, methodologically sound, wide-ranging policy recommendations is a crucial step towards the effective building and practical improvement of the regulatory context surrounding research practices and infrastructures. The recommendations presented in the following pages reflect an accurate selection of the most relevant identified shortcomings of the current regulation, which has been operated on the basis of three criteria: (i) the relevance of legal obstacles at comparative level (e.g., profound regulatory fragmentation and divergences across the five analysed Member States); (ii) the relevance of legal obstacles *vis-à-vis* the guidelines issued to the benefit of individual stakeholders (e.g., specific needs to facilitate good practices); and (iii) the urgency of intervention upon provisions, whose modernization has deemed to be long overdue.

The realization of a cross-border, multinational management of FAIR research data, and the related participation of EU Member States in EOSC services require substantial efforts of legal reforms. As highlighted, in particular, in the report on the 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[132]. Most of the existing recommendations embrace a sector-, if not case-specific perspective relating to the stakeholders advancing them. Making a step forward, and 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.

[132] E.g., OpenAIRE, "Policy Recommendations for Open Access to Research Data in Europe", https://www.openaire.eu/recode (08/12/2020); SIS.NET, "Open Access Policies of the European Commission: Towards open science" (2015); Alma Swan (UNESCO), "Policy guidelines for the development and promotion of open access" (2012), http://www.unesco.org/new/en/communication-and-information/resources/publications-and-communication-materials/publications/full-list/policy-guidelines-for-the-development-and-promotion-of-open-access/ (08/12/2020).

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8.2 Copyright law

From the study of the EU copyright legal framework it became evident that two areas require interventions in order to fill up regulatory gaps and remove obstacles to the realization of FAIR ecosystems and the implementation of Open Access and Open Science policies. The reference goes to the system of exceptions and limitations, and to the harmonization of copyright contract law.

8.2.1 Exceptions and limitations (E&L) on use of copyrighted materials

The closed-list approach, and strict interpretation of copyright E&L, makes it difficult for copyright law to meet the changing needs of contemporary research ecosystems, particularly vis-à-vis the fast evolution of relevant technologies. Overcoming the *numerus clausus* design of E&L is to date not realistic as a feasible policy option. However, the effects of a more flexible and open balancing clause can be achieved by way of section wise reforming of the existing provisions.

A possible policy path ahead may be to intervene with a threefold EU harmonization directed to (i) introduce mandatory E&Ls, (ii) update existing E&Ls, and (iii) move towards a greater flexibility in the interpretation of E&L

Only an EU legal regime of mandatory harmonization 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. In this regard, the most recent developments stemming from the adoption and ongoing implementation of the Copyright in the Digital Single Market Directive (CDSM Directive), and particularly its articles 3, 4, and 5 introducing mandatory E&L for text and data mining practices and digital teaching activities, trace a promising future for EU copyright law-making.

A strongly harmonized 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 flaws underlined in our gap analysis and assessment of legal constraints. The consolidated closed list of exceptions and their strict interpretation represent 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 CJEU case law, thus ensuring a sound case-by-case judicial decision-making process.

8.2.2 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

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environments and FAIR research principles. A few targeted reforms would generate a remarkable beneficial impact. To start with, 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.

In a more encompassing fashion, a regime of ad hoc copyright contract law rules specifically addressing license agreements in the scientific sector would majorly facilitate the emergence of good practices between authors, investors, and publishers, and lead to a more sympathetic perception and stronger incentives towards Open Access and Open Science. In this light, the 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.

8.3 Personal and non-personal data protection law

The personal and non-personal data protection perspective offers valuable insights of how a better regulatory approach, combined with the collection of the best practices developed by stakeholders, may facilitate the policy assessment of the provided analyses.

The comparative study on personal and non-personal data identified two main barriers: the risk of overlapping for cross-border data flows and conflicts of laws with the sectorial applicable frameworks.

Despite the fact that topics are regulated by EU initiatives, the national implementations are not enacted by equivalent legal sources, as national legislators introduced exceptions both by hard law and soft law instruments. Therefore, the same provision may encounter a different level of efficacy in different legal systems. National safeguards have been also developed following different, and sometimes conflicting, approaches, including those that are dealing with technical and organizational measures and/or those that are identifying some boundaries under the general research purposes regime and/or those that are bridging consistency mechanisms between data protection laws and other sectorial legislations. Moreover, in this context of possible overlapping and conflicts of laws, relevant norms do not rely on technical standards required to technically achieve standards of interoperability. The integration with the legal framework applicable to non-personal data and copyright and IP protections aimed at enhancing FAIR principles could be frustrated, unless these issues are properly addressed in a standardization perspective.

To this end, policy recommendations are hereby advanced with regards to four main legal aspects that may contribute to overcome 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 practices in order to mitigate the envisaged risks of overlapping and conflicts of laws.

8.3.1 Private/public data controllers harmonization

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

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who process personal and non-personal data for research purposes shall be harmonized under a unique legal framework.

Article 89 GDPR refers to "Safeguards and derogations relating to processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes", while national legislations could find application despite of the public/private nature of the data controller, like the Italian Ethics Code that defines the research institute or body the one private or public whose purposes of statistics or scientific research result as an institutional or statutory scope and the consequent activity can be proven. This excludes, for example, conflicts of laws whereas research partnerships/consortia also include private bodies/entities. Also, the Austrian FOG refers to persons who are in an employment or contract relationship under the FOG either to public or private universities and non-university research institutions.

The harmonization of the legal regimes for private and public research entities would facilitate cross-border and federated FAIR ecosystems.

8.3.1.1 Pseudonymization / anonymization procedures harmonization

The GDPR compliance constitutes a logical priority towards a FAIR ecosystem for research data. Therefore, the standardization of procedures and requirements to allow the openness purposes may facilitate the achievement either of GDPR compliance purposes or Open Data. Combining technical safeguards with practical requirements and standards could facilitate the standardization of some recurrent processes, required for re-using data, like pseudonymization procedures.

For example, Belgian law establishes, in case of health data processed for research purposes, that pseudonymization could not be performed by the data controller, but by an independent body, who is subject to specific confidentiality obligations (i.e., professional secrecy). The "technical separation" between those who perform the two activities and an explicit obligation for those who pseudonymized to avoid re-identification might constitute a barrier in case of cross-borders partnerships. To harmonize best practices on the fundamental conditions to process personal datasets for research purposes would also facilitate the interoperability and re-use of research data.

8.3.1.2 Harmonization of safeguards for selected sectors (e.g., health, genetics)

Each Member State may decide to adopt general safeguards for personal data processed for research and statistics purposes, but it could also decide to regulate several profiles of a specific sector, including the related data management. Safeguards may at least be standardized 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 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.

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8.3.1.3 Development of an Organisation Chart

Organisational measures to process data for research purposes include a series of obligations to demonstrate the compliance with the applicable legal framework. Roles and responsibilities are attributed to the apical point of a body/entity even if – and this is particularly true for research activities – a more granular assignment could better represent the control flow.

To standardize roles and responsibilities within the research centre/funding body/principal investigator that develops research data could facilitate a responsible and legal attentive development of research data, as it would confirm the responsibility of taking care of data management upon the principal investigator. In this regard, for example, part of the process could be delegated along the life cycle of the research to experts and advisors as a part of the research management, similarly to what happens for other activities developed along the project time span.

In this regard, the role of 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 organization chart for research data management is particularly urgent in case of AI-based technologies R&I considering, for example, the possible mandatory obligation for the AI-controllers/developers to perform an Impact Assessment, as envisaged by the most recent Resolutions of the EU Parliament.

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9 Appendix D - Examples of Instituted Data Policies

9.1 EOSC-Hub

Although it contributed to much of the technical infrastructure of EOSC, the EOSC-Hub[133] project doesn't itself produce data, but from a large diversity of sources is processed by the services involved. EOSC-Hub has produced a "Data policy recommendations"[134] document, which builds on the legacy of the EOSC-pilot project. The abstract states: "Building on current best practice, notably the EOSCpilot policy recommendations and the EC Expert Group report on FAIR data, we recommend 22 practical steps bridging general policy recommendations and future technical implementation of data sharing within the EOSC-hub service ecosystem." Three areas are considered in this document regarding openness: intellectual property, personal data restrictions according to the EU General Data Protection Regulation (GDPR) and ethical data restrictions including for example the embargo period. These recommendations are applicable in the general context of most data accessible via EOSC.

The recommendations continue the use of "DataTags", which follows from an EOSC-pilot recommendation. A DataTag is defined as "a label indicating a level of protection to be applied to the processing of the tagged data object.". In the framework of EOSC-Hub DANS developed the first DataTags concrete prototype for GDPR. The project also "recommends that working groups be set up between communities in which different kinds of data sensitivity arise (e.g. biodiversity) and data curation professionals to develop similar decision tree-based approaches to assessing and tagging sensitive data objects.".

9.2 ELIXIR

Life Science data especially in the context of clinical and health research are known to be generally restricted due to their personal and sensitive aspects. The ELIXIR[135] community has worked on this topic for several years and published its ELSI policy approved by the ELIXIR Board in 2016. ELIXIR does not produce data but its services offer data for secondary use. ELIXIR is also a distributed infrastructure of Nodes that archive data and provide users with services. ELIXIR deals with human and animal data.

ELIXIR ELSI policy[136] (ethical, legal and societal issues policy) relies on legal basis, basic ethical principles and provides requirements to be met by the service providers and the data providers. It is a concrete and detailed example that relies on national laws and relevant international regulations in this domain. The scope section of the policy makes data underlying specific regulatory requirements available [137]. Copyright, intellectual property or license considerations are not covered in this policy. The policy ensures that the data is made "available for research in a way that is compliant with all relevant (e.g., EU-level, national and local or internal) legal and ethical requirements". It deals with

[133] http://eosc-hub.eu
[134] https://documents.egi.eu/document/3419
[135] https://elixir-europe.org/
[136] https://drive.google.com/file/d/0BxqILhwJcm1qME00QWRKUmtEVXM/view
[137] https://www.elixir-europe.org/sites/default/files/images/schema_0.png

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protection of Personal Data including Sensitive Data in the human health context. It provides a standard that allows data sharing beyond borders.

Access to specific types of data such as for example clinical and health research data may be more restricted due to their personal and sensitive aspects. The ELIXIR ELSI policy (ethical, legal and societal issues policy) is a concrete and detailed example that relies on national laws and relevant international regulations in this domain. It follows also basic ethical principles such as Human dignity and autonomy, Non-discrimination, Good scientific practice and public benefit.

9.3 LHC and high energy physics

An established services structure that predates many of today's service infrastructures is the worldwide LHC computing grid (WLCG)[138]. WLCG is a global collaboration of around 170 computing centres in more than 40 countries, linking up national and international grid infrastructures that provide the computing and storage platform for particle physics. Many of the federating concepts that dominate the core of EOSC have been modeled during the development of the 'Grid', a technology with a specific deployment model elaborated in the late 1990s in the MONARC project.

9.3.1 Data policies in High energy physics

Data in High Energy Physics (HEP) data is known to be open which makes it interesting to understand how this data is managed from a security viewpoint.

CERN has set up a portal dedicated to Open Data[139]. This portal is the access point to data produced through the research performed by the large HEP collaborations. Data is categorised in four different levels (1 to 4) set up by DPHEP, the study group for Data Preservation and Long term Analysis in High Energy Physics. The portal gives access to data from level 2 and 3 with a persistent identifier (DOI) and a citation recommendation. Level 1 data is published as additional numerical information to publications and archived in the long term by trusted third parties.

An important point to note is that the experiments link the ability to open their data to the preservation of the data they are responsible for. They provide their open data with the associated software and documentation but they advertise they do not have resources to support the potential users of this data.

9.3.2 Data policies in LHC

Each of the four LHC experiments has its own data access policy and they all make their data available (except level 4 data) and after the embargo period. The reasons to keep level 4 data closed are that these data and associated software are complex and require important resources to be open that the experiments cannot provide.

[138] https://wlcg.web.cern.ch/
[139] http://opendata.cern.ch/

CMS

- First version dedicated to the CMS collaboration policy on long-term data preservation, re-use and open access. The policy was approved by the CMS Collaboration Board in March 2012.
- The current version: CMS collaboration (2018). 2018 CMS data preservation, re-use and open access policy. CERN Open Data Portal. DOI:10.7483/OPENDATA.CMS.7347.JDW
- The open data are released under the Creative Commons CC0 waiver[140]. Neither CMS nor CERN endorse any works, scientific or otherwise, produced using these data. All releases will have a unique DOI that you are requested to cite in any applications or publications.
- Embargo period: The objectives of the embargo period allow CMS collaborators to fully exploit the scientific potential of the data before open access is established.

ATLAS

- The policy regarding the access to ATLAS data by non-ATLAS members was endorsed by the ATLAS Collaboration Board in June 2014: ATLAS collaboration (2014). ATLAS Data Access Policy. CERN Open Data Portal. DOI:10.7483/OPENDATA.ATLAS.T9YR.Y7MZ
- The open data are released under the Creative Commons CC0 waiver[141]. Neither ATLAS nor CERN endorse any works, scientific or otherwise, produced using these data. All releases will have a unique DOI that you are requested to cite in any applications or publications.
- Embargo period: The document states that "There would be an embargo period on each dataset to allow the members of the collaboration a reasonable time to perform analyses. Given the complexity of particle physics analyses, this embargo period will be measured in years, not months."
- The policy suggests the partnership with ATLAS collaboration as the most practical mean for projects willing to conduct a specific new analysis that requires level-3 data. They have established a specific Short Term Association programme.

LHCb

- The document contains the LHCb Data Access Policy. This was adopted at the Collaboration Board meeting on 27th Feb 2013.
- Clarke, Peter; LHCb collaboration (2013). LHCb External Data Access Policy. CERN Open Data Portal. DOI:10.7483/OPENDATA.LHCb.HKJW.TWSZ
- The open data are released under the Creative Commons CC0 waiver[142]. Neither LHCb nor CERN endorse any works, scientific or otherwise, produced using these data. All releases will have a unique DOI that you are requested to cite in any applications or publications.

[140] https://creativecommons.org/publicdomain/zero/1.0/
[141] https://creativecommons.org/publicdomain/zero/1.0/
[142] https://creativecommons.org/publicdomain/zero/1.0/

- Embargo period: periods and portions of data made open are reviewed by the Collaboration Board (normally 50% after 5 years and 100% after 10 years.). Requests are also possible to get access to more data.

ALICE

- This document contains the ALICE data preservation strategy and policy. It was adopted in 2013.
- ALICE collaboration (2013). ALICE data preservation strategy. CERN Open Data Portal. DOI:10.7483/OPENDATA.ALICE.54NE.X2EA
- Embargo: "Data with high abstraction, such as AOD, will be conditionally made publicly available after an embargo period of 5 years after publication for 10% of the data and 10 years for 100% of the data."
- Level 4 data: "ALICE does not currently consider these data suitable for the general public but leaves open the possibility of re-processing, by members of the collaboration and after approval by the ALICE Physics Board"

Even though all particle physics data is open, there might be restrictions due to important specific cases. An example is the High Energy Physics domain. CERN and each of the four LHC experiments have their own data access policy and they all make their data available (except level 4 data) and after the embargo period. The reasons to keep level 4 data closed are that these data and associated software are complex and require important resources to be open that the experiments cannot provide.