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Editorial

The democracy of emergency at the time of the coronavirus: the virtues of privacy

Giovanni Comandé, Denise Amram, Gianclaudio Malgieri*

The emergency of the Coronavirus imposes a cultural debate on the balancing of rights, freedoms and social responsibilities, finalized to the protection of individual and collective health.

So much and rightly has been written in these days about strategic errors of the past, and authoritarian and social control risks exploiting the fear of contagion to further compress individual freedoms. A lot has been said about the futility of privacy as well.

But is there a democratic way that respects fundamental rights in an emergency? Is there a model that can turn respect for democratic freedoms into a tool for effective common struggle in an emergency?

Of course, there is one! It is an ethical duty to raise this issue here, now and publicly to strengthen the fundamentals of democracies at this very time of their stress. This will provide a suitable basis for a different and stronger return to normality.

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* LIDER Lab, Scuola Superiore Sant'Anna (Pisa) g.comande@santannapisa.it; d.amram@santannapisa.it; gianclaudio.malgieri@gmail.com. This editorial is not peer-reviewed as it is the result of a dialogue between the Authors during the first week of lockdown in Canada, Italy, and Belgium. For deep comparative remarks on the special regulations under the Covid-19 emergency in several fields, please see the contributions included in Opinio Juris in Comparatione Special Issue 2020. This Editorial has been developed within the "SoBigData Plus Plus: European Integrated Infrastructure for Social Mining and Big Data Analytics" Project, funded by the EU Commission under the H2020 INFRAIA-1-2019 programme (GA 871042).

To do so, the emphasis on the democracy of emergency must be distinguished from the criticism directed against abuses (in non-democratic systems), past mistakes (the economic undermining of health care as a public service), and the failure to consider certain components of production as strategic national assets, which were instead abandoned to a delocalization based only on cost reduction for the benefit of profits rather than on risk management.

Let's make this straight: the often denounced risks of a surveillance capitalism, incubated in our open societies by certain uses of information technology and other collective fears (e.g. terrorism), remain in all their brutality today during the coronavirus emergency. However, precisely for this reason we must understand if and how our balancing instruments allow us not to give in to positions as extreme as trivializing: the so-called privacy is now seen as a "faddishness"; criticized for being a totem higher than human life itself.

Our illustrative example of what democracy of emergency should mean, however divisive it may seem, will be precisely the much criticized privacy, not a useless ornament but a suitable instrument of democratic strength and efficiency, the starting point and not the end point for a democracy of emergency able to stand as a model against all dictatorships.

In a democracy, emergency time unfolds within a framework of clear and shared values; it is a temporarily different "normality", different from the state of emergency with which dictatorships "justify" the compression of freedoms.

From the outset, an entirely Italian preamble, suitable for many sister democracies. The Italian Republican Constitution, the offspring of extreme moments and struggles against totalitarianism, is well aware of the need to protect democracy, to balance individual liberties and social needs (Articles 2, 3, 4, 13-24 Cost.), and to balance the fundamental right to health as an individual and a collective interest. These are the bases on which every concrete action moves, these are the foundations with which every emergency provision must reckon.

The first constraint of an emergency is the temporariness of measures that limit or distort the ordinary course of rights and freedoms; the second is its founding reason that permeates like a red thread all principles of our Constitution: namely solidarity, common good, sharing with those in need.

On the first constraint, the lexical and phenomenological twisting of the original concept of dictatorship is illuminating. The term was born in Roman law as an emergency institution that concentrated, while maintaining some safeguards of checks and balances, in a single individual many powers otherwise divided among many. This power ceased once the emergency objective of the appointment was achieved and, in any case, it could only last for six months. What made these extraordinary limitations acceptable was the certainty that they would not last more than six months and that they were necessary for the common good: if you want, their impermanence and their solidarity nature. A solidarity based on the awareness that a community stands with mutual support, especially at extreme times. A model of extraordinary stewardship that is legitimate precisely because it is provided for by the normal regime to which it returns.

Against this background, let us see the impact of the collective fight against the spread of the epidemic from the point of view of the democracy of emergency, through the eyes of the fundamental right to the protection of personal data.

The digital transition of everyday life. The most evident impact is the limitation of the freedom of movement which, however, seems to be mitigated by the possibility of conducting a "smart life" that hinges on a series of activities that can be "remote-conducted": some working activities, communications, recreational and educational activities. This means changing our own habits and sacrificing individual freedoms in view of a common mobilization of responsibility (and in light of infrastructures that were not prepared for a sudden "remotization" of activities). Nevertheless, already at the very first level of the social structure, things are getting complicated. Family status and cohabitation are increasingly not coinciding and even where they do coincide, solutions must be sought for those who cannot operate remotely and have their children at home (for example, health care workers or those who must ensure that there are supplies or electricity in all homes).

Leaving aside these issues, as they deserve specific attention, let us focus on the protection of personal data in a massive, sudden and intensive use of digital technology. Infrastructures are overloaded and the technical-organizational measures to ensure data protection in terms of availability, confidentiality and security may not meet immediate needs, also taking into account the different levels of digital literacy of users. These factors ideally put at risk the " substitutive" effect of a smart life for the exercise of freedom of circulation, of information, of assembly, and of expression, making it necessary to increase vigilance against possible discrimination already during the emergency!

The safeguards corresponding to the impermanence and the reasons of solidarity (common good) mentioned above can be found in the protection of people in the processing of their personal data under the ordinary and extraordinary regulatory regimes.
An open and rigorous application of the rules and principles of personal data protection is the founding reason for the smooth – but vigilant – acceptance of the restrictions on freedoms.

Let us give concrete examples to illustrate that the democratic path to emergency is not weak but uses the strength of the rule of law and the primacy of rights to maximise the use of data by promoting adhesion rather than coercion.

Personal data flows to handle the emergency. The most striking example is the relationship between health protection and privacy. Mapping the spread of the virus appears to be the most effective organizational measure for containment purposes. The price is our privacy: collective health is a common good and justifies the processing of personal data, even sensitive ones through simplified procedures that, in any case, do not threaten democratic values (the protection of fundamental rights). Recital 46 of the General Regu-

lation on Data Protection (EU Reg. No 2016/679, so-called GDPR), in illustrating what is meant by "*an interest which is essential for the life of the data subject or that of another natural person*" and "*important grounds of public interest*" quotes "*for instance when processing is necessary for humanitarian purposes, including for monitoring epidemics and their spread*".
Accordingly and for example, the Italian emergency statute describes the cases in which it is justified to process personal data – regulated in Articles 6, 9, 10 of the GDPR – but does not provide for any derogation from the technical and organizational measures to be adopted for its processing. In other words, the state of emergency does not justify the non-application of the GDPR rules. It does not justify anarchy of processing but allows for the provision of highly exceptional situations. It is no coincidence that the Italian emergency statute of March 9th 2020 dedicates the entire article 14 to the processing of personal data, invoking the legal basis for processing and identifying the persons expressly authorized to implement, or to discontinue, data flows in execution of the emergency plan. The article provides the following, illustrating why keeping fundamental rights protected increases the flow of data and preserves democratic values:

The processing of "sensitive" and judicial personal data may be carried out by medical and health care personnel or by persons authorized by the statute on the COVID-19 emergency (D.L. 9 March 2020 n. 14): civil protection, public and private structures operating in the health sector, entities appointed to ensure the implementation of emergency measures. All who need to process them but only them!
The communication and sharing of data between the entities referred to in the previous point must respect the principles of minimisation, proportionality and purpose limitation: it must be "necessary for the performance of the functions assigned to it in the context of the emergency caused by the spread of COVID". Emergency is not an excuse to crash fundamental rights.
The exchange of sensitive and judicial data with public and private entities other than those mentioned in the point a., or of general data referred to in art. 6 GDPR, is justified only if "essential for the performance of activities related to the handling of the health emergency in progress". In other words, all the public and/or private bodies that contribute to the handling of the emergency could well be recipients of the flows of personal data collected in the implementation of the tasks aimed at limiting the diffusion of the COVID, but this does not mean creating an indiscriminate access to them.
Pending the emergency, the collection and storage of information must take place in a lawful and transparent manner: the statute does not encourage information asymmetries or the generation of privileged positions. Only emergency medical personnel are exempted, pursuant to article 23, paragraph 1, letter e) GDPR, from providing notice or are authorized to formulate a simplified one. In any case, it is required to communicate the limitations to the person orally: the patient today is not interested in "useless privacy", but will be interested tomorrow to avoid discrimination, for example; it is the task of a mature and supportive democracy to think about it for him, already today.

Access to information must be arranged in a granularly way, data storage must be instrumental to the policies of anonymisation and destruction, sharing must be only with public and private entities that pursue the specific purpose of handling the health emergency.
The internal authorizations to delegate processing within organizations (art. 2-*quaterdecies* of Legislative Decree no. 196/2003) can be given orally only by the persons "in the front line" listed in article 1 of the same statute. The state of emergency enables the temporary suspension of ordinary procedural paths thanks to the certainty that there is a time limit to it and, in any case, there are further safeguards in the system (such as, for example, general duties of confidentiality, data flows are stored through secure channels specifically designed for the particular nature of the data,…).
From this perspective, it is right to map the prior movements of the subject who tested positive to the swab, perhaps even using 007 technologies. Nevertheless, once the "quarantine time" has elapsed, it is equally right to destroy unnecessary information. This way once the emergency is over democratic values are not compromised. A word of warning: destroying superfluous information does not mean destroying valuable epidemiological data, it means ensuring that this information cannot be used to violate the fundamental rights and freedoms of the individual concerned. Let us not forget that the GDPR has twofold aims (Art. 1) ruling both "*the protection of natural persons with regard to the processing of personal data*" and "*the free movement of personal data*". It is the protection of fundamental rights of individuals that ensures greater and better flow of data.
The sharing of the information flow outside the ordinary schemes moves on the footsteps of the exceptionality of the functions attributed by legislation. It can do it, and can do so without turning into a (further?) instrument of (undue) social control precisely because it is inserted in a context of principles that safeguards rights and freedoms even when they are limited and, at the same time, reassures on the reasons of solidarity and temporariness of such limits. These possibilities are by definition lacking in undemocratic societies. To renounce them or to trivialise them means to renounce the democratic characteristic of our societies, to renounce to the difference between democratic and non-democratic civilisations.

Emergency technology: risks and opportunities. It is again the balancing between fundamental human rights and the balance between individual and collective freedoms as a symbol of democracy.
In the COVID-19 containment task force, personal data is an invaluable resource to allow the coordination of the work of the emergency: portability, interoperability, reuse are the characteristics that allow the front line operators to dialogue with those on the second line.

Consider the services offered by public and private companies that, through the analytical extractions of data "owned by them", provide or enhance the supply of services and products to replace the "physical lockdown" of the cities or allow to track the spread of the epidemic, as already happened in Africa for Ebola. Also, consider scientific and experimental research: the use of Machine Learning technologies to process large amounts of

data and meet the needs of diagnosis and therapy more effectively and efficiently become the added value of the task force, as the announced Google app in San Francisco.

For the massive use of personal data, including health data, to remain an opportunity, the risks arising from improper processing must be assessed and mitigated. Likewise, developed technologies cannot fail to respond to the values shared in the relevant system.
The legal framework allows, through the appropriate technical and organizational measures, to ensure the correct balance between the values, also in emergency, keeping personal data flows and automated decision-making processes within the limits of lawfulness, correctness and robustness.
The cultural challenge is to consider the preservation of technical and organizational measures for personal data processing as an integral part of the wider process of managing emergencies in order to protect democratic values.
Exceptions to the system of checks and balances must be instrumental and proportionate to the protection of the common good. This is the contribution that experts in the field can give to the COVID-19 task force: availability and promptness in evaluating protocols, experiments involving personal data especially of health data.
The streamlining of procedures revolves around the availability of the various parties involved (the issue of smart activities returns) and the timeframe for the evaluation of proposals, but it cannot affect the substance of the evaluation because this would compromise democratic values, and it would also affect the adhesion to the emergency plan.
If I trust that the system protects me both in the ordinary regime and in the extraordinary one, I will not be afraid of adhering to it, and I adhere to the limitations, considering them only temporary and necessary for the pursuit of the common objective of solidarity.
An example to test the meaning of our discourse is the facial recognition system for faces with masks. It was implemented in China for monitoring and surveillance purposes, including the detection of body temperature. In our system, its use could successfully be considered lawful at hospitals (if accompanied by a positive Data Protection Impact Assessment, for example), and perhaps at people transport hubs in an effort to reduce the involvement of health personnel in intensive care or to track possible infected people to warn them. Here the aim would be to protect individuals' right to health and, at the same time, to reduce the epidemic spread pursuing the collective interest in an environment with limited access, such as boarding areas. However, such a system could hardly be accepted in other contexts and circumstances without compromising the values on which society is based.
Similarly worrying, in absence of the above-mentioned safeguards, it appears the hypothesis of "tracking infected people", as imprudently suggested on social networks.
Who should track them in addition to the health personnel who care for them and who of course "tracks" them in the medical files and shares these data with those who should do so by law? What is meant by tracking the infected person? With a bracelet? By intercepting their private and family life through IoT-connected devices? What further information would be collected? And for how long? Above all, how to avoid the use of this information

for lynching, even verbally, and summary justice as during the plagues described in novels? Awareness on democracy in emergency is needed to answer these questions.
We are going through a culturally dark age when populism and fear of those different from us constantly challenge fundamental rights. In recent weeks, in Italy and elsewhere, we have witnessed anti-Semitic or homophobic inscriptions on doors of private homes; do we really want the inscription "here infected"?

The step to discrimination is short if privacy is considered a "physima": limits and boundaries to the use of personal data must be mapped out by design and applied by default so that – once the emergency is over and it does not require anymore to balance confidentiality and protection of personal data with collective protection in emergency – the relationship between freedom and responsibility can be rebalanced. The same duty of solidarity that allows the limitation of rights and freedoms requires ensuring that such limitations have no further adverse effect.
All this is possible if one believes in democracy even in emergencies, if one is aware that holding firm to the cornerstones of the protection of rights and freedoms means not giving in to the easy assertion that its protection is a futile ornament in emergency.

Our system of values and regulations allows us not to block the efficient use of personal data precisely because we can confidently entrust them to the broadest safeguards of the system.
In other words, "the mere suspension of privacy law" in emergency weakens the use of personal data itself and undermines democratic values. To the contrary, it is the same personal data protection law that already provides for the right to life and health to prevail. However, in order to avoid compromising tomorrow's democratic life, individual and collective freedoms, it is sufficient to follow those solutions suggested by the law itself today, including the law on handling the COVID emergency. In a democracy, the extraordinary is managed and provided for already by the ordinary!
Let us therefore seize the opportunity to speed up the digital transition of our daily life, to exploit artificial intelligence and technology for the service of the common good, without undermining human dignity and democratic values.
The legal instruments to do so are available. It is enough to interpret them in light of fundamental rights, being aware that privacy will never limit in our legal systems the use of every resource aimed at protecting individual and collective life and health, but on the contrary, it makes it possible, legal and ethical.
This is the difference between the use of a state of emergency in a democratic and in a non-democratic system. In the former, the protection of fundamental rights and freedoms allows a wider processing of personal data also in emergencies, precisely because it preserves values by building a basis of trust and legitimacy. In the latter, the emergency becomes an excuse to further compress rights and freedoms by concentrating even more the power of data outside any guarantee.

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Responsabilità civile da usi *off-label* di farmaci nell'UE: una prospettiva precauzionale

Andrea Parziale*

Abstract

Gli usi *off-label* di farmaci (cioè per indicazioni diverse da quelle autorizzate) ampliano le opzioni terapeutiche, ma possono esporre i pazienti a incertezze sostanzialmente sperimentali. Il contributo valuta in che misura la responsabilità civile e altre risposte istituzionali possano chiarificare una simile "zona grigia" tra ricerca e pratica medica. A tal fine, il contributo svolge un'analisi comparata della giurisprudenza e della legislazione di UE, Italia e Francia, ordinamenti dove gli usi *off-label* hanno indotto rilevanti innovazioni giuridiche. Tale analisi mostra che sono in atto delle tendenze dall'impatto potenzialmente positivo per l'ambito degli usi *off-label*, in particolare: (a) a livello giurisprudenziale, una reinterpretazione "precauzionale" delle regole di responsabilità; (b) a livello legislativo, la previsione di forme di ristoro *no-fault* per chi non può accedere al risarcimento e di meccanismi di ADR in ambito medico-sanitario. Tali tendenze contribuiscono a chiarire i doveri di medici, produttori e regolatori e a facilitare il ristoro dei danneggiati nell'ambito preso in esame.

Keywords

Usi off-label – Regolazione farmaceutica – Responsabilità civile – No-fault – ADR

* PostDoc Researcher, Sant'Anna School of Advanced Studies (Pisa, Italy).

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1. Introduzione

In assenza di alternative terapeutiche testate e autorizzate, i medici possono, a certe condizioni, prescrivere farmaci per indicazioni o secondo modalità diverse da quelle riportate nelle rispettive autorizzazioni amministrative. Pur rappresentando un importante vettore di innovazione medico-scientifica, tali prescrizioni, cosiddette *off-label* o "fuori etichetta", si collocano tuttavia in una "zona grigia" tra sperimentazione e pratica clinica, in quanto possono esporre i pazienti a incertezze analoghe a quelle proprie del contesto sperimentale, al di fuori delle garanzie previste per *i clinical trial*.

L'ipotesi del presente contributo è che la responsabilità civile e altre risposte istituzionali (ad esempio, i meccanismi no-fault) possano contribuire a chiarificare i doveri dei principali attori coinvolti nella zona grigia degli usi *off-label* (medici, produttori e regolatori), fornendo ai danneggiati idonei mezzi di tutela. Al fine di verificare una simile ipotesi, il contributo analizza e confronta le regole di responsabilità e le alternative istituzionali previste da diversi sistemi giuridici, considerandone le implicazioni pratico-operative[1]. In particolare, si procederà a comparare la giurisprudenza e la legislazione europea, italiana e francese, dato l'interesse mostrato da tali ordinamenti verso il fenomeno considerato.

[1] G. Comandé, *Risarcimento del danno alla persona e alternative istituzionali. Uno studio di diritto comparato*, Torino, 1999, pp. 120 ss.

Il presente contributo si struttura come segue. In primo luogo, si procede a una descrizione fattuale del fenomeno delle prescrizioni "fuori etichetta", che si collocano all'intersezione tra ricerca e pratica clinica. Dopodiché, si analizza il quadro regolatorio di riferimento. Il contributo considera quindi il ruolo della responsabilità civile di medici, produttori e regolatori, attraverso un'analisi comparata della giurisprudenza europea, italiana e francese. Si fa poi riferimento al principio di precauzione per chiarire la portata delle decisioni analizzate. Infine, il contributo esamina il ruolo dei fondi *no-fault* e dei meccanismi di *Alternative Dispute Resolution* (ADR), a partire dagli esperimenti italo-francesi in materia. Le conclusioni riassumono i risultati dell'analisi e indicano ulteriori linee di ricerca.

2. Gli usi *off-label* di farmaci

Secondo la definizione adottata dalla Commissione in un suo recente studio sul fenomeno, è *off-label* l'uso intenzionale di un farmaco già autorizzato, non coperto dalla rispettiva autorizzazione all'immissione in commercio (AIC) e dal riassunto delle caratteristiche del prodotto (RCP)[2]. Una prescrizione *off-label* ricorre, dunque, non solo quando un medico somministra un medicinale per un'indicazione non autorizzata, ma anche quando la prescrizione avviene per l'indicazione autorizzata ma, ad esempio, con un dosaggio o per una popolazione diversa. In linea di principio, i medici sono liberi di prescrivere medicinali *off-label*. Ciò può rivelarsi necessario per curare i pazienti, in mancanza di alternative autorizzate, come accade di frequente nell'ambito delle malattie rare e dell'oncologia, nonché in pediatria, poiché i medicinali sono normalmente testati su e approvati per popolazioni di adulti[3].
In alternativa, i professionisti sanitari possono scoprire che dei prodotti prescritti *off-label* offrono un'alternativa più efficace ed economica rispetto a medicinali già autorizzati, anche alla luce delle peculiari caratteristiche dei singoli pazienti[4].

[2] Commissione europea, *Study on off-label use of medicinal products in the European Union*, Bruxelles, 2017, p. 13.

[3] Id., p. 166; M. Di Paolo, B. Guidi, L. Nocco, *La prescrizione off-label: dentro o fuori la norma?*, in *Resp. Prev.*, 2010, pp. 2165 ss.; L. Cuzzolin, A. Zaccaron, V. Fanos, *Unlicensed and off label uses of drugs in paediatrics: a review of the literature*, in *Fundamental & Clinical Pharmacology*, 2003, XVII, pp. 125-131; A. Querci, *Responsabilità per danno da farmaci: quali i rimedi a tutela della salute?*, in *Danno e resp.*, 2012, pp. 353-369.

[4] S.A. Shapiro, *Limiting Physician Freedom to Prescribe A Drug for Any Purpose: The Need for FDA Regulation*, in *Northwestern Un. L. Rev.*, 1978, 73, 5, p. 814.

3. Gli usi *off-label* di farmaci tra sperimentazione e pratica clinica

Per fini di salute pubblica[5], prima di essere immesso in commercio, ogni farmaco deve essere testato e ricevere un'apposita autorizzazione sulla base dei dati sperimentali raccolti (art. 6, Regolamento 726/2004). Il controllo sugli effetti del farmaco prosegue anche dopo il momento autorizzativo con la cosiddetta farmacovigilanza[6]. Ciò posto, è opportuno consentire ai professionisti sanitari di discostarsi dalle autorizzazioni amministrative[7]. Infatti, i rischi e i benefici associati all'uso di un medicinale possono variare tra pazienti in modo significativo.

Tuttavia, gli usi farmaceutici non approvati possono prestarsi a un'errata analisi del rapporto rischio-beneficio, data la mancanza di dati conclusivi[8]. Gli usi *off-label* possono esporre i pazienti a incertezze analoghe a quelle proprie del contesto sperimentale, non essendo stati oggetto di sperimentazioni cliniche.

Una simile preoccupazione è espressa nel Rapporto Belmont (1978) [9], un documento tuttora di riferimento nel dibattito sulla distinzione tra ricerca e pratica medica, redatto, su incarico del Congresso degli USA, da un'apposita Commissione nazionale per la protezione dei soggetti sperimentali. Secondo quest'ultima, le terapie innovative, compresi gli usi *off-label*, possono essere più rischiose di una ricerca ben progettata, in quanto non convalidate da studi clinici randomizzati. La Commissione espresse preoccupazione per la mancanza di un'adeguata sorveglianza su queste pratiche, raccomandando l'inclusione di innovazioni terapeutiche significative in progetti di ricerca formali[10].

La Dichiarazione di Helsinki riflette un simile timore[11]. Il paragrafo 37 della Dichiarazione prevede che, in mancanza di interventi efficaci e comprovati, il medico può utilizzarne uno non provato, se "offre la speranza di salvare la vita, ristabilire la salute o alleviare la sofferenza" del paziente. Il medico deve comunque consultare un esperto, ottenere il consenso informato del paziente, studiare la sicurezza e l'efficacia dell'intervento e pubblicare, se del caso, le informazioni ottenute.

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5 N. Chowdury, *European Regulation of Medical Devices and Pharmaceuticals*, Berlino, 2014; S. Shorthose, *Guide to EU Pharmaceutical Regulatory Law*, Alphen aan den Rijn, 2014.

6 WHO, *Safety Monitoring of Medicinal Products: Guidelines for Setting Up and Running a Pharmacovigilance Centre*, Uppsala, 2000; M. Kaeding, J. Schmälter, C. Klika, *Pharmacovigilance in the European Union: Practical Implementation across Member States*, Springer, 2017, pp. 11-17.

7 S.K. Gupta, R.P. Nayak, *Off-label use of medicine: Perspective of physicians, patients, pharmaceutical companies and regulatory authorities*, in *Journal of Pharmacology & Pharmacotherapeutics*, 2014, V, 2, pp. 88-92.

8 S.A. Shapiro, *Limiting Physician Freedom to Prescribe A Drug for Any Purpose: The Need for FDA Regulation*, cit., p. 815.

9 Department of Health, Education, and Welfare, *The Belmont Report. Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, Washington, 1979, p. 3.

10 Id., p. 4.

11 R.V. Carlson, K.M. Boyd, D.J. Webb, *The revision of the Declaration of Helsinki: past, present and future*, in *British J. Clin. Pharmacol.*, 2004, pp. 695-713. L'ultima versione è stata approvata a Fortaleza, in Brasile (2013).

Le terapie innovative non hanno invece uno statuto giuridico particolare nella regolazione europea delle sperimentazioni cliniche. Il Regolamento 536/2014 definisce gli studi clinici come qualsiasi indagine sugli effetti di un determinato medicinale sugli esseri umani (art. 2(1), Regolamento 536/2014). Pertanto, quando sono estranee a scopi conoscitivi, le prescrizioni *off-label*, pur esprimendo delle incertezze sperimentali, si sottraggono alle garanzie proprie dei *clinical trial*, come la revisione dei comitati etici[12]. Tali usi descrivono dunque una "zona grigia" tra ricerca e pratica medica.

4. La regolazione degli usi *off-label* di farmaci nell'UE

La giurisprudenza europea afferma che il diritto dell'UE non vieta gli usi *off-label*, in quanto non esiste alcuna disposizione che la vieti[13]. Tuttavia, risulta rilevante anche per gli usi "fuori etichetta" l'articolo 5, Direttiva 2001/83/CE, esaminato approfonditamente dalla Corte di giustizia nel caso *Commissione c. Polonia*[14]. Tale disposizione consente infatti agli Stati membri "conformemente alla legislazione in vigore e per rispondere ad esigenze speciali, [di] escludere dal campo di applicazione della presente direttiva i medicinali forniti per rispondere ad un'ordinazione leale e non sollecitata, elaborati conformemente alle prescrizioni di un medico autorizzato e destinati ai suoi malati sotto la sua personale e diretta responsabilità".

Nel 2012, inoltre, gli obblighi di farmacovigilanza imposti dalla regolazione farmaceutica europea sono stati estesi agli usi non conformi al contenuto dell'AIC e del RCP (Direttiva 2010/84/UE e Regolamento 1235/2010), ivi compresi, dunque, gli usi *off-label* di farmaci[15].

Entro questa cornice regolatoria, vi è un gruppo di Stati membri dell'UE che non ha adottato particolari strumenti di *policy*. In questi ordinamenti, gli usi *off-label* sono demandati all'autoregolazione dei professionisti sanitari[16].

La maggior parte degli Stati membri, invece, ha predisposto degli strumenti di *policy* specifici[17]. Alcuni di questi, come Francia e Italia, regolano direttamente i requisiti delle prescrizioni *off-label*, nonché le modalità di fissazione del prezzo e di rimborso dei relativi prodotti farmaceutici.

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[12] Tale principio, insieme a quelli del consenso informato e della proporzionalità tra rischi e benefici, è sancito da una serie di strumenti internazionali, quali la Dichiarazione di Helsinki e la Convenzione di Oviedo sui diritti umani e la biomedicina, nonché dalla regolazione euro-unitaria delle sperimentazioni cliniche.

[13] Trib. primo grado, sentenza del 11 giugno 2015, causa T-452/14, par. 79.

[14] Corte giust., sentenza del 29 marzo 2012, causa C-185/10.

[15] M. Kaeding, J. Schmälter, C. Klika, *Pharmacovigilance in the European Union*, Springer, 2017, pp. 25 ss.; I.R. Edwards, *Off-Label Pharmacovigilance*, in *Drug Safety*, 2011, pp. 795-797.

[16] Commissione europea, *Study on off-label use of medicinal products in the European Union*, cit., p. 60.

[17] Id., p. 61.

La regolazione italiana degli usi *off-label* trova le proprie origini nel caso Di Bella, che riguardava un particolare *mix* di farmaci prescritti "fuori etichetta", rivelatosi inefficace[18]. Ai sensi dell'art. 3, secondo comma, d.l. 23/1998, convertito in l. 94/1998:

> In singoli casi il medico può, sotto la sua diretta responsabilità e previa informazione del paziente e acquisizione del consenso dello stesso, impiegare un medicinale prodotto industrialmente per un'indicazione o una via di somministrazione o una modalità di somministrazione o di utilizzazione diversa da quella autorizzata, ovvero riconosciuta agli effetti dell'applicazione dell'articolo 1, comma 4, del decreto-legge 21 ottobre 1996, n. 536, convertito dalla legge 23 dicembre 1996, n. 648 [cioè, ai fini del rimborso del farmaco, *NdR*], qualora il medico stesso ritenga, in base a dati documentabili, che il paziente non possa essere utilmente trattato con medicinali per i quali sia già approvata quella indicazione terapeutica o quella via o modalità di somministrazione e purché tale impiego sia noto e conforme a lavori apparsi su pubblicazioni scientifiche accreditate in campo internazionale.

Successivamente, l'art. 2, comma 348, l. 244/2007 ha precisato che le prescrizioni *off-label* sono permesse solo in presenza di dati favorevoli di sperimentazione clinica di fase II per l'indicazione non autorizzata.
Il SSN rimborsa gli usi *off-label* secondo quanto previsto dalla l. 648/1996, una normativa giudicata conforme al diritto dell'UE dalla Corte di giustizia[19].
In Francia, a seguito dello scandalo *Mediator*, dovuto alla negligente sorveglianza sugli effetti di un farmaco usato anche *off-label*, è stato introdotto, con l. 2011-2012, un sistema di monitoraggio di tali prescrizioni. In base a esso, i titolari di AIC devono informare l'agenzia nazionale del farmaco (*Autorité Nationale de Sécurité du Medicament*, ANSM) quando delle prescrizioni *off-label* di cui vengono a conoscenza. L'ANSM ha poi la facoltà di chiedere al titolare di AIC tutti i dati relativi tale uso e di pubblicare delle "raccomandazioni temporanee d'uso". Il titolare di AIC deve, quindi, monitorare gli effetti della prescrizione e inviare all'ANSM i dati sulla sicurezza e l'efficacia.

5. La responsabilità medico-sanitaria

Le innovazioni giuridiche relative agli usi *off-label*, dunque, nascono spesso da gravi scandali sanitari. Tuttavia, lo studio della Commissione del 2017 ha rilevato come il monitoraggio degli usi *off-label* rappresenti tuttora un'evidente debolezza sistemica, data la mancanza di incentivi, per gli attori coinvolti, di implementare forme di controllo efficaci[20].

[18] Comitato nazionale di bioetica, *Nota sulla sperimentazione e l'impiego di nuove terapie farmacologiche. Risposta al quesito posto dall'Istituto Nazionale per la Ricerca sul Cancro in merito al "Caso Di Bella"*, Roma, 1998, p. 6.

[19] Corte giust., sentenza del 21 novembre 2018, causa C-29/17.

[20] Commissione europea, *Study on off-label use of medicinal products in the European Union*, cit., pp. 63-64.

Com'è noto, le regole di responsabilità civile possono, a certe condizioni, veicolare incentivi alla prevenzione, fornendo una prima forma di regolazione dei rischi[21]. Il presente contributo esplora se e in che misura la responsabilità civile possa chiarificare la "zona grigia" degli usi *off-label*, incentivando medici, produttori e regolatori a adottare pratiche corrette.

La prima forma di responsabilità da considerare è, naturalmente, quella del medico che prescrive il farmaco *off-label*. Al riguardo, il principio fondamentale da cui partire è quello della libertà terapeutica del medico che è un dato acquisito non solo negli ordinamenti nazionali, ma anche a livello europeo. Infatti, la Corte di giustizia ha affermato che l'articolo 5, Direttiva 2001/83/CE presuppone che la scelta del trattamento più appropriato debba essere orientata da considerazioni terapeutiche, piuttosto che dal contenuto di atti amministrativi[22].

Le attività prescrittive dei medici, tuttavia, sono sottoposte a forme di auto-regolazione deontologica anche a livello nazionale. Nel nostro paese, ad esempio, il codice di deontologia medica disciplina espressamente le prescrizioni *off-label*, permesse solo se la loro tollerabilità ed efficacia sono scientificamente accertate e i loro rischi sono proporzionali ai benefici attesi. In tal caso, il medico giustifica la prescrizione, acquisisce il consenso scritto e informato del paziente e valuta gli effetti della prescrizione nel tempo (art. 13, Codice di deontologia medica). Un modello diverso è fornito dalla deontologia francese: i medici sono liberi di formulare le prescrizioni che ritengono più appropriate nel caso singolo, che siano *on* o *off-label*, prendendo in considerazione i dati scientifici disponibili (art. 8, *Code de déontologie médical*).

Le disposizioni deontologiche (e legali) in materia di *off-label* forniscono ai medici dei criteri generali di condotta, la cui violazione può fondare, accanto a una responsabilità disciplinare, anche una responsabilità civile a titolo di colpa. Quando non sono disponibili valide alternative *on-label,* il medico può valutare prescrizioni *off-label* alla luce dei dati (incompleti) disponibili, ottenendo naturalmente il consenso informato del paziente.

La giurisprudenza francese ha da tempo affrontato il rapporto tra diligenza medica, autorizzazioni amministrative e conoscenze scientifiche. La *Cour de Cassation* ritiene che un medico sia diligente quando prescrive ai pazienti, con il loro consenso informato, dei trattamenti conformi alle *connaissances médicales validées* o *acquises*[23]. Un tale principio comporta due conseguenze fondamentali. La prima è che il test per valutare la diligenza del medico nella prescrizione e nell'ottenimento del consenso del paziente, non è rap-

[21] G. Comandé, *La responsabilità civile per danno da prodotto difettoso…assunta con "precauzione"*, in *Danno e resp.*, 2013, pp. 107-112.

[22] Corte giust., sentenza del 11 aprile 2013, causa C-535/11, par. 48.

[23] Cass. 1ère civ., 18 settembre 2008, n. 07-15.427; Cass. 1ère civ, 11 dicembre 2008, n. 08-10.255; J.-M. Debarre, *Prescription des médicaments hors autorisation de mise sur le marché (AMM): fondements, nécessité limites, et responsabilités*, Parigi, 2016, pp. 376-377

presentato dall'AIC o dal RCP del farmaco, ma dalle conoscenze medico-scientifiche.[24] La seconda è che, in mancanza di conoscenze convalidate, il medico diligente deve fare riferimento ai dati comunque *acquisiti* in un determinato momento storico.
La giurisprudenza di legittimità italiana si colloca sostanzialmente sulla stessa lunghezza d'onda, nell'affermare che il medico deve fare riferimento alle conoscenze acquisite[25]. Ciò trova un pieno riscontro nella giurisprudenza penale in tema di usi *off-label*, secondo cui i medici che prescrivono farmaci "fuori etichetta" sono tenuti a considerare tutti i rischi prevedibili, cioè tutti i rischi noti, anche se sembrano eccezionali, comunicandoli chiaramente al paziente.[26]

6. La responsabilità del produttore

Gli usi *off-label* di farmaci possono fondare anche una responsabilità civile dei produttori. Ciò trova una conferma nel fatto che la riforma del 2012 ha esteso gli obblighi di farmacovigilanza incombenti sul produttore e sui regolatori anche agli usi "fuori etichetta" di prodotti farmaceutici.
Un titolo di responsabilità civile che può essere invocato nei confronti dei produttori farmaceutici nell'UE è quello previsto dalla Direttiva 1985/374/CEE, relativa alla responsabilità civile da prodotto difettoso. Un prodotto, come noto, è difettoso quando non offre la sicurezza che ci si può legittimamente attendere, tenuto conto di "tutte le circostanze" (art. 6, Direttiva 1985/374/CEE). Tra queste si colloca "l'uso al quale il prodotto può essere ragionevolmente destinato". Una prescrizione *off-label* è ragionevolmente prevedibile quando è nota al produttore, ad esempio tramite le segnalazioni dei medici o la letteratura scientifica.
Un'altra circostanza da considerare nel valutare il carattere difettoso di un prodotto è la "presentazione" dello stesso, che plasma direttamente le aspettative di sicurezza dei consumatori. Di conseguenza, un farmaco prescritto *off-label* è da considerarsi difettoso se tale prescrizione è ragionevolmente prevedibile e il relativo rischio non è indicato nel foglietto illustrativo (c.d. difetto di informazione)[27].

[24] La giurisprudenza francese ammette la responsabilità civile del medico da mancata prescrizione di un farmaco *off-label*, ormai accettata come pratica clinica standard (Cass. 1ère civ., 14 ottobre 2010, n. 09-68.471, *Bull.*, 2010, I, n. 201).

[25] Cass., sentenza del 13 ottobre 1972, n. 3044; Cass. pen., sentenza del 8 febbraio 2001, n. 2865, in *Diritto penale e processo*, 2002, p. 459; B. Guidi, L. Nocco, *The debate concerning the off-label prescriptions of drugs: a comparison between Italian and U.S. Law*, in *Opinio Juris in Comparatione*, 2011, I, 1, p. 4; M. Bilancetti, *La responsabilità penale e civile del medico*, Padova, 2006, pp. 737; A. Fiori, *Medicina legale della responsabilità medica*, Milano, 1999, p. 429 ss.

[26] Cass. pen., sentenza del 13 marzo 2008, n. 17499, in *Foro it.*, 2008, c. 376 ss.

[27] R. Goldberg, *Medicinal Product Liability and Regulation*, Oxford, 2013, p. 67.

Tuttavia, il problema centrale della responsabilità civile per danno farmaco in generale è quello causale[28]. Il problema che si pone al riguardo è, essenzialmente, se e come instaurare un nesso causale tra difetto del prodotto e danno, quando lo stato attuale delle conoscenze scientifiche non consente di stabilire né escludere con certezza un simile rapporto causale[29]. Tale questione risulta particolarmente problematica nell'ambito degli usi *off-label*, i cui effetti, non essendo pienamente testati, possono presentare un tasso elevato di incertezza scientifica.

Un primo filone giurisprudenziale applica, in sostanza, la regola della *res ipsa loquitur*[30], in base al quale, in ipotesi di incertezza scientifica, sussiste il nesso causale quando il danno si manifesta in un soggetto in precedenza sano dopo un breve lasso di tempo dall'utilizzo del prodotto e in assenza di fattori eziologici alternativi. Un simile test causale è emerso a più riprese nella giurisprudenza francese[31] e italiana[32] in materia di danno da vaccinazione ed è stato avallato dalla Corte di giustizia nel caso *Sanofi*[33]. In tale occasione, la Corte di giustizia ha affermato che la breve distanza di tempo tra una vaccinazione contro l'epatite B e l'insorgenza dei sintomi della sclerosi multipla, unitamente alla mancanza di precedenti familiari, può essere ritenuta in grado di fondare una presunzione di nesso causale tra difetto del prodotto e danno ai sensi della Direttiva 1985/374/CEE.

Nel decidere sul caso, tuttavia, la *Cour de Cassation* ha rigettato l'approccio sposato dalla Corte di giustizia, affermando che i fatti allegati non sono idonei a fondare una presunzione chiara, precisa e concordante di nesso causale[34]. Infatti, il danno subito dal paziente (la contrazione della sclerosi multipla) normalmente si sviluppa in un arco di tempo più lungo delle poche settimane trascorse tra la somministrazione del vaccino contro l'epatite B. Inoltre, nel 90% dei casi di sclerosi multipla, mancano dei precedenti familiari. L'approccio della corte di legittimità francese, che instaura un confronto dialettico con i dati scientifici disponibili, pur in un contesto di incertezza, è seguito anche da una parte della giurisprudenza italiana in tema di indennizzo per danno da vaccinazioni obbligatorie o raccomandate. In un caso, ad esempio, i giudici di merito hanno escluso la configurabilità del nasso causale tra vaccino e danno perché la letteratura scientifica citata a sostegno considerava la questione come una mera ipotesi teorica, di per sé inidonea a fondare una

[28] R. Goldberg, *Causation and Risk in the Law of Torts: Scientific Evidence and Medicinal Product Liability*, Oxford, 1999.

[29] M. Geistfeld, S*cientific Uncertainty and Causation in Tort Law*, in *Vanderbilt Law Review*, 2001, 54, p. 1011.

[30] R. Pucella, *Danno da vaccini, probabilità scientifica e prova per presunzioni*, in *Resp. Prev.*, 2017, p. 1796.

[31] Trib. Nanterre, 4 settembre 2009, come citato in Corte giust., sentenza del 21 giugno 2017, causa C-621/15, par. 14.

[32] Cass., sentenza del 1° febbraio 2017, n. 2684.

[33] Corte giust., sentenza del 21 giugno 2017, causa C-621/15, par. 14.

[34] Cass. 1ère civ., 18 ottobre 2017, n. 14-18.118.

qualsiasi conclusione circa la sussistenza della causalità sul piano scientifico e su quello giuridico[35].

Accanto alle difficoltà inerenti alla prova del nesso causale, un ulteriore ostacolo al risarcimento è rappresentato dall'eccezione del rischio da sviluppo (art. 7, lett. e, Direttiva 1985/374/CEE)[36]. In base ad essa, come noto, il produttore non risponde dei danni causati dal prodotto difettoso se dimostra che "lo stato delle conoscenze scientifiche e tecniche al momento in cui ha messo in circolazione il prodotto non permetteva di scoprire l'esistenza del difetto"[37]. Non è un caso che una delle rare applicazioni pratiche dell'eccezione in esame riguardi proprio un caso di danno da farmaco[38]. In particolare, le prescrizioni *off-label* possono agevolmente ricadere nell'ambito di operatività del rischio da sviluppo, in quanto si diffondono nella pratica clinica solo dopo la messa in circolazione di un determinato prodotto farmaceutico.

A fronte di tali difficoltà, la giurisprudenza italiana tende a ricondurre la responsabilità del produttore farmaceutico alla responsabilità da attività pericolosa (art. 2050 c.c.). Come noto, in base a tale regola di responsabilità, l'esercente un'attività pericolosa risponde dei danni causati dalla stessa, salvo che non dimostri di aver fatto tutto il possibile per evitare il danno. L'art. 2050 c.c. richiede dunque al danneggiato di dimostrare la pericolosità dell'attività, piuttosto che la difettosità del prodotto, una nozione piuttosto sfuggente quando si tratta di farmaci. La produzione e la commercializzazione di farmaci rappresentano, secondo la giurisprudenza maggioritaria[39], delle attività pericolose, in quanto espressive di rischi più elevati del normale[40]. Inoltre, risulta particolarmente gravoso per l'esercente provare di aver fatto "tutto il possibile" per prevenire il danno.

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[35] Cass., sentenza del 25 luglio 2017, n. 18358, in *Foro it.*, 2017, I, c. 2597, confermata da Cass., sentenza del 23 ottobre 2017, n. 24959; Cass., sentenza del 24 ottobre 2017, n. 25119, in *Guida al diritto*, 2017, 46, p. 35.

[36] R. Goldberg, *Medicinal Product Liability and Regulation*, Oxford, 2013, p. 168.

[37] Corte giust., sentenza del 29 maggio 1997, causa C-300/95, par. 26.

[38] Cass., 28 luglio 2015, n. 15851, con nota di A. Parziale, *La responsabilità del produttore tra onere della prova e nesso causale – responsabilità (presunta?) da farmaco difettoso: onere della prova, valore degli accertamenti amministrativi e causa ignota del difetto*, in *Danno e resp.*, 2016, pp. 41-56.

[39] Trib. Napoli, sentenza del 9 ottobre 1986, in *Resp. prev.*, 1988, p. 407; App. Trieste, sentenza del 16 giugno, 1987, in *Resp. prev.*, 1988, c. 334; Trib. Roma, sentenza del 27 giugno 1987, in *Nuova giur. comm.*,1988, I, p. 475; Trib. Milano, sentenza del 19 novembre 1987, in *Foro it.*, 1988, I, 144; App. Roma, sentenza del 17 ottobre 1990, in *Giur. it.*, 1991, I, p. p. 816; Cass., sentenza del 15 luglio 1987, n. 6241, in *Foro it.*, 1988, I, c. 144; Cass., sentenza del 27 luglio 1991, n. 8395, in *Giur. it.*, 1992, I, p. 1331; Cass., sentenza del 20 luglio 1993, n. 8069, in *Foro it.*, 1994, I, c. 445; in *Resp. prev.*, 1994, p. 61; Cass., sentenza del 1° febbraio 1995, n. 1138, in *Resp. prev.*, 1996, p. 164; Cass., sentenza del 27 gennaio 1997, n. 814, in *Corr. giur.*, 1997, p. 291; Trib. Milano, sentenza del 11 luglio 2014, n. 9235, in *Rass. dir. farmaceutico*, 2015, p. 40; Trib. Bergamo, sentenza del 23 novembre 2013, in *Rass. dir. farmaceutico*, 2014, p. 292; Trib. Roma, sentenza del 20 giugno 2002, in *Rass. dir. farmaceutico*, 2003, p. 305.

[40] Cass., sentenza del 23 giugno1967, n. 1550, in *Resp. prev.*, 1967, p. 554; Cass., sentenza del 11 novembre 1987, n. 8304, in *Foro it.*, *Repertorio* 1987, voce «Resp.», n. 116; Cass., sentenza del 21 dicembre 1992, n. 13530, in *Resp. prev.*, 1993, p. 821; G. Gentile, *Responsabilità per l'esercizio di attività pericolose*, in *Resp. prev.*, 1950, p. 97; M. Comporti, *Esposizione al pericolo e responsabilità civile*, Napoli, 1965, p. 291; M. Franzoni, *Dei fatti illeciti,* in *Comm. Scialoja e Branca,* Bologna-Roma 1992, pp. 482 ss.; Trib. Bergamo, sentenza del 23 novembre 2013, in *Rass. dir. farmaceutico*, 2014, p. 292; Trib. Roma, sentenza del 20 giugno 2002, in *Rass. dir. farmaceutico*, 2003, p. 305.

7. La responsabilità del regolatore

Accanto ai titolari di AIC, anche i regolatori farmaceutici possono essere chiamati a rispondere civilmente dei danni derivanti da farmaci, anche quando sono usati *off-label*. Essi, infatti, sono titolari di obblighi di farmacovigilanza, che dal 2012 riguardano espressamente anche le prescrizioni "fuori etichetta".

La giurisprudenza europea non si è ancora cimentata sul tema della responsabilità del regolatore farmaceutico. Nel caso *Schmitt*[41], tuttavia, la Corte di giustizia si è pronunciata su una questione analoga, affermando che gli organi privati di notificazione hanno il dovere di proteggere gli utenti finali dei dispositivi medici e possono rispondere civilmente dei danni causati dal negligente inadempimento di tale dovere, in base alle legislazioni domestiche, nel rispetto dei principi di equivalenza ed efficacia[42].

I principi stabiliti nel caso citato possono essere rilevanti anche in tema di responsabilità dei regolatori pubblici, titolari di un analogo dovere di proteggere i pazienti. Il tema della responsabilità del regolatore farmaceutico si intreccia inevitabilmente con quello della responsabilità dello Stato. Il modello prevalente in proposito è quello della responsabilità per colpa, e Italia e Francia non fanno eccezione. In relazione al noto scandalo del sangue infetto, la giurisprudenza italiana ha affermato la responsabilità per colpa del Ministro della Salute per omessa vigilanza[43]. Il Ministero, infatti, aveva consigliato ai centri trasfusionali di utilizzare uno speciale trattamento idoneo a prevenire le infezioni da epatite e HIV solo nel 1985, nonostante queste fossero già identificabili fin dagli anni Settanta e Ottanta.

Uno scandalo simile scosse anche la Francia, contribuendo al progressivo ampliamento della sfera di operatività della responsabilità civile del regolatore. Infatti, nel caso *Stalinon* (1968), riguardante gli obblighi di farmacovigilanza del regolatore farmaceutico nazionale, il *Conseil d'État* aveva subordinato la configurabilità della responsabilità dello Stato alla commissione di una colpa grave (*faute lourde*), escludendola nel caso di specie[44]. Un simile orientamento restrittivo è stato progressivamente abbandonato[45], al punto che, nel caso del *sang contaminé* (1993), la suprema corte amministrativa ha affermato che una "qualsi-

[41] Corte giust., sentenza del 16 febbraio 2017, causa C-219/15.

[42] Corte giust., sentenza del 16 febbraio 2017, causa C-219/15, par. 64(2).

[43] A. Mantelero, *Il ruolo dello stato nelle dinamiche della responsabilità civile da danno di massa*, Torino, 2013, pp. 98-99. Cass. s.u., sentenza del 11 gennaio 2008, n. 576, in *Giustizia Civile*, 2009, 11, I, p. 2577; Trib. Roma, sentenza del 27 novembre 1998, in *Giustizia civile*, 1999, I, p. 2851; App. Roma, sentenza del 23 ottobre 2000, in *Danno resp.*, 2001, p. 1067, con nota di U. Izzo, *La responsabilità dello stato per il contagio di emofilici e politrasfusi: oltre i limiti della responsabilità civile*; Trib. Roma, sentenza del 4 giugno 2001, in *Giur. rom.*, 2001, p. 301; App. Roma, sentenza del 12 gennaio 2004 n. 133; Trib. Roma, sentenza del 3 gennaio 2007, in *Guida al diritto*, 2007, n. 19, p. 57.

[44] Ch. Bonah, *L'affaire Stalinon et ses conséquences réglementaires, 1954-1959*, in *La revue du practicien*, 15 settembre 2007, pp. 1501 ss.

[45] J.-M. Debarre, *Prescription des médicaments hors autorisation de mise sur le marché (AMM) : fondements, nécessité limites, et responsabilités*, cit., p. 345.

asi colpa" (*toute faute*) può fondare la responsabilità civile dello Stato[46]. Questo *revirement* ha poi trovato un riscontro diretto nel settore farmaceutico nel caso *Mediator*[47]. Il medicinale eponimo, autorizzato per il trattamento del diabete, veniva spesso prescritto *off-label*, soprattutto a donne sane, come soppressore della sensazione di appetito. A partire dal 1999, si sono moltiplicati i casi in cui all'esposizione al *benfluorex*, il principio attivo del Mediator, si associava l'ipertensione arteriosa polmonare, con una significativa riduzione del rischio a seguito della cessazione dell'esposizione. Tuttavia, il regolatore farmaceutico francese ha informato i pazienti di tali rischi solo nel novembre 2009. La giurisprudenza francese, chiamata a pronunciarsi sul punto, ha affermato che la condotta del regolatore dopo il 1999 è da considerarsi colposa, in quanto le informazioni disponibili da allora avrebbero dovuto condurre le autorità competenti alla sospensione dell'AIC del *Mediator* e al suo ritiro dal mercato[48].

I regolatori farmaceutici nazionali non sono le sole istituzioni pubbliche a poter essere chiamate a rispondere dei pregiudizi causati da prescrizioni *off-label* dannose. Il sistema europeo di farmacovigilanza, infatti, trova il suo perno nella Commissione europea, che, nella sua veste di regolatore farmaceutico sovranazionale, si avvale delle competenze scientifiche dei comitati tecnici dell'Agenzia europea del farmaco (*European Medicines Agency,* EMA).

La responsabilità civile della Commissione trova il suo fondamento nell'art. 340(2) TFUE, che fa riferimento, a sua volta, ai "principi generali comuni" alle legislazioni degli Stati membri. In particolare, secondo la giurisprudenza consolidata[49], la condotta dell'istituzione danneggiante deve costituire una violazione del diritto dell'UE, l'attore deve aver subito un danno effettivo e deve sussistere un nesso di causalità tra il comportamento del regolatore e il pregiudizio sofferto. Il principale ostacolo al risarcimento è dato dal fatto che la responsabilità extracontrattuale di un'istituzione europea presuppone una violazione "sufficientemente flagrante" del diritto dell'UE. Ciò può essere difficile da dimostrare nel campo della regolazione farmaceutica, trattandosi di attività a elevato tasso di discrezionalità. Considerando gli sviluppi della giurisprudenza francese in materia, non è inopportuno chiedersi se sarà necessario uno scandalo sanitario di portata europea per indurre la Corte di giustizia a adottare un orientamento più estensivo in tema di responsabilità civile delle istituzioni dell'UE.

[46] Conseil d'État, 9 aprile 1993, n. 138653, in *recueil Lebon*.

[47] J. Petit, *L'affaire du Mediator: la responsabilité de l'État*, in *RFDA*, 2014, p. 1193

[48] Conseil d'État, 9 novembre 2016, n. 393108.

[49] Corte giust., sentenza del 29 settembre 1982, causa C-26/81, *Oleifici Mediterranei*, EU:C:1982:318, par. 16; Trib. primo grado, sentenza del 14 dicembre 2005, causa T-383/00, par. 95; Trib. primo grado, sentenza del 28 settembre 2016, causa T-309/10.

8. Il principio di precauzione

Le decisioni giurisprudenziali sopra analizzate, pur nella loro specificità, cercano tutte di sciogliere il nodo dell'incertezza scientifica, che è il problema centrale della responsabilità per danni da usi *off-label* di farmaci. La domanda sottesa alle pronunce esaminate è, in sostanza, cosa deve fare l'agente umano quando le conoscenze disponibili non consentono di stabilire né escludere con certezza un determinato rischio di danno. L'impressione che si ricava da una lettura superficiale di questi precedenti è che i giudici esigono una qualche considerazione dei dati scientifici disponibili, che varia caso per caso. Questa giurisprudenza risulta più chiara se analizzata con le lenti di un principio giuridico che ha rivoluzionato il rapporto dell'uomo con l'incertezza: il principio di precauzione[50].

L'obiettivo di tale principio è quello di rispondere a un rischio incerto di danno grave e irreparabile prima che un simile rischio diventi attuale, cioè scientificamente stabilito[51]. Secondo la Comunicazione della Commissione sul principio di precauzione (2000), "esso trova applicazione in tutti i casi in cui una preliminare valutazione scientifica obiettiva indica che vi sono ragionevoli motivi di temere che i possibili effetti nocivi sull'ambiente e sulla salute degli esseri umani, degli animali e delle piante possano essere incompatibili con l'elevato livello di protezione prescelto dalla Comunità"[52]. Ciò significa, in sostanza, che il principio trova applicazione solo se un determinato rischio risulta scientificamente plausibile, alla luce dei dati (incompleti) disponibili. L'intervento precauzionale deve essere proporzionato, non discriminatorio, avere un rapporto costi-benefici favorevole ed essere sottoposto a revisione alla luce dei nuovi dati scientifici via via disponibili.

Il principio di precauzione supera quindi la tradizionale logica preventiva, che considera esclusivamente i rischi "attuali", formalmente stabiliti[53]. Esso introduce un nuovo livello nell'ambito delle azioni umane:[54] rischi un tempo ritenuti imponderabili devono essere ora governati dall'uomo.

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[50] P. Craig, *EU Administrative Law*, Oxford, 2012, cap. 19; Id., *UK, EU, and Global Administrative Law. Foundations and Challenges*, Cambridge, 2015, p. 344; M. Boutonnet, *Le principe de précaution en droit de la responsabilité civile*, Parigi, 2005; U. Izzo, *La precauzione nella responsabilità civile: analisi di un concetto sul tema del danno da contagio per via trasfusionale*, Padova, 2004. B. Bertarini, *Tutela della salute, principio di precauzione e mercato del medicinale*, Torino, 2016, p. 132 ss.

[51] Commissione europea, *Future Brief: The precautionary principle: decision-making under uncertainty*, Bruxelles, 2017, p. 13.

[52] Commissione europea, *Comunicazione sul principio di precauzione*, 2 febbraio 2000,

[53] G. Comandé, *L'assicurazione e della responsabilità civile come strumenti e veicoli del principio di precauzione*, in Id. (a cura di), *Gli strumenti della precauzione*, Milano, 2006, p. 29; J.B. Wiener, *Whose Precaution After All? A Comment on the Comparison and Evolution of Risk Regulatory Systems*, in *Duke Jou. Compar. & Int. Law*, 2003, vol. 13, p. ss.; T. O'Riordan (a cura di), *Reinterpreting the Precautionary Principle*, Londra, 2001; O. Godard, *Trainté des nouveaux risques*, Parigi, 2002; F. De Leonardis, *Il principio di precauzione nell'amministrazione del rischio*, Milano, 2005.

[54] G. Comandé, *L'assicurazione e della responsabilità civile come strumenti e veicoli del principio di precauzione*, cit., p. 29 ss.

9. L'influenza implicita del principio di precauzione nella giurisprudenza

La giurisprudenza sopra analizzata, pur non nominandolo espressamente, fa ricorso al linguaggio e alla metodologia del principio di precauzione, allo scopo di adattare le regole di responsabilità a contesti di incertezza scientifica.
Tale operazione si riflette, *in primis*, in una rilettura precauzionalmente orientata della colpa. La nozione di negligenza, infatti, si correla a rischi prevedibili ed evitabili, il cui novero può espandersi, se si adotta una prospettiva precauzionale[55]. Ciò trova una conferma nella tendenza della giurisprudenza francese e italiana a valutare la condotta dei medici non solo alla luce delle conoscenze formalmente convalidate, ma anche di quelle comunque "acquisite". Un altro esempio a sostegno è offerto dalla giurisprudenza francese sul *Mediator*, che ha affermato la responsabilità dello Stato per non aver gestito dei rischi incerti ma divenuti plausibili con l'accumularsi dei dati disponibili.
Un secondo elemento su cui si riflette l'influenza implicita del principio di precauzione è la causalità, dove si confrontano due concezioni molto diverse dell'incertezza scientifica. La prima si affida, come visto sopra, alla regola della *res ipsa loquitur*, con cui una mera ipotesi causale diventa, di fatto, prova di sé stessa. Ciò contrasta non solo con una logica genuinamente precauzionale, ma anche con i canoni legali della prova presuntiva (una mera ipotesi non può fondare una presunzione grave, precisa e concordante) e con il principio di effettività (di fatto si trasferisce automaticamente l'onere della prova della causalità sul produttore, in violazione dell'art. 4, Direttiva 1985/374/CEE).
La seconda concezione, al contrario, valuta la plausibilità scientifica dell'ipotesi causale, pur alla luce di informazioni incomplete e non definitive. Tale secondo orientamento sembra più coerente con il principio di precauzione, promuovendo una "valutazione scientifica quanto più completa possibile", offrendo ai danneggiati la possibilità di fondare una presunzione persuasiva del nesso di causa – senza, tuttavia, alterare surrettiziamente l'allocazione dell'onere della prova.
Anche una reinterpretazione precauzionale dell'eccezione del rischio da sviluppo può beneficiare i danneggiati. In base a tale rilettura, il produttore può rispondere anche per i rischi che, al momento dell'immissione in commercio del prodotto, non erano ancora formalmente stabiliti (attuali), ma erano comunque plausibili (potenziali). Questo può ridurre la portata dell'eccezione, ampliando quella della responsabilità del produttore. Tuttavia,

[55] R. Montinaro, *Dubbio scientifico e responsabilità civile*, Milano, 2012, pp. 1-28; F. Massimino, *La prescrizione dei farmaci «off label»*: adempimenti, obblighi e responsabilità del medico, in *Danno e Resp.*, 2003, p. 925; Id., *La responsabilità nella prescrizione dei farmaci tra scienza, coscienza e condizionamenti normativi*, in *Danno e resp.*, 2013, p. 5; M. Zana, *Ai limiti della responsabilità medica: l'uso off-label dei farmaci*, in Aa.Vv., *Liber amicorum per Francesco D. Busnelli. Il diritto civile tra principi e regole*, Milano, 2008, p. 729 ss.

l'eccezione del rischio da sviluppo resta un ostacolo importante al risarcimento dei danneggiati nelle ipotesi di danno da prescrizioni "fuori etichetta".

L'art. 2050 c.c. rappresenta uno strumento più promettente della responsabilità da prodotto difettoso nell'ambito dei rischi potenziali, ivi compresi quelli associati agli usi *off-label*. La disciplina sulla responsabilità da attività pericolose, infatti, incorpora una logica precauzionale, poiché l'esercente può liberarsi da responsabilità solo dimostrando di aver fatto "tutto il possibile" per evitare il danno, anche attraverso l'implementazione di conoscenze e processi d'avanguardia[56]. In questo senso, non sembra coerente con l'ispirazione precauzionale della norma in esame quell'orientamento giurisprudenziale[57] secondo cui il titolare di AIC non risponde *ex* art 2050 c.c. quando abbia aggiornato foglietto illustrativo, dato che gli interventi in precauzione non si limitano all'informazione del pubblico, ma comprendono anche la ricerca scientifica[58], la sospensione della commercializzazione del prodotto ed eventualmente il suo ritiro dal mercato[59]. Il risarcimento resterebbe precluso, invece, con riguardo ai rischi ignoti associati a usi *off-label* prima non conosciuti né conoscibili, che resterebbero attratti alla sfera del caso fortuito.

In dottrina[60], è stata sollevata la questione della compatibilità dell'art. 2050 c.c. con la Direttiva 1985/374/CEE. Quest'ultima non pregiudica i diritti che i danneggiati possono esercitare in virtù di regimi nazionali di responsabilità contrattuale o extracontrattuale o di un regime di responsabilità speciale già esistente al momento della notifica della direttiva (art.13, Direttiva 1985/374/CEE). Secondo la giurisprudenza della Corte di giustizia[61], la Direttiva mira a un'armonizzazione completa della responsabilità per danno da prodotto difettoso, in quanto persegue gli obiettivi assicurare la libera concorrenza nel mercato interno e una protezione uniforme della sicurezza dei consumatori. La Direttiva può dunque limitare i diritti risarcitori che le legislazioni nazionali conferiscono ai danneggiati, laddove si tratti di regimi di responsabilità aventi la stessa base della disciplina sulla responsabilità da prodotto difettoso[62]. La Direttiva resta compatibile, per converso, con i regimi di responsabilità aventi una base diversa, come la garanzia per difetti o la colpa, oltre che con le discipline speciali in vigore prima della notificazione della Direttiva stessa[63]. Una parte della dottrina italiana sostiene che l'art. 2050 c.c. potrebbe essere incompatibile con la

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[56] G. Comandé, *La responsabilità civile per danno da prodotto difettoso…assunta con "precauzione"*, cit., pp. 107-112.

[57] F. Massimino, *Recenti interventi normativi e giurisprudenziali in materia di prescrizione dei farmaci off-label*, in *Danno e resp.*, 2010, p. 1117; Trib. Milano, sentenza del 29 marzo 2005, n. 3520, in *Rass. dir. farm.,* 2006, I, p. 34.

[58] Sulla capacità di forme di responsabilità civile per rischi ignoti di incentivare ricerca e innovazione cfr. M. Faure, L. Visscher, F. Weber, *Liability for Unknown Risks: A Law and Economics Perspective*, in *Journal of European Tort Law*, 2016, vol. 7, 2, pp. 206-207, doi: <https://doi.org/10.1515/jetl-2016-0010>.

[59] EMA, *Guideline on good pharmacovigilance practices*, *Module XV – Safety communication* (Rev 1), Londra, 2017.

[60] A. Querci, *Responsabilità per danno da farmaci: quali i rimedi a tutela della salute?*, in *Danno e resp.*, 2012, p. 353.

[61] Corte giust., sentenza del 25 aprile 2002, causa C-183/00, par. 28.

[62] Id., parr. 31-34.

[63] Id.; Corte giust., sentenza del 25 aprile 2002, causa C-154/00; Corte giust, sentenza del 4 giugno 2009, causa C-285/08.

disciplina sulla responsabilità da prodotto difettoso, con cui condividerebbe la stessa base *no-fault*[64]. La responsabilità *ex* art. 2050 c.c., tuttavia, si basa sulla pericolosità dell'attività svolta dal danneggiante, che è una caratteristica diversa dalla difettosità dei prodotti. La pericolosità si esprime in una serie di atti funzionalmente coordinati, caratterizzata da una rischiosità superiore al normale. La difettosità, al contrario, è un attributo proprio dei prodotti che non soddisfano le legittime aspettative di sicurezza dei consumatori.
Vi è, infine, un elemento, comune a tutte le fattispecie di responsabilità, su cui il principio di precauzione potrebbe esercitare un'influenza benefica in un'ottica di allocazione dei costi dell'incertezza scientifica: si tratta del danno risarcibile[65]. Nell'ambito medico-sanitario, è un dato acquisito che i processi causali sono probabilistici e multifattoriali. Su tale presupposto, che ha messo definitivamente in crisi la tradizionale eziologia positivistica, la giurisprudenza ha elaborato dei *test* causali fondati sulle leggi statistiche e sulla credibilità razionale delle spiegazioni causali dei fenomeni[66]. Una parte della dottrina[67], seguita dagli *European Principles of Tort Law*[68], ha poi messo in discussione anche il dogma del risarcimento integrale[69], proponendo modelli di responsabilità proporzionale. Se, infatti, il nesso causale è probabilistico e si compone di una pluralità di fattori, non è possibile allocare con certezza l'intero ammontare del danno su uno solo di questi. Più in linea con le concezioni eziologiche contemporanee risulta un sistema di ripartizione del totale del risarcimento tra i diversi fattori causali in gioco, ciascuno per la rispettiva "quota" di probabilità. Al fine di adattare un simile modello anche ai rischi potenziali, sprovvisti di percentuali di probabilità, una parte della dottrina[70] ha proposto di commisurare, in tali casi, i danni risarcibili al livello di prova raggiunta del nesso causale, stabilendo di fatto un rapporto di proporzionalità diretta tra persuasività dei dati disponibili e *quantum* risarcitorio.

[64] A. Querci, *Responsabilità per danno da farmaci: quali i rimedi a tutela della salute?*, cit., p. 353.

[65] P. Jourdain, *Le Mediator devant la Cour de cassation : appréciation des conditions relatives à la causalité et à la défectuosité du médicament*, in *Revue Trimestrielle Droit Civil*, 2016, p. 386.

[66] G. Mor, B. Heurton, *Evaluation di préjudice corporel*, Parigi, 2010; L. Nocco, *Il nesso di causalità materiale, la probabilità logica e la ritrovata (?) centralità della colpa in responsabilità sanitaria*, in *Danno e resp.*, 2005, 10, p. 1015; Id., *Il «sincretismo causale» e la politica del diritto: spunti dalla responsabilità sanitaria*, Giappichelli, 2010.

[67] S. Steel, *Proof of Causation in Tort Law*, Cambridge, 2015, p. 290 ss.; S. Shavell, *Uncertainty Over Causation and The Determination of Civil Liability*, Cambridge (MA), 1983.

[68] F.D. Busnelli *et al.*, *Principles of European Tort Law. Text and Commentary*, Berlino, 2005, p. 47.

[69] Cass. s.u., sentenza del 11 novembre 2008, n. 26972-5, in *Resp. prev.*, 2009, p. 38; C. Salvi, *Il risarcimento integrale del danno non patrimoniale, una missione impossibile. Osservazione sui criteri per la liquidazione del danno non patrimoniale*, in *Eur. dir. priv.,* 2014, p. 517 ss.

[70] G. Comandé, L. Nocco, *Proportional Liability as an Application of the Precautionary Principle. Comparative Analysis of the Italian Experience*, in *Opinio Juris in Comparatione*, 2013, I, 1, p. 13.

10. Il ruolo dei sistemi *no-fault*

Precisando i doveri di medici, produttori e regolatori in materia, l'influenza del principio di precauzione sulla responsabilità civile permette di chiarificare quella zona grigia tra sperimentazione e cura dove si collocano gli usi "fuori etichetta", integrando un quadro regolatorio frammentario e incerto in un processo, lento ma organico, di prova ed errore[71]. Anche se precauzionalmente orientata, la responsabilità civile incontra, tuttavia, dei limiti strutturali. Essa, ad esempio, non permette il risarcimento dei danni causati da rischi del tutto imprevedibili e inevitabili, in quanto tali costituenti un caso fortuito. Si pensi ai soggetti danneggiati da un uso *off-label* del tutto nuovo, rispetto al quale non sia configurabile una responsabilità civile del medico, del produttore o del regolatore. Tali soggetti (cioè coloro che vengono danneggiati per primi da un uso *off-label* del tutto nuovo) svolgono un importante ruolo di "*avertisseurs*"[72] a favore della collettività. La società ha il dovere morale di fornire un ristoro a queste vittime sacrificali del progresso tecnico-scientifico[73]. Alla realizzazione di questo obiettivo potrebbe contribuire un sistema *no-fault*[74], con cui indennizzare i danneggiati laddove le regole di responsabilità civile non trovino applicazione. In Italia, un esempio di piano *no-fault* nel settore medico-sanitario è offerto dal fondo statale d'indennizzo per i danni da vaccinazioni obbligatorie o raccomandate (l. 210/1992). Il fondo in questione offre ai danneggiati uno strumento di ristoro meno gravoso rispetto al contenzioso civile. Infatti, il danneggiato è tenuto semplicemente a dimostrare a un organo tecnico-amministrativo la sussistenza del nesso causale tra vaccinazione e danno. Al contrario, le regole di responsabilità civile impongono all'attore di dimostrare degli elementi aggiuntivi (ad es., colpa, difetto) nel contradditorio delle parti e forniscono al convenuto esenzioni e prove liberatorie. Tuttavia, questa semplificazione ha incanalato i costi dei danni da vaccinazione verso lo Stato (*rectius*: i contribuenti), deresponsabilizzando, di fatto, i produttori di vaccini. Il fondo pubblico francese per l'alea terapeutica (cosiddetto ONIAM), istituito con l. 2002-303[75], sembra invece maggiormente in grado di coniugare la responsabilizzazione degli attori coinvolti con la velocità di ristoro dei danneggiati. In sostanza, per ottenere il relativo indennizzo, il danneggiato presenta il proprio fascicolo a una commissione regionale mista, che raccomanda agli assicuratori dei responsabili di fare un'offerta di risarcimento. Nei casi di *aléa thérapeutique*, cioè laddove un *accident médical* causi danni gravi e anormali, ma non sia configurabile una respon-

[71] M.U. Scherer, *Regulating Artificial Intelligence Systems: Risks, Challenges, Competencies, And Strategies*, in *Harvard Journal of Law & Technology*, 2016, XXIX, 2, p. 391; B.N. Cardozo, *The Growth of The Law*, New Haven, 2009, p. 55.

[72] G. Mor, M Gréard, *La responsabilité du fait des produits pharmaceutiques et la protection des victimes*, Parigi, 2001, p. 46.

[73] S. Flatin, *Incertitude scientifique et responsabilité civile, thèse de doctorat droit privé*, Lyon, 2000, p. 433.

[74] K. Fiore, *No-fault compensation systems*, in M. Faure (a cura di), *Tort Law and Economics*, Cheltenham, 2009, p. 409.

[75] P. Pierre, *De la responsabilité à la solidarité nationale*, in *Revue générale de droit médical*, 2012, pp. 83-98; L. Leveneur, Y. Lambert-Faivre, *Droit des assurances*, Parigi, 2017, p. 512.

sabilità civile, la commissione raccomanda un'offerta di indennizzo a carico dello Stato. Al finanziamento di un simile fondo, su cui può riversarsi una parte dei costi dei danni da *off-label*, dovrebbe partecipare anche l'industria, che, dal suo funzionamento, potrebbe trarre preziose informazioni sui prodotti farmaceutici[76].

11. Il ruolo dei meccanismi ADR

Un secondo limite della responsabilità civile è dato dai costi del contenzioso, soprattutto laddove, come negli usi *off-label*, l'incertezza scientifica si riflette sull'esito del processo. Per attenuare tali costi, il legislatore francese, a seguito dello scandalo del *Mediator*, ha istituito un apposito fondo per i danneggiati (anche dall'uso "fuori etichetta") del *benfluorex* (l. 2011-900)[77]. Ai sensi degli artt. L. 1142-24-1 ss., *Code de Santé Publique*, i danneggiati devono presentare il proprio fascicolo a una commissione mista (con competenze giuridiche, mediche e assicurative), che accerta, nel contraddittorio delle parti, la sussistenza del nesso causale e il deficit funzionale subito dal danneggiato. Se riscontra un'ipotesi di responsabilità, la commissione raccomanda all'assicuratore del responsabile di formulare un'offerta risarcitoria di un determinato ammontare. L'accettazione dell'offerta risarcitoria da parte del danneggiato equivale alla conclusione di un contratto di transazione. Se, invece, l'assicuratore non dà seguito alla raccomandazione della commissione, lo Stato anticipa la somma al danneggiato, salvo rivalsa verso l'assicuratore stesso. A carico di quest'ultimo è prevista una penale pari al 30% del *quantum* risarcitorio. La medesima penale è prevista nel caso in cui l'assicuratore abbia formulato al soggetto danneggiato un'offerta manifestamente insufficiente rispetto alla raccomandazione della commissione[78].
In un'ottica simile si colloca la tendenza italiana a cercare di favorire la conciliazione del contenzioso medico-sanitario[79], una tendenza culminata nella la l. 24/2017[80], che subordina la procedibilità della domanda risarcitoria a una consulenza tecnica preventiva *ex* art. 696 *bis* c.p.c.

[76] Il sistema della responsbailità civile può fungere da catalizzatore di informazioni sui rischi farmaceutici (R. Goldberg, *Medicinal Product Liability and Regulation*, Oxford, p. 149). Una funzione analoga può essere svolta anche dai procedimenti nell'ambito di sistemi *no-fault*.

[77] A. Legoux, *Indemnisation des accidents sériels de santé publique : l'exemple du Mediator*, in *Gazette du Palais*, 30 agosto 2016, XXIX, p. 2094 ss.

[78] Un fondo di compensazione analogo è stato implementato in risposta al caso *Dépakine* (artt. L.1142-24-9 ss., *Code de Santé Publique*).

[79] Sulla costituzionalità dei tentativi obbligatori di mediazione, cfr. Corte cost., sentenza del 5 novembre 1993, n. 406, in *Foro it.*, 1993, I, c. 3214; Corte cost., sentenza del 16 aprile 2014, n. 98, in *Diritto Costituzionale*, 2014, 2, p. 1723, con nota di R. Chieppa, *A proposito del reclamo-mediazione tributaria, ancora sulla legittimità costituzionale di obbligatorietà di procedimenti precontenziosi*.

[80] F. Gelli, M. Hazan, D. Zorzit (a cura di), *La nuova responsabilità sanitaria e la sua assicurazione*, Milano, 2017; M. Lovo, L. Nocco (a cura di), *La nuova responsabilità sanitaria. Le novità introdotte dalla Legge Gelli*, Milano, 2017.

Al di là delle macroscopiche differenze, gli esperimenti francesi e italiani in materia sembrano condividere un fondamento pratico comune. In sostanza, entrambi prevedono un meccanismo di ADR, incentrato sul ruolo di esperti indipendenti. Laddove abbia un effetto parzialmente predittivo dell'esito della controversia risarcitoria, un simile meccanismo di questo genere può facilitare la conciliazione delle parti, riducendo i costi della tutela risarcitoria[81]. Viceversa, laddove il meccanismo di ADR abbia un effetto predittivo nullo, l'esito più probabile sarà il contenzioso[82].

12. Osservazioni conclusive

Nonostante la diversità delle regole di responsabilità previste dagli ordinamenti giuridici considerati, la condotta analisi comparata della giurisprudenza europea, italiana e francese mostra una tendenziale convergenza verso soluzioni operative analoghe, ispirate alla logica del principio di precauzione. L'influenza implicita di tale principio sulla giurisprudenza europea, italiana e francese in materia di incertezza scientifica può avere delle implicazioni positive sulla quella zona grigia tra sperimentazione e cura in cui si collocano le prescrizioni *off-label* di farmaci. Una rilettura precauzionale delle regole di responsabilità civile può, infatti, contribuire a chiarificare i doveri di medici, produttori e regolatori rispetto ai rischi potenziali associati agli usi "fuori etichetta" di medicinali, integrando un quadro regolatorio frammentario e incerto. Si tratta di una tendenza che può avere delle ripercussioni positive in tutti quegli ambiti in cui a un'incertezza scientifica anche significativa si accompagna un quadro regolatorio "leggero", in cui non è prevista un'autorizzazione preventiva alla commercializzazione, come nel caso dei prodotti di confine tra alimenti, cosmetici e farmaci, su cui potrebbero concentrarsi future linee di ricerca.
Inoltre, al di là delle loro macroscopiche differenze, i sistemi *no-fault* e ADR congegnati dal legislatore francese e italiano in ambito medico-sanitario sono ispirati dalla comune esigenza di garantire una forma di ristoro anche a favore dei danneggiati che non possono accedere alla tutela risarcitoria, nonché di favorire la risoluzione stragiudiziale delle controversie. Future linee di ricerca potrebbero indagare le caratteristiche necessarie per costruire un sistema efficiente di questo genere.

[81] S. Shavell, *Alternative Dispute Resolution: An Economic Analysis*, in *The Journal of Legal Studies*, 1995, XXIV, 1, p. 21.

[82] Uno strumento alternativo di riduzione dei costi del contenzioso per i danneggiati è offerto, in linea di principio, dalle azioni di classe, che però, negli ordinamenti considerati, hanno avuto sinora un'applicazione limitata. Con la *loi de modernisation de la justice du XXIe siècle*, n. 2016-1547, il legislatore francese ha introdotto una *class action* specificamente dedicata alla materia sanitaria (*action de groupe en santé*), prevista dagli artt. L.1143-1 ss., la cui applicazione è però ancora limitata. Anche nell'ordinamento italiano le azioni collettive, previste dall'art. 140 bis, Codice del consumo, non hanno ancora avuto fortuna [E. Cesàro, F. Bocchini (a cura di), *La nuova class action a tutela dei consumatori e degli utenti, Commentario all'art. 140 bis del Codice del consumo*, Padova, 2012] e, al momento, è prematuro valutare se la recente riforma in materia (l. n. 31/2019) sia riuscita a invertire la tendenza.

Selective Distribution Online in the Aftermath of the *Coty Germany* Case

Maria Casoria*

Abstract

The paper provides an overview of the EU legal framework on vertical restraints as evolved over the years and with a focus on the peculiarities of the selective distribution in the digital marketplace. Then, it highlights the inconsistencies in the European case law which have dealt with the conditions for allowing online sales in distributive networks. The last paragraph emphasises the unresolved questions of the rule of law governing online vertical restraints in Europe, also in comparison with the distribution norms adopted on the other shore of the Atlantic, in the attempt to demonstrate that the planet of the vertical restraints is far from being unveiled.

Keywords

Brand image defence – Buyer power – Coty Germany – Luxury goods – Online sales –Selective distribution –Third-party platforms –Vertical restraints

* General Counsel and Assistant Professor of Commercial Law, Royal University for Women, Kingdom of Bahrain.

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1. Introduction

The history of the selective distribution of goods in the European Union is, at the very least, convulsive. On the one side the Court of Justice (CJEU) has tried, with a sequence of four main judgments rendered in the span of forty years, to draw the line between its qualitative version, compatible under certain conditions with the anti-monopoly rules, and the quantitative one, to be completely ostracised. On the other hand, the European Commission, playing the role of peacemaker between the supplier and its distributors, has issued two regulations on vertical restraints[1] and resorted to an economic approach – i.e. the market power of the operators involved – to determine the legitimacy of selective networks.

The widespread dissemination of online commerce has surely complicated the already stormy scenario, adding questions about compliance with the competition norms of selective distribution agreements prohibiting Internet sales. The answer has been found, at first, in the luxury nature of the products distributed; yet, the criteria to identify such goods are not clear enough in the EU jurisprudence. Therefore, the buyer power has been seen, most recently, as a panacea, disarming the traditional approach to the selective distribution agreements in favour of legal standards borrowed from the discipline on unfair practices. The European case law has strived to cope with the ongoing transformation by developing a set of guidelines – which seem to create more problems than those they aim to resolve – to differentiate between immaculate distributive networks and those not worthy of any blessings for their ability to hinder the competitive dynamics inside and outside the selective digital channel. However, the latest ruling of the CJEU dealing with the subject matter,

[1] Commission Regulation 330/2010/EU of on the application of Article 101(3) of the Treaty on the Functioning of the European Union to categories of vertical agreements and concerted practices, repealing the Commission Regulation 2790/1999/EC on the application of article 81(3) of the Treaty to categories of vertical agreements and concerted practices OJ L336., [2010] OJ L102/1.

Coty Germany[2], appears somehow anachronistic insomuch as the court has considered legitimate to restrict the use of discernible third-party platforms, like Amazon, in the selective distribution of luxury goods in order to preserve the image of the brand in a period when the digital economy is driving the development and sustainability of the society and the electronic commerce has mostly replaced brick and mortar exchanges, even more so in the current times challenged by the restrictions stemming from the worldwide spread of the novel coronavirus Covid-19[3].

In a nutshell, while the perimeter of the distribution agreements is progressively shrinking as a result of contemporary events and due to the undeniable success of online platforms, whose use has minimised the role of the intermediaries by connecting directly the supplier with the consumers, the European judiciary still needs to reconcile its judicial apparatus, rather than persisting with a case-by-case analysis, to regulate more effectively the disruption caused by the few giants which dominate the borderless marketplace.

2. The CJEU's Approach to Marketplace Restrictions from the *Metro* Test to the Pierre Fabre Judgment

The judicial chronicles of the selective distribution of goods in Europe began almost forty years ago when the CJEU, in the well-known *Metro* cases[4], firstly addressed the issue of the anticompetitive outreach of selective networks by setting boundaries between qualitative and quantitative distribution channels. In these two judgments, the court established that only the former type of network can be deemed compliant with Art. 101 TFEU in case it passes a triple conditions test, namely if: 1) the retailers are chosen on the basis of objective criteria of a qualitative nature relating to the technical qualifications of the reseller and his staff and the suitability of his trading premises. Moreover, such conditions must be applied uniformly and in a non-discriminatory fashion to all the potential resellers; 2) the nature of the products (and in particular their high quality or highly technical nature) requires a distributive network to preserve quality and ensure proper use; 3) the selection criteria do not go beyond what is necessary and proportionate. In the second decision, while confirming the above requirements, the court added a fourth element, that is the existence of a certain number of distribution systems in the relevant market shall not result in a rigidity in the price structure which is not counterbalanced by other aspects of com-

[2] Case C-230/16 *Coty Germany GmBH v Parfumerie Akzente GmbH* [2017] ECLI:EU:C:2017:603 referred to as "Coty" or "Coty Germany".

[3] Statistics on the growth of e-commerce during the pandemic Covid-19 can be found at <www.statista.com/statistics/1109296/online-retail-y-o-y-order-trends-during-coronavirus-in-europe/> accessed 20 May 2020.

[4] Case C-26/76 *Metro SB-Großmärkte GmbH & Co. KG v Commission of the European Communities* [1977] ECR 1977-01875 (referred to as "Metro I") and Case C-75/84 *Metro SB- Großmärkte GmbH & Co. KG v Commission* [1986] ECR 1986-03021 (referred to as "Metro II").

petition between products of the same brand and by the existence of effective competition between different brands.

In subsequent decisions, the court identified additional parameters to evaluate the compatibility of these systems with the EU competition rules, i.e. that the use of selective distribution systems based on qualitative criteria may be licit in the sector of high-quality consumer goods without infringing Article 101(1) TFEU if the aim is to maintain a specialist trade chain capable of supplying specific services for such products[5]. As for the nature of the product, while the CJEU has ruled that a selective distribution system may be necessary in order to preserve the 'quality' of the product, irrespective of whether the products concerned are 'luxury' products[6], in a following case the Tribunal of the EU has stated that the specific characteristics or properties of the products, which may be capable of rendering a selective distribution system competition compliant, can be found in the 'luxury' image of such products[7].

Concerning online sales, the CJEU ruled at first that, to assess the compatibility with Art. 101(1) TFEU of the contractual clause imposing a ban on sales via the Internet, it is indispensable to consider the object of the agreement in connection with the economic context in which it is utilised. Indeed, in case the anti-competitive nature of the agreement is detected based on its object, it will not be necessary to further verify its effects on the functioning of the market, since the two conditions of 'object' and 'effect' set by Art. 101(1) TFEU are connected by the disjunction 'o' and, thus, they must be understood as alternative[8]. Furthermore, with a ruling rendered in a dispute concerning the sale on the web of drugs non requiring a medical prescription, the court held that the alleged necessity to provide personalised advice to the customers and to protect them against the incorrect use of the drugs does not justify the ban of online distribution[9].

The connection between Internet sales and selective distribution systems has been examined more closely in a famous decision delivered by the Court of Justice in October 2011, *Pierre Fabre*[10], initially seen as the cure-all, but soon labelled as paradoxical by most of the European doctrine[11]. In particular, the court was called to assess the anti-competitive

[5] Case C-107/82 *AEG-Telefunken v Commission* [1983] ECR 1983-03151.

[6] Case C-31/80 *NV L'Oréal and SA L'Oréal v PVBA "De Nieuwe AMCK"* [1980] ECR 1980-03775.

[7] Case T-88/92 *Leclerc v Commission* [1996] ECR II-01961.

[8] Joined Cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P *GlaxoSmithKline Services Unlimited, formerly Glaxo Wellcome plc v Commission of the European Communities* [2009] ECR I-09291.

[9] Case C-322/01 *Deutscher Apothekerverband eV v 0800 DocMorris NV and Jacques Waterval, Deutscher* [2003] ECR I-14887, whose ***dēcīsum*** has been confirmed by case C-108/09 *Ker-Optika bt v ÀNTSZ Dél-dunántúli Regionális Intézete* [2010] ECR I-12213.

[10] Case C-439/09 *Pierre Fabre Dermo-Cosmétique SAS v Président de l'Autorité de la concurrence and Ministre de l'Économie, de l'Industrie et de l'Emploi* [2011] ECR I-09419 (referred to as "Pierre Fabre").

[11] A quite comprehensive list of the comments on the case can be found on the official website of the CJEU at <http://curia.europa.eu/juris/fiche.jsf?id=C%3B439%3B9%3BRP%3B1%3BP%3B1%3BC2009%2F0439%2FJ&oqp=&for=&mat=or&lgrec=en&jge=&td=%3BALL&jur=C%2CT%2CF&num=C-439%252F09&dates=&pcs=Oor&lg=&pro=&nat=or&cit=none%2

nature of the general and absolute ban imposed by the supplier on its distributors to use the telematic channel for selling cosmetics and personal care products. In brief, the judges stated that selective distribution agreements cannot prohibit online sales unless an objective justification exists and that a clause containing such a ban, being a restriction by object, cannot benefit from the Block Exemption Regulation, but only from the individual exemption where the conditions required by Art. 101(3) TFEU are met. Most importantly – especially in the light of the last ruling on the issue – while looking into the defensive arguments in support of the absolute prohibition of online sales regarding the need to preserve the luxury image of the products (ensured through the presence, in the brick and mortar store, of a pharmacist able to advise the customers), the court ruled that the brand image defence cannot be employed to justify the introduction of a selective distribution system which, by default, restricts competition[12]. However, some of these principles have been overruled in the lapse of less than a lustrum with the decision in *Coty Germany* and so the already stormy scenario appears now even fuzzier.

3. *Coty Germany* and the Revamp of the Brand Image Defence in the Sales Online

Consumer discernment as the core parameter to evaluate the compliance with the EU competition rules of the ban to resort to third-party platforms for selling luxury goods in the context of selective distribution agreements: this is the cryptic message sent by the CJEU in the last episode of the EU saga about selective distribution online, a saga where the supporting actor is – *ça va sans dire* – Amazon. This message, along with the corollary that the defence of the product image matters as much as to justify a limitation to the use of the Internet as a commercial channel, has given rise to a plethora of questions about the powers of the supplier to relegate in a nook the entrepreneurial skills of the retailers, obliged to abide by a detailed rulebook with very little room for *manoeuvre* if they wish to distribute the products of the vendor.

The specific legal issue which led the *Oberlandesgericht Frankfurt am Main* to seek for a preliminary ruling from the CJEU was the doubt that a clause contained in the distribution agreement between *Coty Germany* and *Parfümerie Akzente* prohibiting the recognisable engagement of a third-party undertaking for the internet sales of the contract goods (namely luxury cosmetics) could be a hardcore restriction according to Article 4 letters b)

52CC%252CCJ%252CR%252C2008E%252C%252C%252C%252C%252C%252C%252C%252C%252C%252Ctrue%252Cfalse%252Cfalse&language=en&avg=&cid=1559798#section_analyse> accessed 20 April 2020.

[12] *Pierre Fabre*, para 46 reads: 'The aim of maintaining a prestigious image is not a legitimate aim for restricting competition and cannot therefore justify a finding that a contractual clause pursuing such an aim does not fall within Article 101(1) TFEU'.

and c) of the Block Exemption Regulation. On a more general note, the German tribunal enquired about the compatibility with Article 101(1) TFUE of the use of a selective distribution system to ensure primarily the protection of the 'luxury image' of the products.
Starting with the latter point, after citing its precedent *Pierre Fabre*, where the main criteria enucleated in the *Metro I* case were referred to in order to assess the competitive nature of selective distribution networks[13], the CJEU resorted to a completely different controversy – *Copad* – relating to the protection of the trademark in the sale of lingerie Dior, to uphold the principle that luxury goods may require the implementation of a selective distribution system to preserve their quality and ensure that the goods are used properly[14]. Consequently, the luxury aura of the products sold becomes a valid reason to restrict the competitive dynamics in the market concerned.
After swinging between competition and trademark law to support its approach to selective distributive networks, the court goes back to *Pierre Fabre*, at first eulogised, to deny that the statement contained in that decision on the lack of connection between prestigious image of the product and legality of the clause aimed at limiting online sales produces any impact, as alleged by some of the disputants, on the ***dēcīsum*** rendered in *Coty* for at least two reasons. Firstly, because the current quarrel relates to the assessment of the entire selective distribution system, whereas the earlier focused only on the specific clause banning online sales *per se*; secondly, due to the nature of the product, since in the former case the object of the contract were not luxury goods, but just cosmetic and products for body hygiene which, as it seems to emerge within the lines of the decision, cannot be luxurious.
Once the fine line between the old and the new quarrel has been sketched, the court addresses the key controversy in the case, that is the compatibility with the competition rules of a contractual clause which prohibits authorised distributors in a selective distribution system of luxury goods designed, primarily, to preserve the image of those goods from using, in a discernible manner, third-party online platforms. In this regard, the judgment clarifies that the decision on the merit will be obviously rendered by the referring judge based on the facts in the dispute. Nevertheless, the court writes down some coordinates to help the domestic decision-maker to issue the final decision and dwells upon the criteria

[13] On the path of the previous jurisprudence, the court confirmed that the use of selective distribution networks is not prohibited by Article 101(1) TFEU to the extent that resellers are chosen on the basis of objective criteria of a qualitative nature, laid down uniformly for all potential resellers, and not applied in a discriminatory fashion; that the characteristics of the product in question necessitate such a network in order to preserve its quality and ensure its proper use; and, finally, that the criteria laid down do not go beyond what is necessary.

[14] Case C59/08 *Copad SA v Christian Dior couture SA, Vincent Gladel and Société industrielle lingerie (SIL)* [2009] ECR I-03421, where the Court ruled that 'the proprietor of a trade mark can invoke the rights conferred by that trade mark against a licensee who contravenes a provision in a license agreement prohibiting, on grounds of the trade mark's prestige, sales to discount stores of goods, provided it has been established that that contravention, by reason of the situation prevailing in the case in the main proceedings, damages the allure and prestigious image which bestows on those goods an aura of luxury'.

to evaluate the appropriateness, the proportionality, and the necessity of the limitation imposed upon the distributors at stake.

The CJEU asserts that the ban of discernible third-party platforms provides the supplier with a guarantee, from the outset, that products commercialised electronically will be exclusively associated with the authorised retailers and that this will ensure the quality of the network because of the direct contractual relationship between supplier and distributor, which allows the former to require the respect of the quality standards contractually agreed upon by the parties and pursue legal actions for breach. Such right to act in case of not compliance is instead missing if a third party, with no legal relationship with the supplier, is permitted to distribute the goods object of a contract binding only for supplier and distributor. Thus, in the reasoning of the court, the ban is justifiable with the need to ensure quality and protect the luxury image of the goods through the enforcement of the contractual provisions whenever necessary.

In the attempt to make a sharp distinction with the facts in *Pierre Fabre* and minimise the risk of incurring self-contradiction, the judges clarify that the two rulings are completely different as it pertains to the ban of internet sales, since in *Coty* the prohibition to resort to the web is not absolute because the distributors are allowed to sell the contract goods online both via their own websites, as long as they have an electronic shop window for the authorised store and the luxury character of the goods is preserved, and through unauthorised third-party platforms when the use of such platforms is not discernible to the consumer. This circumstance, in the view of the court, seems to support the proportionality of the ban imposed on *Parfümerie Akzente GmbH*. Moreover, because the results of the e-commerce sector enquiry published by the European Commission[15] demonstrate that, despite the growing importance of third-party platforms for selling distributors' goods, the main digital commercialisation channel remains the distributors' online shop, according to the court the factual data confirm that prohibiting perceivable third-party platforms does not go beyond what is necessary to preserve the allure of the luxury products[16]. Consequently, the ban imposed in the case appears to be lawful in the sense of Art. 101(1) TFUE.

In its conclusive section, the decision deals quite swiftly with the other two questions submitted by the referring court concerning the qualification of the ban to use a discernible third-party platform as a hardcore restriction in the form of restriction of the distributors' customers or restriction of passive sales to end-users[17] and provides some insight to the national judge for the eventuality that the decision on the merits will lead to a violation

[15] Commission, 'Final report on the E-commerce Sector Inquiry' COM (2017) 229 final)

[16] *Coty Germany*, para 56 reads: 'given the absence of any contractual relationship between the supplier and the third-party platforms enabling that supplier to require those platforms to comply with the quality criteria which it has imposed on its authorised distributors, the authorisation given to those distributors to use such platforms subject to their compliance with pre-defined quality conditions cannot be regarded as being as effective as the prohibition at issue in the main proceedings'.

[17] Respectively within the meaning of article 4, letter b, and article 4, letter c, of the Block Exemption Regulation.

of Art. 101(1) TFUE. On this point, the CJEU reckons that the clause inserted by *Coty Germany* in its distribution agreements can benefit from the Block Exemption Regulation for several reasons: the supplier does not impose an absolute ban on Internet as a commercial tool; it does not appear possible in practice to identify, within the group of online purchasers, third-party platform customers; and the selective distribution agreement enables authorised distributors, under certain conditions, to advertise the products via third-party platforms and also use online search engines, with the practical result that customers are usually able to find the products online through such engines.

4. The Unresolved Knots of the Ruling

A thorough analysis of the *dēcīsum* leads to the conclusion that the court, perhaps to correct some of the aberrations originated from the previous jurisprudence, has attempted to limit *Coty*'s outreach by establishing that the prohibition under scrutiny was a partial ban because it referred only to a specific type of online distribution and did not target Internet as a whole distributive channel. In fact, the compatibility with the EU competition rules of the clause used in Coty's distribution agreement seems to derive from the assumption that some types of online sales are deemed licit. Moreover, suppliers are allowed to restrict the commercial freedom of their authorised retailers only if the distributive network is organised according to the consolidated maxims of the European case law regarding qualitative standards and preservation of the luxury image of the goods, even though nothing in the ruling disentangles the doubts about the luxurious nature of the products, apart for a vague reference to the perception of the consumers. Yet, this remains a much debated topic amongst scholars and practitioners[18].

Although the CJEU does not make an explicit declaration in this regard, the reasoning applied to support the pro-competitive character of the ban to use perceivable third-party platforms follows quite closely the principles laid down in the Commission Guidelines on Vertical Restraints, which entrust the supplier with the power to require the distributors using third-party platforms to abide by standards and conditions, such as prohibiting the consumer's access to the distributor's website through a site carrying name and logo of the third-party platform[19].

[18] In a decision relating to trade mark rights and copyright, Case C-337/95 *Parfums Christian Dior SA and Parfums Christian Dior BV v Evora BV* [1997] ECR I-06013, the CJEU refers to prestigious image and allure to identify what constitutes a luxury good. However, no judgment in the field of selective distribution, either online or offline, has provided a clear definition for such goods. A similar outcome can be found in the doctrine, with some authors stating that exclusivity is what defines the luxury nature of a product. Among others, M. Tavassi and G. Bellomo, "Online Markets, Geo-blocking and Competition" in Gabriella Muscolo and Marina Tavassi (eds), *The Interplay Between Competition Law and Intellectual Property. An International Perspective* (Wolters Kluwer 2019).

[19] European Commission, Guidelines on Vertical Restraints [2010] OJ C130/1, para 54.

Lastly, the legal relationship arising out of the selective distribution agreements does not appear confined anymore to the contractual dealing between suppliers and retailers but, on the one side, it spreads binding effects upon unrecognisable third commercial undertakings and, on the other, confers to the consumers the right to tip the balance towards the anticompetitive nature of third-party platforms based on their ability to detect the presence of an external entity – the search engine used to sell the products online – in the middle of a trading connection between two contractual parties. From this angle, the judgement appears to borrow principles entrenched in the discipline of unfair practices and their possible misleading effects for the consumers[20] to preserve the luxury aura of the product and, accordingly, limit the generalised access to the goods object of the contract if certain qualitative standards are not ensured.

It seems interesting to highlight that in April 2018 the European Commission published a brief on the marketplace bans after *Coty*21 where, in the light of the e-commerce enquiry, it tried to extend the applicability of the decision to high-quality and high-technology products since in previous judgments the CJEU vouched for the compliance with the competition norms of selective distribution agreements whose object was represented by such types of goods[22]. Also, the Commission states that the distinction between luxury and non-luxury goods is not always easy in practice, especially for cosmetics and body hygiene products, and therefore, as far as the *Metro* criteria are fulfilled by the selective distribution system, compliance with Art. 101(1) TFUE should be implied unless otherwise proven in the specific case.

Even more interesting is the approach taken by the Commission a few months later in imposing a fine of almost € 40 million on the clothing manufacturer Guess for having prohibited its authorised distributors from bidding on its brand names and trademarks as keywords on Google AdWords[23]. Indeed, the Commission considered the restriction of online advertising imposed by Guess unlawful and, by applying the *Coty* judgment, decided that such kind of prohibition in the context of selective distribution is permitted only if it has a legitimate objective. In the Commission's view, this did not happen in the case under scrutiny because Guess, through the ban, attempted to reduce its advertisement costs while maximising the number of accesses through its own website, which entailed a restriction of the competition since "findability" and "viability" of the authorised distributors were limited without a sound justification. In essence, the Commission applied to online

[20] Ignacio Herrera Anchustegui, "Buyer Power in EU Competition Law" (Concurrences 2017).

[21] Commission, 'EU competition rules and marketplace bans: Where do we stand after the Coty1 judgment?' (Competition Policy Brief 2018-01), available at <https://ec.europa.eu/competition/publications/cpb/2018/kdak18001enn.pdf> accessed 15 May 2020.

[22] *Metro I* and *AEG-Telefunken v Commission*.

[23] European Commission - Competition Directorate, Case AT.40428 *Guess* [2018], available at <2020https://ec.europa.eu/competition/antitrust/cases/dec_docs/40428/40428_1205_3.pdf> accessed 18 May 2020.

advertisements rules similar to those utilised for the anti-competitive assessment of restrictions to online sales and, in doing so, declared its strict approach to unjustified restraint of the competitive dynamics in the digital environment.

5. Third-Party Platforms Ban in the Jurisprudence of the National Courts

Despite its clarificatory endeavour, the ruling in *Coty* has left some room for discussion regarding the limits which can be imposed to the use of the digital channel as a commercial tool in the context of selective networks. Hence, in the aftermath of the CJEU's judgment, domestic courts across Europe have adopted slightly divergent approaches to decide disputes involving third-party platforms in online sales.

Germany judiciary bodies have been extremely active in handling legal issues in this field. For instance, in its decision dated December 2017, the Federal Court of Justice decided that *Asics*[24] may not ban its dealers from using price comparison engines, because any prohibition which is not tied to quality requirements has to be considered illegal[25]. The court, adopting an argumentation very similar to the one of the European Court concerning the consumer sovereignty in the competitive assessment of third-party platforms, supports its verdict by emphasising that, in the light of the large range of products, suppliers, and distributors available on the Internet, price comparison engines are of core importance for consumers, since they enable the individuals who have already decided to buy a specific product to search selectively for retailers offering the best economic conditions. The Frankfurt Higher Regional Court – the referring court in *Coty* – in July 2018 simply followed the *dēcīsum* of the CJEU and stated that the ban imposed by the manufacturer in the distribution agreement with Parfümerie Akzente GmbH was permissible[26]. Earlier in March 2018 another German Court – the Higher Regional Court of Hamburg – extended the criteria set by the CJEU beyond the domain of the luxury goods by ruling that a supplier of food supplements, fitness drinks, and various toiletries may also prohibit distributors from using third-party platforms if the principles set by the European Court are adhered to[27].

As for the French jurisprudence, in June 2019 the Paris Court of Appeal, in a case related to Samsung products, considered that running a brick and mortar store is a lawful criterion

[24] *Asics Gruppe* [2017] BGH. The Federal Court of Justice, upholding the decision of the Düsseldorf Higher Regional Court dated April 2017, confirmed a corresponding decision of the Bundeskartellamt against ASICS rendered in August 2015.

[25] In October 2017 the District Court of Amsterdam ruled that the selective distribution system used by Nike allowing sales only via certain authorised third-party platforms, namely Zalando and Otto, did not infringe the EU competition rules because the retailers were authorised to use certain types of digital channels. Indeed, the Rechtbank Amsterdam considered the Nike's products sufficiently prestigious to justify such ban.

[26] *Coty Germany GmBH v Parfumerie Akzente GmbH* [2018] OLG Frankfurt.

[27] *Aloe2Go* [2018] HansOLG.

to be imposed to participants in a selective distribution network[28]. A similar approach was taken in a quarrel against *Coty France*[29], where the same court judged lawful the obligation imposed on the retailers to use a physical point of sale, along with digital commercial channels, in order to preserve the luxury nature of the goods. In July 2018 the Paris Court of Appeal applied the ruling in *Coty* to a case concerning the prohibition to sell cosmetics and body care products through online platforms different from the distributor's digital shop dedicated to the products branded Caudalie and decided that such ban complies with the competition rules[30].

Another significant judgement is the one rendered by the UK Competition Appeal Tribunal, which in September 2018 upheld the UK Competition and Market Authority's decision fining *Ping Europe Ltd*, a manufacturer of golf clubs, for violating EU and UK competition law by prohibiting two UK retailers from selling online Ping golf clubs. Even though the tribunal reduced the amount of the fine, it still confirmed that outright online sales bans in the context of selective distribution networks are a restriction by object[31].

From the foregoing overview it emerges that, even though national courts across Europe have mostly followed the case law of the Court of Justice in assessing the legality of some types of vertical restraints in the online distribution of goods, few attempts have been made in order to diverge from the rules issued at Kirchberg and broaden their application beyond the realm of luxury, perhaps to promote more clarity about the legal evaluation of vertical restrictions in the context of distributive networks with a digital component.

6. Conclusion

The merit of the *Coty Germany* case is that the CJEU has made one more step towards improving the approach of the judiciary to vertical restraints in selective distribution agreements through reinvigorating the debate on the old-age question concerning the admissibility of different commercial channels in selective networks and eliminating some of the incongruities caused by the previous jurisprudence on the absolute prohibition of sales online.

The ruling is characterised by a profile never examined in the past, that is the admissibility of resorting to a platform different from the online store of the contractual parties to sell

[28] *Concurrence v Samsung Electronics France* [2019] Paris CA, No 17/11700.

[29] *Showroom Privé v Coty France* [2018] Paris CA, No 16/02263.

[30] Enova Santé v Caudalie [2018] Paris CA, No 17/20787.

[31] *Ping Europe Limited v Competition and Markets Authority* [2018] CAT 13. The decision concluded that the selective distribution system in the case did not meet the criterion of necessity because Ping (i) allowed account holders to sell off-the-shelf clubs in stores and by telephone without a prior custom fitting, (ii) did not impose a similar online sales ban in the United States and (iii) failed to take account of the fact that some customers do not require a custom fitting. The judgment has been confirmed by the Court of Appeal in January 2020.

the products object of the contract. While reviewing this new issue and trying to support the permissibility of the sales via the Internet as a general tool to reach out to consumers, the court has firstly reinstated the validity of several principles laid down in old judgments to evaluate the legal compliance of the selective distribution networks irrespective of the use of the web (principles which, indeed, nobody has been challenging since a long time and have also been incorporated in the EU written rule of law). However, when it comes to the pros and cons of resorting to a third-party online marketplace to conduct sales, the reasoning becomes complex and two sole conclusions are reached: 1) luxury goods cannot be treated like any other product because their brand image is what matters the most; 2) nonetheless, if the consumer is unable to perceive that the online store does not belong to the distributor, but to a plebeian platform accessible to everybody from anywhere and anytime, then the luxury aura does not matter anymore.

While it still remains indeterminate what qualifies as a luxury good[32] – with the consequence that this important parameter for discerning between competitive and anti-competitive restrictions is left to a subjective interpretation of the *ad hoc* decision-maker – another point for further discussion is why the buyer and his discernment become so powerful within the contractual relationship between the manufacturer and its distributors. Likewise, if the core bone of contention is the paternalistic protection of the consumer to guarantee quality and avoid misleading practices, the reasons which pushed the court to banish one of the possible selling methods, rather than requiring the respect of quality criteria – and, eventually, the creation of a separate shop window for luxury goods –, from the owners of third-party platforms in order to qualify for the commercialisation of high-end goods, are unclear. Hence, the attempts of some domestic tribunals to extend the canons established by the Court of Justice beyond the boundaries delineated at Luxembourg, a trend that has produced a non-uniform legal treatment at a national level.

An accurate examination of the cases decided across Europe highlights a bunch of inconsistencies especially about the conditions for allowing online sales in distributive networks, inconsistencies that become even more apparent when comparing the regulation of the digital collusion practices in the EU with the distribution norms set by the jurisprudence on the other shore of the Atlantic. Indeed, in the homeland of the Antitrust law, the situation appears less complicated since the purely economic approach to vertical restraints developed in the *Continental T.V. Inc. v. GTE Sylvania Inc.* case[33] minimises the distortions of the EU sophisticated recipe for the selective distribution networks by relying on the rule

[32] The Advocate General Wahl, in paragraph 92 of his opinion in *Coty Germany GmbH v Parfümerie Akzente GmbH*, refers also to "quality products" as a second category which should be treated in the same manner as luxury goods. However, no definition of quality products can be found in the opinion.

[33] *Cont'l T.V. Inc. v GTE Sylvania Inc.* [1977] SCOTUS 433 U.S. 36, where the Court has ruled that if a manufacturer can justify that the limit to the retailers' freedom to sell outside certain territories or groups of customer complies with the rule of reason analysis, no infringement shall be detected by the US judges.

of reason for the assessment of distribution restraints, as also subsequently proclaimed in the renowned *Leegin* judgment[34]. In brief, any contractual request made by the supplier in the context of the distribution agreements is judicially evaluated in the US by weighting anti-competitive and pro-competitive effects of the restriction and assessing whether or not the limitations imposed on the retailer are necessary to achieve a competitive benefit. Ergo, notwithstanding the peculiarities of the dispute at stake, the compatibility with competition rules is always appraised by applying the same legal methodology, which dispels possible contortions deriving from the specificity of the quarrel and entails a relaxation of the American-style scrutiny for this type of conduct.

To conclude, while electronic transactions increase in volume on daily basis, the antitrust enforcement in the field of selective distribution of goods via the Internet, irrespective of their luxury nature, still appears in need of further development due to the inability of the EU regulators and judiciary to provide definite solutions to the challenges stemming from the uncontrolled propagation of digital clicks. One cannot deny that few ambiguities exist due to the choice of the CJEU to disregard a plainer approach to selective distribution networks. Yet, the worldwide growth in the sales online derived from the unprecedented situation created by the pandemic Covid-19 seems to demonstrate that distributive platforms, like Amazon or Alibaba, stand as consumer's saviours when unexpected contingencies disarm the brick and mortar commerce and suppliers and distributors are faced with the difficulty of rethinking suddenly their business models and converting physical shops into digital marketplaces ready to be accessed. In blunt terms, we are currently experiencing a situation where the change in the logic of selective distribution online has been led by events, but the legal arena should now re-invent the existing legal framework and cope with the distributive disruption by providing quicker and more effective responses to the old-fashioned obstacles faced by the economic actors in the digital marketplace[35].

[34] *Leegin Creative Leather Products Inc. v PSKS Inc.* [2007] SCOTUS 551 U.S. 877.

[35] A move in this direction is European Commission – Directorate-General for competition, Support studies for the evaluation of the VBER" (Final Report, 2020-02). The report is available at <https://ec.europa.eu/competition/publications/reports/kd0420219enn.pdf> accessed 26 May 2020.

Articles

Remote Teaching During the Emergency and Beyond: Four Open Privacy and Data Protection Issues of 'Platformised' Education

Chiara Angiolini[*], Rossana Ducato[**], Alexandra Giannopoulou[***], Giulia Schneider[****]

Abstract

Due to the spread of Covid-19 in the first months of 2020, almost all Universities across Europe had to close their buildings and migrate online. This rapid shift towards the provision of education online has been characterized by the externalization to and use of third-party service providers, such as Zoom, for ensuring the continuity of learning. The 'platformisation' of education, however,

[*] Chiara Angiolini, PostDoc Researcher, University of Trento.
[**] Rossana Ducato, Lecturer in IT Law & Regulation, University of Aberdeen.
[***] Alexandra Giannopoulou, Researcher, Institute for Information Law (IViR), University of Amsterdam.
[****] Giulia Schneider, PostDoc Researcher, Sant'Anna School of Advanced Studies (Pisa, Italy).

raises several concerns, especially from a privacy and data protection perspective. The aim of this paper is to map the possible data protection risks emerging from the platformisation of education by focusing on the most pressing points of friction with the European data privacy regime: 1) allocation of roles and responsibilities of the actors involved; 2) transparency of the processing and possibility to effectively exercise data subjects' rights; 3) extra-EU data transfers after Schrems II; 4) challenges of e-proctoring systems.

The paper argues that the implementation of the right to privacy and data protection in remote teaching is not merely an issue of compliance, but a substantial measure that Universities shall ensure to guarantee the fundamental rights of our students and colleagues. The paper concludes with recommendations for ensuring a safer and fairer remote teaching experience, also discussing long-term strategies beyond the emergency and beyond the mere compliance with the General Data Protection Regulation.

Keywords

Privacy – Data protection – GDPR – EdTech – Emergency Remote Teaching – digital education – online platforms

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Introduction

Due to the spread of Covid-19 in the first months of 2020, schools and higher education institutions (HEIs) were among the first places to experience the lockdown. From Italy to the UK, from Spain to Greece, almost all Universities across Europe had to close their buildings and migrate online[1].

[1] See, the European University Association, *Briefing: European higher education in the Covid-19 crisis* (September 2020) https://eua.eu/downloads/publications/briefing_european%20higher%20education%20in%20the%20covid-19%20crisis.pdf (last

Despite the use of online tools and educational technology ("Edutech" or "EdTech") was nothing entirely new[2], the pandemic dictated a paradigmatic digital turn in education, promptly labelled as Emergency Remote Teaching (ERT)[3]. If compared to pre-pandemic online learning, ERT presents the distinctive and unknown convergence of three main elements:
1) The velocity of the migration. In order to ensure the continuity of education, traditionally non-distance education providers had to switch online in a matter of days. HEIs tended to use third-party services already in their portfolio or to search for popular options available on the market. In either case, there was little time to consider all the possible EdTech options and their consequences, including the legal ones.
2) The volume of activities that had to be transferred online. If the repository hosted on the University servers was enough for sharing teaching materials (such as slides and suggested reading), with ERT the HEIs have started relying on digital means to carry out very diverse aspects of education activities, such as teaching, correcting assignments, holding school meetings, running PhD defences, etc.
3) The variety and combination of tools to be used for synchronous and asynchronous teaching, research, and administrative work. Especially at the beginning of the pandemic, no EdTech online service offered all the features requested for ERT (e.g. videoconferencing tools, hosting space, forums, videomaking, automated captioning, students record systems, etc.). Therefore, many institutions and teachers had to do "patchwork", searching for the right tool, the right add-on, and then checking its compatibility requirements.
As an effect, these "3Vs" (velocity of migration, volume of activities, and variety of tools) have resulted in a general shift towards the 'platformisation' of education, i.e. a major reliance and outsourcing of tasks to third party online platforms. As a matter of fact, the vast majority of Universities did (and still do) not have a technological infrastructure designed to fully support academic life online[4]. Therefore, the recourse to third party providers (from Zoom to Skype, from MS Teams to Whatsapp) was a path followed by many Institutions during the lockdown.
The use of third-party providers is not, by itself, an inherent shortcoming in an educational environment. This situation requires, however, careful scrutiny. Some of the platforms used are not specifically designed for education, the vast majority offer standard services that cannot be customised according to the specific needs of HEIs, and the platforms' business

accessed: 11 November 2020).

[2] There are already several accredited online Universities and also "traditional not-distance education providers" have been delivering part of the academic activity online (e.g., skype sessions with students, online communities for sharing teaching materials, virtual student record systems, etc.).

[3] C. Hodges, S. Moore, B. Lockee, T. Trust, A. Bond, *The Difference between Emergency Remote Teaching and Online Learning* (2020) 27 *Educause Review*, https://er.educause.edu/articles/2020/3/the-difference-between-emergency-remote-teaching-and-online-learning (last accessed: 11 November 2020)..

[4] There are some notable exceptions however. For example, the Italian GARR consortium (https://www.garr.it/en/garr-en) or the portal "Fare" of the Politecnico di Torino (https://fare.polito.it/) Last accessed: 11 November 2020

model is often incompatible with the public interest goals of Universities. Most importantly, the 'platformisation' can affect the level of control that HEIs can exercise over the delivery of education and, as a consequence, over the lawful processing of students' and teachers' data. While much attention has been, rightly, dedicated to the pedagogical challenges, we intend to contribute to the debate on ERT by outlining its legal implications, in particular from a data protection perspective. We argue that the implementation of the right to privacy and data protection in the ERT environment is not merely an issue of compliance, but a substantial measure that Universities shall ensure to guarantee the fundamental rights of our students and colleagues. The right to privacy and data protection are in fact constitutional enablers of other fundamental rights such as the freedom of expression, education, research, and interests, as our digital well-being[5]. To this end, the paper intends to map the possible data protection risks emerging from the platformisation of education, by discussing four topical points of friction with the European data privacy regime.

Firstly, the roles of the entities responsible for the data processing in an ERT context are outlined, showing that data collected for educational purposes are often subject to further processing. The unclear definition of purposes of the processing and allocation of roles and responsibilities between the University and the platform create a situation of opaqueness that can harm students and teachers directly. Therefore, the respect of the transparency principle is examined by highlighting the practical difficulties in exercising data subject rights as described in the GDPR.

Following this analysis, the paper will assess the implications brought by the recent *Schrems II* decision. The latter, invalidates the adequacy decision allowing EU-US data transfers and questions the validity of other transfer mechanisms as well. Thus, such a decision is a serious warning against the platformisation trend in education, considering that cross-border data flow is a common feature of providers' business models in this sector. Later on, we turn our attention to the concerns raised by the use of 'e-proctoring' services, a growing set of information technology tools adopted for ensuring digital invigilation of students during exams. Even though such tools are not prohibited as such and, in a first national decision, have been considered compliant with GDPR principles, we question whether we should seek less intrusive solutions.

Finally, the paper proposes recommendations for ensuring a safer and fairer remote teaching environment: it discusses possible ways forward to support the implementation of edTech in a short, medium, and long-term perspective beyond the emergency and beyond mere compliance with the GDPR.

[5] G. Comandè, *Tortious Privacy 3.0: a Quest for Research*, in J. Potgieter, J. Knobel, R. M. Jansen, *Essays in Honour of Huldigingsbundel vir Johann Neethling* (Lexis Nexis, 2015), pp. 121-131.

1. Data protection roles: Untangling the powers and responsibilities of actors involved in remote teaching

When a University builds its remote teaching infrastructure relying on an external service provider, it must choose how to organise the processing of data concerning students and teachers. This Section will consider one main aspect of this choice: the allocation of the data protection roles among different actors (students, teachers, the University, and the service provider). This issue is of particular importance because that distribution of roles has significant consequences on the attribution of data protection responsibilities and duties.
Considering the processing of data for educational purposes, the allocation of data protection roles should be generally articulated as follows (Fig. 1).

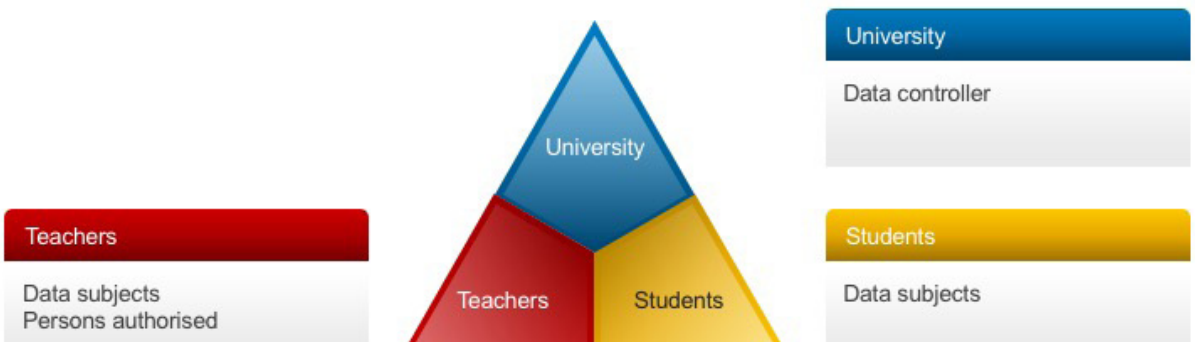

Figure 1. Basic scheme of data protection roles in the processing for education purposes.

Universities are data controllers, i.e. the entity determining the purposes and the means of the processing, while students are data subjects. Teachers can be considered data subjects vis-à-vis the University, when the latter processes data concerning them (e.g. their email address for sending communications, their workload, their pay slip, etc.). They can also vest another data protection role, as 'persons authorised' under Art. 29 GDPR. In other terms, when teachers have access to students data (e.g. for grading and assessment, teaching, tutoring, etc.), they do so on

instructions from the University-controller[6]. However, the shift toward ERT and the reliance on platforms affects this general scheme by altering the role of teachers and that of Universities.
With regard to the first aspect, teachers could be considered data controllers in certain circumstances. For example, at the beginning of the lockdown, lacking sufficient (or any) instruction by Universities on the tools to use for remote teaching, many teachers decided to act autonomously, searching for solutions that would allow them to ensure delivery of their courses. By choosing the means and the purposes of processing, they became *de facto* controllers[7]. In this way, they have assumed, often unaware, the corresponding responsibilities established at Art. 28 GDPR.
The introduction of the platform in the educational cycle also affects the University's position. When HEI partially or entirely outsources the processing of data to a third-party provider, the latter should be appointed as data processor (see, Fig. 2)[8].

Figure 2. Data controller and data processor roles when the purpose of the processing is the provision of educational services.

[6] The definitions of data protection roles are provided by Art. 4 Regulation EU 2016/679/EU 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 of 4 May 2016, General Data Protection Regulation (hereafter GDPR) [2016] OJ L 119/1.

[7] The recent European Data Protection Board, 'Guidelines 07/2020 on the concepts of controller and processor in the GDPR' (https://edpb.europa.eu/our-work-tools/public-consultations-art-704/2020/guidelines-072020-concepts-controller-and-processor_it) adopted in the version for public consultation on 2 September 2020, may result particularly useful for determining, in each specific case, data protection roles.

[8] Processor is defined at Art. 4(1)(8) GDPR as "a natural or legal person, public authority, agency or other body which processes personal data on behalf of the controller".

Within this context, Universities must ensure that the platform offers appropriate safeguards for the protection of data and, in general, guarantees GDPR compliance[9]. Nowadays, the importance of this duty is becoming particularly pressing. Several security issues have been uncovered from the extended use of EdTech for ERT, such as hackers intruding meetings, a phenomenon known as "zoombombing"[10].

The controller shall provide the processor with instructions about processing, through an agreement or another act. However, in the definition of the data processing agreement the platform may play the most active and powerful role, with the consequence that the University formally determines purposes and means of processing, but the platform exercises a substantial power in planning data processing and its limits.

The schema according to which the University is a controller and the platform a processor (as in Fig. 2) is only one possible configuration and not necessarily the most common one. If we consider the business model of many of the digital providers (education-native or repurposed by users for education), we will find that online platforms usually perform further processing on the data collected within an ERT context for their own purposes[11]. Not entering into the lawfulness of such a processing for the moment, but only considering the data protection roles, in such a case the platform may be classified as controller for the processing of data for its own purposes, as it determines the means and purposes of this specific processing. Meanwhile, the University can act as a joint controller for certain processing operations.

In this respect, the recent European Data Protection Board (EDPB) guidelines 7/2020 on the concepts of controller and processor in the GDPR are of particular interest[12], jointly with the CJEU's case law[13]. As to the Guidelines, the EDPB stated that joint controllership exists not only in cases of common decisions taken by two or more entities concerning the means and the purposes of processing, but also where those decisions are the result of *converging decisions* by two or more entities[14]. According to the EDPB, an important element of joint controllership is that the processing would not be possible without both parties' participation in the sense that the processing by each party is "inextricably linked"[15]. The CJEU *Fashion ID* case is worth mentioning to this end. In that case, the Court stated

[9] As established by Art. 28 GDPR.

[10] On Zoom's privacy issues is of particular interest the message published by the CEO of Zoom, available at: https://blog.zoom.us/a-message-to-our-users/ (last accessed: 24 August 2020).

[11] In that regard, for analysis of some of data protection policies of some of the most popular online platforms see R. Ducato et al., 'Emergency Remote Teaching: A Study of Copyright and Data Protection Policies of Online Services (Part. II)', (*CopyRightBlog*, 4 June 2020) http://copyrightblog.kluweriplaw.com/2020/06/04/emergency-remote-teaching-a-study-of-copyright-and-data-protection-policies-of-popular-online-services-part-ii/ (last accessed: 11 November 2020).

[12] See European Data Protection Board, *Guidelines 07/2020 on the concepts of controller and processor in the GDPR*, cit.

[13] See, Case C-40/17 *Fashion ID GmbH & Co.KG v Verbraucherzentrale NRW eV* [2019] ECLI:EU:C:2019:629.

[14] European Data Protection Board, 'Guidelines 07/2020 on the concepts of controller and processor in the GDPR', cit., p. 3.

[15] *Ibid.*, p. 3. See, with specific regard to service providers, paras 79-82.

that the operator of a website that embeds on that website a social plugin transmitting to Facebook personal data of the visitor shall be considered a controller for the operations consisting of the collection and transmission of visitor's data[16].

Thus, in light of *Fashion ID* and of the EDPB Guidelines, if the platform processes data collected within educational activities for further purposes, the University might be classified as a joint controller for the transmission of that information, because without the processing of data for educational purposes, where the University is a controller, the platform may not have access to data, and may not process them for other purposes. Therefore, the processing by each party may be defined as "inextricably linked". This conclusion is supported also by the fact that the University complies with some of the criteria elaborated by the EDPB in order to affirm that an entity is a controller: the University participates in the definition of what kind of personal data is collected and further processed and the categories of data subjects[17].

In case of joint controllership, it is necessary to contractually establish the allocation of responsibilities between the controller and the processor and towards the data subjects. This (contractual) agreement "would provide certainty and could be used to evidence transparency and accountability"[18]. In cases where multiple actors are engaged in data processing, it is recommended that transparency and accountability would be better served if the joint controllers "organise and agree on how and by whom the information will be provided and how and by whom the answers to the data subject's requests will be provided. Irrespective of the content of the arrangement on this specific point, the data subject may contact either of the joint controllers to exercise his or her rights in accordance with Article 26(3)"[19]. In that regard, according to the EDPB, "requiring data subjects to contact the designated contact point or the controller in charge would impose an excessive burden on the data subject, that would be contrary to the objective of facilitating the exercise of their rights under the GDPR"[20].

Nevertheless, as the "assessment of joint controllership should be carried out on a factual, rather than a formal, analysis of the actual influence on the purposes and means of the processing"[21], in each case a concrete assessment must be done, taking into account all relevant factual circumstances in order to determine if the two entities are determining both and jointly the means and/or the purposes of processing.

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[16] See, Case C-40/17. For an overview of the most important aspects of that judgment, see: J. Globocnik, *On Joint Controllership for Social Plugins and Other Third-Party Content – a Case Note on the CJEU Decision in Fashion ID* (2019) 50 IIC 1033.

[17] *Ibid.*, pp. 46-48.

[18] European Data Protection Board, *Guidelines 07/2020 on the concepts of controller and processor in the GDPR*, cit., p. 43.

[19] *Ibid.*, p. 44.

[20] *Ibid.*, p. 45.

[21] *Ibid.*, p. 49.

Figure 3. Data protection roles when the processing is jointly determined.

2. Setting the boundaries of processing: Determining the legal basis and purposes and enforcing data subjects' rights

The attribution of data protection roles to the actors involved in remote teaching implies the mutual acknowledgement of power and responsibility in setting boundaries to data processing. Thus, it is essential that the legal basis and purposes for processing be determined according to GDPR imperatives. Furthermore, these same actors would be liable to ensure that data subjects rights are respected[22].

Universities, as controllers or joint controllers, determine both the purposes and the legal basis for processing. Beyond compliance, that planning is informed by and constitutes a political and cultural choice for the University. Consequently, when Universities rely solely on an external online platform, they need to perform an adequate assessment not only of the suitability of the tool for educational purposes, but also of the guarantees that the platform offers in terms of data protection. An overview of the processing activities is usually contained in the privacy policies of such platforms. However, as previously explained[23], these policies and overall applied business models do not always align with the Universities' objectives.

[22] As highlighted by the CJEU, the concept of 'controller' is defined broadly in order to ensure "effective and complete protection of data subjects": Case C-131/12 *Google Spain and Google* [2014] ECLI:EU:C:2014:317, para 34; Case C-210/16 *Wirtschaftsakademie Schleswig-Holstein*, [2018] ECLI:EU:C:2018:388, para 28; Case C-40/17, *cit.*, para 70.

[23] R. Ducato et al. (n. 11).

As for the purposes pursued by Universities with the ERT processing, educational purposes are the obvious candidate. For those purposes, as the Italian Data Protection Authority has stated[24], consent does not appear to be the appropriate legal basis for processing. Therefore, the relevant lawful bases for the processing would be the public interest or, depending on the jurisdiction, contractual necessity.
Conversely, when processing of data is performed also for secondary purposes, such as promotional ones, it would need to be anchored to the lawful basis of legitimate interests[25]. In any case, personal data can only be processed for the specified, explicit lawful purposes for which they were collected, and cannot be further processed in a manner incompatible with those purposes (see Articles 5 and 6 GDPR).
This also applies when Universities use external services for providing remote teaching. Specifically, HEIs would have to carefully consider if these platforms process students' or teachers' personal data for independent purposes (e.g. marketing), and if those purposes are compatible with the purposes of data collection. Beyond compliance and considering the importance of the definition of the data processing purposes for the cultural and institutional policies, it should be highlighted that the choice of the platform becomes crucial especially when Universities and platforms are considered autonomous or joint controllers, because Universities will not be considered as having any power or direction over these platforms[26]. Moreover, when the University is classified as a controller which engages the platform as a processor, the question arises as to whether these processors could lawfully pursue autonomous purposes without prior controller authorisation[27].
Any institutional choice for the determination of data processing other than the educational purpose should take into consideration the impact that these choices will have on student and teacher activities. In that regard, transparency plays a crucial role in determining how data subjects can interrogate the platforms on which they (as students and teachers) progressively rely to study and to work. The principle of transparency, as enunciated in Art. 5 and Recital 58 GDPR, is a fundamental enabler of data protection. It is an obligation that data controllers are required to take into consideration when building their data

[24] Italian Data protection Authority, act of 26th March 2020, n. 9300784 – "Didattica a distanza: prime indicazioni", https://www.garanteprivacy.it/home/docweb/-/docweb-display/docweb/9300784 (last accessed: 11 November 2020).

[25] Article 29 Data Protection Working Party, 'Opinion 06/2014 on the "Notion of legitimate interests of the data controller under Article 7 of Directive 95/46/EC", (9 April 2020) https://ec.europa.eu/justice/article-29/documentation/opinion-recommendation/index_en.htm (last accessed: 24 August 2020). See also I. Kamara, P. De Hert *Understanding the balancing act behind the legitimate interest of the controller ground: A pragmatic approach* (2018) 4, 12 Brussels Privacy Hub.

[26] The lack of legal clarity in the allocation of liability and responsibility between joint controllers does not facilitate this choice for Universities.

[27] As pointed out by the Italian Ministry of Education, where a school decides to rely on an external platform, it will be necessary to appoint the platform as data processor and verify with the Data Protection Officer that only the services related to the remote teaching will be activated. These general indications seems to exclude the possibility that platforms act as controllers. See, Italian Ministry of Education, *Didattica Digitale Integrata e tutela della privacy: indicazioni generali* (4 September 2020) https://www.istruzione.it/rientriamoascuola/allegati/Didattica-Digitale-Integrata-e-tutela-della-privacy-Indicazioni-generali.pdf (last accessed: 11 November 2020).

processing systems, but also it constitutes the foundation based on which data subjects are entitled to exercise their rights, as prescribed in the GDPR.

It has already been highlighted in our previous work[28] that platforms used in ERT have manifested significant shortcomings in fulfilling their transparency obligations. For instance, there is considerable lack of clarity in the personal data collected and the respective lawful grounds of processing that data within the platforms that were part of the study. As a consequence, transparency, as a pillar in facilitating the exercise of data subjects' rights, is effectively hindered. Unclear phrasing, simple mentions of data subjects' rights without further support, all point to a rather superficial approach towards ensuring the respect of these rights. These practices chip away from the available tools that data subjects possess to keep data processing powers in check[29].

Admittedly, the examined platforms differ in their focus and business plan. Some are designed and specialized in the educational infrastructure field, and others are generalistic platforms, with education being remotely linked to their group video functionalities and capabilities. The discrepancy in business goals has undoubtedly impacted the types of personal data collected and the purposes for collecting them.

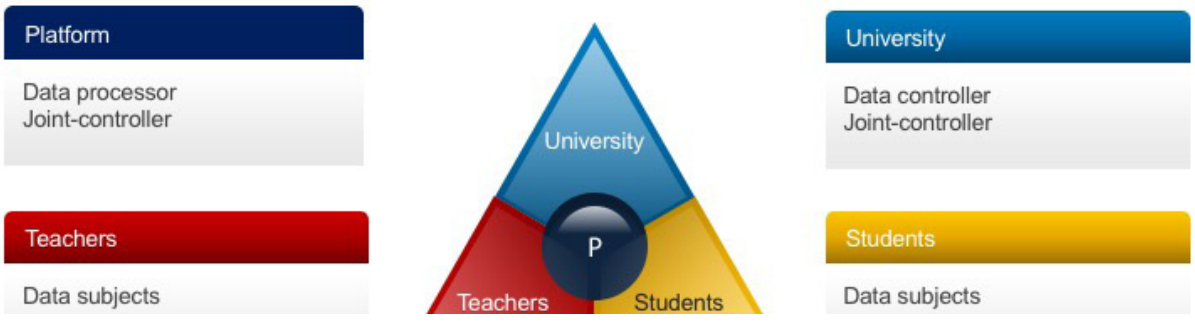

Figure 4. Overview of various data protection roles of actors involved in ERT.

[28] R. Ducato et al. (n. 11).

[29] For a detailed analysis of data subjects' rights, see: J. Ausloos, *The Right to Erasure in EU Data Protection Law: From Individual Rights to Effective Protection* (Oxford University Press 2020). See also, J. Ausloos, M. Veale, R. Mahieu, *Getting Data Subject Rights Right: A submission to the European Data Protection Board from international data rights academics, to inform regulatory guidance* (2019) 10(3) Journal of Intellectual Property, Information Technology and Electronic Commerce Law 283.

Keeping accountability within the remote teaching agenda is key in creating a safe environment for data subjects to be able to exercise their rights. Take for instance, the right of access (Art. 15 GDPR). It is difficult to imagine how a data subject would be able to convey the access request focused solely on their remote teaching or learning activity on a given platform. The response from a generalistic platform like Facebook to that data access request appears, for instance, quite challenging. Specifically, the parsing of the data to focus solely on all data collected via the educational/teaching platform activity of the data subject, could likely become cumbersome. Even if that distinction is not relevant to some, it is essential in helping all interested parties hold the platforms accountable for their data processing practices happening during the ERT-provision services. Education-oriented platforms do not appear to provide the level of information required for the exercise of data subjects' rights, at least on an individual level[30]. More focus is placed on deferring to a relevant representative body (often with misleading information), rather than ensuring that the rights demand in question can be effectively responded to[31].

Considering teachers as both data subjects and possible data controllers, their level of engagement towards responding to a data access request will probably be quite limited. This *de facto* controllership puts teachers in a position to carry considerable responsibilities towards their students, a responsibility which the University would traditionally carry. Furthermore, the elements that guided the teacher in choosing a specific platform would most probably have little to do with privacy protection and more with opportunity, usability, prevalence among students and teachers alike, cost of maintenance, inclusivity, etc. Should the remote teaching infrastructure remain unchecked, the dissonance between offline and online education will keep growing. The choice of ERT is fundamental in that regard. With little decision making in the hands of data subjects, they remain subject to terms and policies that risk disempowering them.

In this respect, in order to foster a substantial role of the University as a controller *vis-à-vis* the platforms, associations which represent groups of Universities, at the national or European level, could support HEIs in negotiations with platforms, for example providing guidelines or technical assistance with regard to institutional choices concerning the legal basis for processing and purposes of the latter. Moreover, a debate can be opened on the possibility that a collective entity representing Universities, or a group formed by members (e.g. DPOs) of several Universities would offer guidelines on these agreements, enhancing the role of Universities in shaping the legal architecture of EdTech platforms. While

[30] R. Ducato et al. (n. 11).

[31] Noyb, *Interrupted transmission. Zooming in on video conferencing privacy policies* (02 April 2020) https://noyb.eu/en/interrupted-transmission (last accessed: 11 November 2020).

this solution would enhance Universities' bargaining power, it would have to be balanced against the principle of autonomy of each University[32].

Following the trend of collective engagement in personal data, it would not sound far-fetched to envisage a possibility of a collective agreement, or ensuring the representation through a data subjects' administrative body, that would claim a seat at the negotiating table with regard to the ERT choice or infrastructure design principles. This collective engagement is not in contrast with the GDPR, which recognizes the need for collective means of safeguarding data subjects' rights in Article 80 GDPR. More generally, the nascent calls for collective empowerment of individual data subjects are highlighted in some jurisdictions which envisage data trusts and other forms of intermediaries representing data subject collectives (e.g., data cooperatives, data commons, data collaboratives)[33].

Finally, the importance of teachers' and students' engagement in data protection issues related to ERT platforms cannot be overstated. Their involvement in the negotiations and decision-making processes would ensure *ex ante* empowerment of them as data subjects. This collective data protection exercise would preserve transparency, accountability, and it would ultimately promote the educational and teaching values of each institution.

3. The Platformisation of Education: Life after Schrems II

The majority of platforms employed in ERT expressly relies on cross-border data flows as a fundamental element of their digital service model, in particular for storage and maintenance purposes. As the analysis of the privacy policies of some of the most employed service providers shows[34], until recently, most of these platforms' privacy policies were re-

[32] An example in that regard is the initiative of the Conference of Rectors of Italian Universities, which launched a survey within Universities, in order to negotiate at a collective level with Microsoft, for changing certain (only technical) aspects of Microsoft Teams. See EUA, 'Survey on Digitally Enhanced Learning in European Higher Education Institutions' https://www.fondazionecrui.it/wp-content/uploads/2020/05/Survey_03-04-2020_.pdf (last accessed: 11 November 2020).

[33] On the topic, see S. Delacroix, N. D. Lawrence, 'Bottom-up Data Trusts: Disturbing the 'One Size Fits All' Approach to Data Governance' (2019) 9, 4, *International Data Privacy Law* 326. These intermediaries are also mentioned under the umbrella term data cooperatives. According to the European Commission, "Data cooperatives seek to strengthen the position of individuals in making informed choices before consenting to data use, influencing the terms and conditions of data user organisations attached to data use or potentially solving disputes between members of a group on how data can be used when such data pertain to several data subjects within that group". See European Commission, Proposal for a regulation of the European Parliament and of the Council on European data governance (Data Governance Act) COM (2020) 767 final, para. 24.

[34] R. Ducato et al. (n. 11) where the authors have examined the privacy policies of Discord, Facebook, G-Suite for Education, Jitsi Meet, MoodleCloud, Microsoft Teams, Youtube, Skype, Zoom.

ferring to the Commission adequacy decision allowing EU-US data flows, generally known as the *Privacy Shield*[35], as the legal basis for these transfers[36].

However, in the recent *Schrems II* decision[37], the Court of Justice of the European Union invalidated the Privacy Shield and stated that any transfer shall be subject to a specific risk assessment. By ruling so, the Court has discarded the legal basis for the transatlantic data flow, retaining that US law (and in particular the surveillance programs for security purposes) did not grant an equivalent level of protection to the EU.

This decision has two important consequences in the ERT context (and beyond): 1) if the processing relies on the Privacy Shield, it is no longer lawful; 2) if it is done under an alternative legal basis, the HEI, as the controller, must perform the necessary risk assessment considering the law of the "data importer" and the appropriate safeguards that might be implemented to ensure the importer is up to the European standards[38]. Therefore, ERT providers using the Privacy Shield shall now find an alternative legal basis if they have to transfer data extra-EU. For the sake of the discussion, we will try to investigate the possible alternatives and to what extent these can be used in the short-term period. The European Data Protection Board's recently enacted recommendations are just a first step towards the establishment of a very much needed clearer framework regarding extra-EU data transfers[39].

A first option, already proposed by some platforms, is to use SCCs[40]. The latter have been formally upheld by the Court. However, reading carefully the decision of the Court one can reasonably doubt the ability of SCCs to support the extra-EU data transfer of data col-

[35] Commission Implementing Decision (EU) 2016/1250 of 12 July 2016 pursuant to Directive 95/46/EC of the European Parliament and of the Council on the adequacy of the protection provided by the EU-U.S. Privacy Shield [2016] OJ L 207 (no longer in force).

[36] This is the case of Moodle, Zoom, Teams, Jitsi, Youtube, Skype, Facebook, Discord. Other Platforms, as Google Meets do not mention the case of extra EU data transfers.

[37] Case C–311/18 *Data Protection Commissioner v. Facebook Ireland Limited and Maximilian Schrems* [2020] ECLI:EU:C:2020:559, para 201. For a comment see C. Kuner, 'The Schrems II Judgment of the Court of Justice and the future of data transfer regulation' (*European Law Blog*, 17 July 2020) https://europeanlawblog.eu/2020/07/17/the-schrems-ii-judgment-of-the-court-of-justice-and-the-future-of-data-transfer-regulation/ (last accessed: 11 November 2020).

[38] The reference is to the "essential equivalence" standard related to European Union law and in particular to the rights established in the EU Charter of Fundamental Rights. See recital 104 GDPR and Case C–311/18, para 99. See also European Data Protection Board, Frequently Asked Questions on the judgment of the Court of Justice of the European Union in Case C-311/18 - Data Protection Commissioner v Facebook Ireland Ltd and Maximillian Schrems, ECLI:EU:C:2020:559, https://edpb.europa.eu/sites/edpb/files/files/file1/20200724_edpb_faqoncjeuc31118_en.pdf.

[39] European Data Protection Board, *Recommendations 1/2020 on measures that supplement transfer tools to ensure compliance with the EU level of protection of personal data* (10 November 2020) https://edpb.europa.eu/sites/edpb/files/consultation/edpb_recommendations_202001_supplementarymeasurestransferstools_en.pdf.

[40] SCCs are referred to in the privacy policies of Moodle, Zoom, Teams, Youtube, Google Meet, Facebook. See, here, the list of responses received by Noyb after inquiring the platforms directly. Noyb, 'Opening Pandora's Box: How Companies Addressed Our Questions About Their International Data Transfers After the CJEU's Ruling in C-311/18- Schrems II (25 September 2020) https://noyb.eu/files/web/Replies_from_controllers_on_EU-US_transfers.pdf (last accessed: 11 November 2020).

lected during digital education activities, at least toward the US[41]. First, SCCs are contracts, this means that they only bind the parties. Contractual measures do not prevent third parties, as public authorities, to access transferred data and do not establish effective remedies for data subjects *vis à vis* those third parties[42]. That is why the Court of Justice concluded that it might be necessary for controllers, especially in the case of transfers towards the US, to provide supplementary guarantees to ensure that data subjects will enjoy an equivalent level of protection[43]. What these supplementary guarantees should be is a question that was left open by the CJEU. The EDPB's Recommendations advise controllers to define the relevant technical, organisational and contractual measures, on the basis of careful evaluation of the *length and complexity* of the data processing workflow; the *number* of actors involved and their respective relationships; as well as the possibility of *onward transfers*[44]. What is certain is that Universities choosing an ERT provider relying on SCCs for the transfer will have to perform their own evaluation considering all the concrete circumstances of the transfer, including the possible legal, technical and organisational safeguards that they or their providers can put in place. This is a task that inevitably requires investments of time, effort, and money (most probably beyond the limited resources available to Universities DPOs).

Among the conditions that can legitimise the transfer, the GDPR includes Binding Corporate Rules (BCRs)[45]. These rules provide a framework specifically designed on the basis of the specificities of a given sector and are approved by the supervisory authority[46]. However, this option raises some doubts. Firstly, BCRs usually take into account the reality of large companies. In the ERT scene, to the contrary, there are also smaller providers (and previously largely unknown, such as Jitsi and Discord) that have become widely used. One might then reasonably doubt that BCRs shaped upon the features of the bigger players in the ERT sector could encompass the varied design of the businesses that are active in the field. In addition to this, the effective implementation of BCRs could take a very long time. Most importantly, BRCs might experience the same fate of SCCs, as, given the current

[41] As retained by Solove D., 'Schrems II: Reflections on Decision and Next Steps' (*TeachPrivacy*, 23 July 2020) https://teachprivacy.com/schrems-ii-reflections-on-the-decision-and-next-steps/ (last accessed: 11 November 2020).

[42] As it is possible to read in Court of Justice of the European Union, Case C-311/18, cit., paras 126-127

[43] *Ibid.*, para 133.

[44] Emphasis added. European Data Protection Board, 'Recommendations 1/2020 on measures that supplement transfer tools to ensure compliance with the EU level of protection of personal data', cit., 15-17.

[45] Article 29 Data Protection Working Party, 'Working Document Setting Up a Table with the Elements and Principles to be Found in Binding Corporate Rules' (28 November 2017, modified 6 February 2018) https://ec.europa.eu/newsroom/article29/item-detail.cfm?item_id=614109, para 6.1.1, which outlines a series of essential elements and data protection principles to which BCRs must comply with.

[46] *Ibidem*.

US surveillance law, it is difficult to identify supplementary measures able to assure the equivalent standard of protection[47].

Ultimately, in accordance with Art. 46 GDPR, international transfers of personal data regarding digital education activities could be grounded in codes of conduct issued under Art. 40 GDPR or in approved certification mechanisms under Art. 42 GDPR[48]. Also, the reliance on these alternative transfer tools compels data controllers or processors to implement "appropriate" safeguards for the protection of the rights and freedoms of involved data subjects. In this case, however, problems of vagueness regarding what safeguards would be appropriate to these ends are likely to impair the achievement of the standard of essential equivalence with European Union law.

Finally, international data transfers could find legitimising grounds in some of the exceptions outlined by Art. 49 GDPR. In the context of ERT the following would be relevant: 1) explicit consent of the data subject and reinforced information obligations of the controller[49]; 2) necessity of the transfers for the conclusion or performance of a contract; 3) necessity of the transfer for important reasons of public interest.

The use of each of the three exceptions is highly questionable in the context at stake. For the purposes of the legal basis of consent, controllers would need to adequately inform data subjects regarding the envisaged transfer of personal data to countries that have a lower standard of protection, exposing themselves to objections or erasure requests. Moreover, in case the consent to the transfer is an outright condition for accessing the service, concerns regarding the free nature of such consent arise[50].

Furthermore, ERT service providers could argue that the transfer is necessary for the performance of the contract having as the object of the contract the digital educational service. In this case, however, according to the EDPB, the transfer needs to be "occasional" and most of all "objectively necessary for the performance of the contract"[51]. Thus, these two requirements will have to be demonstrated by ERT platforms, as they might clash with their business models and the scalability of their solutions.

Finally, also the derogation regarding the achievement of a public interest could be relied on by ERT service providers for conveying their datasets overseas. However, in respect to this possible derogation, substantial restrictions apply. As the EDPB has stated, public

[47] Solove D. (n. 41).

[48] European Commission, *Data Protection Certification Mechanisms – Study on Articles 42 and 43 of the Regulation (EU) 2016/679* (February 2019) https://ec.europa.eu/info/sites/info/files/data_protection_certification_mechanisms_study_final.pdf, which also defines the specific data protection framework relevant for the purposes of certification mechanisms, in particular the principles under Articles 5; 24, 25 and 28 GDPR.

[49] The controller will have to inform the data subject about the possible risks of the transfers due to the absence of an adequacy decision and appropriate safeguards. See, Art. 49(1)(a) GDPR.

[50] This point has been raised by R. Ducato et al. (n 11).

[51] European Data Protection Board, *Guidelines 2/2018 on Derogations of Article 49 under Regulation 2016/679* (25 May 2018) https://edpb.europa.eu/sites/edpb/files/files/file1/edpb_guidelines_2_2018_derogations_en.pdf, 9.

interest must be clearly identified by the processing organisations irrespective of their public or private nature[52]. Different from the transfers justified in the performance of a contract, data transfers under public interest grounds do not have to be restricted to occasional transfers. Nonetheless, these transfers cannot occur in a systematic way nor on a large scale.

On a general level, the EDPB has highlighted that these derogations need to be "interpreted strictly so that the exceptions do not become the rule"[53]. This means that these derogations can only be applied in specific circumstances, in strict observance of the necessity test. A restrictive interpretation of such derogations is additionally encouraged by the data protection by design and by default principles[54]. These principles require businesses to arrange themselves in a way that maximises data protection. In this respect, the limitation of data transfers to third countries could be a means for minimizing the risks to data subjects' rights stemming from controllers' activities.

Given the new scenario of international data transfers opened up by the *Schrems II* decision, it is crucial for Universities to revise their ERT practices and implement the CJEU *decisum*. For instance, when universities (controller) outsource the digital delivery of teaching to external services (processor), the question arises as to whether HEIs are able to know that the processor transfers collected personal data outside the European Union, under which legal basis and for which purposes. This is not a trivial task as it might appear to be, as the privacy policies of most of the platforms employed for education purposes[55] remain quite vague about these aspects. Contractual agreements shall then define these issues in more clear terms.

In accordance with Art. 28(1) GDPR, controllers shall choose processors that guarantee technical and organisational measures "in such a manner that processing will meet the requirements of this Regulation and ensure the protection of the rights of the data subject". This means that HEIs, as controllers, should be sure about the employed platform's organizational structure and the legal bases relied on for extra-EU data transfers. In addition to those aforementioned measures, the authorisation to transfer should be contained in the contract between the university and the service provider, specifying the nature of the transferred data and the location of storage. Such authorization is also needed for the entrustment of sub-processors for extra-EU transfers by the processor, to maintain consistency with the principle of lawfulness. In this respect, it must also be recalled that in case a

[52] European Data Protection Board, 'Frequently Asked Questions on the Judgment of the Court of Justice of the European Union in Case C-311/18 – *Data Protection Commissioner v Facebook Ireland Ltd and Maximilian Schrems*, cit., 4.

[53] European Data Protection Board, *Initial Legal Assessment of the Impact of the US Cloud Act on the EU Legal Framework for the Protection of Personal Data and the Negotiations of an EU-US Agreement on Cross-Border Access to Electronic Evidence* (10 July 2019) https://edps.europa.eu/sites/edp/files/publication/19-07-10_edpb_edps_cloudact_annex_en.pdf.

[54] Art. 24 GDPR.

[55] Again, reference is made to the privacy policies of the platforms analysed in the study by R. Ducato et al. (n 11).

joint controllership relationship under Art. 26 GDPR exists between the university and the platform, the contract among the parties should allocate respective liabilities in regards to the specific case of international data transfers.

With the falling of the Privacy Shield, most universities relying on processors transferring data to the US should act promptly as to stop these unlawful transfers and renegotiate the terms of the processing agreement in order to find a more legally-sound solution. To these ends, a means to contractually empower universities vis à vis ERT platforms could be found in the establishment of outright associations of universities, which could collectively manage and regulate envisaged international transfers that mostly involve sensitive data.

Moreover, HEIs can rely on supervisory authorities to choose the most convenient legal basis for the eventual extra-EU data transfers and for the related adequacy assessments. As the CJEU has highlighted, especially as a result of the falling of the Privacy Shield, these authorities have a central role in the oversight of international transfers: they can also suspend the transfer in the case where no effective equivalence is found and when the controller or processor fails to do so[56]. In this perspective, a stronger collaboration between universities' DPOs and supervisory authorities should be encouraged, so as to tighten the supervision over recurring cross-border flows of educational-related personal data.

The international dimension of digital educational models and the frequency of resulting data flows, should garner greater attention by European regulators due to the need of establishing a clearer normative framework for the extra EU circulation of European citizens' data collected during educational activities. In light of the transnational nature of remote teaching services, it is useful to look at the phenomenon of data flows originating from remote teaching services through the concept of "data space" used by the European Commission in the latest European data strategy for indicating a market zone of free data exchanges[57]. It is interesting to note that in the list of the "data spaces" envisaged by the Commission in various sectors such as health, energy, financial, and agricultural[58], any reference to the field of education is missing.

Nonetheless, the recently released Digital Education Action Plan 2021-2027[59] directly targets objectives related to the "cross-sector collaboration", the establishment of "new models for the exchange of digital learning content", addresses "issues such as common standards, interoperability, accessibility and quality-assurance". In this respect, more defined rules regarding the sharing practices of education-related data, specifically in regards to extra EU flows, are needed in order to meet those objectives more effectively.

[56] Case C-311/18, cit., paras 113 and 135.

[57] European Commission, *A European Strategy for Data* (Communication) COM (2020) 66 final.

[58] *Ibid.*, pp. 22-23.

[59] European Commission, 'Digital Education Action Plan (2021-2027) – Resetting Education and Training for the Digital Age' (Communication) COM (2020) 624 final.

A clearer framework regarding overseas data transfers involving sensitive personal information and adhering to the "essential equivalence" rule is key for shaping of a fundamental rights-oriented European digital education mode to act as a benchmark when interacting with other legal systems and emerging foreign digital education systems that have lower protection standards[60]. It is of note that in accordance with Art. 6 TFEU, as with the health sector, the education sector is also within a Member States' competence. In this field, the European Union thus has only supporting competences aimed at coordinating or complementing Member States' actions.

Nonetheless, it appears that the digitisation of education tools is triggering a "Europeanisation" of the education sector[61]: the set focus of digital education through a European Action Plan suggests that technological developments are attracting the regulation of this traditionally national-based subject matter at the European level. The fact that technologies and related risks are mainly addressed at the European level, is causing a spillover regulatory effect in those areas that are being most affected by technological transformations, such as the health sector[62] and now, under the pressure of the Coronavirus pandemic, the education sector. This is clearly demonstrated by the planned establishment of a European Education Area by 2025[63].

Under these premises, the emerging shift of competences of the European Union in the field of digital education may soon reveal that the regulation of the international transfer of European citizens' data for education-related purposes is a fundamental prerequisite for the achievement of the more general goal of strengthening the European leadership in global competition[64] and of consolidating the role of the European Union as a partner in education at the global level[65]. In addition to purely normative responses, technical solutions could speed up the achievement of these ambitious goals: among the available options the establishment of an EU-wide standardised digital learning infrastructure could be useful in order to curb the degree of extra EU flows of data concerning sensitive aspects of European teachers' and students' education activities.

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[60] Think, for example, of the developing a Chinese digital learning environment, based on the collection of sensitive data through facial recognition technologies, invasive surveillance mechanisms, and a weak cybersecurity coverage, exposing students' to data leakages. See among others, L. Lin, *Thousands of Chinese Students' Data Exposed on Internet – Information Leak From Facial Recognition Databases Raises Questions About School Surveillance and Cybersecurity in China*, *The Wall Street Journal* (18 January 2020) https://www.wsj.com/articles/thousands-of-chinese-students-data-exposed-on-internet-11579283410 (last accessed: 11 November 2020).

[61] For a general overview seeEuropean Parliament, Research for CULT Committee, *The Use of Artificial Intelligence (AI) in Education – Concomitant Expertise for INI Report* (May 2020) https://www.europarl.europa.eu/RegData/etudes/BRIE/2020/629222/IPOL_BRI(2020)629222_EN.pdf (last accessed: 11 November 2020).

[62] European Commission, *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions- A European Strategy for Data*, cit., COM (2020) 66 final, 22.

[63] European Commission, *Achieving the European Education Area by 2025* (Communication) COM (2020) 625 final.

[64] *Ibid.*, p. 8-9.

[65] *Ibid.*, p. 23-24.

4. E-proctoring: Is this the best we can do?

The paradigmatic shift from the physical to the online University environment invested another core area of the students' life: exams. When it was clear that the spread of COVID-19 was going to impact the spring and summer sessions, the whole academic community had to embrace the additional challenge of guaranteeing the legal and pedagogical value of the exam in the online environment, including how to prevent students' fraud. Within this context, many solutions have been proposed and adopted. For example, oral exams have been carried out in synchronous via videoconferencing tools, implementing safeguards to verify the candidate's identity.

However, the majority of concerns focused on written assessments, because of the challenges present in ensuring the integrity and validity of this type of exams. Many institutions decided to rely on e-proctoring systems, which allow the monitoring of students via computer's webcam and microphone. More specifically, depending on the system, the e-proctoring can be "online live" and/or the session can be recorded for later review. In the latter case, the system records both the video and the audio, and analyses the data collected to identify unusual patterns or suspicious behaviours, e.g. the student stands up, takes books or the mobile phone, talks to someone else in the room, surfs online[66], or even looks away from the computer screen. If the software detects any issue, it sends a notification to the examiner. The examiner then has the possibility to verify the portion of the recording in question and makes a decision.

E-proctoring systems aim to replicate the function of in-class invigilation. However, the transplant of an offline concept to an online setting raises additional issues and concerns in this context. If we look at e-proctoring features and use, such tools are likely to be more problematic than their analogue version. The most prominent change is that the exam is not held within the University premises, but it is brought into students' homes[67]. This shift has to be carefully considered as, in principle, it already constitutes an invasion of one of the most intimate spheres of an individual, their home. Second, the inspection of the work station (desk, walls, etc.), which is a preliminary step to be taken before the exam starts, might be frustrating, uncomfortable and humiliating (for the invigilator and) for students in a moment where many of them are already stressed for the exam[68]. Third, we have to consider that, with e-proctoring, the invigilation becomes systematic: an online watchdog examines and records all the movements for the entire duration of the exam. Preliminary

[66] Although some systems block browsing by default.

[67] E-proctoring can be used also in the physical environment of the University (to replace human invigilation) or, in any case, it does not mandate that students stay in their own home. However, considering the lockdown measures during the pandemic, almost all students had to connect from their own room or studio.

[68] Research shows that proctored exams generate more anxiety in test takers if compared to non-proctored exams. M. N. Karim, E. S. Kaminsky, T. S. Behrend, *Cheating, reactions, and performance in remotely proctored testing: An exploratory experimental study* (2014) 29, 4 Journal of Business and Psychology 555.

research underlines that this kind of non-stop monitoring not only is considered upsetting and intrusive, but it is likely to have a negative impact on the performance of those students particularly anxious[69].

Furthermore, a consistent body of literature is showing the lack of accuracy of automated decision-making systems and the problem of algorithmic bias[70]. Thus, there is the risk that these problems will affect the e-proctoring technology as well, leading to inaccurate results and discriminatory outcomes[71]. The issue is not merely hypothetical. Even if what has been reported so far is anecdotal, e-proctoring systems are showing some difficulties in correctly recognising black students[72]. Finally, the negative consequences of such systems on students might be exacerbated if the e-proctoring tool makes automated decisions, e.g. the exam is automatically suspended or failed, without human oversight[73].

In addition to privacy and data protection concerns, this kind of technology does not take into account the difficulties that a student might have in ensuring a stable connection, a computer or other IT device, and a room only for herself during the exam. This logistic issue can become a proxy for bringing out new inequalities or highlighting existing ones. The widespread adoption of e-proctoring has piqued the attention of students and privacy scholars, questioning the intrusiveness of the tool[74]. Some of these concerns have been

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[69] D. Woldeab, T. Brothen, *21st Century Assessment: Online Proctoring, Test Anxiety, and Student Performance* (2019) 34, 1 *International Journal of E-Learning & Distance Education* 1.

[70] *Ex multis*, F. Pasquale, *The black box society* (Harvard University Press 2015).

[71] See M. Foulkes, *Exams that Use Facial Recognition May be Fair – But They Are Also Intrusive*, *The Guardian*, (London, 22 July 2020) https://www.theguardian.com/law/2020/jul/22/exams-that-use-facial-recognition-are-fair-but-theyre-also-intrusive-and-biased?CMP=Share_iOSApp_Other (last accessed: 11 November 2020).

[72] See S. Swauger, *Software that Monitor Students During Tests Perpetuates Inequality and Violates their Privacy* (*Technology review*, 7 August 2020) https://www.technologyreview.com/2020/08/07/1006132/software-algorithms-proctoring-online-tests-ai-ethics/ (last accessed: 11 November 2020); and the ongoing discussions on Twitter https://twitter.com/uhreeb/status/1304451031066083331?ref_src=twsrc%5Etfw%7Ctwcamp%5Etweetembed%7Ctwterm%5E1304451031066083331%7Ctwgr%5Eshare_3&ref_url=https%3A%2F%2Fwww.insider.com%2Fviral-tiktok-student-fails-exam-after-ai-software-flags-cheating-2020-10 (last accessed: 11 November 2020). See also S. Swauger, *Our Bodies Encoded: Algorithmic Test Proctoring in Higher Education* (*HybridPedagogy*, 2 April 2020) https://hybridpedagogy.org/our-bodies-encoded-algorithmic-test-proctoring-in-higher-education/ (last accessed: 11 November 2020).

[73] It became viral the TikTok's video of a student falsely accused of cheating during a proctored exam. See Swauger, S., *Remote Testing Monitored by AI is Failing the Students Forced to Undergo it* (7 November 2020) https://www.nbcnews.com/think/opinion/remote-testing-monitored-ai-failing-students-forced-undergo-it-ncna1246769 (last accessed: 11 November 2020).

[74] S. Hubler, *Keeping Online Testing Honest? Or an Orwellian Overreach?*, *New York Times* (New York, 10 May 2020) https://www.nytimes.com/2020/05/10/us/online-testing-cheating-universities-coronavirus.html (last accessed: 11 November 2020); M. Chin, *Exam Anxiety: How Remote Test-Proctoring is Creeping Students Out – As Schools go Remote, So Do Tests and So Does Surveillance* (*TheVerge*, 29 April 2020) https://www.theverge.com/2020/4/29/21232777/examity-remote-test-proctoring-online-class-education (last accessed: 11 November 2020); D. Harwell, *Mass School Closures in the Wake of the Coronavirus are Driving a New Wave of Student Surveillance*, *Washington Post* (Washington DC, 1 April 2020) https://www.washingtonpost.com/technology/2020/04/01/online-proctoring-college-exams-coronavirus/ (last accessed: 11 November 2020). It should be mentioned that privacy concerns were raised even before the pandemic crisis, when e-proctoring was adopted for online testing. See, for example, A. Majeed, S. Baadel, A. Ul Haq, *Global triumph or exploitation of security and privacy concerns in e-learning systems* (2017) *International Conference on Global Security, Safety, and Sustainability*. Springer, pp. 351-363.

brought before the Courts and a first and preliminary decision was issued by the Court of Amsterdam in June 2020[75]. In that case, two student associations and an individual student at the University of Amsterdam complained about the use of the software "Proctorio" adopted by their University, alleging a number of data protection violations. They argued, in particular, the lack of an appropriate legal basis for the specific processing, the violation of the principles of purpose limitation (as the software was collecting more data than necessary for the exam) and proportionality (since there were less privacy-intrusive tools). The judge, however, rejected the complaint, recognizing that the use of the software was done in accordance with the GDPR principles. First, the University was performing a task carried out in the public interest [Art. 6(1)(e) GDPR], namely the provision of education and the issuing of diplomas, which includes the steps to guarantee their quality and validity[76]. Furthermore, according to the Court, the University demonstrated that there were no suitable e-proctoring alternatives and that the chosen system was used only as a last recourse, when it was not possible to convert the exam in essay assignments due to the typology of the assessment or the number of students. In addition, appropriate safeguards were taken, also on the basis of the results of the data protection impact assessment. Hence, the Dutch judge held that the processing was necessary and proportionate given the concrete circumstances[77].

Despite this first decision, several questions remain open. Of course, there are different types of software available on the market, whose deployment may vary from one University to the other. Therefore, such a decision cannot be generalized. GDPR compliance is and remains a case-by-case evaluation. Nevertheless, we should start asking ourselves what level of interference with the rights to privacy and data protection would we be inclined to accept in our educational environment and, considering the fallibility of such systems, which level of reputational risks Universities might want to take.

As the Amsterdam case shows, during the Covid-19 emergency, e-proctoring has been used for exams based on multiple choice or short answer questions. These are all cases where the teacher tests the general knowledge of the student on a specific topic. Lacking any invigilation, there is a higher risk of cheating, as the *mala fide* student can easily check the response online or in books, notes, group chats, etc. Is then the use of e-proctoring the best option available to ensure the validity of the exam?

We must preliminarily observe that if the purpose of e-proctoring is to prevent or reduce the risk of copying in notional exams, setting up a time limit could be already a solution. Namely, when available time is calibrated in function of the number of questions, precious seconds are less likely to be wasted wandering around in search for the correct answer. We

[75] Rb. Amsterdam - C/13/684665 / KG ZA 20-481 (an unofficial translation in English is available here: https://gdprhub.eu/index.php?title=Rb._Amsterdam_-_C/13/684665_/_KG_ZA_20-481 (last accessed: 11 November 2020).

[76] See, para 4.10, Rb. Amsterdam – C/13/684665 / KG ZA 20-481.

[77] The decision is currently under appeal.

do not suggest this solution as an ideal way out of the exam dilemma, however, especially considering the potential cognitive diversity in the cohort of students. People with disabilities might be negatively affected by a constrained time limit. Other ways to minimise cheating could consist in the preparation of different versions of the same assessment and their randomised distribution to students. If this solution would reduce the collusion among students, it would not prevent dishonest behaviours *tout court*.

Overall, structuring the exam in a way where pure notions and basic knowledge are not directly evaluated, could offer a better alternative that might solve the copying problem *ab origine*. There are plenty of assessment strategies that can be successfully implemented as a take-home exam (essays, open questions, opinions, reports, interviews) or in the form of continuous evaluation (projects, case studies, group presentations, group works, artifacts, etc.). In these kinds of assessments, the student does not have to demonstrate that she "knows", but that she critically masters the knowledge and uses the skills acquired during the course. Something that is usually the highest desirable learning outcome in all our syllabus. After all, the etymology of assessment comes from the Latin "assidere", that means "to sit with"[78]. As pointed out by Green: "In an assessment, one sits with the learner. It is something we do *with* and *for* the student, not something we do *to* the student"[79].

Such a typology of exam involves a more complex exercise, indeed, not only for the students, but also for the evaluators. It requires more time than a set of multiple choices and it is hard to manage with a huge number of students. Therefore, it cannot always be considered a suitable – although less intrusive – alternative. This was indeed one argument used by the University of Amsterdam to justify the necessity of Proctorio. If such a line of defense is somewhat understandable during the peak of the emergency, it raises the question about whether we should pretend more for the 'postpandemic university'[80].

In other terms, there are less intrusive means than e-proctoring to organise an exam session, but their implementation is going to require systemic changes. First of all, it means to continue/or increase the effort required for the education of our students to the value of academic integrity. The purpose of the University is also to form responsible citizens and accountable future professionals.

Second, non-invigilated exams require setting a reasonable ratio between the number of teachers and students. This will make it possible to structure the exam in a way that would permit testing the analytical and critical thinking of students, so as to render the evaluation manageable for a teacher. Allowing us a "physical" metaphor, the restructuring of the learning experience around the size of the class and not the auditorium will contribute to

[78] As reported in J.M. Green, *Authentic Assessment: Constructing the Way Forward for All Students* (1998) Education Canada 38, 3, 8-12: 11.

[79] *Ibidem*.

[80] As labelled and investigated in the initiative led by Mark Carringan at the Faculty of Education, University of Cambridge. See, https://postpandemicuniversity.net (last accessed: 11 November 2020).

set the main condition for promoting a dialogue and a constructive exchange between all the participants.
The problem of class size, the possibility to have a truly formative experience also during the assessment, and the increasing workload for teachers, are all questions that have been with us for a while. The emergency situation we are experiencing is simply reminding us that those issues remain and that we should no longer postpone looking for an answer.

In lieu of conclusion: Shaping the right to digital education beyond GDPR compliance

Data protection and privacy laws are a first regulatory frame for addressing transformations affecting educational means in (post) pandemic times. They provide a fundamental benchmark upon which the transition to a digital university dimension needs to be measured, and which is useful also for the identification of the deeper socio-legal consequences of the ongoing shift.
During the pandemic, the generalised answer of Universities for coping with remote teaching has been the recourse to third-party digital providers. This 'forced' choice has unveiled a critical weakness of our education systems: the lack of an adequate digital infrastructure to support the provision of education online, not only during an emergency, but, more generally, in a way that makes the most out of EdTech tools.
The trend toward 'platformisation' of education, exacerbated during the COVID crisis, present several challenges for Universities in terms of privacy and data protection. As we have shown in this contribution and in our previous work, there are still serious concerns about the implementation of data protection principles in this context[81]. Each of the identified data protection challenges (concerning purpose limitation, transparency, and extra EU data transfers) suggests that both the platforms and Universities should more effectively embed data protection principles in the design and deployment of their remote teaching policies.
When Universities decide to rely on third-party services (for necessity or convenience), adherence to the data protection framework by them and the platform is a necessary starting point. Privacy and data protection not only deserve protection as such; they are also a precondition of a full protection of other fundamental rights in this context, such as aca-

[81] One concern highlighted in our previous work was related to the reference made, for example, by Facebook and Zoom's privacy policies to legitimate interests as a lawful basis for the processing, without any mention of the balancing between the controller's legitimate interest and the data subjects' interests; furthermore, other platforms as Youtube, Skype, Zoom, Jitsi and Gsuite did not provide sufficient information regarding the purpose for which the categories of collected data mentioned in the privacy policies were processed. Jitsi and Gsuite, for example, generally refer to the purpose of "improvement of the service". See, R. Ducato et al. (n 11).

demic freedom, right to education, freedom of expression, human dignity[82]. The pandemic did not establish any special derogation to the privacy and data protection rights framework under the EU Charter, the European Convention of Human Rights and the GDPR, which therefore must apply. To this end, national data protection authorities should carefully scrutinise the services specifically tailored for education and offered to schools and Universities[83]. The "Sweep days", promoted by the Global Privacy Enforcement Network (GPEN), could be already a first initiative to be launched in the short term[84].

In the medium- and long-term, it will be then relevant to open a channel of collaboration with DPAs for addressing teaching-related personal data collection and processing practices in the educational context when platforms are critically involved. The respect of privacy and data protection are, indeed, a necessary but not sufficient condition. As the case of e-proctoring demonstrates, it might be needed to go beyond mere compliance with the EU data privacy law and consider the broader implications of the tools we are using.

More generally, when Universities outsource whole or part of the processing to platforms, two issues should be carefully considered: 1) who decides what platform to use (hence, what are the characteristics it must have); and 2) how the standardisation of the service is going to impact on the level of (digital) autonomy and independence of Universities in this context.

With reference to the first aspect: the choice of a platform is not a neutral decision. Having an impact on the academic community, the decision-making process for determining the eligible educational infrastructure should be vetted with the inclusion of all the interested persons of that community.

The first point to consider concerns the body within the University making decisions related to data protection (i.e. determining the purposes of processing, and choosing the platform). These decisions undoubtedly affect students and teachers. Therefore, their participation (through representatives or "information champions") in the decision-making process should be considered, especially in view of efforts to establish inclusive educational values. This aspect is particularly relevant because it would shape the governance of data collected and further processed, especially taking into consideration the importance

[82] Analogous considerations hold true for the copyright aspects involved in remote teaching, particularly with reference to the respect of the legitimate uses (so-called exceptions and limitations). On this, see L. Pascault *et al.*, *Copyright and Remote Teaching in the Time of COVID-19: A Study of Contractual Terms and Conditions of Selected Online Services* (2020) 42.9 *European Intellectual Property Review* 548.

[83] As announced by the Italian Data protection Authority, act of 26th March 2020, n. 9300784 – *Didattica a distanza: prime indicazioni*, cit. For a brief analysis of the decision (in English), see R. Ducato *et al.*, *Emergency Remote Teaching and digital data privacy: first instructions from Italy* (*Blog de Droit Europeen*, 16 July 2020), https://blogdroiteuropeen.com/2020/07/16/emergency-remote-teaching-and-digital-data-privacy-first-instructions-from-italy-by-rossana-ducato/ (last accessed: 11 November 2020).

[84] The GPEN is an international network of DPAs for privacy enforcement co-operation, created in 2010 within the OECD. The "Sweep day" is an yearly initiative where data protection authorities, part of the GPEN, investigate practices in the data privacy field and examine specific areas of concern (e.g. transparency of medical apps, privacy communications directed to children, etc.). See, https://www.privacyenforcement.net/ (last accessed: 11 November 2020).

that the recent European Commission proposal for a data governance act has placed in the re-use of (personal) data held by public sector bodies[85].

With regard to the second aspect, the interplay between standardization of the service and Universities autonomy cannot be neglected, as the latter is an essential touchstone for the well-functioning of evolving online institutions[86] HEIs.

Admittedly, standardisation is essential to norm-setting. For instance, it could help smaller institutions to foster lawful requirements, such as data protection and minimum lawful copyright policies. However, the conditions *de facto* imposed by platforms are at odds with the fundamental principle of institutional autonomy of each University. As a constitutional principle in some European countries[87], university autonomy is a foundational value for HEIs. Independence of choice of digital infrastructures is an expression of this autonomy and standardisation could end up rendering aspects of this choice becoming non-negotiable. There is indeed a flagrant asymmetry in bargaining power between platforms, which operate on a global scale, and Universities, which lack sufficient contractual power for affecting the conditions of the service. Collective negotiations could be a possible way out here. Groups of Universities could join forces when negotiating with platforms, proposing their own data protection conditions, shaped according to their cultural mission and educational needs. This collective negotiation may cover several data protection and privacy issues: the data to be collected, the data minimisation safeguards and features[88], the clear distribution of roles and responsibilities vis-à-vis the data subject, the location of the servers, the purposes of the processing, the eventual admissible repurposing, and data sharing.

Considering the input from students and teachers would potentially democratise the drafting of necessary technical and legal conditions that platforms must guarantee.

The shape of these collective negotiations will determine the degree to which institutional values are reflected in the infrastructure choice.

As already stressed, the full reliance on third-party providers has been a general response dictated by the emergency. It does not mean that alternative options might not be considered.

[85] European Commission, Proposal for a regulation of the European Parliament and of the Council on European data governance (Data Governance Act), cit., COM (2020) 767 final, Chapter II.

[86] The issue of the latent conflict between University autonomy and US-based platforms is not new. It was already raised last year by Dutch Rectors in a public letter, as reported here: https://www.volkskrant.nl/columns-opinie/digitalisering-bedreigt-onze-universiteit-het-is-tijd-om-een-grens-te-trekken~bff87dc9/ (last accessed: 18 December 2020).

[87] See for example, Art. 33(6) of the Italian Constitution.

[88] For instance, how to implement a proper technical feature for allowing the recording of an online seminar, minimising the processing of participants' data at the same time (e.g. impeding to process name and video of attendants which do not want to be recorded or "pinned" during the livestream). Some platforms ask for dubious manifestations of consent to the recording, as stressed here: R. Ducato *et al.* (n. 11).

Thinking on a medium to long-term perspective, it would be worth discussing bringing the digital infrastructure "in-house". New public infrastructures, or the enhancement of existing ones, should be put in place, highly customisable at the local level, in order to ensure a proper balance with the principle of University autonomy.

Institutions could opt to reuse or to create new infrastructures that not only embed fundamental rights from the design stage and throughout the lifecycle of the system, but are also representative of European digital values[89]. This issue is of particular importance if we take into consideration the consequences of EdTech platform standardisation on a global scale for "educational diversity"[90]. The circulation of cultural, educational, learning, and supervision models promoted through the structure of a specific platform could end up hurting the diversity of learning experiences guaranteed in different institutions. This standardization would potentially end up becoming the norm of an educational global monoculture. The conciliation of competing interests could be found in hybrid formulations as well. For instance, some functions could be delegated to the central structure, e.g. storage of data in a secure environment and others would be retained by the single entity. This, from a data protection perspective, might be an example of joint-controllership with clearly set out rules that ensure transparency, accountability, and ultimately, respect of data subjects within the broader institutional and cultural value model.

Seen more broadly, there is still a whole array of unexplored issues related to the implications of the platformisation of education, including possible discriminatory outcomes. For instance, it is critical to consider the divergences in digital skills across different social strata as well as the impact of the considered phenomenon on the access to education by physically or mentally impaired students, whom may not be able to use ordinary digital services. Ultimately, assessments of the quality of digitally provided educational services should be conducted against the backdrop of the fundamental right to education.

With remote teaching having become "an integral part of our future"[91], targeted institutional responses such as the enactment of funding programs and the establishment of specific oversight mechanisms related to EdTech solutions, should move to the top of regulators' agenda. The first institutional moves in this direction are being announced by

[89] European Commission, 'Digital Education Action Plan (2021-2027) – Resetting Education and Training for the Digital Age', cit., COM (2020) 624 final, making reference to the importance of the incorporation of ethical standards in emerging digital education systems.

[90] This notion has been taken into consideration by sociological literature, see Y. Taylor, 'Educational Diversity: the Subject of Difference and Different Subjects', in Y. Taylor, *Educational Diversity: the Subject of Difference and Different Subjects* (Palgrave McMillan, 2012). More recently see V. Harpalani, *Safe Spaces and the Educational Benefits of Diversity* (2017) 13 *Duke Journal of Constitutional Law & Public Policy* 117. Specifically focusing on educational diversity in the remote teaching environment, C.J.K. Sandoval *et al.*, *Legal Education in the Era of Covid-19: Putting Health, Safety and Equity First* (24 July 2020) *Santa Clara Univ. Legal Studies Research Paper* https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3660221.

[91] M. Vestager, *Speech by Executive Vice-President Margrethe Vestager on a New Digital Education Action Plan 2021-2027 and a New European Research Area* (30 September 2020) https://ec.europa.eu/commission/presscorner/detail/en/SPEECH_20_1786 (last accessed: 11 November 2020).

the European Commission in its recent Communication on Achieving the European Education Area by 2025[92]. This document envisages training programs to consolidate the digital skills of subjects operating at all levels[93] and, in particular, specialised education programs for advancing digital skills[94]. The objectives currently targeted by the Commission focus on the increase of competences, participation, and inclusiveness of a digitally-fuelled European education system[95], as well as, on the enhancement of connectivity and cooperation of higher education institutions[96]. However, digital infrastructures channelling education efforts are not included among the targets and indicators of the proposed changes. This rapidly changing infrastructural environment deserves more attention, given that in the digital, more than in the physical dimension, the form shapes the matter, and thus, our education.

[92] European Commission, *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on Achieving the European Education Area by 2025*, cit., COM (2020) 625 final.

[93] *Ibid.*, p. 9.

[94] *Ibid.*, p. 11, where the lack of experts in the fields of artificial intelligence, cybersecurity and high performance computing is highlighted.

[95] *Ibid.*, pp. 13 ff.

[96] *Ibid.*, p. 20.

The Role of the GDPR in Designing the European Strategy on Artificial Intelligence: Law-Making Potentialities of a Recurrent Synecdoche

Denise Amram*

Abstract

Starting from an analysis of the EU Reg. n. 2016/679 on General Data Protection Regulation (GDPR), the Author deals with the opportunity to translate the current strategies on Artificial Intelligence into a possible general risk-based framework that combines hard and soft law instruments with the practical needs emerging in different sectors where AI technologies find application (i.e. healthcare, industrial innovation and robotics, workplace, etc.). This analysis allows the Author to provide a notion of "AI Controller", whose main roles, responsibilities, and obligations are listed in a "General AI Regulation" proposal, illustrated in the last paragraphs.

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* Dr. Denise Amram, Affiliate researcher at LIDER-Lab, DIRPOLIS Institute, Scuola Superiore Sant'Anna. This paper has been developed within the "SoBigData Plus Plus: European Integrated Infrastructure for Social Mining and Big Data Analytics" Project, funded by the EU Commission under the H2020 INFRAIA-1-2019 programme (GA 871042). I am grateful to the anonymous referees for their fruitful comments.

Keywords

GDPR – Accountability – Data Processing – Artificial Intelligence Regulation – AI Controller

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1. Introduction

Scientific progress opened new challenges in term of research and development thanks to the opportunity to process and exploit big amounts of data to automatically perform tasks, provide new solutions and predict unexplored scenarios. Technology innovation has become ubiquitous and pervasive with respect to the individual's daily routine. Therefore, a cultural change has progressively arisen, highlighting the value of personal information and their safe processing.

Considering that many tasks Artificial Intelligence systems may automatically perform are related either to data exploitation, or users' identification and tracking, including facial and voice recognition, or profiling and predict behaviours, personal data protection constitutes one of the main boundaries of the AI legal framework.

Accordingly, the EU General Data Protection Regulation n. 2016/679 (hereinafter "GDPR") provides a series of principles to enable personal data processing whose relevance goes beyond their strict field of application related to personal data processing. In a data-driven society a harmonised and binding regulation solely on a restricted category of data (like the personal ones) could be included as a possible scenario, but – as we will demonstrate

– it could also be taken into consideration as an effective model for further legislative initiatives[1].

This paper aims at analysing how the GDPR structure, principles, and obligations may not only be a necessary component but also inspire – *mutatis mutandis* – a possible EU General Regulation on Artificial Intelligence. Considering peculiarities and possible accommodation due to the widest field of application of AI technologies, such a general regulation should encompass not only personal data, but also structured as well as raw non-personal ones. New legislative initiatives, indeed, shall be tailored to protect fundamental rights both in case of human and artificial data processing, regardless the personal or non-personal nature of data. In fact, AI-based systems may affect individual and collective fundamental rights despite of the fact that analysis are performed through personal, pseudonymised, anonymised, or non-personal data.

In the following paragraphs, we will analyse GDPR principles, notions, and provisions that define the data protection by-design and by-default model, in order to extract possible legal concepts to set the AI compliance paradigm, to be developed considering the different nature, means, methodologies, and purposes of the data processing.

2. GDPR structure, principles, and notions

The GDPR has been introduced with the aim to both protect natural persons with regard to the processing of personal data and to ensuring the free movement of such data. From this perspective, the harmonization of the data protection legal framework within EU, that inspired many other extra-EU legislations[2], turned into a new ethical approach for a number of sectors[3].

The legislative technique consists of a series of 173 recitals that address the interpretation of the principles and obligations stated in the 99 articles divided into 9 chapters (princi-

[1] See the proposal for a Regulation of the European Parliament and of the Council on a framework for the free flow of non-personal data in the European Union 2017/228 that promotes the free movement of data within the EU, meaning for data "other than personal data as referred to in Article 4(1) of Regulation (EU) 2016/679".

[2] Data protection regulatory framework in a comparative perspective see R. Walters, L. Trakman, B. Zeller (eds.), *Data protection Law. A comparative analysis of Asia-Pacific and European Approaches* (Springer, 2019). Specific examples in the next paragraphs.

[3] Within the financial sector, see Franklin J., 'GDPR has kept AI ethical despite concerns' (2019), International Financial Law Review. October 2019: N.PAG. http://search.ebscohost.com/login.aspx?direct=true&db=bth&AN=139213623&site=ehost-live. Accessed 17.6.2020; within the healthcare sector, Filippo Pesapane, Caterina Volonté, Marina Codari, et al. 'Artificial intelligence as a medical device in radiology: ethical and regulatory issues in Europe and the United States' (2018), *Insights Imaging* 9, 745–753, https://doi.org/10.1007/s13244-018-0645-y; Chartrand G, Cheng PM, Vorontsov E *et al*, 'Deep learning: a primer for radiologists' (2017), *Radiographics* 37:2113–2131; Krittanawong C, Zhang H, Wang Z, Aydar M, Kitai T, 'Artificial intelligence in precision cardiovascular medicine' (2017), J Am Coll Cardiol 69:2657–2664; in the insurance sector see Guido d'Ippolito – Enzo Maria Incutti, 'I processi decisionali interamente automatizzati nel settore assicurativo' (2019) Rivista di diritto dell'impresa, 3, p. 735 ff., More in general, see Luciano Floridi, *La quarta rivoluzione. Come l'infosfera sta trasformando il mondo* (Milano, 2017).

ples, rights of the data subjects, controllers and processors, transfers to third countries, independent supervisory authorities, cooperation and consistency, remedies, liability and penalties, provisions relating to specific processing situations), plus those chapters dedicated to general and final provisions, and to delegated and implementing acts.

In short, under the article 5 GDPR to process personal data in a lawful, fair, and transparent manner, the data controller shall implement technical and organizational measures to meet the purpose limitation, data minimisation, accuracy, storage limitation, integrity and confidentiality requirements[4]. In addition, she/he has to demonstrate to have met them (*i.e.* the principle of accountability puts the burden of proving compliance on data controllers).

A risk-based approach regulation[5], like the GDPR, combines hard law (obligations and enforcement tools, auditing, authorizations, report and monitoring, sanctions) and soft law instruments (opinions, standards, codes of conducts, self-regulation, binding corporate rules, …) in order to address compliance needs, considering priorities and urgencies. This approach allows a strategic efforts and resources allocation in light of the overall conditions of the obliged person – *rectius* the person who is responsible to mitigate and avoid risks determined by a given activity[6].

The risk-based approach of the GDPR identifies a series of obligations for the data controller all leading to a continuous assessment and monitoring of the personal data processing they enable. In the daily routine, this approach helps to follow a pre-determined standard check-list of activities to be performed in light of a tailored gap analysis performed by data controllers. Such a gap analysis aims to identify those measures that are appropriate to fulfil the obligations related to each and every unique characteristics of the personal data processing aimed at. This paradigm allows to protect data "by design" before enabling a data processing and "by default" within the given processing itself. Each data processing has to be analysed in order to tailor the compliance activity in light of its features[7].

Very often data flows – in this context we mean, in general, the processed information – encompass both personal and non-personal data. GDPR applies only to personal ones although it acknowledges at referral 26 that their borderlines are fluid. Accordingly, pseu-

[4] Aurelia Tamò-Larrieux, *Designing for Privacy and its Legal Framework* (Springer, 2018).

[5] Malkom Sparrow, *The Regulatory Craft: Controlling Risks, Solving Problems, and Managing Compliance* (Washington DC: Brookings Institutions Press, 2011).

[6] David Wright & Charles Raab (2014) Privacy principles, risks and harms, International Review of Law, Computers & Technology, 28:3, 277-298.

[7] Mary Donnelly and Maeve McDonagh, 'Health Research, Consent and the GDPR Exemption' (2019) 26 European journal of health law 97, see also Denise Amram, 'Building up the "Accountable Ulysses" model. The impact of GDPR and national implementations, ethics, and health-data research: Comparative remarks' (2020) Computer Law & Sec. Rev. Vol: 37: 105413; G. Comandé. 'Ricerca in sanità e data protection un puzzle... risolvibile' (2019), *Rivista italiana di medicina legale e del diritto nel campo sanitario*, 188; See the Irish Data Protection Commission, *Guidance Note: Guidance on Anonymisation and Pseudonymisation*, June 2019.

donymised data (i.e. that information that can disclose one's identity only if associated to other ones) are included in its field of application[8].

Considering the broader category of personal data, their flows can be classified as general data-related or sensitive-data-related. The former ones refer to personal information that may identify data subjects, while the second ones refer to that information that may expose the data subject to a direct or an indirect discrimination. In particular, the latter may disclose racial or ethnic origins, political opinions, religious or philosophical beliefs, or trade union membership. The processing of genetic data, health-related data or sex life or sexual orientation are considered as particular category of data as well. Appropriate legal bases for data processing shall be identified respectively within article 6 GDPR for the general data (contractual relationship, legal obligation to be accomplished by the data controller, data subject's vital interest, public interest, legitimate interest of the data controller) and article 9 GDPR for the sensitive ones. The latter shall not be processed unless a specific legal basis has been identified. Article 9, para 2, *sub* a)-j) identifies the following legal conditions: data subject's explicit consent, legal obligation to be accomplished by the data controller, data subject's vital interest, legitimate activities with appropriate safeguards by a foundation, association or any other not-for-profit body with a political, philosophical, religious or trade union aim, manifestly made public data, or to establish, exercise or defence within a legal claims, or for reasons of substantial public interest – within the purposes of preventive or occupational medicine – or for the assessment of the working capacity of the employee, or for medical diagnosis and health or social care, or to manage the related services, or the necessity for reasons of public interest in the area of public health, research and statistics purposes[9].

Considering who determines means and purposes of the data processing, flows can be governed by a single data controller, or by joint data controllers at the conditions agreed under article 26 GDPR, or on behalf of the data controller(s) by a data processor appointed under article 28 GDPR.

The illustrated classifications of data are functional to understand how the new cultural approach towards personal data protection could affect other legislative initiatives aimed at framing other potentially risky data-processing activities like the use of Artificial Intelligence (hereinafter also "AI"). In the next paragraphs, we will analyse possible accommodations to be addressed to the GDPR ecosystem in order to draft a regulatory framework for AI.

[8] Sophie Stalla-Bourdillon – Alison Knight 'Anonymous Data v. Personal Data – False Debate: An EU Perspective on Anonymization, Pseudonymization and Personal Data' (2016-2017) 34 Wis. Int'l L.J. 284.

[9] See Giusella Finocchiaro (ed.), *Il nuovo Regolamento europeo sulla privacy e sulal protezione dei dati personali* (Zanichelli, 2017); Vincenzo Cuffaro, Roberto D'Orazio, Vincenzo Ricciuto, *I dati personali nel diritto europeo* (Giappichelli, 2019); Giovanni Comandé- Gianclaudio Malgieri (eds.), *Guida al trattamento e alla sicurezza dei dati personali* (IlSole-24Ore, 2019).

3. Is the GDPR structure suitable to frame the Artificial Intelligence regulatory model?

The last decade has been identified as the "big data era", where Artificial Intelligence techniques provide the opportunity to process huge amount of structured and unstructured data and to develop and share high speed and high level performance applications within the Internet of Things has driven a revolution of the way of thinking and producing, affecting all sectors from economics and finance, to industrial, agriculture, healthcare, education etc[10]. For Artificial Intelligence, that is not uniquely defined[11], we consider those "*systems that display intelligent behaviour by analysing their environment and taking actions – with some degree of autonomy – to achieve specific goals*"[12], through "*the reproduction of human cognitive functions such as problem solving, reasoning, understanding, recognition, etc. by artificial means, specifically by computer*"[13], or by systems "*that mimic cognitive functions, such as learning and problem-solving*"[14]. A horizontal and a vertical dimension has been identified to distinguish AI excellence in performing a task from the versatile human intelligence[15].

In this context, despite of the recognition of the rights to privacy[16] and data protection within the international conventions, national constitutions and *ad hoc* legal frameworks, the legislative process is a step behind the development of AI-based systems[17].

[10] See Seamans, recalling several reports from stakeholders and economic operators, like Accenture, McKinsey Global Institute, World Economic Forum, see Robert Seamans, 'Artificial Intelligence and Big Data: Good for Innovation?', *Forbes* (Sept. 7th 2017), https://www.forbes.com/sites/washingtonbytes/2017/09/07/artificial-intelligence-and-big-data-good-for-innovation/#1409eb5f4ddb. Accessed on 21.06.2020; Viktor Mayer- Schönberger – Kenneth Cukier, *Big data: a revolution that will transform how we live, work, and think* (John Murray Publishers, London, 2013). See OECD, Report on 'Data-driven innovation. Big Data for Growth and Well-Being', 2016, http://www.oecd.org/sti/data-driven-innovation-9789264229358-en.htm, accessed on 22.6.2020

[11] Miriam C. Buite, 'Towards Intelligent Regulation of Artificial' (2019), *European Journal of Risk Regulation*, 10(1), 41 ff, 43.

[12] Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions on Artificial Intelligence for Europe, Brussels, 25.4.2018 COM (2018) 237 final.

[13] K. K. Ogilvie and A. Eggleton, Challenge Ahead: Integrating Robotics Artificial Intelligence and 3D Printing Technologies into Canada's Healthcare Systems (2017), 5, https://sencanada.ca/content/sen/committee/421/SOCI/reports/RoboticsAI3DFinal_Web_e.pdf, accessed on 22.6.2020.

[14] Russell S, Bohannon J, *Artificial intelligence. Fears of an AI pioneer* (2015), Science 349:252.

[15] Giovanni Comandé, 'Multilayered (Accountable) Liability for Artificial Intelligence', in Sebastian Lohsse - Reiner Schulze - Dirk Staudenmayer (eds), *Liability for Artificial Intelligence and the Internet of Things* (Hart Nomos, 2018) 165ff, 167.

[16] Among others, see Article 12 of the Universal Declaration of Human Rights, 1948, article 17 of the International Covenant on Civil and Political Rights, 1966; article 16 of the Convention on the Protection of all Migrant workers and members of their families, 1990; article 8 of the European Convention on Human Rights, and article 11 of the American Convention on Human Rights, 1969; and the article 18 of the Cairo Declaration of Human Rights in Islam, 1990; articles 16 and 21 of the Arab Charter on Human Rights, 1994; and article 19 of the African Charter on the Rights and Welfare of the Child.

[17] For a comparative analysis between GDPR and data protection regulations in the United States considering the life cycle of personal data addressing possible issues within an AI system, see John Frank Weaver, 'Artificial Intelligence and Governing the Life Cycle of Personal Data' (2018) 24 Rich JL & Tech 1.

To pretend that AI regulation challenges are satisfied by regulating data protection and privacy rights can work within the rhetoric figure of the "synecdoche", where a part stands for the whole. In this context, however, the potentialities of the GDPR shall boost a coherent protection of the "other" fundamental rights involved within the massive development of AI technologies within the current societal context. A number of soft law initiatives, in fact, identified some pillars to address a possible regulatory framework of the Artificial Intelligence paradigm, including lawfulness, ethics, and robustness[18].

Lawfulness could be met only if all legal requirements are filled (and not only the ones emerging from the data protection legislation): this is particularly complicated as an organic regulation has not been enacted yet. Nevertheless, the EU Commission is focusing on the impact of AI systems on fundamental rights, launching a strategy aimed at achieving both excellence and trust within the development.

According to the White Paper on Artificial Intelligence – A European Approach to Excellence and Trust[19], in fact, the use of AI "*entails a number of potential risks, such as opaque decision-making, gender-based or other kinds of discrimination, intrusion in our private lives or being used for criminal purposes*". Fairness, indeed, is achievable whereas such risks are avoided. Although a complex and fragmented framework applicable to AI might derive from a recognition of technical standards, binding rules applicable to specific fields, and soft law regulations, a general, coherent, and widely applicable one has become not only a priority, but also an urgent action, as AI-based services and products are already part of our daily routine.

The structure of the GDPR may influence the new legislative process as well. To analyse principles stated in the GDPR and extend their possible efficacy specifically to a AI regulation is a first exercise to assess the legislative model in terms of suitability in order to identify boundaries and frontiers of what lawfulness means for the AI context[20].

To this end, a regulatory framework on AI shall adopt a risk-based approach to assess, and therefore accept, for each AI application, a solution/model/implementation in light of a check and balances system of hard law and soft law instruments.

From this perspective, the High-Level Expert Group on AI within the Ethics Guidelines for Trustworthy Artificial Intelligence presented in April 2019 at the EU Commission an extended notion of AI systems including software and hardware "*designed by humans that, given a complex goal, act in the physical or digital dimension by perceiving their environment through data acquisition, interpreting the collected structured or unstructured*

[18] See the Working Party Article 29, *Guidelines on Automated individual decision-making and Profiling for the purposes of Regulation 2016/679*, https://ec.europa.eu/newsroom/article29/item-detail.cfm?item_id=612053, last access 21.06.2020, recalling notions, legal bases, and principles for profiling and automated decision-making.

[19] *White Paper on Artificial Intelligence – A European Approach to Excellence and Trust*, https://ec.europa.eu/info/sites/info/files/commission-white-paper-artificial-intelligence-feb2020_en.pdf.

[20] Celine Castets-Renard, 'Accountability of Algorithms in the GDPR and beyond: A European Legal Framework on Automated Decision-Making' (2019) 30 Fordham Intell Prop Media & Ent LJ 91.

data, reasoning on the knowledge, or processing the information, derived from this data and deciding the best action(s) to take to achieve the given goal", distinguishing machine learning techniques, machine reasoning, and robotics applications[21].
Starting from this wide definition, since the AI system is designed by humans, the first step consists of identifying who shall be responsible, accountable, and liable to assess risks that may occur in the given application, monitoring the development, and comply with the regulatory framework according to the current standards and scientific knowledge. As above-stated, the GDPR paradigm assigns obligations to the one who determines means and purposes of the personal data processing. Within the AI context, we shall identify the *mutatis mutandis* "AI controller".
For the development of the AI system, the algorithm control consists of *methods for data acquisition* (*i.e.* what function/algorithm is chosen and which data train the algorithm), *actions required* (*i.e.* what task shall the AI perform), and *goals* (*i.e.* which is the final purpose of the automated decision making/reasoning activity)[22]. Therefore, the "AI controller" could be the one who determines methods, actions, and goals of a given AI-based system.
In addition, a series of roles could be identified to support the AI controller in the assessment and monitoring activities: likewise the GDPR, an internal distribution of roles and responsibilities, a so-called RACI matrix – that identifies who is Responsible, Accountable, Consultable, and Informed of the AI processing – may offer a best practice to follow (and perhaps to make it as a binding provision) to better distinguish and trace human choices and interventions on the development and use of AI technologies.
A second regulatory step may refer to the opportunity to identify rules addressing the AI external governance in order to verify case-by-case conditions to share responsibilities within the development and the use of technology. For instance, to consider whether or not (and how) more than one controller is involved in determining methods, actions, and goals[23].

3.1. Methods.

Methods generally refer to "algorithms libraries" that define functions for a variety of goals, operating on ranges of elements. They are therefore comparable to the materials used in a given supply chain.
In this perspective, several scenarios might be identified considering different grounds of control within the choice (terms of application are the ones emerging in the source; the

[21] *Ethics Guidelines for trustworthy AI*, https://ec.europa.eu/digital-single-market/en/news/ethics-guidelines-trustworthy-ai.

[22] Enza Pellecchia, 'Profilazione e decisioni autmatizzate al tempo della *black box socieety*: qualità dei dati e l leggibilità dell'algoritmo nella cornice della *responsibile research and innovation*', *Nuova giur. civ. comm.*, 2018, p. 1209 ff.

[23] On the human control on algorithms, see Stefano Rodotà, *Il mondo in rete* (Roma-Bari, 2017), Remo Bodei, *Dominio e sottomissione. Schiavi, animali, macchine e l'intelligenza artificiale* (Bologna, 2019), and Giuseppe Zaccaria, 'Figure del giudicare: calcolabilità, precedenti, decisione robotica' (2020), *Riv. Dir. Civ.*, 277 ff.

use of that specific algorithm is – or is not – included in the ones that are meant for it; the use of that specific algorithm is timely applied or obsolete), recalling notions developed in the context of the so-called Consumer[24] and General Product Safety Directives[25] and related national implementations.

Methods consist also of the activities related to data acquisition: which dataset shall train the algorithm, under the premise that "*data accuracy and relevance is essential to ensure that AI based systems and products take the decisions as intended by the producer*"[26]. At this stage, an overlap /correspondence accommodation between "AI controller" and "data controller" under GDPR is unavoidable whereas the AI system processes personal data. In this perspective, the pillars of personal data protection shall be taken into consideration and further room of accommodation shall be investigated.

In particular, the principle of data minimization, that is applicable for personal data seems to not properly fit with the aims of the AI systems development, where algorithms become more accurate with the largest amount of data processed. Therefore, a legislative initiative on AI shall introduce provisions aimed at identifying actions to properly select datasets for data acquisition as well as applicable technical standards and organizational measures to ensuring that the developer will responsibly train the chosen algorithm. In this regard, a testing/validation of outcomes shall be performed by the AI controller in order to assess whether or not the data acquisition and exploitation ensure the accurate and predicted results.

To this end, a possible collaboration between the AI controller and the data protection officer as well as the identification of "AI officer/advisor", possibly with an interdisciplinary background for the purposes that we will further illustrate, could be a fruitful support to address compliant choices, also in terms of "consultable" and "responsible" roles, within the above-mentioned RACI matrix.

In this step, artificial intelligence is fully controlled by human behaviours: therefore, the GDPR structure of rights and duties and the general enforcement paradigm emerging from the accountability principle (*i.e.* the burden of the proof to have accomplished is on the data controller) appears suitable, with all the consequences in terms of liability rules and insurable risks.

[24] Directive (EU) 2019/2161 of the European Parliament and of the Council of 27 November 2019 amending Council Directive 93/13/EEC and Directives 98/6/EC, 2005/29/EC and 2011/83/EU of the European Parliament and of the Council as regards the better enforcement and modernisation of Union consumer protection rules.

[25] Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety.

[26] White Paper on On Artificial Intelligence – A European approach to excellence and trust. Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics, https://ec.europa.eu/info/publications/commission-report-safety-and-liability-implications-ai-internet-things-and-robotics-0_en, p. 8.

3.2. Required actions

To determine the "required actions" is paramount in terms of fairness, transparency, and lawfulness. Tasks shall be entailed within legal basis and be explainable to the scientific community, in order to guarantee technical standards of safety and performance and, at the same time, it shall be explainable to the data subject, in case the automated decision making individually impacts on her/his rights.

In other words, regulation shall include black box as well as white box scenarios. For example, automated "sensitive" data profiling will be approved if it comes with a so-called "white box", where the way of profiling is understandable. By opposition, the so called "black box", where the profiling is not understandable, shall be duly regulated as it may present more problematic effects[27]. This principle emerges already from article 22 GDPR on automated decision-making producing legal effects on the individual person[28].

Within this context, the relationship between artificial intelligence and human intelligence is double. Actions are determined by the "AI controller", but the results of the processing may affect other subjects, namely the data subjects or final users, whose fundamental rights shall in any case be protected and enhanced by the AI application[29].

Therefore, this step shall be regulated both in terms of ethical and legal compliance, as the developer has to proactively assess possible direct and indirect risks on human beings caused by the AI processing. Again, at this stage, the developer shall be accountable as she/he has to demonstrate to have considered and assessed any risks connected to the use of AI, also during a testing/validating step of the developed technology[30].

A RACI matrix is particularly effective if we consider that different expertise shall establish a unique dialogue to fully assess, test, validate, and responsibly internally approve a given AI-system, despite of the external controls that a given sector may introduce to allow the exploitation of the possible innovative outcome.

[27] Mélanie Bourassa Forcier, Hortense Gallois, Siobhan Mullan, Yann Joly, 'Integrating artificial intelligence into health care through data access: can the GDPR act as a beacon for policymakers?' J Law Biosci. 2019 Oct; 6(1): 317–335; Mike Ananny – Kate Crawford, 'Seeing without Knowing: Limitations of the Transparency Ideal and its Application to Algorithmic Accountability', New Media & Soc'Y 973, 980 (2016).

[28] Giovanni Comandé, 'The Rotting Meat Error: From Galileo to Aristotle in Data Mining?' (2018), *European Data Protection Law*, 270 ff, Margot E. Kaminski – Gianclaudio Malgieri, 'Algorithmic Impact Assessments under the GDPR: Producing Multi-layered Explanations' (2019) U of Colorado Law Legal Studies Research Paper No. 19-28. Available at SSRN: https://ssrn.com/abstract=3456224 or http://dx.doi.org/10.2139/ssrn.3456224

[29] Celine Castets-Renard, 'Accountability of Algorithms in the GDPR and beyond: A European Legal Framework on Automated Decision-Making' (2019) 30 Fordham Intell Prop Media & Ent LJ 91.

[30] See the proposal of Human Rights Impact Assessment Paul De Hert, 'A Human Rights Perspective on Privacy and Data Protection Impact Assessments' in Wright and De Hert (n 21), 33-76; James Harrison, and Mary-Ann Stephenson, 'Human Rights Impact Assessment: Review of Practice and Guidance for Future Assessments' (Scottish Human Rights Commission, 2010) http://fian-ch.org/content/uploads/HRIA-Review-of-Practice-and-Guidance-for-Future-Assessments.pdf , and its variation oriented to social profiles as well, namely the Human Rights, Ethical and Social Impact Assessment (HRESIA) proposed by Alessandro Mantelero, 'AI and Big Data: A blueprint for a human rights, social and ethical impact assessment', 34 Comp. L. & Sec. Rev. 754 (2018).

This is particularly true, for example, where the AI controller appoints (or he/she has asked a third party) to develop an AI based system for a field that needs specific requirements. This could be the case of an AI-based tool for medical devices[31] where computer science skills shall understand needs and values of healthcare sector and protect data subjects not only from possible attempts to their personal data and privacy, but also their health, and sometimes to the private life of their family members, or their work. Same issues emerge for robotics applications that may be added in a supply chain to support the human-activities: fundamental rights to be protected are not only related to personal data and privacy, but also to freely express opinions, work-life, health, etc.
For these reasons, the above-mentioned White Paper has identified few grounds of assessment for AI technology in order reach the excellence and trustworthy target.

– *Human agency and oversight*: human intelligence shall always maintain the control on artificial intelligence. Therefore, actions shall be oriented towards a specific goal and limited to it, as for each combination of methods, tasks, and goals a given assessment shall be performed by the AI controller. In this perspective, auditing activities could be established in order to make a procedure of external and independent check.

– *Technical robustness and safety*: the AI system shall follow the highest standards and requirements developed by the competent agencies and bodies. In this regard, the ENISA (the European Union Agency for Cybersecurity) and ISO/IECJTC 1/SC 42 are providing standardization in the area of Artificial Intelligence in order to build up a robust and technically safe ecosystem, defining technical specifications to be followed. In terms of the principle of accountability, the developer could be asked to demonstrate to have followed the current technical standards and to justify his/her choices.

– *Privacy and data governance*: as above-stated, this part shall not only recall and be compliant with the GDPR, but it has to be the opportunity to introduce specific obligations to verify the alignment of procedures, responsibilities, and obligations. In particular, the data protection impact assessment under article 35 GDPR shall be synergically embedded in the AI impact assessment as a specific ground of evaluation of

[31] The EU Regulation 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (hereinafter "MDR") provides a series of obligations for the manufacturer, including the appointment of a (or more) person(s) responsible for regulatory compliance under article 15 to ensuring the conformity and the quality of devices, monitoring the technical documentation, fulfilling the post-market compliance obligations, issuing the due reports, and accomplishing the provisions for clinical investigations, entering into force in 2021. See Brian Daigle and Mihir Torsekar, 'The EU Medical Device Regulation and the U.S. Medical Device Industry' (2019) 2019 J Int'l Com & Econ 1 and Cesare Bartolini – Gabriele Lenzini, 'Sistemi medici e conformità legale' (2019) Riv. It. Med. Leg., 225 ff.

the system[32]. Accordingly, a new regulation could identify a provision where the "AI controller" has to collect and demonstrate GDPR compliance, whereas personal data are processed, identifying possible scenarios: i) if the "AI controller" is the same person/body of the data controller, then the AI controller shall directly deal with the GDPR compliance; ii) if the "AI controller" is only a "data processor" of a personal data flows, before collecting personal data to be processed by the AI, she/he shall be appointed as data processor under article 28 GDPR. This could be the case of an agreement where the data controller asks a R&D company to provide an automated tool to automatize a given process starting from a database structured by the same data controller; iii) if the "AI controller" acts also as a joint controller of the personal data flows, an agreement under article 26 GDPR shall be drafted. This could happen between partners that share different datasets and only one of them trains an algorithm.

– *Transparency*: within the GDPR this principle is mainly accomplished through the information sheet that informs the data subject about the privacy governance, including contacts of the data controller and data protection officer, type of data processed, means, purposes and legal basis, recipients, duration and possible data retention, possible re-use policy, and overall which rights can be enforced and how. Transparency is also relevant within a data breach procedure as in case of notification to the data protection authority, the lack of information to data subject shall be expressly justified. Article 22 GDPR adds something more as it requires a specific legal basis to allow an automated decision-making directly producing legal effects on data subjects (contractual relationship, legitimate interests, expressly given consent), introducing a substantial provision in case of personal data acquisition and collection to be applied to an AI-based system. The formula is expressed through a negative statement that allows data subjects to access to a regime of opposition, consisting of the right to obtain a human intervention, express point of views, contest the outcome of the automated decision making. These rights shall find a proper field of application within the AI regulation, identifying conditions to be applied also whereas non-personal data are used, in order to maintain the human-centric approach towards the AI.

– *Diversity, non-discrimination, and fairness*: these principles refer to possible bias that the AI system may incur or produce while processing data and reproducing results in the decision-making or within the final tasks. In order to avoid them, beyond the proof to have followed specific technical standards, a validation step aimed at testing the results under the possible ground of discrimination shall be provided before approving

[32] Charles D. Raab, 'Information privacy, impact assessment, and the place of ethics' (2020), Computer Law & Security Review, 37, 105404 and previously, Colin J. Bennett, Charles C. Raab, 'Revisiting the governance of privacy: contemporary policy instruments in global perspective' (2018) Regulation a& Governance, 14, 3.

the developed technology. However, a couple of difficulties may arise. Firstly, this step includes a strong interdisciplinary evaluation, not always familial for the AI developers. Secondly, a double ground of analysis shall be provided: a first assessment on possible attempts to diversity, non-discrimination, and fairness can address the development strategy towards a peculiar activity of data pooling as a technical measure to mitigate risks of biases. Then, a second evaluation on unpredictable risks and attempts emerging from the results shall be performed, as biases have mostly been discovered *ex post* (like the well-known case of Google Photos where the annotation algorithm had identified black people like gorillas)[33]. The "AI officer" may support the "AI controller" in this activity of test and validation: a deep knowledge and sensitive attitude towards inclusiveness and fundamental rights shall become the key-skill to turn a biased algorithm to a trustworthy and excellent one. Paths to strengthen the efficacy of these provisions could be encouraged by institutions and economic operators in terms of accountability.

– *Societal and environmental wellbeing*: as a consequence of the illustrated challenges, the AI regulation shall encourage the societal and environmental wellbeing, by providing possible incentives in developing specific sectors: awareness and positive actions against the digital divide shall be promoted. To answer this challenge the legislative initiative may encourage the adherence to codes of conducts and certification mechanisms aimed at addressing compliance on the accountability ground.

The legal challenge is to develop a framework able to identify those measures that allow the AI controller to meet a by design and by default compliance as well as boundaries for an enforceable accountable behaviour.

3.3. Goals

Goals refer to the main purposes defined by the AI controller. In this part, a general regulation shall maintain the opportunity for national legislators to implement possible safeguards and national accommodation considering that AI could be applied to several sectors, governed by national legal frameworks, where the introduction/application of new systems based on machine learning, deep learning, automated decision-making may need to re-frame or amend specific provisions to allow a full harmonization with the EU paradigm.

For instance, if we consider the healthcare system[34], the development of solutions that can support the early-detection, diagnosis, and treatment are affecting both the services organization and the clinician-patient relationships. Therefore, the compliance activity

[33] Aylin Caliskan, Joanna J. Bryson, Arvind Narayanan, 'Semantics derived automatically from language corpora contain human-like biases' (2017), Science: Vol. 356, Issue 6334, pp. 183-186, DOI: 10.1126/science.aal4230.

[34] Tokio Matsuzaki, 'Ethical Issues of Artificial Intelligence in Medicine' (2018) 55 Cal W L Rev 255.

related to the above-mentioned grounds could be adapted to the specific needs and constrains emerging from the different national health protection paradigms. In this case a double assessment – one for the development and another one for its placement in the market – shall be performed as well. The introduction of the ethical-legal assessment is more immediate for the AI-applications within the healthcare system, as the impact of research activities on fundamental rights usually needs the involvement of competent ethics committees. According to the Declaration of Helsinki medical research, in fact, is subject to the definition of a protocol that shall be drafted and submitted for approval. It has to illustrate the background and rationale, purposes and activities, benefits and risks, developing the information sheet, and the informed consent template, including the privacy policy, according to the applicable national legal framework[35]. Innovation and research in clinical and medical sectors are usually subjected to follow the principles and protocols developed within the scientific community. A risk-based approach is also applied to allow the diffusion of a new medical device, treatment, pharmaceutical product and a series of national and international authorizations have to be obtained for the pre-trials and trials before placing it within the market. The use of AI-technologies becomes an element of evaluation by the competent ethical committees.

A different approach could be applied in case of robotics applications or digital twin: both domains are regulated only in terms of ISO safety and technological standards, and not addressed in terms of binding regulation neither for their physiological development nor in case of accidents or misuse. From this perspective, the interaction between the use of AI systems and the Internet of Things (IoT) environment shall be taken into consideration as a possible scenario to be regulated beyond the technical standards followed to put the final product into the market as a certified one. An AI regulation shall cover this scenario from a top-down level, able to combine different issues.

From this perspective, considering the massive use of AI systems, a regulatory framework shall establish possibly independent authorities and bodies. This shall support the existing ones in the assessment and evaluation of the AI-based applications in the given sectors (like the ethics committees for clinical trials that have to deal with AI-systems, or data protection authorities, or competition committees, or bodies to protect vulnerable groups, or animals wellbeing, etc.). Otherwise, it could be appropriate to identify centralized – at least at EU level – mechanisms of preventive as well as of assessment/consultation as a pre-requirement to access the sectorial/specific procedures of authorization/approval from the decentralized competent body. Also on this field, the GDPR experience on the Euro-

[35] L. Williatte-Pellitteri, 'New Technologies, Telemedicine, eHealth, Data...What Are You Talking About? The Lawyer's Point of View', in A. André (ed), *Digital Medicine* (Springer, Cham, 2019) 93; Nathan Cortez, 'The Evolving Law and Ethics of Digital Health', in Homero Rivas – Katarzyna Wac (eds.), *Digital Health Scaling Healthcare to the World* (Springer, Cham, p. 249 ff; Denise Amram, 'L'Ulisse accountable. Ricerca e protezione dei dati concernenti la salute: il tentativo di armonizzazione al livello europeo post GDPR e le interpretazioni offerte dai sistemi irlandese, belga, spagnolo e italiano' (2019), *Rivista Italiana di Medicina Legale e del Diritto nel campo sanitario*, 209 ff.

pean Data Protection Supervisor and national data protection authorities as well as the European Data Protection Board and the mechanism of prior consultation under article 36 GDPR can offer, at least at organizational level, an efficient model to be pursued.

4. Beyond the principles and the legal obligations: room for contractual agreements

Once that we have identified what is meant for AI, which could be the principles and main roles to be regulated, and the relationship between soft law and hard law tools, we may consider the boundaries of the legislative activity in reference to the contractual autonomy of the main players, namely the AI controller and data subjects (or end-users, addressees). In particular, looking at the GDPR structure once again, and to its multilevel system of check and balance, contractual autonomy could govern some aspects of the AI technology development as well[36].

First of all, the profiles related to the data protection agreements under the mentioned articles 26 and 28 GDPR in case of personal data. Secondly, issues related to the ownership of the collected data. Thirdly, the protection of intellectual property rights of the final output. To avoid disputes the AI regulation may standardize some notions and address possible binding content to be included in these agreements, especially oriented to guarantee the exercise of data subjects' rights[37].

Another contractual issue that could be included is the identification of insurable risks to better protect data subjects from possible bias (in case that one of the algorithm fails on one of the ethical profiles, or for undesired outcomes during the test phase), or errors (like the false or over and/or under prediction for a future event), or reputational ones[38]. Furthermore, the occurrence of external threats like cyberattacks to the system or misuse of the outcome shall be made subject to compulsory insurable. In fact, this would establish a fairer equilibrium to ensuring damage compensation to the data subject/addressee/end-user for those risks that are more severe or frequent[39].

[36] See Zeno-Zencovich remarks on who owns big data and the relative consequences on contractual clauses on personal data and data access: Vincenzo Zeno-Zencovich, 'Ten legal perspectives on the "era of big data revolution" (2016), *Concorrenza e mercato,* 29 ff., see remarks on law-making by Roberto Pardolesi – Antonio Davola, 'Algorithmic legal decision making: la fine del mondo (del diritto) o il paese delle meraviglie' (2020), *Questione Giustizia*, 1, 104 ff. at 110.

[37] Michael Mattioli, 'Disclosing Big Data' (2014), Minn. L. Rev., 99, 535 ff; W. Nicholson Price II, 'Big Data, Patents, and the Future of Medicine' (2016) Cardozo L. Rev., 37, 1401 ff.

[38] See Sonia K Katyal, 'Private Accountability in the Age of Artificial Intelligence' (2019) 66 UCLA L Rev 54.

[39] See the Expert Group on Liability and New Technologies – New Technologies Formation, 'Liability for Artificial Intelligence and Other Emerging Digital Technologies', https://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupMeetingDoc&docid=36608, last access 23.06.2020, also recalling the principles stated in Article 15:101 of the Principles of European Insurance Contract Law (PEICL).

5. Towards an EU General Regulation on Artificial Intelligence?

This paper has shortly illustrated the potentialities of the GDPR regulation as model in order to propose a possible more extensive normative system for Artificial Intelligence, whose peculiarities and challenges have been addressed pragmatically taking into consideration both current soft law initiatives and the identified pillars towards a trustworthy and excellent AI for Europe.

To sum up our remarks, we propose how to address some contents for a General AI Regulation, according to a risk-based oriented system of check and balance aimed at ensuring the development of any AI-systems in light of the applicable principles. The Regulation shall consider the peculiarities emerging within the different sectors and therefore provide the opportunity for each AI controller to establish within his/her organization a RACI matrix to allocate tasks, roles, and responsibilities. Under this system, independent authorities shall provide assistance, consultancy and incentives to develop awareness and trustworthiness among data subjects/end-users/stakeholders as well as to promote possible interdisciplinary skills development aimed at facilitating the internal assessment activities and boost the cultural and inclusive challenge that the AI is driving. Below a tentative table of contents:

A. Principles and definitions.

Principles and definitions shall provide a short overview of the main pillars of the AI regulatory framework, identifying what is meant for the following legal and technical concepts: Fundamental rights (Human Dignity, Health, Data protection and privacy (and the ones stated under article 5 GDPR); Technical Safety and Robustness; Ethical-legal by design and by default; Accountability; Artificial Intelligence; Methods, Required Actions, and Goals of the AI System; AI governance and RACI matrix; AI controller, AI joint controllers, and AI processor.

B. General obligations.

General obligations shall be addressed to the defined steps of the AI system development: Methods, Required Actions, and Goals. It shall also reflect the risk-based approach: all the provisions shall be functional to perform a continuous impact assessment of the design, development, and validation steps. Therefore, it shall include records of the technical specifications for the designed application, the list of the applied technical standards, the results of a comparative assessment of the possible applicable methods, a list of designed actions and predictable ones, goals pursued with the development of the given AI tool, a list of the involved fundamental rights affected by the AI system, an ethics assessment[40]

[40] See the interesting proposal of algorithmic DPIA in Kaminski - Malgieri, *cit.*, 25 ff., on the way of Reuben Binns, 'Data protection impact assessments: a meta regulatory approach' (2017) 7 Int'l. Data Priv. L. 22.

under them in terms of risks and benefits as well as the organisational and technical measures to be implemented, a data protection impact assessment under article 35 GDPR (if applicable), a list of possible end-users including measures to mitigate possible digital divide or boost awareness.

This part shall also identify the organizational measures to allocate roles and responsibilities, including: a RACI matrix identification and governance (*e.g.* relationships between data protection officer, AI officer, system administrator, security manager, AI manager, and AI controller), conditions to sign data protection and/or ownership agreements, possible binding contents to better achieve the trustworthy and excellence purposes, and to avoid disputes/pre-determine responsibilities in case of mistakes/errors/bias/damages, possible enforcing tools (*i.e.* the *astreinte* in case of delay in submitting authorizations/application for ethics approvals, or in case of defaulting collaboration etc.), terms and conditions to avoid/submit for application for authorizations and approvals from ethics committees and/or competent bodies (for pre-trials, trials, and validation of the AI-based product/service).

Technical measures: technical standards requirements and procedures to reach acceptable levels of robustness (including trade and certification procedures, ISO norms, auditing activities, and incentives for training) both of the AI developed system and the whole IoT ecosystem interacting with it.

Data subjects, stakeholders, and end-users' rights: requirements to be included in the information, clauses stated in the terms and conditions of the AI-system, identification technical and organizational measures to mitigate vulnerabilities, possible assessment activities to be performed in order to make the given AI-system interoperable and interactive with other ones in a complex smart solution.

C. Specific obligations for AI tools in the Healthcare Sector.

This section shall be coherent with the regulatory frameworks on Medical Device Regulation (Medical Device Regulation, EU Reg. n. 745/2017), Clinical Trials Regulation (Clinical Trials Regulation, EU Reg. n. 536/2014), and the European regulatory system for medicines, including the related procedures emerging from the given sector also at national level.

As above-illustrated, AI-systems that either process health-data or support clinical decisions have a significant impact on individual and collective fundamental rights both in a patient-oriented perspective and in a professionals' one. From this perspective, the regulatory framework aimed at identifying the compliance activity shapes new frontiers of the Health Technology Assessment[41], providing the most sustainable and efficient solution for

[41] Mark L. Flear, Anne-Maree Farrel, Tamara K. Harvey, Thérèse Murphy, *European Law and New Health Technologies* (Oxford, 2013), see also Leopoldo Trieste et al., 'Razionale e strumenti della valutazione economica in sanità', in G. Carnevale, P. Manzi (eds), *Manuale di governance sanitaria* (PM edizioni, 2017), 427 ff.

the development of services and products in the healthcare sector *by design* (during its development) and *by default* (in terms of acceptability, usability, and market placement)[42]. Measures to ensuring a massive data training could be required before allowing a concrete support of AI tools within the clinical decision making[43].

D. Specific obligations for AI tools in the workplace.

This section shall embed principles stated within the workplace safety regulations and non-discrimination directives as well as provide consistency mechanisms of national agreements and protocols to be agreed with the workers representations and trade unions.
It shall promote, in particular, an assessment of the introduction of AI tools to develop new skills and expertise related to the automated-support in the workload, designing specific paths to facilitate the digitalisation of services and supply chain boosting the individual and collective acceptability.

E. Specific obligations for AI-system for industrial innovation and robotics (including obligations for human-robot interactions).

This section shall provide specific obligations in order to enhance the principles stated within the *Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics*, addressing the adherence to mechanisms aimed at continuously performing the assessment of the related deep learning features of the AI-systems once the innovation has been placed in the market[44]. A system to provide alerts, or develop awareness for stakeholders and end-users in the market shall be considered and expressed in terms of follow-up monitoring, that could be promoted through self-regulation mechanisms (codes of conducts, trades, and certifications)[45] or it could be attributed to external boards (like consumers associations) or independent authorities (for example, the opportunity to maintain a registry on approved AI-tools, linked to insurance renewal or taxes purposes whether applicable to the specific innovation).

[42] WHO, *2015 Global Survey on Health Technology Assessment by National Authorities*, World Health Organization 2015 and the Strategy for EU cooperation on Health Technology Assessment (HTA) adopted by the HTA Network in Rome on 29.10.2014.

[43] Andrew L Beam – Isaac S. Kohane, 'Big Data and Machine Learning in Health Care' (2018) 319 JAMA 1317. An attempt to identify an ethical path for AI in healthcare is proposed by Tokio Matsuzaki, 'Ethical Issues of Artificial Intelligence in Medicine' (2018) 55 Cal W L Rev 255: 272-273.

[44] Yann LeCun et al., 'Deep Learning' (2015) 521 Nature 436.

[45] Article 40 GDPR introduces the opportunity to approve Codes of Conduct at EU level, providing a de facto self-regulation tool with an extensive effectiveness, see Franco Pizzetti, 'GDPR e Intelligenza Artifciale Codici di condotta, certifcazioni, sigilli, marchi e altri poteri di sot la previsti dalle leggi nazionali di adeguamento: strumenti essenziali per favorire una applicazione proattiva del Regolamento europeo nell'epoca della IA', in A. Mantelero – D. Poletti (eds), *Regolare la tecnologia: il Reg. UE 2016/679 e la protezione dei dati personali. Un dialogo fra Italia e Spagna* (Pisa University Press, 2018) 69 ff, 93.

As far as human-interaction is concerned, a truly human-centric approach shall also analyse the impact of such an interaction has on the daily-routine in light of the values shared in a given historical eve. For example, the possibility to interact with an avatar[46] or with a robot may support a workload in a supply chain, better train some professional skills, but it can also reduce the distress or trauma related to the bereavement damage. The psychological implications of dual-twin environments are a challenge that shall be addressed as well: avatars may be used to cover the concepts of presence/absence, support some process, but they can also emphasize some human vulnerabilities. This kind of consequences need a deep assessment both at individual level and collective one.

F. Specific obligations for AI tools addressed to vulnerable individuals or groups.
AI-tools and systems shall take into consideration the vulnerabilities of the end-users, in order to reduce the digital divide, not to create disadvantages for individuals or group of individuals. However, it is possible that the analysis of information related to some vulnerabilities could be the main task of the developed technology, in order to provide a technological support for a given service or product. In this case, a specific obligation to not misuse the outputs of the tool shall be provided together with specific policy related the re-use or sharing of methods, actions, purposes and, of course, data.

G. Independent authorities and supervisors.
Independent body and authorities aimed at monitoring, standardizing, controlling, sharing awareness and training on AI systems shall be established. Furthermore, this section shall rely with possible mechanisms and relationships between the independent authorities and supervisors, both at EU and national levels shall be included.

H. Breach, accidents, and remedies.
The AI-regulation shall identify what is meant for breach and accidents, and the consequent paradigm of controls, sanctions, and remedies in case of defaulting behaviours from the AI controller and his/her delegates.
Considering that the GDPR provides for a series of civil, criminal, and administrative offences in case of infringement of the stated obligations, it appears coherent to identify a graduated and multilevel system of prevention, deterrence, and punishment tools according to the binding nature of some obligations and the (attempted) damage produced to individuals, groups, or collectively with the defaulting behaviours.

[46] Ravaja, N., Harjunen, V., Ahmed, I. et al., 'Feeling Touched: Emotional Modulation of Somatosensory Potentials to Interpersonal Touch' (2017) *Sci Rep* 7, 40504. https://doi.org/10.1038/srep40504.

As far as the liability model is concerned, strict liability or fault-based paradigms suitability have been explored both from authors[47] and policy makers[48]. The article 82 GDPR states any person who has suffered material or non-material damage because of an infringement of the GDPR is entitled to seek compensation, and any controller involved in the data processing shall also be liable. As a consequence of the principle of accountability, to avoid liability, data controllers need to prove that they are not in any way responsible for the event that caused the harm. Some authors argued that as far as liability in the field of AI is concerned, "*gradual layered approach to liability grounded on accountability principles*"[49] including "*reversal of the burden of proof, compulsory insurance, funds, regulatory constraints, criminal sanctions*"[50] tailored to the significant deviation from the required standard of compliance, as it can be assessed by humans only if it refers to their action, otherwise "*the deviation from the standard of conduct by AI is assessable only with the help of 'technologies' with the characteristics required by the accountability principle*"[51]. From this perspective, the *Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics*[52] confirmed the human-centric perspective aimed at guaranteeing the same protection to individuals for harm caused by AI-based technology as other technologies. The possibility to amend/introduce that ground within the Product Liability Directive has been already envisaged in the mentioned report. Whether this is the final approach adopted by the EU legislative initiative or not, it may be useful to complete the frame with the measures aimed at promoting the exercise of data subject/addressee's rights as well as the enforcement tools in light of the principle of accountability, as suggested by authors, in terms of multi-layered accountable liability.

6. Potentialities of the proposed model in light of extra-EU data protection law initiatives

The proposed model finds a validation in light of the role that GDPR has got on recent extra-EU reforms on data protection law.

[47] Paulius Čerka - Jurgita Grigienė, Gintarė Sirbikytė, 'Liability for damages caused by artificial intelligence' (2015) Computer Law & Security Review, 31, 3, 376-389; Gerhard Wagner, 'Robot Liability', in Sebastian Lohsse, Reiner Schulze, Dirk Staudenmayer, *Liability for Artificial Intelligence and the Internet of Things*, cit., 27 ff. and Ernst Karner, 'Liability for Robotics: Current Rules, Challenges, and the Need for Innovative Concepts', *ibidem*, 117 ff., Erica Palmerini - Andrea Bertolini, 'Liability and Risk Management in Robotics', in Reiner Schulze and Dirk Staudenmayer (eds), *Digital Revolution: Challenges for Contract Law in Practice* (Hart Nomos, 2016), 225 ff.

[48] European Parliament Resolution of 16 February 2017 with recommendations to the Commission on Civil Law Rules on Robotics [2015/2103(INL)].

[49] Giovanni Comandé, *cit.*, 177.

[50] *Ibidem*, 182.

[51] *Ibidem,* 177. See also Sonia K. Katyal, cit., that proposes a system based on culture of accountability for algorithms.

[52] See footnote 27.

In this regard, we observe that a whole chapter of the GDPR is dedicated to personal data transfer to third countries (or international organisations) regulation. The first condition to allow these extra-EU flows is that the EU Commission considers the given foreign data protection legislation as adequate (*i.e.* the adequacy decision issued under article 45 GDPR). This approach enabled a mechanism of compliance harmonization to facilitate personal data flows from (and to) non-EU Member States.

For example, the Turkish Protection of Personal Data entered into force in October 2016. It shares with the GDPR the structure aimed at providing notions, principles, and a governance to frame the legal conditions for data processing[53]. First of all, the Turkish legislation defines what is a data processing and identifies a series of roles within the data processing: Relevant person, Personal Data, Special Personal Data, Person in Charge of Data, Data Processor. Significant principles include lawfulness, purpose limitation, proportionality and measurability of all data processing tools, data retention. Also legal conditions to enable data processing recall articles 6 and 9 GDPR structure, even if categories of data are not distinguished in terms of legal basis of the data processing. Despite of the GDPR, the Turkish system provides a specific and separated regulation for health data processing[54], mainly addressed to health service providers and operators, as well as to data subjects and individuals and entities who provide hardware, software, and file systems for healthcare services, in order to define specific safeguards and constraints for this kind of data.

Analogies with the GDPR structure emerge also from an analysis of the Israeli framework. The data protection system is part of a more general protection of the right to privacy, that is considered an expression of the human dignity[55]. The technological progress that characterizes Israeli infrastructures and services allowed to set a direct bridge between the right to privacy, as recognized by the constitution, and the need to regulate the consequences of its violation under the Privacy Protection Act in 198156 that regulates databases under a series of principles that recall the ones stated in the GDPR. Transparency, purpose limitation, confidentiality ad data security, data integrity, providing a series of rights to the data subjects like the right to access, correction of stored information, deletion, objection, consent withdraw. In addition, in 2017, the Privacy Protection Regulations (security) have been enacted, focusing on data security for data storage[57]. Accordingly, a data govern-

[53] Burcak Unsal, 'Protection of Personal Data in Turkey and Japan' (2016) 2 Turk Com L Rev 187.

[54] Personal Health Data Regulation, https://www.resmigazete.gov.tr/eskiler/2019/06/20190621-3.htm.

[55] Basic Law: Human Dignity and Liberty § 7, SH No. 1391, 5752 (Mar. 25, 1992), as amended, see *Soren* Zimmermann, 'The Legal Framework of Data Protection in Israel: A European Perspective' (2019) 5 Eur Data Prot L Rev 246; on the legal strategy see Eldar Haber, Aurelia Tamò-Larrieux (2020), 'Privacy and security by design: Comparing the EU and Israeli approaches to embedding privacy and security', Computer Law & Security Review, 37, 105409.

[56] The Privacy Protection Law, 5741-1981, 35 Laws of The State of Israel [LSI] 136 (5741-1980/81), as amended.

[57] Privacy Protection Regulations (Data Security), 5777-2017 (PPDS), Kovetz Hatakanot [KT] [Subsidiary Legislation] 5777 No. 7809 p. 1022, available on the Ministry of Justice website, http://www.justice.gov.il/, Ruth Levush, Israel: Online Privacy Protection Regulations Adopted, Global Legal Monitor (June 14, 2017),http://www.loc.gov/ law/foreign-news/ article/israel-online-privacy-protection-regulations-adopted/, archived at https://perma.cc/QCU8-TJS3.

ance has been established to identify duties and responsibilities. In particular, a databank owner has to provide an information similar to the one stated in the GDPR. Furthermore, four categories of database are identified with different safeguards considering a predetermined risk-assessment. This basic regime has been integrated by the Supreme Court jurisprudence that interpreted the statutory law in light of the human dignity introducing a more effective data subject-oriented regime. Thanks to these features, Israel has received the adequacy decision in January 2019.

Another legislative initiative inspired by the GDPR is the Brazilian General Data Protection Law (LGPD), Federal Law no. 13.709/2018, that has been enacted in order to provide a comprehensive legal framework on data protection. It will enter into force in 2021, considering the one year postponing due to Covid-19 emergency. In short, GDPR constituted an expressed model as long as notions, principles, and legal basis for data processing are similar to the ones stated for the EU, including the identification of a data protection officer and a data breach policy[58]. The main difference with the GDPR consisted of the lack of a national control entity, like a data protection authority, that indeed has been established in 2019.

The provided examples identified a trend towards a cross-fertilization inducted both by the adequacy decision system, that directly impacts on the compliance activities of any third-party transfer, and by the fact that GDPR constitutes an opportunity to enhance an effective cultural change on data protection in light of the by-design and by-default principles.

The alignment could be more problematic if we consider the Chinese system. Even if the Chinese Cybersecurity law introduced in 2018 has seriously made a step forward towards data subjects' rights, several issues remain open[59]. Main differences emerge, in fact, in light of the possibility to exercise data subjects' rights whereas the data controller is not private[60], justifying monitoring and surveillance activities that, threating the democratic values, prevent EU from opening data flows without the needed technical and organizational safeguards provided under articles 46 GDPR.

These reasons, including the lack of any other specific strategies on AI regulation, support and endorse the proposed "interoperability" of the GDPR-model for further purposes, as

[58] Brazilian General Data Protection Law (LGPD), Federal Law no. 13,709/2018. Fernando Bousso, 'Perspectives of the European General Data Protection Regulation (GDPR) in Brazil' (2018) 2 Int'l J Data Protection Officer, Privacy Officer & Privacy Couns 31.

[59] Sarah Wang Han and Abu Bakar Munir, 'Information Security Technology – Personal Information Security Specification: China's Version of the GDPR' (2018) 4 Eur Data Prot L Rev 535.

[60] In fact, it does not provide strict conditions for data processing and data subjects' consent could be implicit (unless a given provision states that it has to be expressed and explicit). The new regulation addresses specific information obligations, included a set of shared principles (like confidentiality, lawfulness, fairness, transparency, and necessity) that are concretely applied as technical measures to avoid possible data breach. Data subjects' information covers a significant chapter within the new regulation, including the notification of data breach. Jyh-An Lee, 'Hacking into China's Cybersecurity Law', 53 Wake Forest L. Rev. (2018), at 101.

it is already considered as a model to follow to better enhance fundamental rights protection within different systems.

7. Conclusive remarks

This paper aimed at discussing some key-issues emerging from the debate on possible AI regulation initiatives, highlighting how the GDPR – at this stage mainly assumed to cover the lawfulness pillar – shall be taken into consideration as a model of law-making under its structure and approach.

However, contents for AI-systems shall be extended to the entire challenges that the processing – also of non-personal data – of a huge amount without human control of the results launches.

Current works issued by policy making on the EU Commission strategy on AI are addressed to promote a risk-based and human-centric approach, strengthening the role of interdisciplinary skills and competence to serve the new paradigm.

Our contribution to shape the new cultural approach to face the societal and technological challenges within the "big data processing era" proposes, indeed, the development of a legal paradigm able to develop a multilevel system of compliance for AI-based technologies on shared principles and a predetermined suggested governance to allocate roles and responsibilities in every relevant step of the AI-process development, identifying possible follow-up mechanisms that must be supported not only by the stakeholders and economic operators, but also by institutions.

Within these terms, the GDPR still recalls the synecdoche literary figure of speech, not only because it is a part of the lawfulness compliance of an AI-system that processes personal data, but because it stands for a larger efficient risk-based model, built up on compliance by design and by default principles, that is suitable to be replicated to regulate a more comprehensive accountable use of the Artificial Intelligence techniques.

Regulating Algorithms in The European Data-Driven Economy: The Role of Competition Law and Civil Liability

Andrea Parziale*

Abstract

While showing the potential to make the market more competitive and efficient, algorithms are acknowledged to pose a challenge to competition law enforcement. This is because algorithmic tacit collusion does not amount to an outright agreement but is something more than mere market parallelism, which is normal in competitive markets. This essay reviews the economic and legal scholarship, the national and supranational case law and the supranational policy debate on this issue to explore if and how competition law can play a role in clarifying such a grey area, without discouraging technological innovation and economic development.

In this regard, this essay finds that, while the case law has already addressed algorithms implementing explicit anticompetitive agreements under Article 101 TFEU, scholars fail to agree on how

* PostDoc Researcher, Sant'Anna School of Advanced Studies (Pisa, Italy). The author wants to thank the reviewers of the original manuscript. Their constructive comments made a substantial contribution to this paper.

to tackle algorithmic tacit collusion. This has come under the radar of ongoing policy initiatives, such as the European Commission's New Competition Tool initiative. Waiting for innovative regulatory and competition law solutions to better tackle algorithmic collusion, this essay proposes to use, as an alternative to Article 101 TFEU, the notion of collective abuse of dominant position under Article 102 TFEU. Finally, this essay considers how civil liability and private enforcement may contribute to competition law enforcement against algorithmic collusion.

Keywords

Competition Law – Concerted practice – Collective abuse of dominant position – Algorithmic collusion – Private Enforcement

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1. Introduction

Algorithms and Big Data have revolutionised digital markets, offering new commercial opportunities to companies and more information to consumers. They have the potential to make the market more competitive and efficient for the benefit of all the stakeholders involved. They are essential to the EU Single Digital market Strategy of 2015, and so is competition in digital markets for the sake of innovation and economic development.
At the same time, the EU Commission sector inquiry into e-commerce (2017) found that two-thirds of market operators employ algorithms to monitor their competitors' prices[1].

[1] EU Commission, *Report from The Commission to The Council and The European Parliament. Final report on the E-commerce Sector Inquiry*, Brussels, 10.5.2017, COM(2017) 229 final, p. 5, available at: http://ec.europa.eu/competition/

This is suspected to be the sign that algorithms are being used to create collusive, anti-competitive outcomes.
Algorithms have become a competition law concern and pose several challenges to competition law enforcement. We are shifting from a world were corporate executives negotiated cartels in physical meetings or by exchanging correspondence or phone calls to a world were algorithms detect competitors' information and adapt to it, retaliating to any deviation from a collusive equilibrium. Algorithm-driven tacit collusion does not amount to an outright agreement but is something more than mere market parallelism, where firms rationally adapt to changing market conditions, which is normal in competitive markets. In other terms, 'algorithmic collusion' inhabits a grey area, calling for regulatory clarification. Building on the scholarly and policy debate on this issue, this essay will explore if and how competition law and civil liability can play a role in clarifying such a grey area without discouraging technological innovation and economic development[2].

2. Algorithms and Big Data in a digital market economy: benefits and risks for competition

Businesses have always used data to gain an advantage in the marketplace. However, the digitalisation of the economy has significantly increased the amount of available data as well as the scope for its commercial application. Smartphone use and web surfing feed unlimited volumes of information. This is used for an expanding number of economic activities. An essential productive factor in a data-driven economy, Big Data has become key to optimising decision-making processes, driving innovation, and fostering markets' efficiency[3]. Nevertheless, Big Data would be useless if it were not for algorithms, which treat wide amounts of data automatically and at an ever-increasing speed.
Algorithms are nothing new. Wilson and Keil (1999) defined algorithms as «unambiguous and precise lists of simple operations applied mechanically and systematically to a set of tokens or objects, where the initial state of the tokens is the input and the final state is the output»[4]. Put this way, virtually any list of instructions aimed at a certain result (including recipes) is technically an algorithm. As such, algorithms are integral to the experience of every human being. As computer science improved, algorithms have been created to

antitrust/sector_inquiry_final_report_en.pdf. Last accessed 3 Dec 2020.

[2] N. Petit, A*ntitrust and Artificial Intelligence: A Research Agenda*, in *Journal of European Competition Law & Practice*, 2017, Vol. 8, No. 6, p. 361.

[3] AGCM, AGCOM, *Big data. Interim report nell'ambito dell'indagine conoscitiva di cui alla delibera n. 217/17/CONS*, June 2018, pp. 5 ff., available at: https://www.agcom.it/documents/10179/10875949/Studio-Ricerca+08-06-2018/c72b5230-354d-444f-9e3f-5467ca450714?version=1.0. Last accessed 3 Dec 2020.

[4] R.A. Wilson, F.C. Keil, *The MIT Encyclopedia of the Cognitive Sciences*, Boston, 1999.

automatically carry out complex calculations and data processing, relieving humans from repetitive tasks[5]. Artificial Intelligence[6] and Machine Learning[7] are now enabling algorithms to solve problems, make predictions, and take decisions more efficiently than human beings. Deep Learning is a particularly promising subfield of Machine Learning where computer systems generate digital neural networks to imitate the human brain[8]. While granting higher complexity and abstraction than traditional, linear algorithms, Deep Learning algorithms do not allow their own programmers to understand the decision-making process behind their outcomes. Nevertheless, more and more companies are using Deep Learning to make predictions and optimise business processes. Predictive algorithms can estimate demand, anticipate price variations and customer preferences, as well as appraise commercial and even natural risks. This greatly improves companies' decision-making capacity[9]. Algorithms can also optimise business processes, allowing enterprises to cut production and transaction costs by setting optimal prices and ensuring significant operational results (e.g., fraud prevention, corporate security)[10]. This way, algorithms analysing complex fluxes of data in real time have come to play a pivotal role in the competitive processes of the contemporary digital economy.

Governments and supranational institutions have appraised the potential benefits of economic digitalisation and set policy strategies to foster it. In May 2015, the European Commission set the target to create a European Digital Single Market, shifting towards a data-driven economy to increase economic growth and employment, offer innovative services to consumers, and promote social progress[11]. A Digital Single Market is one where «the free movement of goods, persons, services and capital is ensured and where individuals and businesses can seamlessly access and exercise online activities under conditions of fair competition, and a high level of consumer and personal data protection, irrespective of

[5] OECD, *Algorithms and Collusion – Background Note by the Secretariat*, June 2017, available at: https://one.oecd.org/document/DAF/COMP(2017)4/en/pdf. Last accessed 3 Dec 2020.

[6] Artificial Intelligence (AI) investigates and designs intelligent agents that perform tasks of significant difficulty (P. Swarup, *Artificial Intelligence*, in *International Journal of Computing and Corporate Research*, 2012, Vol. 2, No. 4, http://www.ijccr.com/july2012/4.pdf. Last accessed 3 Dec 2020).

[7] Machine learning (ML) is an AI subsector which designs intelligent machines based on algorithms that iteratively learn from experience without being explicitly programmed. (P. Anitha, G. Krithka, M.D. Choudhry, *Machine Learning Techniques for learning features of any kind of data: A Case Study*, in *International Journal of Advanced Research in Computer Engineering & Technology*, 2014, Vol. 3, No. 12, pp. 4324-4331, http://ijarcet.org/wp-content/uploads/IJARCET-VOL-3-ISSUE-12-4324-4331.pdf. Last accessed 3 Dec 2020).

[8] I Goodfellow, Y. Bengio, A. Courville, *Deep Learning*, Boston, 2016, http://www.deeplearningbook.org/. Last accessed 3 Dec 2020; Y. LeCun, Y. Bengio, G. Hinton, *Deep Learning*, in *Nature*, 2015, Vol. 521, pp. 436-444, https://www.cs.toronto.edu/~hinton/absps/NatureDeepReview.pdf. Last accessed 3 Dec 2020.

[9] A. Ezrachi, M.E. Stucke, *Virtual Competition: The Promise and Perils of the Algorithm-Driven Economy*, New Haven, 2016.

[10] Id.

[11] EU Commission, *A Digital Single Market Strategy for Europe*, Brussels, 6 May 2015, COM(2015) 192 final, available at: https://eurlex.europa.eu/legalcontent/EN/TXT/?uri=COM%3A2015%3A192%3AFIN. Last accessed 3 Dec 2020.

their nationality or place of residence»[12]. The Digital Single Market Strategy relies on three pillars, where competition plays a multidimensional role:

1. «Better access for consumers and businesses to online goods and services across Europe – this requires the rapid removal of key differences between the online and offline worlds to break down barriers to cross-border online activity».
2. «Creating the right conditions for digital networks and services to flourish – this requires high-speed, secure and trustworthy infrastructures and content services, supported by the right regulatory conditions for innovation, investment, fair competition and a level playing field».
3. «Maximising the growth potential of our European Digital Economy – this requires investment in ICT infrastructures and technologies such as Cloud computing and Big Data, and research and innovation to boost industrial competitiveness as well as better public services, inclusiveness and skills»[13].

Against this backdrop, algorithms are acknowledged to have pro-competitive effects both on the supply and demand side[14]. On the supply side, algorithms increase transparency, improve existing products and services, and help develop new ones. This lets companies reduce production costs and selling prices. On the demand side, algorithms can provide consumers with quick access to well-organised information, thus reducing transaction costs and helping consumers make more rational and faster decisions.
All these advantages, however, do not come without risks. The very structure and functioning of the digital market may jeopardise both individuals' rights and interests and the correct functioning of the market. Within the so-called Big Data ecosystem, data subjects, especially internet users, generate data; then data brokers gather and sell them to companies; in turn, companies explore and exploit data through algorithms[15]. European public regulators have started to address the striking information asymmetries between users and operators and the resulting data protection concerns with the much-hyped Regulation (EU) n. 679/2016 (General Data Protection Regulation, GDPR), which entered into effect on 25 May 2018.
At the same time, the European Commission has expressed concerns over the economic distortions that may occur in the digital market, where a small number of highly integrated transnational companies interact with loads of small-sized specialised enterprises[16]. An

[12] Id.

[13] Id.

[14] OECD, *Algorithms and Collusion - Background Note by the Secretariat*, cit. Last accessed 3 Dec 2020.

[15] AGCM, AGCOM, *Big data. Interim report nell'ambito dell'indagine conoscitiva di cui alla delibera n. 217/17/CONS,* cit.

[16] EU Commission, *Report from The Commission to The Council and The European Parliament. Final report on the E-commerce Sector Inquiry*, cit.

issue of the utter importance for competition dynamics, the EU Commission expressed concerns that «pricing software, detecting deviations from 'recommended' retail prices» in «a matter of seconds» may enable manufacturers «to monitor and influence retailers' price setting. The availability of real-time pricing information may also trigger automatised price coordination. The wide-scale use of such software may in some situations, depending on the market conditions, raise competition concerns»[17]. In a remarkable example of conciseness, the OECD labelled this risk as 'algorithmic collusion'[18].

Authoritative scholars persuasively argued that the algorithmic collusion conjecture should not be presented as a given[19]. This is because significant technological challenges may prevent algorithms from approaching a collusive equilibrium. However, the most updated economic literature largely shares the concerns of policymakers. Previous works had found that algorithmic collusion, albeit possible, is rather unlikely[20]. Conversely, while conceding that we still have a limited understanding of algorithmic pricing collusion, recent studies suggest that algorithmic collusion is a real possibility that may challenge competition policy[21]. These findings are somehow confirmed by novel empirical research[22], which found that AI adoption actually has significant effects on competition[23]. Therefore, these studies confirm that policymakers should be concerned about the widespread implementation of algorithmic pricing software in the market.[24]

These policy, theoretical and empirical developments suggest that the day has come when self-learning and independent algorithms have become a competition law issue. It is feared that they may enable innovative ways of co-ordination between competing firms.

[17] Id., para 13.

[18] OECD, *Algorithms and Collusion – Background Note by the Secretariat*, cit.

[19] A. Ittoo, N. Petit, *Algorithmic Pricing Agents and Tacit Collusion: A Technological Perspective*, in H. Jacquemin, A. De Streel (eds.), *L'intelligence artificielle et le droit*, Bruxelles, 2017, pp. 241-256, available at: https://ssrn.com/abstract=3046405 or http://dx.doi.org/10.2139/ssrn.3046405. Last accessed 3 Dec 2020.

[20] *Ex multis*, I. Dogan, A.R. Guner, *A Reinforcement Learning Algorithmic pricing approach to Competitive Ordering and Pricing Problem*, in *Expert Systems*, 2015, 32, pp. 39-47.

[21] E. Calvano, G. Calzolari, V. Denicolò *et al.*, Algorithmic *Pricing What Implications for Competition Policy*, in *Rev Ind Organ*, 2019, 55, pp. 155-171, doi: 10.1007/s11151-019-09689-3. In line with these results, a recent study found that that Q-learning pricing algorithms systematically learn to collude and punish deviations by trial and error, without prior specific knowledge (E. Calvano, G. Calzolari, V. Denicolò, S. Pastorello, *Artificial Intelligence, Algorithmic Pricing and Collusion*, in *American Economic Review*, 2020, 110(10), pp. 3267-3297).

[22] S. Assad, R. Clark, D. Ershov and L. Xu, *Algorithmic Pricing and Competition: Empirical Evidence from the German Retail Gasoline Market*, CESifo Working Paper No. 8521, available at: https://ssrn.com/abstract=3682021. Last accessed 3 Dec 2020.

[23] Id.

[24] Id.

3. Algorithmic collusion: tacit vs. explicit

By and large, competition law frames illicit conducts as human behaviours. While antitrust law is used to sanction corporate executives manipulating prices and sharing markets, sophisticated pricing algorithms could increase the risk of new forms of sustainable tacit collusion. This raises the question of what role competition law can play in this domain. To answer this question, one must first define the concept of collusion.

Collusion can be either explicit or implicit. Explicit collusion consists in oral or written agreements. Therefore, there must be a meeting of minds between the representatives of competing companies, who act in a concerted way to restrict competition. Article 101 TFEU foresees an outright prohibition of this kind of illicit agreements (see *infra*, para 4.1).

In contrast, tacit collusion is an anti-competitive co-ordination reached in lack of any explicit agreement between the competing companies. These collude by recognising their mutual interdependence. Each company achieves an anti-competitive result by pursuing its own profit-maximisation strategy separately from its competitors[25]. This usually happens when certain conditions are met, i.e. the competing companies must offer homogeneous goods and services in oligopolistic and transparent markets, with high entry barriers[26]. This is why this phenomenon is known as the oligopoly problem. Few companies protected by high entry barriers have an incentive to start and continue colluding as they can aspire to large supra-competitive gains, which will not attract newcomers. In addition, transparent markets enable companies with frequent interactions to assess each other's decisions and identify and sanction violations of an arrangement. Conversely, a high number of companies decrease the incentives for collusion since each competitor would obtain a smaller share of the supra-competitive gains. Likewise, in lack of entry barriers, collusion is unsustainable since any increase in profits will increase the incentives to deviate from the collusive equilibrium and will attract new entrants.

Competition law does not tackle tacit collusion explicitly because, so far, the conditions thereof were unlikely to happen. However, Big Data and algorithms might render their occurrence more frequent[27]. While their impact on the number of firms and entry barriers is ambiguous, they are likely to increase market transparency, as well as the frequency of interactions between firms. Algorithms allow companies to gather and monitor in real-time competitors' behaviours, consumers' preferences, and other market data. For instance, pricing algorithms can update prices in real-time and retaliate immediately to any devia-

[25] OECD, *Roundtable on Competition Enforcement in Oligopolistic Markets*, DAF/COMP(2015)2, 2015 http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=DAF/COMP(2015)2&docLanguage=En. Last accessed 3 Dec 2020.

[26] R. Whish, D. Bailey, *Competition Law*, Oxford, 2012, pp. 559 ff.

[27] OECD, *Algorithms and Collusion – Background Note by the Secretariat*, cit.

tion from the (tacit) collusion. Predictive models may even anticipate competitors' decisions and retaliate to deviations from collusion before they even happen[28]. The immediate detection and punishment of any actual (and even potential) violation of collusion make deviation unprofitable, which contributes to the sustainability of the tacit, anticompetitive collusion.
A scholar vividly depicted the transition algorithms are facilitating in anticompetitive collusion:

> [W]e are shifting from the world where executives expressly collude in smoke-filled rooms to a world where pricing algorithms continually monitor and adjust to each other's prices and market data. In this new world, there is not necessarily any collusive agreement among executives. Each firm may unilaterally adopt its own pricing algorithm, which sets its own price. In this new world, there is not necessarily anticompetitive intent […] The danger here is not express collusion, but more elusive forms of collusion. Computers may limit competition not only through agreement or concerted practice, but also through more subtle means. For example, this may be the case when similar computer algorithms reduce or remove the degree of strategic uncertainty in the marketplace and promote a stable market environment in which they predict each other's reaction and dominant strategy. Such a digitalised environment may be more predictable and controllable. Furthermore, it does not suffer from behavioral biases and is less susceptive to possible deterrent effects generated through antitrust enforcement[29].

Algorithms, then, might increase the risk of coordination between competing firms. Nevertheless, a distinction must be made between tacit collusion between market operators and mere market parallelism, which does not imply any coordination between competitors. Banning market parallelism *per se* could prevent businesses from updating their strategy to markets conditions (e.g. prices, demand), which is key to competition.
In a way, tacit collusion inhabits a grey area between explicit collusion, which is sanctioned, and mere parallelism, which does not fall under the scope of competition law[30]. Tacit collusion is something more than mere parallelism but is something less than an explicit arrangement between competing firms. Algorithms may enlarge this grey area by letting companies coordinate prices in lack of an explicit agreement. Algorithms can generate innovative automatic processes that implement a common policy and monitor the

[28] «Even though market transparency as a facilitating factor for collusion has been debated for several decades now, it gains new relevance due to technical developments such as sophisticated computer algorithms. For example, by processing all available information and thus monitoring and analysing or anticipating their competitors' responses to current and future prices, competitors may easier be able to find a sustainable supra-competitive price equilibrium which they can agree on» (Autorité de la Concurrence, Bundeskartellamt, *Competition Law and Data*, 10 May 2016, p. 14, available at: http://bundeskartellamt.de/SharedDocs/Publikation/DE/Berichte/Big%20Data%20Papier.pdf?__blob=publicationFile&v=2. Last accessed 3 Dec 2020.

[29] A. Ezrachi, M.E. Stucke, *Artificial Intelligence & Collusion: When Computers Inhibit Competition*, in *University of Illinois Law Review*, 2017, p. 1775. doi: http://dx.doi.org/10.2139/ssrn.2591874.

[30] OECD, *Algorithms and Collusion – Background Note by the Secretariat*, cit.

behaviour of competing companies without any human interaction. This way, they substitute explicit collusion with tacit co-ordination.

Algorithms that facilitate tacit collusion might include monitoring and pricing, as well as Machine Learning and Deep Learning technologies.

Monitoring algorithms gather and screen information about competing firms' commercial behaviours searching for deviations from collusion and eventually programming retaliations[31].

Pricing algorithms reduce the costs of collusion and the risk of detection by competition authorities since they let companies update prices automatically to variations in market conditions without any need for renegotiating the terms of collusion continuously via meetings, phone calls, and e-mails. While showing pricing algorithms with competitors can ease the proof of a competition law infringement, more discreet ways to implement tacit collusion include the co-ordination based on the fact that the same ICT service providers develop the same algorithms for rival companies ('hub and spoke' scenario)[32]. Likewise, competitors can use pricing algorithms to follow a market leader in real-time which is in charge of setting supra-competitive prices ('tit-for-tat' strategy or equivalent retaliation)[33]. Indeed, algorithms might reduce the costs of signalling, which consists in unilateral price announcements to other firms. In principle, if the signalled firms do not perceive the signal or do not adapt to it, the signalling company loses profits. Algorithms can reduce such a risk in several ways, e.g. by setting abrupt price changes overnight, which do not affect purchases but are identified as signals by the algorithms of competitors. Alternatively, algorithms can disclose data used as a code to offer and contract increases in price[34].

Finally, Machine Learning and Deep Learning technologies might ensure the most discreet ways to obtain a collusive result. Powerful predictive algorithms can learn to react to other firm's behaviours (either human or artificial) and collude without human interactions. Game theory studies have investigated the capacity of Machine Learning to reach cooperative results[35]. Deep Learning may implement collusion without business operators even being aware of it.

[31] Id.

[32] The spoke and hub paradigm is an organisation model where routes are like "spokes" connecting a central "hub" (id., p. 27).

[33] This is a way to solve the prisoner dilemma (id.).

[34] See the US case Airline Tariff Publishing Company (A.M. Miller, *Did the Airline Tariff Publishing Case Reduce Collusion?*, in *The Journal of Law & Economics*, Vol. 53, No. 3 (August 2010), pp. 569-586.

[35] P. Hingston, G. Kendall, *Learning Versus Evolution in Iterated Prisoner's Dilemma*, in *Proceedings of the Congress on Evolutionary Computation* (CEC'04), 2004, available at: http://www.cs.nott.ac.uk/~pszgxk/papers/cec2004ph.pdf. Last accessed 3 Dec 2020.

While some scholars call for more incisive public intervention to regulate algorithms, e.g. by establishing an independent agency with regulatory powers[36], most governments have adopted a more market-oriented approach. This approach has prevailed since the very beginning of the Internet era, ensuring a fast growth of e-commerce and innovative development.
As shown below, both scholars and supranational policymakers are questioning the ability of existing regulatory and competition tools to tackle the challenges of the digital economy, including those related to algorithmic pricing.

4. Challenges for and potentials of EU competition law

As stated by the OECD report on algorithms and collusion,[37] algorithms pose different kinds of challenges to EU competition law.[38] In some instances, algorithms only magnify behaviours competition law rules already address. In this case, algorithms pose enforcement problems only because legal doctrines already exist that tackle algorithm-driven anticompetitive conducts. Although it might be hard for agencies to detect and prove such conducts, agencies can rely on the current legal framework about agreements and concerted practices.
In other instances, as the previous paragraph pointed out, algorithms can pose anticompetitive risks the current legal framework is not well-suited to tackle, including the grey area (between explicit agreements and mere market parallelism) of tacit collusion, where algorithms can reach an anticompetitive outcome without any human interaction between rival firms. As seen in the previous paragraph, algorithms can magnify the oligopoly problem and make tacit collusion more frequent. Algorithms are increasing market transparency, the velocity of commercial decisions, and the capacity of firms to retaliate rapidly to competitors' behaviours. Therefore, algorithms may render companies' conducts interdependent without any explicit communication, inflating prices up to anticompetitive levels.

4.1. Algorithmic collusion as an agreement (Article 101 TFEU)

As shown below, both scholars and enforcers approach the issue of algorithmic collusion mainly as a matter of anticompetitive agreement. In the EU, these practices are addressed by Article 101(1) TFEU, which prohibits:

[36] M.U. Scherer, *Regulating Artificial Intelligence Systems: Risks, Challenges, Competencies, and Strategies*, in *Harvard Journal of Law & Technology*, 2016, 29(2), pp. 353-400, available at: http://jolt.law.harvard.edu/articles/pdf/v29/29HarvJLTech353.pdf. Last accessed 3 Dec 2020.

[37] OECD, *Algorithms and Collusion - Background Note by the Secretariat*, cit.

[38] A. Capobianco, A. Nyeso, *Challenges for Competition Law Enforcement and Policy in the Digital Economy*, in *Journal of European Competition Law & Practice*, 2018, 9(1), p. 19.

> all agreements between undertakings, decisions by associations of undertakings and concerted practices which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the internal market, and in particular those which:
> (a) directly or indirectly fix purchase or selling prices or any other trading conditions;
> (b) limit or control production, markets, technical development, or investment;
> (c) share markets or sources of supply;
> (d) apply dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;
> (e) make the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.

In essence, Article 101 TFEU prohibits anticompetitive agreements and concerted practices. The term agreement covers any arrangement, be it legally binding or not, in written or verbal form (like so-called gentlemen's agreements)[39]. Therefore, an exchange of correspondence or phone calls may be sufficient to establish an agreement for the purposes of Article 101 TFEU. Algorithm-driven coordination clearly falls under this definition when algorithms are used to implement or monitor a prior, explicit agreement between competitors. In cases like this, algorithms are just the tools for the execution of an illicit agreement. In essence, this was the case the U.S. Department of Justice brought in 2015 against David Topkins[40]. Topkins and other online sellers of posters had coordinated their prices and programmed common dynamic pricing algorithms to act according to their agreement. A similar case caught the attention of the UK Competition and Markets Authority (CMA) in 2016[41]. In that case, the CMA found that two competing online sellers of posters and frames online coordinated their pricing first manually and then using automated repricing software. Finally, the European Commission dealt with similar cases, where the undertakings in several different sectors made use of sophisticated monitoring algorithms to track resale price setting in distribution and intervene quickly in case of price reductions[42]. All

[39] F. Ghezzi, G. Olivieri, *Diritto antitrust*, Torino, 2013, Ch. III.

[40] *United States v. Topkins*, No. CR 15-00201 (N.D. Cal. 2015), available at: https://www.justice.gov/atr/case-document/file/513586/download. Last accessed 3 Dec 2020.

[41] Competition and Markets Authority, decision of 12 August 2016, case 50223 – *Online sales of posters and frames*, available at: https://assets.publishing.service.gov.uk/media/57ee7c2740f0b606dc000018/case-50223-final-non-confidential-infringement-decision.pdf. Last accessed 3 Dec 2020.

[42] EU Commission, case AT.40469 – *Denon & Marantz*, available at: https://ec.europa.eu/competition/antitrust/cases/dec_docs/40469/40469_329_3.pdf. Last accessed 3 Dec 2020; Id., case AT.40465-*Asus*, available at: https://ec.europa.eu/competition/antitrust/cases/dec_docs/40465/40465_337_3.pdf. Last accessed 3 Dec 2020; Id., case AT.40182 – *Pioneer*, available at: https://ec.europa.eu/competition/antitrust/cases/dec_docs/40182/40182_370_3.pdf. Last accessed 3 Dec 2020; Id., case AT.40181 *Philips*, available at: https://ec.europa.eu/competition/antitrust/cases/dec_docs/40181/40181_417_3.pdf. Last accessed 3 Dec 2020. Interestingly, in the *Pioneer* and *Philips* cases, the Commission found that the undertakings put in place anticompetitive agreements also to neutralize the 'pro-competitive' effects of pricing algorithms: the undertakings would deal with the lowest pricing retailers to avoid the possibility that the other retailers would automatically adjust their prices through their pricing algorithms (so-called spiders).

these applications of pricing algorithms are fundamentally unproblematic since they are ancillary to autonomous illicit agreements, which fall under the prohibition of Article 101 TFEU.

Things get trickier when pricing algorithms act in lack of a prior explicit agreement among competitors. As shown below, scholars proposed different ways to tackle such (more subtle) forms of algorithmic collusion through an alternative doctrine under Article 101 TFEU, i.e. the concerted practice doctrine. According to the European Court of Justice (ECJ) case law[43], a concerted practice is in place when two or more undertakings co-operate informally, in lack of any agreement. This notion allows competition authorities to deal with practices that do not represent an agreement but replace competition with co-operation between competitors.

In principle, parallel behaviours among different undertakings may signal a concerted practice. This may be the case when algorithms of competing firms fix prices or other trading conditions. Naturally, rational adaptation to changes in market condition is not *per se* unlawful. Since parallel conducts are usually normal in the marketplace, courts held that these amount to an anticompetitive infringement if they are accompanied by so-called 'plus factors' that indicate that such a parallelism is due to a 'conscious coordination' between competing firms, rather than to a unilateral adaptation to changing market conditions. The plus factors *par excellence* include exchanges of strategic information, which replaces the uncertainty of market-based competition with forms of coordination between competitors[44].

Algorithms may perform this strategic information exchange function through several different means, e.g. the use of the same pricing algorithms by competitors, the hub and spoke scenario or a signalling strategy[45]. However, to be considered as plus factors indicative of a tacit collusion, algorithms must enable 'conscious coordination'. While algorithms do not have any form of consciousness, their code ultimately reflects the intent of the programmer and user to create coordination. This plainly applies to algorithms that include coordination-facilitating elements, i.e. algorithms where the anticompetitive strategy is written in their code (expected coordination)[46]. Accordingly, competition law liability

[43] ECJ, 4 Jun 2009, case C-8/08, *T-Mobile Netherland B.V. v Raad van Bestuur*, para 23; ECJ, 14 Jul 1972, case C-48/69, *Imperial Chemical Industries Ltd v Commission*, paras 64-65.

[44] A. Albors-Llorens, *Horizontal Agreements and Concerted Practices in EC Competition Law: Unlawful and Legitimate Contacts between Competitors*, in *The Antitrust Bulletin*, 2006, 51(4), pp. 837-876. doi: https://doi.org/10.1177/0003603X0605100404.

[45] P.G. Picht, G.T. Loderer, *Framing algorithms: competition law and (other) regulatory tools*, in *World Competition*, 2019, 42(3), pp. 403-404.

[46] M.S. Gal, *Algorithms as Illegal Agreements*, in *Berkeley Technology Law Journal*, 2019, Vol. 34, pp. 67 ff.

could be established when companies adopt algorithms that, based on an expert's examination, actually support supra-competitive prices[47].

More complex is the case of algorithms based on Machine Learning. These are not programmed to act in a certain way. Rather, they are programmed to achieve a general purpose (e.g. maximise profits) but autonomously determine the means to achieve that purpose via self-learning. This may lead the algorithm to adopt a strategy of conscious parallelism (learned coordination). Coordination here is not the result of human conscious decisions but rather the outcome of an autonomous agent. Some scholars[48] claim that, in any case, programmers retain a certain degree of control over the algorithm and, in particular, they can prevent the algorithm from producing such outcomes. Therefore, albeit a Machine Learning algorithm creates anticompetitive coordination independently, this is ultimately the result of conscious human acts[49]. It can be reasonably argued, however, that, in terms of consciousness, one thing is to deliberately program an algorithm to create coordination and another thing is not to foresee and prevent all the possible ways in which an autonomous agent may create such outcomes. This is at the basis of the so-called Paradox of Proof: algorithms «make it easier to coordinate, and at the same time make it more difficult to prove the existence of an explicit agreement given that explicit inter-firm communication may be less essential. This suggests that, while the danger of harm might increase, it might also be less likely to find strong evidentiary inferences of an agreement»[50].

The OECD, therefore, called for a "new definition" of agreement to reduce uncertainty and address the potential algorithm-related competition concerns in digital markets[51]. The proposals of the OECD are essentially two-fold. On the one hand, the traditional concept of plus factors could be refined using economic analysis as an evidentiary tool. For instance, although information is not exchanged, companies always setting the same prices as the market leader could amount to a plus factor indicative of a tacit collusion[52]. On the other hand, the concept of anticompetitive agreement could be reformulated according to

[47] J.E. Harrington, Jr., P.T. Harker, *Developing Competition Law for Collusion by Autonomous Price-Setting Agents*, 22 August 2017, available at: https://ssrn.com/abstract=3037818 or http://dx.doi.org/10.2139/ssrn.3037818. Last accessed 3 Dec 2020.

[48] M.S. Gal, *Algorithms as Illegal Agreements*, cit.

[49] The argument that programmers cannot control pricing algorithms because they are 'black boxes' is rejected by F. Beneke, M.O. Mackenrodt, *Artificial Intelligence and Collusion*, in *IIC – International Review of Intellectual Property and Competition Law*, 2019, vol. 50, pp. 109-134, doi: 10.1007/s40319-018-00773-x: «Firms that offer AI-powered pricing software solutions have developed their products so as to make the predictions transparent. This is because of the fact that the users of the software value the market insights they can derive from the prediction».

[50] M.S. Gal, *Algorithms as Illegal Agreements*, cit., pp. 67 ff.

[51] OECD, *Algorithms and Collusion – Background Note by the Secretariat*, cit.

[52] M. Filippelli, *Il problema dell'oligopolio nel diritto antitrust europeo: evoluzione, prospettive e implicazioni sistematiche*, in *Rivista delle Società*, 2018, pp. 567 ff.

modern game theory to include tacit collusion, assessing the overall market behaviour of the undertakings[53].

The issue of algorithmic collusion has also been the subject of the European Commission public consultation on the New Competition Tool (NCT), which strives to improve EU competition law rules[54]. While a number of contributors claim that existing competition law enforcement can adequately address algorithmic pricing, others put forth several different proposals to better tackle this issue, including «clarifying how and to what extent the parallel use of algorithms can lead to collusive outcomes when there is no prior or ongoing contact between firms»[55].

It is worth noting that facilitating the proof of algorithmic collusion would not practically result in an outright prohibition of pricing algorithms. This is because, under certain conditions, companies are entitled to obtain an individual exemption under Article 101(3) TFEU if, in essence, the algorithmic collusion:

1. Ensures efficiency gains that offset its anticompetitive effects.
2. Allows consumers a fair share of the resulting benefits.
3. Is indispensable to obtain such objectives.
4. Does not eliminate competition in respect of a substantial part of the relevant market.

This was confirmed by the Luxembourg Competition Authority in the *Webtaxi* case of 2018[56]. On that occasion, the Luxembourg Competition Authority found that the prices algorithmically set by a platform bridging users and taxi drivers amounted to a horizontal cartel among competitors. However, such price-fixing agreement was exempted because it produced not only efficiency gains (in terms of reduced empty runs and wating times) but also benefitted consumers (in terms of price reductions). The Competition Authority also found that such benefits could not be obtained but through the price-fixing algorithms of the platform.

4.2. Algorithmic collusion as a collective abuse of dominant position (Article 102 TFEU)

In light of the difficulties inherent in enforcing Article 101 TFEU, and waiting for innovative regulatory or competition law tools to be developed, we contend that, as a complementary

[53] Id.

[54] See https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12416-New-competition-tool/public-consultation. Last accessed 3 Dec 2020.

[55] See *Contributions*, available at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12416-New-competition-tool/public-consultation. Last accessed 3 Dec 2020.

[56] Conseil de la Concurrence du Grand-Duché du Luxembourg, 7 June 2018, case 2018-FO-01 – *Webtaxi – Marché de la réservation préalable des taxis*, available at: https://concurrence.public.lu/dam-assets/fr/decisions/ententes/2018/decision-n-2018-fo-01-du-7-juin-2018-version-non-confidentielle.pdf. Last accessed 3 Dec 2020.

path, the prohibition of abuse of dominant position under Article 102 TFEU[57] could help tackle certain types of algorithm-driven tacit collusion. Article 102 TFEU provides that:
Any abuse by one or more undertakings of a dominant position within the internal market or in a substantial part of it shall be prohibited as incompatible with the internal market in so far as it may affect trade between Member States.
Any dominant position refers to a certain reference market. The latter notion was first introduced by the case law of the ECJ[58], and was then considered by a European Commission Communication[59]. This Communication, followed by the subsequent ECJ case law[60], states that the relevant market is made up of two different dimensions: the product market and the geographic market. The former includes all goods and services that are interchangeable by consumers. The latter consists of the area in which the good or service is marketed, provided that competitive conditions are comparable.
An undertaking holds a dominant position in the relevant market when it has market power, i.e. is able to behave independently of competitors and consumers because these latter do not provide competitive constraints on the former[61]. Competition authorities usually assess market power by referring to such variables as concentration ratios, market shares, or profit margins[62]. In digital markets, however, firms constantly create and reshape markets. This makes the traditional approach unsuitable. Since digital markets continuously change nature, market power cannot be based exclusively on high markets shares because newcomers often challenge incumbents. This, however, does not necessarily imply that first comers have no market power. Since dominance is the ability of behaving independently, based on existing competitive constraints, competition authorities should assess the strength of these latter, such as buying and selling power, the degree of vertical integration, and the level of entry barriers[63]. Alternative sources of market power might include data and analytical capacity. These variables may help identify potential competitors, as well as the competitive pressure that might come more from disruptive entry and innovation[64].

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[57] F. Ghezzi, G. Olivieri, *Diritto antitrust*, cit.

[58] ECJ, 9 Nov 1983, C-322/81, *Michelin v Commission*, in *Racc.*, 1983, p. 3461.

[59] EU Commission, *Notice on the definition of relevant market for the purposes of Community competition law*, in *Off. Bull. EC*, C 372, 9 Dec 1997, p. 5.

[60] ECJ, 16 May 2000, C-344/98, *Masterfood HB v Commission*; in *Racc.*, 2000, p. 11369; ECJ, 24 Oct 2002, C-82/01, *Aéroport de Paris v Commission*, in *Racc.*, 2002, p. 9297; ECJ, 15 Feb 2005, C-12/03, *Commission v Tetra Laval*, in *Racc.*, 2005, p. 987; ECJ, 14 Oct 2010, C-280/08, *Deutsche Telekom v Commission*, in *Racc.*, 2010, p. 9555.

[61] ECJ, 14 Feb 1978, C-27/76, *United Brands Company and United Brands Continental BV v Commission*, in *Racc.* 1978, p. 207, n. 65.

[62] *Commission notice on the definition of relevant market for the purposes of Community competition law,* in *Off. Bull.* EC, C 372, 9th December 1997, p. 5.

[63] A. Streel, P. Larouche, *Disruptive Innovation and Competition Law Enforcement*, in *SSRN Electronic Journal*, 2015, available at: 10.2139/ssrn.2678890. Last accessed 3 Dec 2020.

[64] Id.

Holding a dominant position is not *per se* illegal. Article 102 TFEU only prohibits its abuse, e.g. by setting unfair prices, limiting production, or refusing to innovate to the detriment of consumers. Business behaviours that would be fully legitimate under competitive conditions could be sanctioned under competition law if carried out by a dominant undertaking. This is why dominant undertakings are said to have a "special responsibility"[65].
As the EU Court of First Instance (CFI) held in the case *Società Italiana Vetro SpA, Fabbrica Pisana SpA and PPG Vernante Pennitalia SpA v Commission* (1992), two or more independent, competing firms share a collective dominant position when, in a specific market, they are united by such 'economic links' as, for instance, agreements or licenses granting them a technological lead[66].
Therefore, for a collective dominant position to arise, three cumulative conditions must be met:

1. the competing companies are independent economic and legal entities;
2. they share market power; and
3. they are united by economic links enabling strategic alignment.

Modern economic theories about monopolies and game theory underline that, in a market with certain characteristics, such as transparency and high entry barriers, companies can collude in a sustainable way by simply observing and adapting to each other.
Accordingly, in the *Airtour* case[67], the CFI held that proof of tacit collusion can be given if:

1. the market is highly transparent;
2. deterrent mechanisms are available ensuring that collusion is sustainable; and
3. there are no external competitive pressures.

The *Airtour* conditions are the standard by which EU authorities assess the existence of a collective dominant position *ex ante* (i.e. for the purposes of mergers' control) or *ex post* (i.e. for the purposes of Art. 102 TFEU)[68].
By increasing market transparency and the speed of decision-making and retaliation, algorithms can shape a market's structure in a way that is more conducive to tacit collusion.

[65] ECJ, 9 Nov 1983, C-322/81, *NV Nederlandsche Banden Industrie Michelin v Commission*, in *Racc.* 1983, p. 3461, para 57.

[66] CFI, 10 Mar 1992, Joined cases T-68/89, T-77/89 and T-78/89, *Società Italiana Vetro SpA, Fabbrica Pisana SpA and PPG Vernante Pennitalia SpA v Commission*, in *European Court reports*, 1992, p. II-01403.

[67] EU Commission, 22 Sep 1999, case IV/M. 1524, *Airtours/First Choice*, paras 54-55.; CFI, 6 Jun 2002, case T-342/99, *Airtours plc v Commission*, para 62.

[68] EU Commission, *Guidelines on the assessment of horizontal mergers under the Council Regulation on the control of concentrations between undertakings*, *OJC 31, 5.2.2004*, available at: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A52004XC0205%2802%29. Last accessed 3 Dec 2020.

They can increase transparency and enable immediate retaliation to any deviation from collusion. If the market has high entry barriers, parallel conducts between jointly dominant undertakings can amount to a collective abuse.

The main advantage of framing tacit collusion as a collective dominant position rather than a concerted practice is that the former is a purely objective notion, which does not require proof of intention nor consciousness, whereas the latter requires that a meeting of minds or a conscious co-operation between firms is shown. This proposal, however, is no panacea. An important limitation is that it only applies to oligopolistic markets, whereas algorithmic collusion may materialise in non-oligopolistic ones as well. However, algorithmic collusion can be expected to prove particularly harmful in oligopolistic markets. In such contexts, competition authorities could rely on the doctrine of collective abuse of dominant position as an alternative to the hurdles inherent in the concepts of agreements and concerted practices. Finally, this proposal does not deprive the undertaking from the flexibilities allowed by Article 101(3) TFEU. The undertaking is still entitled to rebut an action under Article 102 TFEU by invoking prevailing pro-competitive effects[69].

4.3. Incentivising 'compliant-by-design' algorithms and monitoring systems

As algorithms become increasingly autonomous, they will replace humans in making an increasing number of key business decisions. The OECD claims that this might question the competition law liability of the entities using algorithms since the link between principal (human) and agent (algorithm) is weak[70].

As early scholarly studies on algorithmic collusion[71] pointed out, the shift from human price-setting to automated price-setting challenges the very foundations of competition law. Competition law relies on the "anthropomorphic concepts" of intent and agreement, which makes it hard to categorize the dynamics of automated price-setting. Also, algorithms are not just tools in the hands of human agents: they can act and set prices autonomously. This raises the question of whether human agents should be liable for actions taken by autonomous agents. Proactive sector regulation, such early studies contend[72], may therefore be best suited to address the competitive concerns arising from algorithmic pricing.

However, it can be reasonably argued that a principle of functional equivalence should apply. If algorithms become ever more similar to humans thanks to AI developments, the company using them can be held liable for algorithm-caused anticompetitive infringe-

[69] ECJ, 27 Mar 2012, C-209/10, *Post Danmark A/S v Konkurrencerådet*, paras 41 ff.

[70] OECD, *Algorithms and Collusion – Background Note by the Secretariat*, cit.

[71] S.K. Mehra, *Antitrust and the Robo-Seller: Competition in the Time of Algorithms*, in *Minnesota Law Review*, 2016, 100, pp. 1323 ff.

[72] Id.

ments, to the same extent it can be responsible for the infringements provoked by a human agent. In fact, for an entity to be liable for a competition law violation there is no need to show that such a violation depended on a factor that was under the full, deterministic control of the company's legal representatives. Generally, any infringement in favour of the company might be relevant, whether it depends on human or informatic resources thereof. This might induce undertakings to do everything possible to use algorithms that are compliant by design with competition law and monitor their functioning to proactively prevent and promptly detect antitrust infringements. For instance, algorithms could be programmed to take into account average prices in the industry while neglecting price changes set by individual firms[73].

Competition law also offers additional tools to prevent anticompetitive infringements. These tools might ease the design and adoption of algorithms that stay clear from competition law issues. First, an increasing number of jurisdictions are implementing antitrust compliance programs, under which firms adopting programs to ensure compliance with competition law are granted a reduced sanction. National Competition Authorities grant a reduction of the fine to companies that implement adequate compliance programs before an investigation is started. This may represent an additional incentive for firms to use competition-law-compliant algorithms, e.g. by implementing auditing mechanisms for algorithms.

Secondly, commitments under Article 9, Regulation n. 1/2003 can facilitate the end of a competition law violation. Once an investigation has started, companies can conclude an agreement with the competent authority under which the former commit to ceasing a certain conduct to avoid suspicion of a competition law infringement. Commitments might include the reprogramming or substitution of the algorithms used by the undertaking.

Finally, algorithms could also be used to ease the detection of algorithmic collusion.[74] For instance, algorithms can help determine if, in lack of transparency of the undertaking's competitors' algorithms, the market equilibrium would have been at such a high level[75]. The EU Commission has considered this strategy. The Commissioner Vestager stated that «we would like to have our own algorithms to be out there, looking into the market, figuring out if there has been collusion taking place»[76].

[73] Id., p. 49. «Recent developments in Europe seem to indicate a similar movement to make algorithms more transparent and accountable for law infringements. In a recent speech at the Bundeskartellamt, the EU Commissioner Vestager (2017) stated that businesses have the obligation of programming algorithms to deliberately comply with data protection and antitrust laws, which can be denominated as 'compliance by design'» (Id., p. 46).

[74] A. Capobianco, A. Nyeso, *Challenges for Competition Law Enforcement and Policy in the Digital Economy*, cit.

[75] M.S. Gal, *Algorithms ss Illegal Agreements*, cit.

[76] F.Y. Chee, *EU considers using algorithms to detect anti-competitive acts*, in *Reuters*, 4 May 2018, available at: https://www.reuters.com/article/us-eu-antitrust-algorithm/eu-considers-using-algorithms-to-detect-anti-competitive-acts-idUSKBN1I5198. Last accessed 3 Dec 2020.

5. The role of civil liability

Competition law has two major limitations. First, it does not compensate damages. Secondly, competition authorities cannot exercise an all-encompassing control on the market, given the high costs of information generally imposed on centralized agencies. This is especially true in digital markets, where infringements of competition law can be both *discreet*, i.e. difficult to detect, and *discrete*, i.e dispersed over the market. Civil liability rules could fill these gaps of competition law. Civil liability has a reparatory function and can support the deterrent effects of antitrust sanctions.

Competition law does not compensate the pecuniary damages suffered by consumer because of an anticompetitive behaviour. This is civil liability's job. National competition legislations consider antitrust violations as civil wrongs entitling injured parties to compensation[77]. This kind of provisions could not be effectively enforced due to the difficulties inherent in the burden of proof. Yet, Directive 2014/104/EU promises to empower plaintiffs *vis-à-vis* those responsible for anticompetitive violations. As for damages, the directive addresses two main issues.

On the one hand, it describes damages in terms of *damnum emergens* (economic loss) and *lucrum cessans* (loss of profits) plus interests, while stating that «full compensation shall place a person who has suffered harm in the position in which that person would have been, had the infringement of competition law not been committed» (Article 3, n. 2, Directive 2014/104/EU). Therefore, punitive damages as well as any other forms of overcompensation are prohibited (Article 3, n. 3, Directive 2014/104/EU).

On the other hand, Art. 4 of the Directive provides that «Member States shall ensure that all national rules and procedures relating to the exercise of claims for damages are designed and applied in such a way that they do not render practically impossible or excessively difficult the exercise of the Union right to full compensation for harm caused by an infringement of competition law» (effectiveness principle).

Accordingly, upon the request of plaintiffs, judges can order the defendant or third parties to disclose relevant evidence (Article 5, n. 1). Moreover, Article 17(1) of the Directive provides that national courts shall have the power «to estimate the amount of harm if it is established that a claimant suffered harm but it is practically impossible or excessively difficult precisely to quantify the harm suffered on the basis of the evidence available». Eventually, national courts can ask for assistance from national competition authorities (Article 17, n. 3). In quantifying relevant damages, the competent authority ought to compare the real situation with a non-infringement scenario, with an estimation of a reference non-infringement price.

[77] In Italy, see Cons. Stato, sez. VI, 12 Feb 2014, n. 693, in *Rass. dir. farmaceutico*, 2014, p. 336; G: Alpa, *Appunti sul divieto di abuso del diritto in ambito comunitario e sui suoi riflessi negli ordinamenti degli Stati membri, in questa rivista*, 2015, p. 245); in Germany, see par. 33, Wettbewerbsbeschränkungen, 2005; in the UK, see Art. 47a, Competition Act, 1998.

Once a competition authority finds an infringement, plaintiffs can use its decision to claim damages in follow on actions. In fact, under Article 16, reg. (EC) n. 1/2003, «when national courts rule on agreements, decisions or practices under Article 81 or 82 of the Treaty [now Articles 101 and 102] which are already the subject of a Commission decision, they cannot take decisions running counter to the decision adopted by the Commission». This way, damages can magnify the deterrent effects of antitrust sanctions.
At the same time, Directive 2014/104 promises to facilitate the private enforcement of EU and national competition law in the form of stand-alone civil actions. The new legislation gives the parties the right to ask the judge to order the defendant or a third «to disclose relevant evidence which lies in their control», provided that the claimant «has presented a reasoned justification containing reasonably available facts and evidence sufficient to support the plausibility of its claim for damages» (Article 5(1), Directive 2014/104 EU). Under Article 8(2), Directive n. 2014/104, the parties that do not comply with the judicial order of disclosure may be subject to «the possibility [for the judge] to draw adverse inferences, such as presuming the relevant issue to be proven or dismissing claims and defences in whole or in part, and the possibility to order the payment of costs». These provisions are intended to make it easier for the public to prove both discrete and discreet violations of the competition law and obtain compensation. Such a widespread and bottom-up control of anti-competitive conducts can also usefully complement the centralised control by the Commission and national authorities, which are burdened with substantial information costs. Private enforcement actions may attract the attention of the antitrust authorities, giving rise to investigations following the initiatives of individuals.

6. Conclusions

Recent theoretical and empirical research suggest that algorithms could facilitate tacit collusion. Tacit collusion inhabits a grey area between anticompetitive agreements, which are prohibited, and mere market parallelism, which is perfectly normal in a competitive market. Both scholars and policymakers question the suitability of existing competition law rules (particularly Article 101 TFEU) to tackle algorithmic collusion.
While current policy initiatives, such as the Commission's NCT initiative start considering the need for regulatory and competition law innovations to better tackle algorithm-driven collusion, this article proposes to use, as an alternative to Article 101 TFEU, the purely objective notion of collective abuse of dominant position under Article 102 TFEU. This way, competing firms holding a collective dominant position in the relevant market, which is transparent and has high entry barriers, could catch the attention of competition authorities if they use pricing algorithms and show parallel conducts. As a result, firms operating in digital markets would be incentivised to use algorithms that steer clear from competition law infringements, as well as to implement adequate monitoring systems. Compliance programs and commitments could also provide such an incentive.

Finally, civil liability actions can complement the intervention of competition authorities in several ways in relation to algorithmic collusion. First, damages compensation may strengthen the deterrent effect of antitrust pecuniary sanctions. Secondly, private enforcement actions, facilitated by recent reforms, may trigger public authorities' investigations, helping these latter detect algorithm-driven competition law infringements, which are both discreet and discrete.

Digital Single Market Copyright Directive: Making (Digital) Room for Works of Visual Art in the Public Domain

Marta Arisi*

Abstract

Establishing that Member States shall provide that any material resulting from an act of reproduction of works of visual art in the public domain is not subject to copyright or related rights, unless the material is original, art. 14 of the Digital Single Market Copyright Directive aims to promote the wider access and circulation of cultural contents. The realization of its objective in the digital and cross-border dimension is ambitious, as it requires extensive harmonization. This proves difficult not only because of some ambiguities that characterize the norm and primarily, amongst those, the absence of a definition of works of visual art, but most of all for the complex juridical scenario evoked: art. 14 stands at the interplay of the Copyright law and, possibly, other norms belonging to different domains, depending on the peculiarities of each Member State. While affirming that art. 14 shall be welcomed as a needed, if not definitive, passage towards further legal certainty, this

* Graduated from University of Trento, Faculty of Law. A special thanks goes to Heike Koehler and Berenike Salome Jacob for helping me with the translations of recent documents related to the implementation of DMS Copyright Directive from German to Italian. All the errors remain my own. All links were last visited as of the 15th of November 2020.

contribution tries to give account of the present challenges, with special focus on related rights in photographs and analysing the German and Italian on-going transposition efforts.

KEYWORDS

Art. 14 Digital Single Market Copyright Directive – Public domain – Reproduction – Works of visual art

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Introducing Article 14 of the Digital Single Market Copyright Directive

The art. 14 of the Directive (EU) 2019/790 for Copyright in the Digital Single Market (also "DSM Copyright Directive" in the text)[1] introduces a new rule for the reproductions of works of visual art in the public domain.

The Directive is primarily aimed at advancing harmonization in the Digital Single Market, with special regards to cross-border circulation of online contents[2]. It represents the

[1] Directive (EU) 2019/790 of the European Parliament and of the Council on copyright and related rights in the Digital Single Market and amending Directives 96/9/EC and 2001/29/EC, 17 April 2019, available at <https://eur-lex.europa.eu/eli/dir/2019/790/oj>.

[2] Recitals n. 1 e n. 3 of DSM Copyright Directive further explain the objective of harmonization in the Digital Single Market. See also the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, *A Digital Single Market Strategy for Europe*, 6 May 2015,

outcome of a long cumbersome legislative path. This started with the first Commission's proposal in early September 2016[3], and became soon one of the most controversial and discussed legislative journey in the history of the European Union[4].

The set of exceptions and limitations of the European Copyright acquis, on which the Information Society Directive (also "InfoSoc Directive" in the text) had previously intervened exercising horizontal effects[5], is dramatically renovated. This contends the evolving complex role of exceptions and limitations in the EU Copyright Law[6]. Especially in the digital environment, exceptions and limitations are framed according to well-known tensions and represented as incidental derogations to exclusive rights or, in contrast, as affirmations of the interests of online users[7].

The Directive caught the strongest attention world-wide, causing major debate about the significance of freedom of expression and censorship in the web space. Most conspicuous interest has been dedicated to articles 15 and 17, respectively dealing with the novel

available at <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52015DC0192&from=EN>, and Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, *Towards a modern, more European copyright framework*, the 9th of December 2015, available at <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52015DC0626&from=EN>.

[3] Proposal for a Directive of the European Parliament and of the Council on copyright in the Digital Single Market, 14 September 2016, available at <https://ec.europa.eu/digital-single-market/en/news/proposal-directive-european-parliament-and-council-copyright-digital-single-market>.

[4] A beneficial timeline is available from CREATe, EU Copyright Reform, last updated on the 26th of March 2019, available at <https://www.create.ac.uk/policy-responses/eu-copyright-reform/>. It was observed the consistent application of trilogues, operating procedures for reaching agreements between the European Commission, European Parliament, and the Council of the EU during the legislative process. See European Parliament decision on the conclusion of the Joint Declaration on practical arrangements for the co-decision procedure, the 22nd of May 2007, available at <https://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P6-TA-2007-0194+0+DOC+XML+V0//EN>.

[5] Directive 2001/29/EC of the European Parliament and of the Council on the harmonisation of certain aspects of copyright and related rights in the information society, 22 May 2001, available at <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32001L0029. See in particular art. 5>.

[6] The literature on the point is vast. See C. Sganga, *A new era for EU copyright exceptions and limitations? Judicial flexibility and legislative discretion in the aftermath of the Directive on Copyright in the Digital Single Market and the trio of the Grand Chamber of the European Court of Justice,* in *ERA Forum* 21, pp. 311-339, 2020, available at <https://doi.org/10.1007/s12027-020-00623-9>; J.P Quintais., *The New Copyright in the Digital Single Market Directive: A Critical Look*, in *European Intellectual Property Review*, 1, 2020, pp. 4-7, available at <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3424770>, also referring to J.P. Quintais, *Copyright in the Age of Online access - Alternative compensation Systems in EU Law*, The Netherlands, 2017, pp. 151-243 and M.C. Janssens, *The issue of exceptions: reshaping the keys to the gates in the territory of literary, musical and artistic creation,* in E. Derclaye (ed.), *Research Handbook on the Future of EU Copyright,* Cheltenham, 2009. On the possibility to read exceptions under the notion of a social function clause in EU Copyright Law see C. Sganga, *Propertizing European Copyright*, Cheltenham, 2018, pp. 250-252.

[7] F. Mezzanotte, *Le «eccezioni e limitazioni» al diritto d'autore UE (parte II: Le libere utilizzazioni nell'ambiente digitale)*, in *AIDA*, 2017, pp. 301-302. For a more general overview, *ibidem*, 303-308. The debate around exceptions and limitations of EU Copyright Law in the digital environment and the possibility of a users' right approach also frequently crosses the US doctrine of fair use in a comparative key. See, inter alia, R. L. Okediji (ed.), *Copyright Law in an Age of Limitations and Exceptions*, Cambridge, 2017.

press publishers' right (also renowned as the "link tax") and the use of protected content by online sharing services providers[8].

However, what is of interest for our purposes is the EU Legislator's effort to promote wider access to cultural content, and to enhance the role of cultural heritage institutions, with a remarked attention to the increasingly digital practices[9]. This paper focuses on the revolutionary impact of art. 14 of the DSM Copyright Directive: shading light on the possibility to reproduce works of visual art in the public domain, it moves towards the flourishing of open culture.

The norm affirms that, with regards to works of visual art for which the copyright has expired – namely, works belonging to the public domain – any material resulting from an act of reproduction shall not be subject to copyright or related rights. This is unless the material is original, hence it represents the author's own intellectual creation. Recital 53 guides the reading of the norm, clarifying its context and objective, plus it introduces the reference to the *faithful* character of the reproductions and to the possibility for museums to sell postcards, which remains intact.

The article and the recital were only added at a later stage in the text[10], but part of the article was already present as a final addition to *ex* art. 5, now art. 6. This is a mandatory exception aimed at enhancing digitisation processes for preservation of cultural heritage[11].

[8] For an overview, see S. Stalla-Bourdillon, E. Rosati, K. Turk, C. Angelopoulos, A. Kuczerawy, M. Peguera, M. Husovec, *A Brief Exegesis of the Proposed Copyright Directive*, 2016, available at <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2875296>. Focusing on the distributive rationale in the reform see G. Priora, *Catching sight of a glimmer of light: Fair renumeration and the emerging distributive rationale in the reform of EU Copyright Law,* 10 JIPITEC, 330, 2019, available at <https://www.jipitec.eu/issues/jipitec-10-3-2019/5043>.

[9] For an overview, see J. Keller, *Explainer: What will the new EU copyright rules change for Europe's Cultural Heritage Institutions,* in Europeana Pro Blog, 9June 2019 (adjourned as of November 2019), available at <https://pro.europeana.eu/post/explainer-what-will-the-new-eu-copyright-rules-change-for-europe-s-cultural-heritage-institutions>. Next to the already mentioned art. 6, Articles 8 and 9 concern the use out-of-commerce works, for which see R. Tryggvadoittir, *The EU proposal to ensure wider access to content in cultural heritage institutions*, in CiTiP Blog, 24 October 2017, available at <https://www.law.kuleuven.be/citip/blog/the-eu-proposal-to-ensure-wider-access-to-content-in-cultural-heritage-institutions/>. About art. 12, foreseeing a mechanism for collective licensing with an extended effect that may be of useful application within the cultural heritage management, see J. Axhamn, *The New Copyright Directive: Collective licensing as a way to strike a fair balance between creator and user interests in copyright legislation (Article 12),* in CiTiP Blog, 25 June 2019, available at <http://copyrightblog.kluweriplaw.com/2019/06/25/the-new-copyright-directive-collective-licensing-as-a-way-to-strike-a-fair-balance-between-creator-and-user-interests-in-copyright-legislation-article-12/>. art. 3 is also seminal for cultural institutions, as they are included as the subjects who may perform text and data mining activities in the sense of the Directive – namely the extractions and reproductions of copyrighted works for the purposes of scientific research, provided they have lawful access and the fulfilment of the conditions set by art. 4: see R. Caso, *Il conflitto tra diritto d'autore e ricerca scientifica nella disciplina del text and data mining della direttiva sul mercato unico digitale*, in *Trento Law and Technology Research Group*, Research Paper n. 38, 2020, available at <https://zenodo.org/record/3648626#.X5WmKy9aab8>. Finally, art. 5 impacts the cultural heritage institutions as it introduces the possibility of the digital use of copyrighted works (and other subject matter) for the sole purpose of illustration for teaching.

[10] Art. 14 and recital 53 were introduced as art. 10b and recital 30a during the revision of the text that took place in the final trilogues between the European Parliament, Council and Commission. See Proposal for a Directive of the European Parliament and of the Council on copyright in the Digital Single Market, Working Paper, the 16th of February 2019, available at <https://www.europarl.europa.eu/meetdocs/2014_2019/plmrep/COMMITTEES/JURI/DV/2019/02-26/Copyright-AnnextoCOREPERletter_EN.pdf>.

[11] The addition was the result of the first revision of the Commission's proposal by the European Parliament. See the amendments adopted by the European Parliament on the proposal for a directive of the European Parliament and of

The bond with art. 6 confirms that art. 14 addresses the subject of public domain to promote the dissemination of cultural content. A choice was eventually made to give public domain explicit recognition in a new provision of autonomous significance[12].
The original text of art. 14 proposed by the Parliament broadly referred to reproductions of (all) materials in the public domain[13], while the scope was later narrowed to works *of visual art* only. Nonetheless, the introduction of art. 14 still indicates a powerful turn in the challenge for the online dissemination of cultural contents in the EU, within the broader narrative on copyright social function and the promotion of cultural rights[14].
Public domain is a key element of the movement for a more open culture[15]. The lack of adequate resources to correctly identify works in the public domain[16] and legal uncertainty around their use are obvious obstacles to their circulation – which shall be immensely empowered in the digital environment, especially on the Internet. With regards to Copyright Law, art. 14 represents the opportunity to enhance legal certainty[17] and it welcomes the appeal of scholars, activists and users that what is in the public domain shall be in the public domain in the digital environment as well[18].

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the Council on copyright in the Digital Single Market, the 12nd of September 2018, available at: https://www.europarl.europa.eu/doceo/document/TA-8-2018-0337_EN.html. art. 6 prescribes Member States to allow cultural heritage institutions to make copies of any work (or other subject matter) that is permanently in their collections, in any format or medium, for purposes of preservation, to the extent necessary for such preservation.

[12] J.P. Quintais, *cit*., p. 15, p. 22.

[13] As evidenced by the analysis of A. Giannopoulou, *The New Copyright Directive: Article 14 or when the Public Domain Enters the New Copyright Directive*, in *Kluwer Copyright Blog*, 27 June 2019, available at <http://copyrightblog.kluwerilaw.com/author/agiannopoulou1/>.

[14] For a study framing cultural rights within Human Rights Law and Intellectual Property see C. Sganga, *Right to Culture and Copyright: Participation and Access*, in C. Geiger (ed.), *Research Handbook on Human Rights and Intellectual Property,* Cheltenham, 2015, pp. 560-576, (also available at <https://ssrn.com/abstract=2602690>).

[15] Public domain as a central element for the promotion of culture is well represented in the literature. See J. Boyle, *The Public Domain: Enclosing the Commons of the Mind,* New Haven, 2008, available at <http://www.james-boyle.com>. On the digital environment, see M. Dulong de Rosnay, J.C. De Martin (Eds.), *The Digital Public Domain – Foundations for an Open culture*, OpenBook Publishers, Cambridge, 2012, available at <https://www.openbookpublishers.com/product/93>. For an interesting perspective, with attention to historical developments, see G. Frosio, *Reconciling Copyright with Cumulative Creativity – The third paradigm*, Cheltenam, 2018.

[16] K. Petraszova, *Building on IPR knowledge exchange in the cultural heritage sector,* in *inDICEs Project*, 19 October 2020, available at <https://indices-culture.eu/building-on-ipr-knowledge-exchange-in-the-cultural-heritage-sector/>.

[17] See recital 53, where it states: «In addition, differences between the national copyright laws governing the protection of such reproductions give rise to legal uncertainty and affect the cross-border dissemination of works of visual arts in the public domain (...)». As noted by A. Giannopoulou, *cit*., both in the European Parliament's press release *Digital Single Market: EU negotiators reach a breakthrough to modernise copyright rules*, 13 February 2019, available at <https://ec.europa.eu/commission/presscorner/detail/en/IP_19_528>, and the European Commission's Memo n. 1849, *Questions and Answers – European Parliament's vote in favour of modernised rules fit for digital age*, the 26th of March 2019, available at <https://ec.europa.eu/commission/presscorner/detail/en/MEMO_19_1849>, the reference to legal certainty is explicit. As it is possible to read the latter: «Thanks to this provision, all users will be able to disseminate online with full legal certainty copies of works of art in the public domain».

[18] See for instance COMMUNIA, Policy Recommendations, available at <https://www.communia-association.org/recommendations/>, Public Domain Manifesto, available at <https://publicdomainmanifesto.org/manifesto/>, Europeana Public Domain Charter, available at <https://www.europeana.eu/en/rights/public-domain-charter>. The Policy Recommendation n.5 of COMMUNIA reads: «Digital reproductions of works that are in the Public Domain must also belong to the

However, while the aim of art. 14 may at first glance appear plain and simple – i.e. clarifying the copyright status of faithful reproductions of certain public domain works in the EU acquis – the provision evokes a complex juridical scenario. The norm stands at the interplay of several rights, where interests of authors, users and cultural heritage institutions, such as GLAM (acronym for Galleries, Libraries, Archives and Museums), are critically at stake. As captured by the literature, given the broad potential of art. 14 and the highly diversified Members States framework, its implementation requires greater efforts, and vital challenges to reach the desired further harmonization shall be tackled.
This contribution tries to give account of them, and it is organised as follows. The second section of the paper proceeds with a brief overview of the key-elements of art. 14 and recital 53, acknowledging their scope. The interplay with related rights in copyright forms a special focus and while different practices shall be affected by the implementation of art. 14 the most relevant example to understand its impact would probably be the photographs of public domain works of visual art. In the third section two examples of the on-going transposition efforts by Member States, selected for their interesting backdrops, are critically examined. The fourth section tries to outline a few considerations about the courses of action needed to transpose the provision while seeking the objective of a further harmonisation. Short conclusions follow.

1. The scope of Article 14

The present section analyses the scope of art. 14. The public domain constitutes a fundamental key to its understanding, at the core of the objective of art. 14: the valorisation of cultural heritage and the promotion of the access to culture.
On top of this, art. 14 concerns *any material* resulting from an act of reproduction of *works of visual art*, a notion to be defined. It also makes a distinction whether the material is original or not, in adherence to the increasingly harmonized originality standard in the EU acquis. The provision is addressed to the digital environment, revealing the impact on certain types of reproductions which may have online circulation. Art. 14 specifies that non-original materials shall not be protected *by copyright or related rights*.
All the mentioned elements will be analysed separately, before focusing on what seems to be one of the most interesting use-cases impacted by art. 14: photographs.

Public Domain (...)». Principle n. 2 Europeana Public Domain Charter states: «What is in the Public Domain needs to remain in the Public Domain. Exclusive control over Public Domain works cannot be re-established by claiming exclusive rights in technical reproductions of the works, or by using technical and or contractual measures to limit access to technical reproductions of such works. Works that are in the Public Domain in analogue form continue to be in the Public Domain once they have been digitised».

1.1. Works of visual art, in the public domain

The title of art. 14 is «Works of visual art in the public domain». The norm refers to any material resulting from acts of reproduction of works of visual art, *when the term of protection of the work has expired*. In explicating so, art. 14 represents the first codification of the notion of public domain[19]. As the first part of recital 53 states: «The expiry of the term of protection of a work entails the entry of that work into the public domain and the expiry of the rights that Union copyright law provides in relation to that work».

A few words must be spent on a very crucial distinction: the expression «when the term of protection has expired» could «mark a point in time from which onwards reproductions newly made would not give rise to any new rights, whereas existing rights with regard to reproductions made before that point in time would continue to exist»[20]. In the same vein, it can be asked whether works that have never benefit from copyright protection shall be covered. These doubts seem to introduce some uncertainty in the interpretation with regards to both the material scope of the norm and its application in time.

Turning to the expression *work of visual arts*, it must be kept in mind that the norm was only later narrowed to these types of works. In the current text, recital 53 seems to justify this choice, when it affirms that «In the field of visual arts, the circulation of faithful reproductions of works in the public domain contributes to the access to and promotion of culture, and the access to cultural heritage». One question that remains to be asked is why, and what can be deemed to fall into this domain.

The definition of works of visual art is not provided in the Directive. It may be looked for elsewhere in EU Copyright law. A reference is found in the Annex n. 3 of the Directive 2012/28/EU[21], as explicitly recognized by the German example of transposition (on which section 3.1 further elaborates), but it represents an open list. The Annex refers to the sources to verify the status of a work as orphan, and states that works of visual art comprise «fine art, photography, illustration, design, architecture, sketches of the latter works, and other such works that are contained in books, journals, newspapers and magazines or other works»[22].

The reference to the international framework of the Berne Convention has not proven beneficial, as such a category is missing in favour of a more analytic and detailed descrip-

[19] A. Giannopoulou, *cit.*

[20] European Copyright Society (ECS), *Comment of the European Copyright Society on the Implementation of art. 14 of the Directive (EU) 2019/790 on Copyright in the Digital Single Market,* 26 April 2020, pp. 3-4, available at <https://europeancopyrightsocietydotorg.files.wordpress.com/2020/04/ecs_cdsm_implementation_article_14_final.pdf>.

[21] Directive 2012/28/EU of the European Parliament and of the Council on certain permitted uses of orphan works, 25 October 2012, available at <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012L0028&from=EN>.

[22] In a similar fashion, see the European Commission's Memo n. 1849, *Questions and Answers – European Parliament's vote in favour of modernised rules fit for digital age*, cit.: «For instance, anybody will be able to copy, use and share online photos of *paintings, sculptures and works of art in the public domain* when they find them in the internet (...)».

tion of literary and artistic works as protected subject matter[23]. With regards to Member State law, the landscape is one of fragmentation as well, since they list works protected by copyright differently[24].
Overall, the reference remains unclear, at the overlap with different nomenclatures and categorization of works and the intuitive understanding of works of visual art as visual in fruition. This is of critical importance because the definition of works of visual art is the backbone of the material scope of the norm.

1.2. Non-original reproductions in the digital environment

In the EU copyright acquis, the right to reproduction entails to reproduction in any means or form, direct or indirect, temporary or permanent, in whole or in part. Art. 2 of the InfoSoc Directive harmonized the right to reproduction including digital practices, in line with the Agreed Statement attached to the WIPO Treaty stating that the right to reproduction fully applies in the digital environment[25].
Art. 14 explicitly stresses the relevance of the digital environment for the act of reproduction, and recital 53 appears to indicate that it is precisely here that the protection of non-original reproductions is inconsistent with the expiry of the copyright. Also, art. 14 refers to *any material* resulting from an act of reproduction, which seems to imply a further stretch and to reinforce an open approach towards the outcome of the reproduction.
Furthermore, the norm especially addresses non-original reproductions. More specifically, Member States are required to provide that the materials resulting from an act of reproduction shall not be subject to copyright or related rights, unless they are original in the sense that they are the authors' own intellectual creations.
Originality has always been a vital element differentiating copyright traditions in the EU, also linked to the justification of copyright. Its threshold has consequently proven of problematic harmonization in EU Copyright Law. The Term Directive, the Software Directive and the Database Directive harmonized the originality standard as the «author's own intellectual creation». This only realized a vertical harmonization, namely confined to the related subjects[26]. The horizontal harmonization was eventually unlocked a few years later,

[23] European Copyright Society (ECS), cit., 2. See Berne Convention for the Protection of Literary and Artistic Works Paris Act, the 24th of July 1971, as amended on 28 September 1979, art. 2: «Protected works».

[24] T.E. Synodinou., *The Foundations of the Concept of Work in European Copyright Law,* in T-E. Synodinou (ed.), *Codification of European Copyright, Challenges and perspectives*, The Netherlands, 2012, pp. 106-111.

[25] Agreed Statements concerning the WIPO Copyright Treaty, adopted by the Diplomatic Conference on the 20th of December 1996, see Agreed Statement Concerning Article 1(4).

[26] Directive 2006/116/EC of the European Parliament and of the Council on the term of protection of copyright and certain related rights, the 12nd of December 2006, available at <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32006L0116>; Directive 96/9/EC of the European Parliament and of the Council on the legal protection of databases, the 11st of March 1996, available at <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A31996L0009>; Directive 2009/24/EC of the European Parliament and of the Council on the legal protection of computer programs, of the 23rd of April 2009, available at <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32009L0024>. See T. Margoni, *The Harmonisation of EU Copyright Law: The Originality Standard*,

when the European Court of Justice gave to this notion a uniform interpretation within the InfoSoc Directive, in the *Infopaq* landmark decision of 2009[27].
At present art. 14 of the DSM Copyright Directive contains a new general reference to the «author's own intellectual creation» standard, defined by the mentioned legislative texts and confirmed by the European Court of Justice. This reference is suggested to represent the next timely step in the on-going harmonization of the concept of originality and a codification of the case law on the point[28].
At the same time, it is worthwhile noting that recital 53 mentions the circulation of *faithful* reproductions. This may introduce a degree of uncertainty in the interpretation of art. 14, as it emphasizes the documentary character of the act of reproduction. How it is possible to combine the element of faithfulness with the originality standard remains unclear. Additionally, recital 53 concludes that *certain* reproductions of works of visual art in the public domain should not be protected, confirming such room for ambiguity.

1.3. The interplay of different rights

Art. 14 requires Member States to provide that any non-original material resulting from an act of reproduction is not subject to *copyright or related rights*. Despite this linear affirmation, its meaning unfolds in multiple directions. This is also why the rule introduced by art. 14 seems difficult to be defined and framed within the set of exceptions and limitations in the DSM Copyright Directive[29]. In this regard, it must also be noted that art. 14 is part of the Title III, concerning «Measures to improve licensing practices and ensure wider access to content», but also stands out, as it constitutes the only norm of Chapter 4, entitled «Works of visual art in the public domain».
The enforcement against practices of illegitimate appropriation of copyright for public domain works, also known as copyfraud[30], is not addressed. Also, in declaring the absence of copyright or related rights, the norm makes room for different uses of the material, in-

in M. Perry (ed.), *Global Governance of Intellectual Property in the 21st Century, Reflecting Policy Through Change*, Switzerland, 2016, pp. 91-94.

[27] European Court of Justice, *Infopaq International A/S v. Danske Dagblades Forening*, C-5/08, Judgment of the Court of the 16th of July 2009, available at <http://curia.europa.eu/juris/document/document.jsf?docid=72482&doclang=EN#>. For an overview, also on criticalities, see *inter alia* T.E. Synodinou, *cit*., 97-102 and E. Rosati, *Originality in a Work, or a Work of Originality: The Effects of the Infopaq Decision,* 58 J. COPYRIGHT Soc'y U.S.A. 795 (2010); Sganga, *Propertizing European Copyright*, *cit*., 123-125.

[28] On this point A. Giannopoulou, *cit*.; E. Rosati, *DSM Directive Series #3: How far does Article 14 go?*, in *The IP Kat*, the 9th of April 2019, available at <https://ipkitten.blogspot.com/2019/04/dsm-directive-series-3-how-far-does.html>; A. Wallace, E. Euler, *Revisiting Access to Cultural Heritage in the Public Domain: EU and International Developments*, in *IIC – International Review of Intellectual Property and Competition Law*, 2020, n. 51, 838, available at: <https://ssrn.com/abstract=3575772>.

[29] This is worth future research within the debate on the evolving nature of exceptions and limitations in EU Copyright Law, on which see note 6.

[30] As noted by A. Giannopoulou, *cit*. The reference is to J. Mazzone, *Copyfraud,* Brooklyn Law School Legal Studies Paper No. 40, 2006, available at <https://ssrn.com/abstract=787244>.

cluding the commercial one[31]. Interestingly, recital 53 mentions that this shall not prevent cultural heritage institutions from *selling* reproductions, such as postcards, suggesting an impact on these particular actors and related use-cases.
Deepening into the realm of the norm, on the one hand art. 14 addresses non-original reproductions and excludes copyright. As illustrated, in doing so the norm implies to consider the increasingly harmonized standard of originality in the EU Copyright acquis, notwithstanding the same art. 14 seems to represent an essential passage in this adventurous story.
On the other hand, even though the resulting material would not be protected by copyright as original, non-original reproductions can surely be protected by neighbouring rights. Here art. 14 fundamentally addresses a subject characterized by considerable fragmentation and a lesser degree of harmonization between Member States. Thus, the reference to related rights arguably provides the decisive element to understand the impact of the norm and helps to envision its most relevant use cases, as explained in the next section 2.4.
For the sake of completeness, it shall be mentioned that the use cases addressed by art. 14 may also meet the existing exceptions and limitations of exclusive rights in EU Copyright law, and this equally points to a fragmentated horizon between Member States. Finally, from a more general perspective, other norms, belonging to different domain than copyright, may prove relevant to the same use cases and even contrast the realization of the objective of art. 14. This issue seems to be better understood by a case-by-case study of the national frameworks. In fact, it has especially emerged in the analysis of the transposition of the norm in Italy, where norms protecting the cultural heritage may limit reproductions of works of visual art in the public domain which fall into the definition of cultural goods, as highlighted in section 3.2.

1.4. Focus: on reproductions, related rights and photographs

Considering the use cases of art. 14, while photographs are worth special attention, there is a plurality of works or subject matter protected by national copyright law which could be of relevance. In the online circulation and fruition of cultural contents the reproductive potential of audio-visual contents, protected by copyright as original, and by the related right of fixation within the EU, must be considered. Similarly, 3D reproductions and works which can be accessed online represent great resources for the reproduction of, especially, artworks. These appear use case of interest, plus for their peculiar characteristics they arguably attract protection as original works[32]. Finally, the further stretch implied by art.

[31] See also the European Commission's Memo n. 1849, *Questions and Answers – European Parliament's vote in favour of modernised rules fit for digital age*, cit., stating that with art. 14 «For instance, anybody will be able to copy, use and share online photos of paintings, sculptures and works of art in the public domain when they find them in the internet and reuse them, including for commercial purposes or to upload them in Wikipedia (...)».

[32] European Copyright Society (ECS), *cit.*, 3.

14 referring to *any material* to be enjoyed by digital means suggests considering more structured works as well or contents incorporated in applications. Increasingly important media for the fruition of cultural contents take the form of a collection, with their own structure and organization, as for example databases, including multimedia works[33]. This type of works, as established by the Database Directive of 1996, may be copyrighted, but also entitle to the *sui generis right* that safeguards the efforts of compilation and organization of the overall work, without extending to its single parts[34].

With regards to photographs, their importance for the digital reproduction and fruition of contents – almost every content – is out of the question[35]. This is of special significance for promoting the access to culture, and photography also constitutes a powerful tool for the digitisation and preservation of cultural heritage[36]. In addition, as photographs are adherent means to reproduce reality but are at the same time a form of art, copyright on photographs leads to discuss the very essence of the originality standard. This is precisely the reasoning proposed in the formulation of art. 14, distinguishing original and non-original reproductions of public domain works of visual art.

Partly owing to the matter of their originality, copyright protection of photographs has proved cumbersome and fragmented since the inclusion in the Berne Convention. At that time, as a new technology, photography was not universally perceived as a mean to produce works which could be copyright subject matter. Interestingly, the Closing Protocol of 1886, while opting for a compromised solution with regards to countries where photographs would already be considered artistic works, assured protection to authorised photographs of protected works of art in all countries[37]. This provision was ruled out when a first agreement about the protection of photographic works as original was reached, within the Berlin revision of 1908. Only with the Brussels revision of 1948 photographic works and works expressed by analogous processes were included in art. 2. This resulted in the application of the character of intellectual creation to them in fully and enabled each State to apply to photographs its own standard of originality[38].

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[33] G. Finocchiaro, *La valorizzazione delle opere d'arte on-line e in particolare la diffusione on-line di fotografie di opere d'arte. Profili giuridici,* in *Aedon*, *Rivista d'arti e diritto online*, 2, 2009, available at <http://www.aedon.mulino.it/archivio/2009/2/finocchiaro.htm>.

[34] Art. 7.1 of the Database Directive states: «Member States shall provide for a right for the maker of a database which shows that there has been qualitatively and/or quantitatively a substantial investment in either the obtaining, verification, or presentation of the contents to prevent extraction and/or re-utilisation of the whole or of a substantial part, evaluated qualitatively and/or quantitatively of the contents of that database».

[35] The memo of the Commission points outs that with art. 14 anybody will be able to copy, use and share *online photos* of paintings, sculptures and works of art in the public domain. See European Commission's Memo n. 1849, *Questions and Answers – European Parliament's vote in favour of modernised rules fit for digital age*, *cit.*

[36] For a detailed study, see T. Margoni, *The digitisation of cultural heritage: originality, derivative works and (non) original photographs* 2014, available at <http://eprints.gla.ac.uk/149774/1/149774.pdf>.

[37] S. Ricketson, *International Conventions*, in Y. Gendreau, A. Nordemann, R. Oesch (eds.), *Copyright and photographs – An international Survey*, London, 1999, pp. 18-19.

[38] *Ibidem*, 22-25.

In EU Copyright law, art. 6 of the Term Directive, Directive 2006/116/EC[39], reiterates that protection of photographs as original works arises when the photographs constitute the author's own intellectual creation – the standard which is now recognised horizontal reach – excluding other criteria. Despite these results, the standard of originality for photographs has proven to be discordant, and the simplicity of a portrait was discussed in *Painer* case in 2011[40] as a potential obstacle to copyrighted pictures. In this striking decision, European Court of Justice confirmed that simplicity or realism would not be a limit.

Photographs are central to the reform brought by art. 14 also because simple photographs receive protection by neighbouring rights in a number of countries in the EU. Prominent examples are the Italian discipline of simple photographs (*fotografie semplici)* in the Law on the protection of copyright and related rights (*Legge sulla protezione del diritto d'autore e di altri diritti connessi al suo esercizio*, also "Lda" in the text)[41] and the protection of *Lichtbilder* in German Copyright law (*Gesetz über Urheberrecht und verwandte Schutzrechte, Urheberrechtsgesetz*, also "UrhG" in the text)[42]. Both are based on art. 6 of the Term Directive, which next to the protection of photographs as authors' intellectual own creations, makes room for the protection of *other photographs* by Member States, within the subject of related rights[43].

Protection of photographs reproducing public domain works was precisely contended[44] in Germany, where the *Museumsfotos* case discussed § 72 of the UrhG, and in United Kingdom, with regards to Section 4 the Copyright, Designs and Patent Act of 1988[45]. In both cases, images of paintings hold by Museal institutions were published on Wikipedia, leading the institutions which detained the work and had the photographs realized to

[39] Art. 6, entitled «Protection of photographs», states: «Photographs which are original in the sense that they are the author's own intellectual creation shall be protected in accordance with Article 1. No other criteria shall be applied to determine their eligibility for protection. Member States may provide for the protection of other photographs».

[40] European Court of Justice, *Eva-Maria Painer v. Standard VerlagsGmbH and Others*, C-145/10, Judgment of the Court (Third Chamber) of the 1st of December 2011, available at <http://curia.europa.eu/juris/document/document.jsf?text=&docid=115785&pageIndex=0&doclang=en&mode=lst&dir=&occ=first&part=1&cid=15117428>.

[41] Art. 87-92, Law on the protection of Copyright and other rights related to its exercise (*Legge sulla protezione del diritto d'autore e di altri diritti connessi al suo esercizio),* Law. n. 633, the 22nd of April 1941, as last amended by Law n. 37, 3 May 2019.

[42] § 72 Photographs (*Lichtbilder*), Act on Copyright and Related Rights (*Gesetz über Urheberrecht und verwandte Schutzrechte, Urheberrechtsgesetz*), 9 September 1965, as last amended by Article 1 of the Act of the 28th of November 2018.

[43] For an overview, see T. Margoni, *Non Original Photographs in Comparative EU Copyright Law*, in J. Gilchrist, B. Fitzgerald (eds.), *Copyright, Property and the Social Contract*, Switzerland, 2018, 157-180.

[44] With regards to Germany the reference is to the case involving Reiss-Engelhorn Museum v. Wikimedia et al., Judgment of December 20, 2018 – I ZR 104/17 – Museum photos – I ZR 104/17. For an overview on the UK context, mentioning the controversy involving the National Portrait Gallery and Wikimedia Foundation in United Kingdom see S. Stokes, *Photographing the public domain – EU to remove Copyright protection from public domain art images*, the 18th of March 2019, www.blakemorgan.co.uk, available at <https://www.blakemorgan.co.uk/photographing-the-public-domain-eu-to-remove-copyright-protection-from-public-domain-art-images/>. For the same issue as framed in the US context, the main reference is to the *Bridgeman* case, Bridgeman Art Library, Ltd. v. Corel Corp., 36 F. Supp. 2d 191 (S.D.N.Y. 1999) (final decision).

[45] Section 4 of the Copyright, Designs and Patent Act of 1988 defines photographs as artistic works, which find copyright protection according to Section 1 of the same Act.

claim copyright infringement. In both cases, the focus of the debate was the non-original character of the photographic reproduction of the paintings.
Only the German case eventually led to a decision, which confirmed the protection of the non-original reproductions according to the national Copyright law, within neighbouring rights. Conversely, despite what could be foreseen as a low threshold for originality, in 2015 a notice published by the UK Intellectual Property Office clarified that the digitised image of a work for which copyright had expired could not be considered original, pointing out to the definition of originality given in the *InfoPaq* decision[46]. As the notice reports, to make a faithful reproduction of an existing work would imply minimal room to exercise free and creative choices.
This overview brings the attention to the existing practice of GLAM in claiming exclusive rights on photographic reproductions of the public domain works they detain[47] and more in general to non-original photographs as fundamental use cases addressed by art. 14 DSM Copyright Directive. It seems possible to agree that Art. 14 may finally respond «to a controversial question, as to whether digital images of out-of-copyright works may give rise to new copyright claims and, thus, in a way affect the public domain status of the underlying work»[48]. It is arguably clear that art. 14 would trigger a change for those Member States which protect non-original photographs when it comes to the protection of public domain works of visual art. This discourse proceeds in the next section, with the analysis of the transposition in the Italian and German context, where such protection is granted.

2. The transposition of Article 14 Digital Single Market Copyright Directive: two examples

Amongst different examples on the ongoing implementation of Art. 14 DSM Copyright Directive[49], Italy and Germany have been chosen because of the passages, including draft measures, already taken in the transposition and based on the interest raised by the com-

[46] UK Intellectual Property Office, *Digital images, photographs and the internet*, Copyright Notice n.1/2014, adjourned in 2015, available at <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/481194/c-notice-201401.pdf>.

[47] As discussed by P. Keller, *Implementing the Copyright Directive: Protecting the Public Domain with Article 14*, COMMUNIA, 25 June 2019, available at <https://www.communia-association.org/2019/06/25/implementing-copyright-directive-protecting-public-domain-article-14/>.

[48] M-C. Janssens., *inDICES: Empowering IPR For Cultural Heritage Institutions, in inDICEs Project*, the 20th of July 2020, available at: https://indices-culture.eu/indices-empowering-ipr-for-cultural-heritage-institutions/.

[49] For the implementation and preparatory works the portals created by CREATe and COMMUNIA represent precious resources. See CREATe, *Copyright in the Digital Single Market Directive - Implementation an EU Copyright Reform Resource*, available at <https://www.create.ac.uk/cdsm-implementation-resource-page/> and COMMUNIA DSM Directive Implementation Portal, available at <https://www.notion.so/DSM-Directive-Implementation-Portal-97518afab71247c-fa27f0ddeee770673>.

parison of their background. More specifically on this point, both the Member States have national legislation protecting non-original photographs by means of neighbouring rights, in accordance with art. 6 Term Directive. Since the analysis has shown how these dispositions are affected by art. 14, these examples may offer interesting insights. Nevertheless, they also contain fundamental suggestions on how the necessary efforts for the transposition may encompass provisions other than copyright.

Turning briefly to Member States in which the protection of non-original photographs is not accorded, the examples of the Netherlands and Belgium follow. These cases seem to imply that not introducing specific norms to transpose art. 14 may also be an option where no such incompatible norms are present[50]. The application of general rules is for instance suggested in the Explanatory notes accompanying the first draft proposal for the transposition of the DSM Copyright Directive in the Netherlands[51], even though the legislative process at the time of the writing is on-going[52]. In Belgium, on the 19th of June 2020, the Intellectual Property Council (*Conséil pour la Propriété Intellectuelle*) published an opinion on the transposition of the DSM Copyright Directive. The opinion advises not to address specific laws to integrate the content of art. 14, based on the fact that the national law would be already compliant[53]. The working part of the document underlines that general rules would apply, the reference being Article XI.165 CRC for original works and Article XI.166 CDE for the public domain[54]. This choice is further supported by the need to avoid risks of confusion and legal uncertainty[55].

[50] For the Netherlands see R. Van Oerle, *The Netherlands*, in Y. Gendreau, A. Nordemann, R. Oesch (eds.), *Copyright and photographs - An international Survey*, Kluwer Law International, London, 1999, 207-208. Originality of photographs in Belgian law is critically discussed, with some references to case law, by A. Strowel, N. Ide, *Belgium*, in *ibidem*, pp. 82-83.

[51] Proposal to amend the Copyright Act, the Related Rights Act and the Database Act in connection with the implementation of Directive (EU) 2019 / PM of the European Parliament and of the Council of 17 April 2019 on copyright and related rights in the digital single market (*Wetsvoorstel houdende wijziging van de Auteurswet, de Wet op de naburige rechten en de Databankenwet in verband met de implementatie van Richtlijn (EU) 2019/PM van het Europees parlement en de Raad van 17 april 2019 inzake auteursrechten en naburige rechten in de digitale eengemaakte markt en tot wijziging van de Richtlijnen 96/9/EG en 2001/29/EG)*, Explanatory notes, 9, available at: https://www.internetconsultatie.nl/auteursrecht.

[52] For an overview consult the reference web page for the implementation of DSM Copyright Directive, House of Representatives of the General States *(Tweede Kamer Der Staten-Generaal)*, Implementation Act on the Copyright Directive in the Digital Single Market *(Implementatiewet richtlijn auteursrecht in de digitale eengemaakte markt)*, available at <https://www.tweedekamer.nl/kamerstukken/wetsvoorstellen/detail?id=2020Z08336&dossier=35454>.

[53] Opinion of the Intellectual Property Council concerning the transposition into Belgian law of Directive (EU) 2019/790 of the 17 of April 2019 on copyright and related rights in the Digital Single Market and amending Directives 96/9 / EC and 2001/29, the 19th of June 2020 (*Avis du Conseil de la Propriété intellectuelle du 19 juin 2020 concernant la transposition en droit belge de la directive 2019/790/UE du 17 avril 2019 sur le droit d'auteur et les droits voisins dans le marché unique numérique et modifiant les directives 96/9/CE et 2001/29/CE*), available at <https://economie.fgov.be/sites/default/files/Files/Intellectual-property/Avis%20Conseils%20Propriété%20intellectuelle/Avis-CPI-19062020.pdf>.

[54] Economic Law Code Book XI «Intellectual Property» (*Code de droit économique Livre XI «Propriété Intellectuelle»*), 28 February 2013.

[55] Opinion of the Intellectual Property Council (*Avis du Conséil pour la Propriété Intellectuelle*), *cit.*, pp. 222-223.

2.1. Germany

The German context is worth examination for the availability of a draft bill for the transposition of the DSM Copyright Directive which explicitly addresses the matter of public domain works. Secondly, due to its discipline of photographs, the country was the stage of one of the few mentioned judicial decisions regarding reproductions of public domain works.

In the UrhG a distinction is made between *Lichtbildwerke*, photographs which satisfy the requirement of individuality and reach the necessary level of creation protected by copyright[56], and *Lichbilder*, namely simple photographs, protected by neighbouring rights based on § 72[57]. As above mentioned, the *Museumsfotos* case of 2018 confirmed that in accordance with § 72 UrhG a faithful photographic reproduction of a painting belonging to the public domain should be protected.

The outcome of *Museumsfotos* and § 72 were at the centre of intense discussion within the consultation process for the implementation of art. 14 of the DSM Copyright Directive that took place from the 17th of April 2019[58]. Reproductions of public domain works were addressed as a tipping point by different stakeholders, for the legal uncertainty such reproductions are surrounded with. Next to § 72, also § 51 Sentence 3, regarding the exception for quotations (*Zitate*) and referring to the use of images or other reproductions of the quoted work, was mentioned to contribute to such blurred scenario.

In the same manner, attention was brought to the definition of works of visual art and on how to frame 3D reproductions, also 2D reproductions of 3D objects. Opinions examining the different purposes of the reproduction envisaged by the norm and considerations about both positive and negative potential consequences for GLAM and other professionals were not missing.

In the draft proposal dated the 13th of October 2020[59] the legislator has fittingly opted for a thorough approach to implement art. 14, with the creation of a new provision, § 68. As it is possible to read in the related explanatory document, the introduction of a new provision may clarify the status of faithful reproductions of works of visual art in the public domain. It would also include both photographs under §72 and reproductions consisting of

[56] The originality standard is enshrined in § 2, par. 2 of the UrhG.

[57] By express provision, economic rights and moral rights are applicable to simple photographs by analogy. See A. Nordemann, *Germany*, in Y. Gendreau, A. Nordemann, R. Oesch (eds.), *Copyright and photographs – An international Survey*, London, 1999, pp. 135-136, pp. 137-139.

[58] Consultation documents are available at the website of the Federal Ministry of Justice and Consumer Protection (*Bundesministerium der Justiz und für Verbraucherschutz*), Public consultation on the implementation of the EU Directives on copyright law (DSM-RL (EU) 2019/790 and Online-SatCab-RL (EU) 2019/789), available at <https://www.bmjv.de/SharedDocs/Gesetzgebungsverfahren/DE/Konsultation_Umsetzung_EU_Richtlinien_Urheberrecht.html?nn=6712350>.

[59] Draft legislative proposal to adapt Copyright Law to the Digital Single Market (*Entwurf eines Gesetzes zur Anpassung des Urheberrechts an die Erfordernisse des digitalen Binnenmarktes*), adjourned on the 2th of September 2020, available at <https://www.bmjv.de/SharedDocs/Gesetzgebungsverfahren/Dokumente/RefE_Urheberrecht.pdf?__blob=publicationFile&v=7>. The first draft regarding the transposition of art. 14 is dated back to the 24th of June 2020, and it is available at <https://www.bmjv.de/SharedDocs/Gesetzgebungsverfahren/Dokumente/DiskE_II_Anpassung%20Urheberrecht_digitaler_Binnenmarkt.pdf?__blob=publicationFile&v=2>.

sequences of images and sounds that are not protected as cinematographic works under § 95[60]. § 68 plainly states that the reproductions of works of visual art in the public domain are not protected by neighbouring rights and remarks that the norm would not address reproductions that represent creations of the author.
Noteworthy, the document confronts the issue whether works that were never protected by copyright or works whose term of protection has passed would be covered. It specifies that the norm would apply both to reproductions created after the law becomes effective and to the ones created before. This is considered in line with art. 26.1 of the DSM Copyright Directive, concerning the application in time and the only way to provide legal certainty[61].
What is of extreme interest for the present work, following the observations made by many during the consultation, the explanatory document further elaborates on the expression *works of visual art*[62]. With sensitive consideration for the issue in point, it is explained that the notion shall be deemed an autonomous concept within EU Law, to be referred to the open list in Annex n. 3 of Directive 2012/28/EU[63]. Crucially, in the German text of the DSM Copyright Directive the term *works of visual art* was translated as *Werk der bildenden Künste* (works of fine art), in correspondence to § 2.1 point 4 of the UrhG[64]. The newly introduced § 68 refers to *Visuelles Werk* (visual works) instead. As the document recites, only the expression *Visuelles Werk* shows a broader semantic spectrum, addressing works that can be perceived visually beyond the definition of *works of fine art* in the UrhG, thus promoting the goal of art. 14 DSM Copyright Directive and allowing the diffusion of reproductions and the access to common cultural heritage[65].
To conclude, due to the creation of a new provision of independent significance and the clarity that accompanies both its terminological choice and temporal scope, several of the uncertainties surrounding the transposition of art. 14 might find a response in the German context. The draft bill was open for consultation until the 6th of November 2020 and at the time of the writing the legislative process is proceeding.

2.2. Italy

The implementation of art. 14 DSM Copyright Directive in the Italian national legal framework shall be discussed starting from the protection of non-original photographs by neigh-

[60] *Ibidem*, 54.

[61] *Ibidem*, 54, 114-115. Art. 26.1 of the DSM Copyright Directive states: «This Directive shall apply in respect of all works and other subject matter that are protected by national law in the field of copyright on or after 7 June 2021».

[62] *Ibidem*, 113-114.

[63] *Ibidem*, 113-114.

[64] The reference is to § 2.1 point 4 of the UrgH, «Works of fine art» (*Werk der bildenden Kunste)*: «Works of fine arts, including works of architecture and applied arts and designs of such works».

[65] Draft legislative proposal to adapt Copyright Law to the Digital Single Market (*Entwurf eines Gesetzes zur Anpassung des Urheberrechts an die Erfordernisse des digitalen Binnenmarktes)*, *cit*., pp. 113-114.

bouring rights granted by the national copyright law. As it is for the German example, these rules seem to contrast the objective of art. 14.

Art. 2.1 n. 17 of Lda links the copyright protection of photographs to the originality standard[66]. Chapter V (*«Diritti relativi alle fotografie»*) of Title II, concerning related rights (*«Disposizioni sui diritti connessi all'esercizio del diritto di autore»*), establishes additional rules for what are defined simple photographs (*fotografie semplici*), protected by related rights even in absence of any degree of originality.

According to art. 87.1 these rules apply to the images of people or aspects, elements or facts of natural and social life, obtained with the photographic process or with a similar one, with the express mention of reproductions of works of figurative art (*arte figurativa)* and photograms of cinematographic works. Art. 87.2 specifically excludes from this discipline photographs of writings, documents, business papers, material objects, and similar products.

For a duration of 20 years (art. 92), the author is reserved a few rights, including the right to reproduce the work, with no prejudice for the copyright of the reproduced work of figurative art (*arte figurativa*) (art. 88). Key information accompanies the reproduction of these photographs (art. 90). Moral rights, differently from Germany, are deemed to be excluded[67].

Next to these provisions, the national legislation in the field of cultural heritage and landscape (*D.lgs. 22 gennaio 2004, n. 42, Codice dei beni culturali e del paesaggio, ai sensi dell'articolo 10 della legge 6 luglio 2002, n. 137*, also "Code of cultural heritage and landscape")[68], a sub-set of administrative law, seems also worth attention. Section II of the Code of cultural heritage and landscape contains provisions on the use of cultural goods, defined by articles 2 and 10[69], and establishes limitations to the reproduction thereof,

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[66] The art. 1.1 of the Lda states that works protected under the present law are the intellectual works of creative character (*opere dell'ingegno di carattere creativo*), which belong to literature, music, figurative arts, architecture, theater and cinematography, whatever the mode or form of expression. Content and duration of the law are detailed in Chapter II, by articles 12 to 32-*ter*, including art. 13, which describes the right of reproduction.

[67] C. Ubertazzi, *Italy*, in Y. Gendreau, A. Nordemann, R. Oesch (eds.), *Copyright and photographs – An international Survey*, London, 1999, pp. 171-178.

[68] Code of cultural heritage and landscape (*Codice dei beni culturali e del paesaggio*), Legislative decree n. 42, 22 January 2004, also known as Codice Urbani, as modified by Legislative Decree. n. 156, 24 March 2006.

[69] Art. 2 of the Code of cultural heritage and landscape defines cultural heritage (*patrimonio culturale)* and distinguishes between cultural goods (*beni culturali)* and landscape assets (*beni paesaggistici)* (art. 2.1). Cultural goods are immovables and movables which, pursuant to articles 10 and 11, present artistic, historical, archaeological, ethno-anthropological, archival and bibliographic interest and other things which are identified by law or on the basis of law as evidencing the value of civilization (art. 2.2). On the other hand, landscape assets are defined as the buildings and areas indicated in article 134, which are an expression of the historical, cultural, natural, morphological and aesthetic values of the territory, and other assets identified by law or on the basis of the law (art. 2.3). These definitions are completed by art. 2.4, which explains that the assets of the cultural heritage belonging to the public are intended for use by the community, compatibly with the needs of institutional use and provided that there are no reasons for protection. Art. 10 of the Code of cultural goods and landscape defines cultural goods, as including movables and immovables belonging to different entities, specifically listed, as including the State, the Regions and others, and presenting artistic, historical, archaeological or ethnoanthropological interest (art. 10.1), and others. Art. 13 regards the so-called declaration of cultural interest

based on the detention of the goods by the relevant entities. Works of visual art in the public domain extensively fall into this discipline.
The entities, art. 107 says, allow the reproduction and the instrumental and temporary use of the good. Importantly, art. 108 also ties the reproduction to the payment of fees to be established by the detaining entity, while only a reimbursement of expenses is asked for reproductions by private parties for private use or study, or by public parties when the reproduction is intended to the valorisation of the good. However, the introduction of paragraph 3-*bis* of art. 108 by the so-called "Art Bonus" Law Decree[70], which became Law in July 2014[71], brought a long-advocated reform for the reproduction of cultural goods that are not for-profit[72]. The new rule covers non-profit activities for the purposes of study, research, freedom of expression, also creative expression, and promotion of the knowledge of the cultural heritage. Both the reproduction (art. 108.3-*bis*, n.1) and the divulgation of images of goods (art. 108.3-*bis*, n.2) are declared "free" (*libere*) upon certain conditions[73]. This enhanced the realization of the constitutional protection that art. 9 and art. 33 of the Italian Constitution confer to the development of culture and research, and to cultural heritage[74].
Since it unburdens the reproductions for non-profit, the discipline, as recently modified, seems to accommodate the aim of art. 14 DSM Copyright Directive. Notwithstanding, art. 14 concerns the right to reproduction of works of visual art in the public domain in its entirety, without differentiating between commercial or non-for-profit scopes. It is thus clear that the existing rules in the Code of cultural heritage and landscape may still contrast with the realization of the objective of art. 14 in a number of cases.

(*dichiarazione dell'interesse culturale*) and essentially explains that this is oriented to ascertain the presence of the interest as defined by art. 10 in relevant cases.

[70] Law Decree n. 83, the 31st of May 2014, containing urgent dispositions for the protection of cultural heritage, the development of culture and re-launching of tourism (*Recante disposizioni urgenti per la tutela del patrimonio culturale, lo sviluppo della cultura e il rilancio del turismo*), so-called "Art Bonus".

[71] Law n. 106, 29 July 2014, Law conversion, with modifications, of the Law Decree n. 81, 31 May 2014, containing urgent dispositions for the protection of cultural heritage, the development of culture and re-launching of tourism.

[72] G. Gallo, *Il decreto Art Bonus e la riproducibilità dei beni culturali*, in *Aedon*, *Rivista d'arti e diritto online*, n. 3, 2014, available at <http://aedon.mulino.it/archivio/2014/3/gallo.htm>.

[73] This result was also achieved through further modifications of art. 108.3-bis, introduced by Law n. 124 of the 4th of August 2017, n.124, Annual law for market and competition (*Legge annuale per il mercato e la concorrenza*). The debate around inconsistencies of the reform of 2014, on which for istance see M. Modolo, A. Tumicelli, *Una possibile riforma sulla riproduzione dei beni bibliografici ed archivistici*, in *Aedon, Rivista d'arti e diritto online*, 1, 2016, available at <http://aedon.mulino.it/archivio/2016/1/modolo.htm>, is well described by F. Minio, *La libera riproducibilità dei beni culturali dopo l'emanazione della Legge 4 agosto 2017, n. 124 (Legge annuale per il mercato e la concorrenza)*, in *BusinessJus,* 2, 76, 2018, available at <https://www.businessjus.com/it/libera-riproducibilita-dei-beni-culturali-dopo-lemanazione-della-legge-4-agosto-2017-n-124-legge-annuale-per-il-mercato-e-la-concorrenza/>.

[74] Constitution of the Italian Republic, Senate of Republic (*Senato della Repubblica*), 2018, Translation supervised by the Senate International Affairs Service, available at <https://www.senato.it/1024>. art. 9 states: «The Republic shall promote the development of culture and scientific and technical research. It shall safeguard natural landscape and the historical and artistic heritage of the Nation»; art. 33, first sentence, states: «Arts and science shall be free and may be freely taught. (...)».

A draft of a European Delegation Law (*Legge di delegazione europea*) for the transposition, inter alia, of the DSM Copyright Directive, was proposed in early 2020. During the informal hearings that followed art. 14 was not as central to the discussion as other norms of the Directive, also given the absence, in the draft art. 9, of a specific provision on the point[75]. However, different stakeholders evidenced how the implementation of art. 14 would necessarily imply to intervene on both the mentioned sets of law. This implies an overlap where the two disciplines meet, in all their divergencies, and most notably in their different aim of protection: the public good – the protection of cultural goods (*beni culturali*) – and the author's right[76]. Also, considering the mandate of art. 14 DSM Copyright Directive, the removal of the obstacles present in the legislation on cultural heritage seems left to the decision of the national legislator, requiring a complex balance.

Furthermore, the implementation of art. 14 DSM Copyright Directive has been linked to the freedom of panorama. The reference is to the non-mandatory exception introduced by art. 5 par. 3 letter h) of the InfoSoc Directive for the reproductions of cultural goods which are visible from public places. At present, in Italy, cultural goods are subject to the described discipline and the reproductions thereof are subject to the relevant constraints, with obvious detrimental effects for their access and circulation, impacting, amongst others, education and tourism[77]. The transposition of art. 14 can be the occasion to put in place coordinate efforts towards this separate but complementary objective.

This approach has been suggested to be in line with the recent resolution proposed by the Cultural Commission, Commission VII, and approved in May 2020 in relation to the difficulties to the Covid-19 pandemic, even though as an outcome of a separate process[78]. The resolution invited the Government to consider the adoption of initiatives aimed at promoting the free reproduction and share of images of public cultural goods, including the one visible from the public space, using Open Access licensing tools and the Creative Common licenses. It also encouraged the recognition to (directors of) institutes of the MIBACT (Ministry for

[75] To an overview on the preparatory works, next to the already mentioned sources, see the beneficial page regarding the implementation of DSM Directive in Italy by COMMUNIA, and maintained by Federico Leva, available at <https://www.notion.so/Italy-ef314e69e7ef42d1893efe5ef0ee39f8>. With regards to the auditions, the main references taken into account for the present article and addressing the transposition of art. 14 DSM Copyright Directive took place at the Senate of Republic the 14th of May 2020. In particular see the auditions of Wikimedia Italia and Creative Commons Italia, whose presented materials are available at <https://zenodo.org/record/3827231#.X9dO1C9aaCQ> and <https://creativecommons.it/chapterIT/index.php/1124/>.

[76] S. Aliprandi, *Vincoli alla riproduzione dei beni culturali, oltre la proprietà intellettuale*, Archeologia e Calcolatori Supplemento 9, 2017, 103, 105-106.

[77] For an overview on images of cultural goods, with considerations on the freedom of panorama, see G. Resta, *Chi è proprietario delle piramidi? L'immagine dei beni tra Property e Commons*, in *Politica del diritto*, Issue n. 4, 2009; A. Tumicelli, *L'immagine del bene culturale*, in *Aedon*, *Rivista d'arti e diritto online*, n. 1, 2014, available at <http://aedon.mulino.it/archivio/2014/1/tumicelli.htm>.

[78] Resolution in final debate Commission n. 8/00073, Measures to support the cultural and entertainment sector in contrast to the effects of the Covid-19 epidemic), the 5th of May 2020, available at <https://aic.camera.it/aic/scheda.html?numero=8-00073&ramo=C&leg=18>.

Cultural Goods and Activities and Tourism, *Ministero per i Beni e le Attività Culturali e il Turismo*), both central and peripheric, of the faculty to license images online within Creative Common licenses for the free re-use. Noteworthy, at the time of the writing other resolutions have been proposed by the Cultural Commission to further addressed the topic of freedom of panorama and of reproductions of works of visual art in the public domain, with primary consideration for cultural goods, and also in reference to the DSM Copyright Directive[79].

Finally, the definition of works of visual arts was also addressed in the auditions. Art. 69-*septies* of the Lda transposes the notion of visual arts (*opere visive*) of the mentioned Directive 2012/28/EU, Annex, n. 3, referring to the sources which can be accessed to verify the status of a work as orphan. As mentioned, this points out to an open list; moreover, this notion coexists with several references to works of figurative art (*opere d'arte figurativa*) in the Lda. Commentators have pledged for the adoption of a broad notion of works of visual arts able to fit in the existing framework, with peculiar regards to the Code of cultural heritage and landscape.

The text of the European Delegation Law 2019-2020 was approved by the Senate on the 29th of October 2020, and it was transmitted to the Assembly, 14ª Permanent Commission in charge of European Union Policy (*Commissione permanente Politiche dell'Unione europea*), on the 2nd of November 2020[80]. In its most recent available version no specific provision explicitly addresses the transposition of art. 14 despite a clear need for revision. However, a few issues of importance in the transposition of art. 14, even if not approved in form of amendments to the text, merged in a few accepted non-binding resolutions (*Ordini del giorno*)[81]. Amongst others, these regard the framing of the notion of *works of visual art* in accordance with the existing provisions and especially with Art. 10 and 13 of the Code of cultural heritage and landscape[82], and the adaptation of potentially incompatible norms in Lda. One resolution also covers the need to recognise the opportunities related to art. 14 DSM Copyright Directive for the cultural sector globally, especially considering the effects of the recent Covid-19 pandemic. As part of the steps to take in the transposition of DSM Copyright Directive, a specific non-binding resolution addressing the need to fully implement

[79] Resolution in Commission n. 7/00423, Resolution n. 7/00550, Resolution n. 7/00552, Resolution n. 7/00553, Resolution n. 7/00557, Resolution n. 7/00558, have been jointly discussed by the Commission VII in November 2020, as described in the Commission convocation overview available at <https://www.camera.it/leg18/1099?slAnnoMese=202011&slGiorno=18&shadow_organo_parlamentare=2807&primaConvUtile=ok>.

[80] Draft Law (*Disegno di legge*) n. 1721, Delegation to the Government for the transposition of European Directives and the implementation of other European Union acts - European Delegation Law (*Legge di delegazione europea*) 2019-2020, as approved on the 29th of October 2020 and transmitted to the Chamber on the 2nd of November 2020, available at <http://www.senato.it/service/PDF/PDFServer/BGT/01179126.pdf. See in particular art. 9 for the transposition of Directive (EU) 2019/790>.

[81] See, inter alia, the following resolutions (*Ordini del giorno*): n. G/1721/46/14 (already amendment n. 9.1), n. G/1721/53/14 (already amendment n. 9.14), n. G/1721/55/14 (already amendment n. 9.50), available at <http://www.senato.it/leg/18/BGT/Schede/Ddliter/testi/52774_testi.htm>. A complete overview can be found at <http://www.senato.it/leg/18/BGT/Schede/Ddliter/testi/52774_testi.htm>.

[82] See note 69.

art. 5 InfoSoc Directive[83], including the set of exceptions and limitations and comprising the freedom of panorama, was instead approved[84]. No further information, except from the fact that the text is currently in pending review, is available at the time of the writing.

3. Preliminary analysis

This final part shortly summarizes the key-insights provided by the analysis of art. 14 DSM Copyright Directive and the transposition examples, and tries to draw some remarks on the main challenges in the transposition by Member States.
In this scrutiny, while emphasis shall go to the room for potential discrepancies within Member State law, the most crucial perspective is the one of how to reach a harmonized transposition. Art. 14 is primarily oriented to the harmonization of the Digital Single Market, where, as explicitly affirmed by recital 53, differences between national copyright laws governing the protection of reproductions of works of visual art in the public domain give rise to legal uncertainty and affect their cross-border dissemination.
While the desired legal certainty would require a substantial degree of harmonization, this seems to heavily rely on how Member States will act in the transposition of the norm. The risk of a fragmented transposition is consistent with the ambiguities in the text of art. 14, but it remains especially true with regards to the complex context in which art. 14 intervenes, at the interplay of different rights in national law, primarily copyright law. Here further research is needed, and an accurate case-by-case analysis may prove beneficial.
With this in mind, the section firstly explores different suggestions towards a harmonized transposition, and then turns to the complex issues at the interplay of art. 14 and national law, on which, if not immediate solutions, offers suggestions for future research, including the very important one about the role of GLAM and incoming changes for the cultural sector.

3.1. Ambiguities

The ambiguity of art. 14 has been invoked in many instances and inherently represents a challenge in the transposition by Member States, as a risk to further harmonization.
The most remarkable issue regards the notion of works of visual art, of which no definition is attached in the Directive. As shown by the legislative process, which only in a second time eliminated the reference to *all* works in the public domain, this element is crucial for defining the scope of art. 14 and thus can be decisive for a more or less fragmented transposition.

[83] Resolution (*Ordine del giorno*) n. G/1721/8/14, approved as Resolution (*Ordine del giorno)* G9.100. See Draft for print n. 4 of the 26th of October 2020 of the Draft Law (*Disegno di legge*) n. 1721, Delegation to the Government for the transposition of European Directives and the implementation of other European Union acts – European Delegation Law (*Legge di delegazione europea*) 2019-2020, pp. 35-36, available at <http://www.senato.it/service/PDF/PDFServer/BGT/01178813.pdf>.

[84] The reference is to the difference between the approval and acceptance of non-binding resolutions (*Ordini del giorno*) within the legislative process, respectively indicating a strong and not as strong degrees of commitment of the Government.

It seems realistic that Member States could refer to their nomenclatures for copyright subject matter. As consequence, the existing fragmentation in that nomenclature and the absence of a definition in the Directive may result in a narrower, not well-founded and heterogeneous transposition by Member States, affecting the core of cross-border dissemination of works[85]. That is why several authors have urged the need to focus on the faithfulness of the reproduction of the public domain work instead[86] or go *beyond* the contours of works of visual art, extending the material scope of the reproduction[87].

Importantly, the German example has paved the way for the possibility to lean on an existing notion in the EU Copyright law described by Directive 2012/28/EU, Annex n. 3, regarding orphan works. Being an open list, this definition offers the advantage, if not to clarify what is deemed to be a work of visual art, at least to confirm the protection of a few categories of works, including, amongst others, photographs, sculpture, fine art, design and architecture. This led the German legislator to the understanding of the work of visual art centred on its visual fruition, suggesting a broad spectrum of works may fall under the material scope of art. 14. This shall be considered a potential place of departure for harmonization.

Similarly, Member States may react differently to the addition of the characterization of the reproductions as *faithful* by recital 53, at the interplay with the originality standard. It is poorly understood how these two requirements may interact in the next future. Nonetheless, the strengthening of the originality standard as author's own intellectual creations that is enshrined, and in a certain sense eventually "codified", in art. 14, might make this issue of secondary relevance in the transposition by Member States.

In addition, considering «any material resulting from an act of reproduction», the openness of this formulation was underlined: its vagueness may prove beneficial to the future evolution of technology. This potentially unlimited definition, when transposed by Member States, would assure that the clause of what may consist of an act of reproduction remains open for all of them. However, to increase the possibility of harmonization and cross-border circulation of contents, authors proposed to introduce further specifications. The inclusion of 3D reproductions, next to 2D reproductions of 3D reproductions, seems particularly delicate, as these works are likely to attract copyright as original[88]. Supplementary remarks regard the inclusion of both digital and analogue reproductions, as the latter shall not be excluded by the special interest of art. 14 for the digital environment[89].

[85] COMMUNIA Guide on the implementation to art. 14, available at <https://www.notion.so/Article-14-Works-of-visual-art-in-the-public-domain-eb1d5900a10e4bf4b99d7e91b4649c86>; A. Wallace, E. Euler, *cit.*, pp. 838-839.

[86] European Copyright Society (ECS), *cit.*, 2.

[87] COMMUNIA Guide on the implementation to art. 14, *cit.*

[88] European Copyright Society (ECS), *cit.*, 3; A. Wallace, E. Euler, *cit.*, p. 839.

[89] European Copyright Society (ECS), *cit.*, 4; P. Keller, *Implementing the Copyright Directive: Protecting the Public Domain with Article 14*, *cit.*

As it refers to the expiration of copyright, and namely the "entering" of the work in the public domain, art. 14 is in principle clear, and it has been argued to confirm the notion of public domain. Against the mentioned doubts whether all reproductions would be protected independently from the moment of creation, it is possible to agree that only a broad understanding of the norm, covering every reproduction of public domain works and irrespective of the time of execution, may be in line with the aim of the provision[90], and with general principles of Copyright law[91]. A further specification by the national legislator on the temporal scope may still prove supportive to legal certainty and is recommended by the literature[92]. The German example, including a specific notation in the explanatory works, is an example of this. Accordingly, it is evident that a different understanding of this point, in the opposite sense that not all reproductions may be protected based on the date of creation, would not only contrast with the aim of the norm but also require extensive right clearance and undermine legal certainty.

3.2. Challenges at the interplay of other rights and future research

The most prominent challenges of the transposition are posed by the interplay of different rights and the context in which art. 14 is framed, given its manifold impact. It must be underlined that a comprehensive understanding on this point could only follow a detailed account on each Member State case. This paper especially focused on related rights in photographs as a use case of art. 14, but the findings may suggest other key issues for the transposition and directions for future research.

Member State Copyright law shall be impacted by art. 14. Considering related rights, the discipline of non-original photographs is one prominent example thereof. This was confirmed in the analysis of the German and Italian examples, both conferring protection to non-original photographs by neighbouring rights. In particular, the first illustrates that the introduction of an ad hoc provision renders the modification of the existing rules about photograph superfluous. A corollary is to consider that other Member States, where such protection is not granted, have claimed the application of general rules on originality, and have not adopted specific laws to transpose the content of art. 14.

Hopefully, the analysis was also able to explain how the new rule of art. 14 may be relevant to other works as well. Particular interest is raised by collections, possibly considered as databases protected by the *sui generis right* in the EU Copyright acquis. In this respect, there are multiple questions that shall be addressed by future studies, for instance how

[90] European Copyright Society (ECS), *cit.,* 3-4.

[91] See, inter alia, art. 18 of the Berne Convention, paragraphs 1 and 2: «This Convention shall apply to all works which, at the moment of its coming into force, have not yet fallen into the public domain in the country of origin through the expiry of the term of protection. If, however, through the expiry of the term of protection which was previously granted, a work has fallen into the public domain of the country where protection is claimed, that work shall not be protected anew».

[92] European Copyright Society (ECS), *cit.*, 3-4.

the protection of single parts of the work versus the protection of the overall work may fit into the scope of art. 14, and whether such an issue would require specific adaptation by Member States. Plus, this problem remains partly consistent with the blurred definition of works of visual art above mentioned.

From a more general perspective, the variety of uses of reproductions allowed by art. 14 also crosses the exceptions and limitations of the EU Copyright acquis. These also include the ones introduced by the DSM Copyright Directive requiring transposition in the next future, such as art. 3 for text and data mining, art. 5 regarding education, art. 6 on preservation of cultural heritage and others.

Art. 14 has raised the question of the implementation of the freedom of panorama in Italy, whose exception appeared in the art. 5.3 letter h) of the InfoSoc Directive. In the German example, the possibility to re-use a content for illustration was linked to art. 14 DSM Copyright Directive, indicating this may be, in the practice, overlapping with the copyright exceptions of quotation for purposes of criticism and review as well as parody, caricature and pastiche. These exceptions, so important in the culture of remix[93], have been introduced as non-mandatory by art. 5.3 letter d) and k) of the InfoSoc Directive, and at the current state they are differently transposed by Member States. Going further, what is of major interest is that these exceptions are incorporated as mandatory by art. 17 of DSM Copyright Directive, in respect to user-generated contents[94]. The possibility to upload/making available copyrighted contents for caricature, parody or pastiche (Art. 17.7 letter a) and criticism, quote or review (Art. 17.7 letter b) will play a critical role in the scrutiny required by art. 14 on the originality of reproductions of works of visual art in the public domain. This is due to the existing fragmentation in Member State law and the doubts surrounding a notion of derivative works in the EU Copyright acquis[95], as opposed to the expected incoming efforts towards a further harmonization with the DSM Copyright Directive. It also seems relevant that the same art. 17 of the DSM Copyright Directive introduces a new liability regime and obligations for user-generated contents platforms[96].

[93] The reference is to the concept promoted, inter alia, by L. Lessig, *Remix: Making Art and Commerce Thrive in the Hybrid Economy*, London, 2008.

[94] G.F. Frosio, *Reforming the C-Dsm Reform: a User-Based Copyright Theory for Commonplace Creativity*, Centre for International Intellectual Property Studies (CEIPI) Research Paper n. 12, 2019, 27, available at <https://ssrn.com/abstract=3500722>. See also recital 70 of the DSM Copyright Directive. For a study on copyright exceptions and user-generated-content, see M. Senftleben, *User-Generated Content – Towards a New Use Privilege in EU Copyright Law*, Forthcoming, in T. Aplin (ed.), *Research Handbook on Intellectual Property and Digital Technologies*, Edward Elgar Publishing, Cheltenham, 2020, pp. 136-162 (also available at: https://ssrn.com/abstract=3325017).

[95] For an overview, see M. Van Eechoud, *Adapting the work*, in M. Van Eechoud (ed.), *The Work of Authorship*, Amsterdam University Press, Amsterdam, 2014, pp. 145-173, (also available at <http://ssrn.com/ abstract=2538509>).

[96] The reference is on how the transposition of DSM Copyright Directive will impact the liability regime of ISP, particularly as defined by art. 15 («No general obligation to monitor») of the Directive on electronic commerce, also e-Commerce Directive, Directive 2000/31/EC of the European Parliament and of the Council on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market, 8 June 2000, available at <https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX%3A32000L0031>.

Overall, moving the conversation away from Copyright law, another fundamental question remains open in the transposition of art. 14. Depending on the peculiarities of each Member State, different laws, also belonging to diverse domains, could limit or pose obstacles to the access and circulation of public domain works and ultimately frustrate the objective of art. 14. Given the mandate of art. 14 in Copyright Law, the possibility to intervene on such obstacles seems less clear and left to the evaluation of the national legislator.
In Italy, in particular, different stakeholders have explained that the norms on cultural heritage limit the access and reproductions of works of visual art in the public domain when they represent cultural goods. Crucially, this indicates GLAM as key protagonists of this challenge. These actors are often not only the material owners of works in the public domain, but also committed to their preservation and access, for instance by the digitisation initiatives addressed in art. 6 DSM Copyright Directive, a norm which seems complementary to art. 14.
This brings to one last point, arguably not only of juridical nature, and moving beyond the transposition of art. 14, as a way of conclusion of the paper. It regards how art. 14 poses its ultimate challenge to the cultural institutions and GLAM in many instances, as shown by the case-law reported and considering the room for the commercial purposes of reproductions opened by art. 14. What seems better understood – despite deserving further, multidisciplinary research – is the opportunity to develop new business models and sharing practices for the cultural sector. This has been a reality and necessity in the shift from analogue towards digital practices of fruition of cultural contents, but it became an emergency in the recent pandemic[97]. In this respect, art. 14 is aimed at enhancing legal certainty, from which not only users but also actors from the cultural sector could benefit in the design of new practices of creation and fruition of contents online.

Conclusions

Art. 14 DSM Copyright Directive affects the very presence of cultural contents online, promoting the wider access and circulation of non-original reproductions of works of visual art in the public domain.
Realizing this objective in the digital and cross-border dimension seems to be very ambitious, as it requires extensive harmonization. This proves difficult not only because of some ambiguities that characterize the text of art. 14 and primarily, amongst those, the absence of a definition of works of visual art, but most of all for the complex context in

[97] As a global phenomenon, numerous initiatives developed around the use of the hashtag *#culturedoesnotstop*. With regards to the museal initiatives in Italy, see for instance G. Giardini, *Coronavirus, i musei italiani che resistono e vanno online*, in *Il Sole24Ore*, 14 March 2020, available at <https://www.ilsole24ore.com/art/la-resistenza-culturale-musei-italiani-ADSSXKD>.

which it intervenes. The transposition of art. 14 requires the national legislator to act at the interplay of the Copyright law and, possibly, other norms belonging to different domains, depending on the peculiarities of each Member State.
Especially thanks to the analysis of the two selected examples on transposition, it was suggested that to reach the desired objective of further harmonization seems to heavily rely on how Member States will act to implement the norm. Despite these relevant challenges, art. 14 still represents a firm assertion for Member States to create a new room for the public domain. It shall be welcomed as a needed, if not definitive, passage towards further legal certainty in the digital environment, to unlock the public domain potential.

La Nuova Via della Seta e il cammino della Cina verso il Modello del *"Sustainable Going Out"*

Barbara Verri*

ABSTRACT

La Belt and Road Initiative (BRI) costituisce l'ambizioso progetto della Cina che, all'interno della *going out policy*, ha lo scopo di dare nuovo impulso agli investimenti cinesi all'estero. L'estensione della BRI, in termini sia territoriali sia di obiettivi prefissati, pone tuttavia alcune rilevanti questioni in materia di protezione ambientale, alla luce delle evidenti ricadute che un progetto di tali dimensioni potrebbe provocare sull'ambiente. L'articolo si propone pertanto di analizzare le *policy* e le misure messe in atto al fine di realizzare l'Iniziativa secondo criteri ispirati alla sostenibilità e alla tutela ambientale.

KEYWORDS

Belt and Road Initiative – Diritto ambientale cinese – Sviluppo sostenibile – Civiltà ecologica – Investimenti cinesi all'estero

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* Barbara Verri, Attorney and Research Fellow at University of Bologna.

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1. La nuova frontiera del *going out* cinese: la Belt and Road Initiative

Prendendo le mosse dall'antica rotta commerciale della Via della Seta che nel passato congiungeva la Cina con il mondo Occidentale, il presidente Xi Jinping nel settembre 2013 ha annunciato per la prima volta l'ambizioso progetto della 一带一路 (*yi dai yi lu*), ossia letteralmente la One Belt, One Road (OBOR), conosciuta anche con il nome di Belt and Road Initiative (BRI)[1]. L'Iniziativa si propone di realizzare un'articolata rete di infrastrutture che, ripercorrendo in parte l'antica Via della Seta, è diretta a collegare la Cina all'Africa e all'Europa attraverso due rotte principali, una terrestre (la Silk Road Economic Belt) e una marittima (la New Maritime Silk Road)[2]. Il progetto ha lo scopo primario di favorire la connettività tra la Cina e i paesi lungo le due rotte con la costruzione non solo di strade, ferrovie e porti, ma anche di tutte le opere connesse a tali infrastrutture quali, ad esempio, impianti per la produzione elettrica, dighe e reti di telecomunicazioni.

[1] Il nome ufficiale in cinese è 一带一路 (*yi dai yi lu*), inizialmente tradotto in inglese One Belt, One Road; tuttavia a partire dal 2015 il Governo cinese ha cambiato la traduzione ufficiale in lingua inglese in Belt and Road Initiative (per un approfondimento sulle origini del nome dell'iniziativa si rimanda a Y. Li, *Belt and Road: A Logic Behind the Myth*, in Alessia Amighini (ed.) *China's Belt and Road: a Game Changer?*, (Edizioni Epoké – ISPI, 2017, 14-17).

[2] La "cintura" terrestre collegherà la Cina all'Asia centrale e meridionale, nonché all'Europa; la "via" marittima collegherà la Cina ai paesi del sud-est asiatico, del Golfo, dell'Africa orientale e settentrionale e dell'Europa. Dalle due rotte principali si svilupperanno poi sei corridoi complementari per ultimare la rete: il corridoio Cina-Mongolia-Russia, il ponte dei territori dell'Eurasia, il corridoio Cina-Asia centrale-Asia occidentale, il corridoio Cina-Indocina, il corridoio Cina-Pakistan e il corridoio Bangladesh-Cina-India-Myanmar. Secondo le stime della Banca Mondiale l'Iniziativa coinvolgerà oltre il 60% della popolazione mondiale.

L'estensione dell'Iniziativa emerge chiaramente nel documento che definisce le linee direttive del progetto, ossia il *Vision and Actions on Jointly Building Silk Road Economic Belt and 21st Century Maritime Silk Road* (il *Vision and Actions*)[3], pubblicato nel marzo 2015 congiuntamente dalla Commissione nazionale per lo sviluppo e le riforme, dal Ministero degli affari esteri e dal Ministero del commercio. Secondo il *Vision and Actions*, la BRI si svilupperà nell'area dell'antica Via della Seta (ma andrà anche oltre) e sarà aperta a tutti i paesi e alle organizzazioni internazionali e regionali «*so that the results of the concerted efforts will benefit wider area*». Il documento individua nel dettaglio cinque macro priorità che il Governo cinese si propone di promuovere con l'Iniziativa: oltre alla già citata realizzazione della rete di infrastrutture, sono elencate quattro ulteriori priorità che riguardano, nello specifico, il coordinamento delle politiche, il commercio senza barriere, l'integrazione finanziaria e lo scambio culturale e scientifico tra i popoli.
Dal un punto di vista delle politiche interne attuate dalla Cina negli ultimi trent'anni, la BRI costituisce una nuova tappa della "*going out policy*", ossia della politica intrapresa a partire dagli anni Novanta del secolo scorso diretta a incoraggiare le imprese cinesi a investire all'estero. I considerevoli sforzi compiuti per conseguire questo obiettivo hanno portato la Cina ad affermarsi come uno dei principali investitori sul mercato internazionale. Nel 2016 il flusso di investimenti in uscita ha persino superato il flusso di investimenti diretti verso il Paese[4]. La BRI pertanto, nel disegno del Governo cinese di promozione degli investimenti verso l'esterno, si prospetta come la strategia che consoliderà ulteriormente il ruolo della Cina tra gli attori di massimo rilievo nel panorama degli investimenti globali.

2. La questione ambientale e gli investimenti cinesi all'estero nell'epoca della civiltà ecologica

È innegabile che, in ragione dell'ammontare delle risorse allocate e dell'estensione in termini sia territoriali sia di obiettivi da raggiungere, l'impatto economico della BRI avrà significativi effetti sull'economia mondiale. Accanto alle evidenti opportunità di crescita connesse all'Iniziativa si affiancano tuttavia alcune insidie legate proprio all'ampia portata del progetto messo in atto. Tra queste spicca *in primis* il tema legato all'ambiente. È, infatti, chiaro che la realizzazione di una complessa rete di infrastrutture pone l'evidente rischio di notevoli ricadute dal punto di vista dell'impatto ambientale, in termini di inqui-

[3] <https://eng.yidaiyilu.gov.cn/qwyw/qwfb/1084.htm>.

[4] V. S. Yu, X. Qian, T. Liu, *Belt and road initiative and Chinese firms' outward foreign direct investment* (2019) 41 *Emerging Markets Review.* Secondo il World Investment Report 2020 pubblicato dalla Conferenza delle Nazioni Unite sul commercio e lo sviluppo nel 2019 gli investimenti cinesi in uscita sono stati pari a 117 miliardi di dollari: United Nations Conference for Trade and Development, *World Investment Report 2020* (Ginevra, 2020) <https://unctad.org/en/PublicationsLibrary/wir2020_en.pdf>.

namento, alterazione degli habitat, sfruttamento delle risorse naturali, consumo di energia ed emissioni di gas serra[5]. Tale rischio è tanto più aggravato dalla circostanza che la maggioranza degli Stati interessati dalla BRI sono paesi ancora in via di sviluppo con legislazioni in materia ambientale molto limitate e lacunose sotto molteplici profili.

La questione ambientale è dunque un elemento da prendere in considerazione con grande attenzione e cautela. Sono, infatti, ormai fin troppi noti gli effetti devastanti che un incontrollato sviluppo economico può provocare a livello sociale e soprattutto ambientale. Di questa circostanza è peraltro ben consapevole la Cina, la cui rapidissima espansione economica, accompagnata da una legislazione ambientale a tratti carente, ha duramente segnato il Paese sul fronte dell'ambiente. Per contrastare l'emergenza ambientale la Cina ha dunque dovuto modificare sensibilmente la sua strategia di sviluppo e progressivamente abbandonare il modello del "*pollute first, control later*" che per anni aveva caratterizzato anche le scelte normative in materia.

Già da diversi anni gli obiettivi di politica economica cinese non si sono più limitati alla massimizzazione della crescita, ma si sono evoluti verso un diverso approccio, ossia uno sviluppo economico basato su un modello più responsabile e consapevole della necessità di salvaguardare l'ambiente e le risorse naturali. Questo cambio di direzione trova ragione anche nella crescente consapevolezza che le problematiche ambientali non si riflettono solo sull'ambiente, ma hanno un rilevante impatto sulla crescita economica (si pensi agli ingenti costi da sopportare in caso di disastri ambientali) e, non da ultimo, sulla stabilità sociale.

La necessità di indirizzare l'economia verso questo nuovo approccio ha quindi portato la Cina a guardare verso modelli di crescita alternativi e, in particolare, verso lo sviluppo sostenibile[6]. Il processo verso una crescita ispirata alla sostenibilità ha iniziato a prendere forma nel 2003, quando è stata introdotta la strategia dello *Scientific Outlook on Development*, ossia la Prospettiva scientifica sullo sviluppo: questo è il documento che ha aperto la strada allo sviluppo sostenibile in Cina e ha delineato strategie e principi guida per raggiungere quella tanto ambita armonia tra la crescita economica, da un lato, e la popolazione, le risorse e l'ambiente, dall'altro lato[7]. Più recentemente l'obiettivo di perseguire

[5] Sull'importanza di realizzare la BRI nel pieno rispetto dell'ambiente, v. S. Bogojevic, M. Zou, *Making Infrastructure "Visible" in Environmental Law: The Belt and Road Initiative and Climate Change Friction* (2020) *Transnational Environmental Law* 1, in cui si sottolinea che i rischi ambientali (tra i quali quelli legati al cambiamento climatico) devono essere presi debitamente in considerazione in quanto, in caso contrario, potrebbero condurre a conflitti a livello sociale con la popolazione locale.

[6] Noto concetto formulato nel contesto internazionale quando nel 1987 la World Commission on Environment and Development pubblicò il *rapporto Brundtland* in cui per la prima volta si teorizzò la necessità di realizzare una crescita economica in grado di soddisfare i bisogni attuali ma senza pregiudicare le risorse delle generazioni future.

[7] Dopo la pubblicazione del *Scientific Outlook on Development*, anche i Piani Quinquennali hanno elevato la questione ambientale a priorità nazionale. A partire, infatti, dall'Undicesimo Piano Quinquennale (2006-2010) sono stati inclusi sempre più stringenti obiettivi vincolanti di protezione ambientale e conservazione delle risorse naturali (come la riduzione degli agenti inquinanti e delle emissioni di gas serra, la promozione delle energie rinnovabili, lo sviluppo di una economia circolare). Prima dell'Undicesimo Piano Quinquennale gli obiettivi ambientali indicati a partire dal Sesto

uno sviluppo inclusivo ed equilibrato ha trovato un importante riconoscimento quando nel 2012 è stata annunciata la nuova strategia nazionale definita la "civiltà ecologica" che ha, tra i suoi obiettivi, quello di creare una società in grado di conciliare le esigenze economiche a quelle ambientali e di attuare uno sviluppo di qualità e non più solo di quantità[8]. La novità di tale strategia risiede nella sua portata applicativa che guarda oltre la sfera economica. Con la civiltà ecologica si vuole, infatti, rivendicare il ruolo centrale della protezione ambientale in ogni settore della società: dagli aspetti sociali e culturali a quelli politici. La civiltà ecologica ha quindi la capacità di racchiudere in sé sia l'antico ideale confuciano di una società fondata sul rapporto armonioso tra uomo e natura, sia il più recente concetto di sviluppo sostenibile.

L'impegno della Cina a portare avanti questo nuovo modello di sviluppo non ha riguardato soltanto la situazione interna ma si è estesa anche alle politiche nel settore degli investimenti cinesi diretti all'esterno. Il processo del *going out* è stato, infatti, accompagnato da molteplici interventi del Governo cinese rivolti a rafforzare l'impegno delle imprese che operano all'estero a condurre le proprie attività mediante comportamenti improntati alla sostenibilità e alla protezione dell'ambiente. Tra queste misure vi sono, ad esempio, le *Guidelines on Environmental Protection in Foreign Investment and Cooperation* adottate dal Ministero del commercio e dal Ministero dell'ecologia e dell'ambiente nel 2013. Le *Guidelines*, in ragione della loro portata e applicabilità generale, rappresentano uno degli strumenti più rilevanti in questo ambito. Il documento ha, nello specifico, lo scopo di incoraggiare le imprese cinesi che investono all'estero ad adottare comportamenti responsabili da un punto di vista ambientale e a promuovere lo sviluppo sostenibile degli investimenti[9]. Le *Guidelines* spaziano da disposizioni di carattere generale, come la necessità di sviluppare un'economia verde a basse emissioni di carbonio (art. 4) o includere la protezione ambientale nelle strategie di sviluppo aziendale (art. 6), a diposizioni di carattere più specifico, come l'invito agli investitori cinesi a svolgere *due diligence* ambientali sulle imprese da acquisire (art. 12) o a elaborare piani per la gestione dei rifiuti pericolosi

Piano Quinquennale (1981-1985) avevano carattere non vincolante e dunque raramente trovavano una concreta realizzazione.

[8] Nelle *Opinions on Accelerating Ecological Civilization* emanate nel 2015 del Comitato centrale del Partito Comunista e dal Consiglio di Stato viene, infatti, affermato che lo sviluppo della civiltà ecologica costituisce un tassello fondamentale del sistema socialista con caratteristiche cinesi al fine di raggiungere i due obiettivi centenari e il sogno cinese. Per un approfondimento sulla civiltà ecologica e sulle riforme attuate a livello amministrativo, v. Y. Gu, Y. Wu, J. Liu, M. Xu, *Ecological civilization and government administrative system reform in China* (2020) 155 *Resources, Conservation & Recycling*.

[9] Art. 1 «[t]*hese Guidelines are hereby formulated in order to direct enterprises in China to further regularize their environmental protection behaviors in foreign investment and cooperation activities, timely identify and prevent environmental risks, guide enterprises to actively perform their social responsibilities of environmental protection, set up good international images for Chinese enterprises, and support the sustainable development of the host country*» <http://english.mofcom.gov.cn/article/policyrelease/bbb/201303/20130300043226.shtml>.

(art. 13) o piani di emergenza in caso di incidenti ambientali tali da garantire un puntuale sistema di segnalazione a tutti i soggetti potenzialmente colpiti (art. 14)[10].
Nel settore degli investimenti cinesi all'estero tuttavia, a differenza di quanto messo in atto nelle politiche interne, gli interventi a carattere normativo sono rimasti più limitati. Infatti, nel contesto interno il mutamento di strategia in campo economico si è tradotto in un progressivo rinnovamento e rafforzamento dell'apparato amministrativo e normativo diretto a fornire strumenti giuridici idonei a contrastare il dilagante degrado ambientale nel Paese[11].
Nel contesto degli investimenti all'estero, invece, è presente solo una – alquanto sommessa – regolamentazione costituita da linee guida, piani di azione o misure analoghe adottata principalmente da ministeri e Consiglio di Stato. Si tratta tuttavia di una regolamentazione che ha natura di mero indirizzo e non è dunque vincolante.
Sussiste pertanto una sensibile discrepanza tra il regime a cui sono sottoposte le imprese cinesi sul fronte interno e quello sul fronte esterno: infatti, mentre nella conduzione delle attività all'interno del territorio cinese le imprese sono vincolate a un rigoroso obbligo di salvaguardia dell'ambiente dettata dal consistente apparato normativo in essere (obbligo peraltro ribadito anche recentemente dal nuovo codice civile all'art. 9[12]), nel settore degli investimenti cinesi all'estero non è ad oggi rinvenibile una legge in materia di protezione ambientale che vincoli le imprese a rispettare *standard* minimi di tutela anche quando operano al di fuori dei confini nazionali.
La scelta di non imporre specifici obblighi in materia di tutela ambientale nel settore degli investimenti all'estero è stata reiterata – ad oggi – anche con riferimento alla BRI. Ciònonostante, la nuova strategia cinese non ha comunque del tutto tralasciato le questioni ambientali: infatti, il Governo cinese fin dagli albori dell'Iniziativa ha mostrato il chiaro intento di voler integrare e attuare nell'Iniziativa i concetti cardine di civiltà ecologica e sviluppo sostenibile.

3. Verso una Nuova Via della Seta "verde"

In corrispondenza alle più recenti *policy* ambientali interne che, come visto nel paragrafo che precede, includono la promozione dell'ambiente anche negli investimenti cinesi all'e-

[10] Le *Guidelines* ribadiscono altresì il dovere per le imprese cinesi di attenersi scrupolosamente alla normativa in materia di protezione ambientale del Paese ospitante (art. 5), raccomandando a tal fine di prevedere un sistema di formazione per i dipendenti per garantire la conoscenza delle leggi e dei regolamenti del Paese (art. 7).

[11] Ciò ha consentito alla Cina di raggiungere un considerevole apparato di norme che copre in larga misura ogni ambito connesso alla tutela ambientale. Per una ricostruzione sulla normativa ambientale nel sistema giuridico cinese si rimanda a B. Verri, *Sustainable Business from the Environmental Protection Perspective*, in M. Timoteo (ed.), *Law and Sustainable Business in China*, (Bononia University Press 2015, 45-59).

[12] L'art. 9 del nuovo codice civile, contenuto nella Parte generale del diritto civile adottata il 15 marzo 2017, recita: «[a]*ll civil subjects engaging in civil activities shall help save resources and protect the ecological environment*».

stero, la Cina ha da subito manifestato la chiara volontà di implementare la BRI seguendo i canoni della civiltà ecologica e dello sviluppo sostenibile[13]. Già con il *Vision and Actions* del 2015 era stata ufficializzata la necessità di rendere la Nuova Via della Seta un progetto ispirato al rispetto dell'ambiente e dunque rivolto al rafforzamento della cooperazione tra paesi per la conservazione delle risorse naturali, la protezione della biodiversità e la lotta al cambiamento climatico.

Al *Vision and Actions* del 2015 sono seguiti due ulteriori documenti, la *Guidance on Promoting a Green Belt and Road*[14] e il *Belt and Road Ecological and Environmental Cooperation Plan*[15], entrambi pubblicati nel 2017, i quali hanno delineato i tratti essenziali della sostenibilità ambientale nella BRI.

Nello specifico, la *Guidance on Promoting a Green Belt and Road*[16] è incentrata sulla formalizzazione della nozione di Via della Seta "verde". La necessità di rendere la BRI "verde" viene individuata dal documento in tre diversi ordini di ragioni: per condividere la filosofia della civiltà ecologica e raggiungere lo sviluppo sostenibile; per partecipare alla *governance* ambientale globale e promuovere il concetto di sviluppo verde; per creare una comunità che possa condividere interessi, responsabilità e futuro. La tutela ambientale, si afferma nella *Guidance*, deve essere ricercata all'interno di tutte le cinque priorità dell'Iniziativa. Lo strumento principale attraverso cui realizzare tale obiettivo è individuato nella cooperazione che, in ragione delle peculiarità della BRI, dovrà essere però ispirata a un nuovo modello definito multicanale, multilivello e multidimensionale.

Rispetto alla *Guidance*, il *Belt and Road Ecological and Environmental Cooperation Plan*[17] presenta connotati più pragmatici circa le azioni da intraprendere per conseguire la sostenibilità ambientale nell'Iniziativa. Due, nello specifico, sono gli obiettivi primari che vengono cristallizzati nel documento. Il primo ha ad oggetto l'integrazione entro il 2025 dei concetti di civiltà ecologica e sviluppo verde nelle cinque priorità dell'Iniziativa. Il secondo riguarda il rafforzamento della cooperazione ambientale al fine di raggiungere entro il 2030 gli Obiettivi di Sviluppo Sostenibile indicati nell'Agenda 2030 delle Nazioni Unite[18].

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[13] Il Comunicato congiunto della Tavola Rotonda dei Leader rilasciato all'ultimo Belt and Road Forum for International Cooperation dell'aprile del 2019 ha ribadito l'impegno «*to protect the planet from degradation, including through taking urgent action on climate change and encouraging all parties which have ratified it to fully implement the Paris Agreement, managing the natural resources in an equitable and sustainable manner, conserving and sustainably using oceans and seas, freshwater resources, as well as forests, mountains and drylands, protecting biodiversity, ecosystems and wildlife, combating desertification and land degradation so as to achieving sustainable development in its three dimensions in a balanced and integrated manner*» <*www.beltandroadforum.org/english/n100/2019/0427/c36-1311.html*>.

[14] <https://eng.yidaiyilu.gov.cn/zchj/qwfb/12479.htm>.

[15] <https://eng.yidaiyilu.gov.cn/zchj/qwfb/13392.htm>.

[16] Il documento è stato pubblicato dai Ministeri dell'ecologia e dell'ambiente, degli affari esteri e del commercio unitamente alla Commissione nazionale per lo sviluppo e le riforme.

[17] Il documento è stato formulato dal Ministero dell'ecologia e dell'ambiente.

[18] Questo obiettivo riflette quanto già annunciato nelle strategie di sviluppo interne. L'impegno della Cina su questo fronte è culminato con la pubblicazione nel 2016 del Piano nazionale cinese sull'attuazione dell'Agenda 2030 per lo sviluppo

Il *Belt and Road Ecological and Environmental Cooperation Plan* prosegue poi specificando per ognuna delle cinque priorità le misure che si propongono di adottare nel corso dell'implementazione dell'Iniziativa. Tra queste, ad esempio, nel settore della cooperazione intergovernativa si prevede lo sviluppo di meccanismi di cooperazione bilaterale e multilaterale per rafforzare il dialogo e lo scambio di conoscenze in materia di politiche, normative, *standard* e tecnologie. Nel settore delle infrastrutture si afferma l'obbligo per le imprese di rispettare le leggi e i regolamenti locali e di adottare condotte responsabili rispetto all'ambiente come favorire la costruzione di opere a basse emissioni di carbonio. Nell'ambito degli scambi commerciali si indica la necessità di impiegare mezzi di produzione sostenibili e incoraggiare prodotti con marchio di qualità ecologica. Nel settore finanziario si prevede l'impegno ad aumentare il sostegno al finanziamento "verde" e l'istituzione di un fondo dedicato allo sviluppo verde. Negli scambi culturali si prevede, infine, la formulazione di strategie e piani d'azione per incentivare i *green foreign aid*, dando priorità agli aiuti destinati a operare nel settore delle politiche e della legislazione ambientale[19].

La *Guidance on Promoting a Green Belt and Road* e il *Belt and Road Ecological and Environmental Cooperation Plan* costituiscono ad oggi i due più importanti documenti di indirizzo che, riprendendo le politiche ambientali interne, proiettano i concetti di civiltà ecologica e sviluppo sostenibile anche nel contesto della BRI, elevandoli così a principi che devono orientare le condotte dei soggetti che partecipano all'Iniziativa. Tuttavia, trattandosi di documenti di *policy*, rappresentano solo il punto di partenza: vi sono, infatti, altri strumenti di dettaglio ai quali è affidato il compito di realizzare in concreto la Green Belt and Road.

4. Dalle *policy* all'attuazione: gli strumenti giuridici per realizzare la Green Belt and Road

Da un punto di vista generale delle regole destinate a governare la BRI, l'ambizioso progetto ha posto la Cina di fronte all'interrogativo circa gli strumenti giuridici da impiegare per realizzare un'iniziativa che presenta caratteri di assoluta unicità in ragione della sua notevole estensione territoriale (Asia, Africa ed Europa), del rilevante numero di attori

sostenibile.

[19] Il *Belt and Road Ecological and Environmental Cooperation Plan* individua anche altre azioni concrete da promuovere come lo sviluppo del *capacity building* e la creazione di parchi eco-industriali e progetti nel settore della tecnologia verde (nello specifico si prevede che «[e]*fforts to facilitate and implement environmental technology and industrial projects will be carried out in the Yangtze River Economic Belt, Economic Rim, Pearl River Delta, and Central Plains Urban Agglomeration as underpinning for green Belt and Road*»).

coinvolti (stati, organizzazioni internazionali e altri organismi pubblici e privati) e degli obiettivi da raggiungere (non solo, come detto, strettamente economici).
Attualmente si possono individuare, da una parte, fonti create *ad hoc* per l'Iniziativa (come, ad esempio, il Memorandum d'intesa tra Italia e Cina firmato nel marzo 2019[20]) e, dall'altra parte, fonti che non riguardano direttamente la BRI, ma che per la materia trattata trovano comunque applicazione (come, ad esempio, i trattati internazionali in materia di commercio e investimenti). Più precisamente, le norme che interessano la BRI si sviluppano lungo due linee principali: da una parte, vi sono i tradizionali strumenti del diritto internazionale rappresentati essenzialmente dai trattati in ambito economico, dall'altra parte, vi sono gli strumenti di *soft law* costituiti da un articolato catalogo di misure e atti.

4.1. I lineamenti giuridici della BRI

Con riferimento alle fonti di diritto internazionale, questi strumenti sono quasi esclusivamente costituiti da accordi economici (trattati bilaterali di investimento o accordi di libero scambio) sorti in epoca antecedente al lancio dell'Iniziativa. Nonostante già a partire dagli anni Ottanta del secolo scorso la Cina si sia resa promotrice di numerosi accordi economici, anche tra i più recenti trattati sottoscritti non esistono convenzioni aventi oggetto esclusivo la BRI né risultano aperte, allo stato, negoziazioni con altri Stati rivolte in questa direzione.
Oltre ai singoli accordi economici, un'altra importante fonte di regolamentazione è poi rappresentata dalle regole dettate all'interno del sistema commerciale multilaterale, ossia il diritto proveniente dall'Organizzazione Mondiale del Commercio. Anche tale diritto è destinato a rivestire un ruolo decisivo in quanto si stima che l'ambito applicativo delle regole dell'OMC riguardi circa il 98% del commercio mondiale e pertanto inciderà inevitabilmente anche sugli scambi generati dall'implementazione dell'Iniziativa.
Accanto al diritto pattizio internazionale, lo strumento giuridico attualmente privilegiato per realizzare la BRI è però rappresentato dalla *soft law* che, nel contesto internazionale, costituisce una delle principali forme attraverso cui si realizza la cooperazione tra Stati[21].
Il motivo di tale preferenza è da individuare nella circostanza che un sistema di regole meno formale e vincolante, come quello della *soft law*, presenta il vantaggio di essere più

[20] Memorandum d'intesa tra Italia e Cina sulla collaborazione nell'ambito della "Via della seta economica" e dell'"Iniziativa per una via della seta marittima del 21° secolo".

[21] La cooperazione internazionale, come enunciato dallo stesso *Vision and Actions* del 2015, rappresenta il principale meccanismo per realizzare gli obiettivi prefissati della BRI. La Cina si sta mostrando sempre più attenta nel coinvolgere nella realizzazione dell'Iniziativa le organizzazioni internazionali e, in particolare, le Nazioni Unite con la quale ha già concluso diversi accordi di cooperazione. Si stima che all'inizio del 2020 siano già stati conclusi oltre 200 accordi di cooperazione con 138 paesi e 30 organizzazioni internazionali (v. J. Coenen, S. Baeger, E. Challies, *Environmental Governance of China's Belt and Road Initiative* (2020) *Environmental Policy and Governance* < https://onlinelibrary.wiley.com/doi/full/10.1002/eet.1901>).

flessibile[22]. La flessibilità è, infatti, un elemento che sembra essere indispensabile alla luce delle peculiarità della BRI. Non bisogna dimenticare che l'Iniziativa è un progetto che ha una marcata dimensione transnazionale e che coinvolge non solo numerosi attori – stati, organizzazioni internazionali, imprese pubbliche e private –, ma anche numerosi ordinamenti che spesso appartengono a tradizioni giuridiche distanti tra loro.
Il tema delle differenze giuridiche dei paesi coinvolti nella BRI è, dunque, una delle questioni più complesse nell'implementazione dell'Iniziativa che deve essere affrontata mediante soluzioni in grado di plasmarsi alle esigenze del caso. Questa capacità della *soft law* di adattarsi alle differenti situazioni si apprezza *in primis* con riferimento alla varietà delle sue forme che dipendono soprattutto in ragione dei soggetti coinvolti. Tra le diverse tipologie di strumenti si ricordano, ad esempio, i *Memorandum* d'intesa (che allo stato attuale costituiscono lo strumento più frequentemente impiegato[23]), le dichiarazioni congiunte, le lettere d'intenti, i piani di cooperazione. Nonostante la molteplicità delle forme impiegate, questi documenti hanno tuttavia sempre un denominatore comune: sono accordi che si fondano sul consenso delle parti ma sono privi di vincolatività per cui la loro attuazione è rimessa esclusivamente alla volontà delle parti stesse. La regolamentazione della BRI predilige pertanto la ricerca della cooperazione volontaria anziché l'imposizione di obblighi attraverso i trattati. Infatti, come è stato osservato, rispetto agli investimenti esteri portati avanti da altri paesi, la Cina ha adottato con la BRI un approccio più informale e meno istituzionale, basato sulla creazione di *partnership* con gli altri Stati partecipanti secondo un modello definito "*one country one approach*" ossia che varia di volta in volta per adattarsi alle esigenze del caso concreto[24].

4.2. La tutela dell'ambiente

Anche la tutela ambientale trova sostanzialmente attuazione all'interno della BRI attraverso i due canali sopra descritti. Dal punto di vista degli accordi internazionali, come già rilevato, ad oggi non si rinvengono convenzioni che contengono disposizioni *ad hoc* per la realizzazione della BRI e, pertanto, nemmeno per l'attuazione degli obiettivi della Green Belt and Road. È dunque necessario ricercare un'eventuale disciplina ambientale all'interno degli esistenti accordi economici.

[22] Su tale aspetto si rimanda a H. Wang, *China's Approach to the Belt and Road Initiative: Scope, Character and Sustainability* (2019) *Journal of International Economic Law* 43 l'autore, più precisamente, parla di "flessibilità massimizzata" per indicare proprio la strategia adottata dalla Cina di formulare un quadro giuridico fluido e modellabile così da poter realizzare diverse tipologie di progetti in diverse aree e in diverse giurisdizioni.

[23] I *memorandum* d'intesa hanno lo scopo di definire il quadro per lo sviluppo prossimo del dialogo e della cooperazione internazionale sulla BRI. Essi tuttavia rivestono anche la funzione di conferire legittimità all'Iniziativa non solo a livello internazionale, ma anche a livello nazionale in quanto testimoniano al popolo cinese l'accettazione da parte della comunità internazionale della BRI. Sul punto si rimanda a J. Wang, *China's Governance Approach to the Belt and Road Initiative (BRI): Relations, Partnership, and Law* (2019) *Global Trade and Customs Journal* 222.

[24] Su questo "*partnership-based relational approach*" si rinvia a J. Wang, *China's Governance Approach to the Belt and Road Initiative*, cit., 222-228.

A tal proposito, la Cina ha già da tempo iniziato a includere nei propri accordi internazionali disposizioni in materia di tutela dell'ambiente e di sviluppo sostenibile. Ad esempio, nell'accordo di libero scambio concluso tra Cina e Corea è contenuto un intero capitolo dedicato all'ambiente in cui i due Stati riconoscono «*their commitments to promoting economic development in such a way as to contribute to the objective of sustainable development and to ensuring that this objective is integrated and reflected in their trade relationship*» (art. 16.1) e adottano una serie di misure tese a dare effettiva attuazione alla normativa ambientale dei rispettivi ordinamenti. E ancora, nel trattato di investimento trilaterale concluso tra Cina, Corea e Giappone all'art. 23 si riconosce il dovere di ogni Stato contraente di non rinunciare o derogare alle misure ambientali vigenti per favorire l'acquisizione o l'espansione di investimenti nel proprio territorio. Nell'accordo bilaterale concluso tra Cina e Uzbekistan, invece, si afferma all'art. 6, comma terzo, che non costituiscono ipotesi di esproprio indiretto le misure adottate dallo Stato per proteggere l'ambiente a condizione che non siano discriminatorie e siano effettuate a vantaggio della collettività[25].

Con riferimento all'applicazione nella BRI delle disposizioni ambientali contenute in questi accordi internazionali è doveroso però effettuare due considerazioni. La prima è che la tutela ambientale all'interno del sistema pattizio internazionale trova espressione in norme isolate e spesso di contenuto molto generico. La seconda è che tali norme non sono sempre presenti in tutti gli accordi economici firmati dalla Cina con i paesi interessati dalla BRI[26]. In ragione di ciò, l'effettiva incidenza di tali disposizioni sul raggiungimento della sostenibilità ambientale dell'Iniziativa pare essere alquanto limitata.

Per rintracciare strumenti con misure concepite specificatamente per la BRI, è quindi necessario rivolgere lo sguardo verso gli strumenti di *soft law*[27]. All'interno di questi, l'impegno di realizzare la Green Belt and Road può trovare innanzitutto riconoscimento negli accordi conclusi con altri Stati. Così, ad esempio, nel Memorandum d'intesa sottoscritto con l'Italia si prevede, tra gli ambiti di collaborazione individuati al paragrafo II, la cooperazione per lo sviluppo verde. L'obiettivo fissato è di «*sviluppare la connettività seguendo un approccio sostenibile e rispettoso dell'ambiente, promuovendo attivamente il processo*

[25] Per un'analisi sulle previsioni ambientali contenute in altri trattati di investimento conclusi dalla Cina si rimanda a M. Chi, *The 'Greenization' of Chinese Bits: An Empirical Study of the Environmental Provisions in Chinese Bits and its Implications for China's Future Bit-Making* (2015) *Journal of International Economic Law* 511.

[26] Di tale circostanza è forse consapevole anche il Governo cinese che nella *Guidance on Promoting Green Belt and Road* ha indicato la necessità di includere i requisiti di protezione ambientale negli accordi di libero scambio.

[27] Anche nell'ambito della *soft law* vi sono poi numerosi strumenti che non sono stati adottati con specifico riferimento alla BRI ma che rivestono grande importanza nella cooperazione ambientale: si veda, ad esempio, la dichiarazione congiunta tra Cina e Francia del gennaio 2018 (<*https://eng.yidaiyilu.gov.cn/zchj/sbwj/43581.htm*>) con la quale i due paesi ribadiscono il loro impegno ad approfondire e ampliare la loro cooperazione in materia di protezione ambientale e cambiamento climatico, impegnandosi al rispetto dell'Accordo di Parigi; o, ancora, la dichiarazione congiunta tra Cina e Singapore del novembre 2018 (<*https://eng.yidaiyilu.gov.cn/zchj/sbwj/71762.htm*>) in cui si afferma l'impegno a rafforzare la cooperazione nella civiltà ecologica, nell'economia circolare, nella ricerca e nello sviluppo ambientale, nonché nella *governance* ambientale.

di transizione globale verso lo sviluppo verde, a bassa emissione di carbonio e l'economia circolare»[28].

Accanto agli accordi con i singoli paesi, vi sono poi le misure adottate di concerto con le organizzazioni internazionali e, in particolare, con le Nazioni Unite e le sue agenzie, tra le quali si ricordano il Programma delle Nazioni Unite per lo sviluppo (UNDP) e il Programma delle Nazioni Unite per l'Ambiente (UNEP)[29]. Gli accordi conclusi con le Nazioni Unite rivestono peraltro grande importanza per la Cina che fin dai primi momenti dell'Iniziativa ha cercato costante supporto da parte di questa organizzazione internazionale, integrando spesso le misure formulate da quest'ultima all'interno della stessa BRI (ad esempio, come sopra richiamato, l'impegno a realizzare gli Obiettivi per lo Sviluppo Sostenibile).

Di fronte a questa molteplicità di fonti (*memorandum* d'intesa, accordi di cooperazione) e alla frammentazione del quadro giuridico che consegue, la Cina ha anche istituito un organismo con il compito di coordinare le azioni intraprese. Si tratta della Coalizione Internazionale per lo Sviluppo Verde nell'ambito dell'Iniziativa Belt and Road (la Belt and Road Initiative International Green Development Coalition) creata dal Ministero dell'ecologia e dell'ambiente cinese e dall'UNEP. L'organismo è composto da 134 membri, tra i quali vi sono ventisei Ministeri dell'ambiente e numerose organizzazioni internazionali (come UNDP, UNIDO e UNECE)[30], e ha lo scopo di integrare lo sviluppo sostenibile all'interno delle cinque priorità dell'Iniziativa anche attraverso una piattaforma per la promozione del dialogo, della conoscenza e dello scambio di tecnologie. La Coalizione, ad oggi, è peraltro l'unico organismo che ha il compito specifico di promuovere la cooperazione in materia di norme, regolamenti e *standard* ambientali per cui è di tutta evidenza che nella definizione delle scelte in materia di tutela ambientale avrà un'importante funzione di indirizzo.

5. Il ruolo delle imprese nella Green Belt and Road

Tra gli attori coinvolti nella costruzione di una Nuova Via della Seta sostenibile non possono essere tralasciate le imprese cinesi. Nei due documenti che delineano la Green Belt and Road, il Governo cinese ha più volte esortato queste ultime ad adottare comportamenti improntati a canoni di sostenibilità e di responsabilità ambientale. Secondo la *Guidance*

[28] L'obiettivo è rimarcato dall'impegno dei due paesi a collaborare nel campo della protezione ambientale, dei cambiamenti climatici, nonché a promuovere la realizzazione dell'Agenda 2030 per lo Sviluppo Sostenibile e l'Accordo di Parigi sui cambiamenti climatici.

[29] Una lista delle agenzie coinvolte e delle iniziative intraprese con queste è disponibile al sito <http://wedocs.unep.org/bitstream/handle/20.500.11822/26318/UN%20Agencies%20BRI%20Involvement%2002%20%2801%20Oct%202018%29.pdf?sequence=17&isAllowed=y>.

[30] <www.unenvironment.org/regions/asia-and-pacific/regional-initiatives/belt-and-road-initiative-international-green>. Come previsto dal Memorandum d'intesa Italia-Cina del marzo 2019 a tale organismo partecipa anche il Ministero dell'Ambiente e della Tutela del Territorio e del Mare.

on Promoting Green Belt and Road le imprese, infatti, rappresentano «*the main player and civil society facilitation so as to render positive contributions to the green 'Belt and Road' Initiative*». Il *Belt and Road Ecological and Environmental Cooperation Plan* ha, invece, specificato alcune azioni concrete che gli imprenditori cinesi sono chiamati ad adottare. Tra queste, oltre al generale dovere di rispetto delle normative e degli *standard* ambientali dei paesi ospitanti, si segnala, ad esempio, l'impiego metodi di produzione e gestione aziendale ispirati a processi sostenibili (cioè a basse emissioni di carbonio e di consumo energetico, indirizzati al riciclo di materiali e riduzione degli scarti e degli agenti inquinanti); la pubblicazione delle informazioni aziendali in materia ambientale anche tramite i siti *internet* (report annuali, piani per la gestione del rischio ambientale); ovvero l'adozione di codici di condotta per regolamentare gli aspetti ambientali degli investimenti esteri.
Come emerge dal *Belt and Road Ecological and Environmental Cooperation Plan,*anche con riferimento al ruolo delle imprese cinesi la realizzazione della Green Belt and Road passa attraverso l'impiego di meccanismi affidati alla volontarietà dei soggetti. La ricostruzione degli strumenti di *soft law* in materia di sostenibilità ambientale della BRI non sarebbe pertanto completa se non si analizzassero, oltre alle misure adottate dagli Stati e dalle organizzazioni internazionali già sopra descritte, anche quelle veicolate dalle imprese.
In questo ambito una prima misura è costituita dalla cosiddetta *green finance*, espressione che indica quel catalogo di prodotti finanziari (come le obbligazioni, i finanziamenti o le assicurazioni "verdi") associati a progetti con ricadute in termini di protezione ambientale. Da un punto di vista generale, la *green finance* è uno strumento già da tempo noto all'ordinamento cinese. Le *Green Credit Guidelines* pubblicate nel 2012 dalla Commissione di Regolamentazione dell'Attività Bancaria della Cina (CBRC) rappresentano la principale fonte normativa in materia di sostenibilità e attività bancaria. In virtù delle *Guidelines* gli istituti di credito possono prevedere tra i criteri per valutare il merito creditizio anche la sostenibilità dell'impresa che richiede il finanziamento. Ciò significa che non solo il rischio ambientale dell'impresa può costituire oggetto di una specifica *due diligence* da parte della banca, ma anche che quest'ultima può rifiutare l'accesso al credito all'impresa che non rispetti le normative in materia di prestazioni ambientali e sociali[31].
Con particolare riferimento alla BRI, le misure interne di *green finance* già attualmente previste dall'ordinamento cinese (come, appunto, quelle in materia di credito "verde") sono state affiancate da ulteriori specifiche azioni. L'importanza di sviluppare un sistema di finanza "verde" nella BRI è stata da subito messa in luce nella *Guidance on Promoting Green Belt and Road*[32]. Tra queste misure specifiche una delle più rilevanti è costituita

[31] Al fine di assistere le banche nell'applicazione delle *Guidelines* la Commissione di Regolamentazione dell'Attività Bancaria della Cina (CBRC) ha introdotto nel 2014 i *Green Credit Implementation Key Audit Standards*.

[32] Il documento afferma, infatti, il seguente impegno «[w]*e will fortify environment management of overseas investment and develop green financial system. We will quicken the pace to formulate and execute policies and measures to prevent eco risks of investment and financing projects, tighten environment management for overseas investment, drive*

dai *Green Investment Principles for Belt and Road Development*, sottoscritti nel 2019 da ventisette istituzioni finanziarie (tra le quali le principali banche cinesi e altre importanti enti creditizi stranieri, come DBS Bank, Deutsche Bank, e UBS Group)[33]. I sette principi, sviluppati di concerto dalla Green Finance Committee of China Society for Finance and Banking e dalla City of London Corporation's Green Finance Initiative, hanno il preciso obiettivo di promuovere gli investimenti verdi nella BRI, operando su tre diversi livelli: a livello di strategia, al fine di incoraggiare a introdurre i fattori di sostenibilità e rischi ambientali nelle scelte aziendali (Principi 1 e 2); a livello operativo, al fine di divulgare a tutti gli interessati le informazioni circa l'impatto ambientale delle attività svolte (Principi 3 e 4); a livello di innovazione, al fine di favorire l'impiego di strumenti finanziari "verdi", la gestione di una catena di approvvigionamento sostenibile, lo sviluppo e la condivisione di competenze (Principi 5, 6 e 7)[34]. In particolare, il Principio 5 precisa l'intenzione di incentivare il ricorso agli strumenti finanziari e assicurativi "verdi" (come «*green bonds, green asset backed securities* [...] *green investment funds*», nonché «*environmental liability insurance and catastrophe insurance*»)[35].

Una seconda misura fondamentale, che consentirà alle imprese di apportare un significativo contributo alla realizzazione della Green Belt and Road, è poi costituita dalla responsabilità sociale d'impresa, intesa come l'insieme di condotte adottate nell'esercizio delle attività imprenditoriali che sono rivolte a favorire lo sviluppo sostenibile e a valorizzare gli interessi di tutti gli *stakeholder*[36].

Anche questo meccanismo è ben noto all'ordinamento cinese che ha introdotto per la prima volta il concetto di responsabilità sociale d'impresa nella Legge sulle società del 2005. Tale legge, infatti, prevede all'articolo 5 il dovere dell'impresa di svolgere la sua attività non solo nel rispetto delle leggi e dei regolamenti, ma anche agendo secondo buona fede e assumendosi le responsabilità sociali[37]. Si tratta di una norma generica che trova poi

enterprises to voluntarily bear environmental and social responsibilities, and strictly protect bio-diversity and ecological environment».

[33] Tale documento era stato preceduto dai Guiding Principles on Financing the Development of the Belt and Road pubblicati nel 2017 nei quali si è riconosciuto che «*financing arrangements for the development of the Belt and Road should benefit all businesses and populations in a way that supports sustainable and inclusive development*» (<https://eng.yidaiyilu.gov.cn/zchj/qwfb/13757.htm>).

[34] <http://gipbr.net/Index.aspx>.

[35] Ad esempio al fine sostenere lo sviluppo ecologico della BRI sono state già emesse obbligazione verdi dalla Export-Import Bank of China per 2 miliardi di RMB e dalla BRICS New Development Bank per 3 miliardi di RMB (<https://eng.yidaiyilu.gov.cn/zchj/qwfb/86739.htm>).

[36] Questa è, in sostanza, la definizione di responsabilità sociale d'impresa adottata dalla Guida sulla responsabilità sociale ISO 26000.

[37] Così recita l'art. 5 «[w]*hen undertaking business operations, a company shall comply with the laws and administrative regulations, social morality and business morality. It shall act in good faith, accept the supervision of the government and the general public, and bear social responsibilities*» (<http://www.leggicinesi.it/view_doc.asp?docID=23>). Vi sono poi altre leggi che prevedono al loro interno il riferimento alla responsabilità sociale d'impresa: la Partnership Enterprise Law del 2006 (v. l'art. 7 secondo cui «[a] *partnership enterprise and its partners shall observe the laws, administrative regulations, social morals and commercial morals, and bear social liabilities*»), nonché la Law State-Owned Assets in

concreta attuazione in altre fonti, quali linee guida, *standard*, raccomandazioni e strumenti simili[38].

Nel settore degli investimenti cinesi all'estero la responsabilità sociale d'impresa viene presa in esame nelle *Guidelines for Environmental Protection in Foreign Investment and Cooperation* del 2013 le quali, nello specifico, incoraggiano le imprese a creare meccanismi di dialogo con la comunità locali al fine di attuare forme di intervento diretto degli interessati per raccogliere pareri e suggerimenti rispetto agli impatti ambientali delle attività all'estero (art. 20)[39].

Nella BRI la necessità di adottare comportamenti socialmente responsabili da parte delle imprese cinesi coinvolte emerge sia nel *Vision and Actions*, in cui si afferma che le imprese devono assumere le proprie responsabilità sociali nella protezione della biodiversità e dell'ecosistema locale, nonché nella *Guidance on Promoting a Green Belt and Road*, in cui si ribadisce l'urgenza di formulare e attuare politiche e misure su questi aspetti.

Tra le azioni già in essere si segnala la *Initiative on Corporate Environmental Responsibility Fulfillment for Building the Green Belt and Road*, istituita nel dicembre 2016 da diciannove imprese cinesi che operano nei settori dell'energia, dei trasporti, della manifattura e dell'ambiente. Il progetto si prefigge lo scopo di far assumere alle imprese cinesi l'impegno, da una parte, a osservare la normativa ambientale vigente e, dall'altra parte, a dare un contributo concreto alla cooperazione internazionale e alla realizzazione della Green Belt and Road[40]. Un altro esempio di misura presa nel settore della responsabilità sociale d'impresa, questa volta adottata da un'associazione di imprese (la China International Contractors Association – CHINCA), sono le *Guidelines of Sustainable Infrastructure for Chinese International Contractors*[41], formulate nel 2017 al fine di indirizzare le imprese cinesi a finanziare, pianificare, progettare, costruire e gestire progetti di infrastrutture sostenibili[42] all'estero. Nella prefazione, le *Guidelines* fanno espresso riferimento alla BRI, sollecitando

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Enterprises del 2008 (v. l'art. 17 secondo cui «[i]*n business operations the State-invested enterprises shall observe laws and administrative regulations, strengthen business management, achieve better economic results, accept the administration and supervision legally exercised by the people's governments and the relevant departments and institutions under them, accept supervision of the general public, shoulder their social responsibilities, and be responsible to the contributors*»).

[38] Si pensi, ad esempio, alla *Notice on Strengthening Listed Companies' Assumption of Social Responsibility* adottata dalla Shanghai Stock Exchange nel 2008 che prevede incentivi alle società quotate che promuovono la responsabilità sociale d'impresa nel settore ambientale. Oltre alle iniziative prese nel settore interno vi sono poi tutte le misure adottate a livello internazionale (come gli *standard* della International Organization for Standardization).

[39] In alcuni trattati bilaterali di investimento è possibile trovare disposizioni dedicate alla responsabilità sociale degli investitori; così, ad esempio, nel trattato tra Cina e Tanzania è previsto nel preambolo l'impegno degli Stati contraenti a «*encouraging investors to respect corporate social responsibilities*».

[40] China Council for International Cooperation on Environment and Development 8 (CCICED), *Special Policy Study on Green Belt and* Road and *2030 Agenda for Sustainable Development*, (2018), <https://cciced.eco/wp-content/uploads/2020/06/cciced-sps-green-belt-roads.pdf.>.

[41] <http://images.mofcom.gov.cn/csr2/201707/20170713103213247.pdf.>.

[42] Con progetti di infrastrutture sostenibili le *Guidelines* fanno riferimento a «*projects which fully integrate the ideology of sus tainable development into the processes of funding, planning, design, building, operation, maintenance and closure so as to eliminate or ensure the least harm to stakeholders' rights and interests throughout their lifecycle, minimize natu-*

le imprese nazionali a realizzare la Nuova Via della Seta attraverso progetti di infrastrutture sostenibili[43]. Queste *Guidelines* si sviluppano intorno a tre principi fondamentali: la necessità di tenere in considerazione le istanze provenienti dagli *stakeholder*; l'esigenza di includere la sostenibilità in tutte le fasi di implementazione del progetto; la necessità di rendere le infrastrutture idonee a soddisfare non solo i bisogni attuali ma anche di rispondere ai cambiamenti futuri. Con specifico riferimento alla sostenibilità ambientale, si chiede alle imprese cinesi di osservare la legislazione ambientale locale, anche attraverso personale dedicato ad attuare o supervisionare il rispetto delle norme, e di porre immediato rimedio in caso di sua violazione[44].

Sia la *green finance* sia la responsabilità sociale d'impresa costituiscono tuttavia misure che, come già precisato, sono lasciate interamente alla volontà delle singole imprese. L'effettiva incidenza di tali strumenti di *soft law* dovrà quindi essere valutata nel tempo con il procedere dell'implementazione della BRI. Tuttavia non v'è dubbio che l'efficacia di tali meccanismi dipenderà anche in gran parte anche dal supporto che il Governo cinese saprà dare a tali misure volontarie, specialmente dal punto di vista di incentivi alla loro adozione (si pensi, ad esempio, a misure dirette a consentire l'accesso agevolato al credito bancario, a riconoscere sgravi in materia fiscale o a garantire priorità nella contrattazione con enti pubblici).

6. Conclusioni

È ormai chiaro che la Belt and Road Initiative rappresenta la nuova fase di espansione degli investimenti cinesi in uscita che condurrà a una maggiore integrazione della Cina nell'economia globale. È parimenti chiaro che in questa nuova fase del *going out* la Cina ha voluto presentarsi alla comunità internazionale attraverso un nuovo modello, più sostenibile e più attento alla salvaguardia dell'ambiente, portando così all'esterno le politiche già intraprese nel proprio ordinamento e che sono culminate con la formulazione della civiltà ecologica[45].

ral resource consumption and adverse environmental effect, keep in harmony with the host community, and meet the local needs for medium-to-long-term socioeconomic growth» (v. par. 1.3).

[43] Sulla necessità di adottare una strategia per realizzare la sostenibilità delle infrastrutture le *Guidelines* si esprimono in termini di scelta inevitabile per le imprese cinesi («[e]*conomically, environmentally and socially sustainable infrastructure projects are, therefore, an inevitable choice for Chinese go-global companies to achieve long-term sustainability*»).

[44] Il rispetto della normativa ambientale è poi accompagnato dalla necessità di allocare appropriate risorse, anche in termini di tecnologia, per promuovere la protezione dell'ambiente e di impiegare razionalmente le risorse naturali riducendo le emissioni di gas serra e di agenti inquinanti.

[45] Questo nuovo modello è veicolato anche attraverso i *memorandum* d'intesa firmati i quali, come è stato notato, sono quasi sempre redatti sulla base di uno schema predisposto dalla Cina (v. J. Wang, *China's Governance Approach to the Belt and Road Initiative*, cit., 222-228).

La promozione della sostenibilità ambientale è quindi considerata un'importante componente per la proficua attuazione dell'Iniziativa. Di tanto v'è conferma non solo nell'adozione di specifici documenti di *policy* (la *Guidance on Promoting a Green Belt and Road* e il *Belt and Road Ecological and Environmental Cooperation Plan*), ma anche nelle misure che si stanno avviando in concreto. Su quest'ultimo aspetto, è stato messo in luce che – sulla scia dell'approccio informale alle regole che caratterizzava il pensiero confuciano[46] – la tecnica adottata dal Governo cinese per realizzare la Green Belt and Road consiste nell'impiegare principalmente strumenti di *soft law* i quali consentono di assicurare, in ragione delle peculiarità della BRI, la necessaria flessibilità nelle azioni da attuare. Questa soluzione è peraltro coerente con le scelte del legislatore cinese, il quale non ha voluto adottare una legge specifica diretta a imporre *standard* minimi di tutela ambientale alle imprese cinesi che investono all'estero. All'interno dell'Iniziativa, pertanto, la *soft law* si propone come alternativa ai "tradizionali" strumenti a carattere impositivo[47] che, ad oggi, trovano nella BRI un ricorso alquanto limitato.

L'impiego prevalente di strumenti di *soft law* potrebbe tuttavia rappresentare un ostacolo sotto altri profili, *in primis* quello dell'effettiva implementazione delle misure rivolte a sostenere la Green Belt and Road. Si tratta, infatti, di misure incoercibili e prive di un sistema sanzionatorio. L'attuale assenza di un sistema coercitivo non si traduce comunque nell'assenza di meccanismi in grado di agevolare, anche indirettamente, l'adozione di tali misure. Ad esempio, con riferimento alle imprese coinvolte nella BRI, la predisposizione da parte del Governo cinese di incentivi (come l'accesso agevolato al credito bancario, sgravi in materia fiscale o priorità nella contrattazione con gli enti pubblici) potrebbe costituire un importante sostegno all'adozione di comportamenti rivolti a conseguire la Green Belt and Road.

Essendo l'adozione di tali misure lasciata alla mera volontà delle parti, al fine di determinare l'effettività e l'incidenza degli strumenti giuridici impiegati rispetto agli obiettivi prefissati in campo ambientale, saranno pertanto necessarie ulteriori indagini dirette a monitorare nel tempo le tipologie e le modalità di azioni intraprese con l'evolversi dell'Iniziativa. In ogni caso, il dato che allo stato emerge con tutta evidenza è che la Cina ha inteso di indirizzare la BRI verso un nuovo modello, un modello "indigeno", ispirato alla civiltà ecologica e allo sviluppo sostenibile[48]. Tale modello potrà peraltro essere fonte di

[46] Sulle interazioni tra norme culturali tradizionali e diritto formale in Cina si rimanda a L.A Di Matteo, *Rule of Law in China: The Confrontation of Formal Law with Cultural Norms* (2018) *Cornell International Law Journal* 391.

[47] L'impiego della *soft law* nel settore ambientale è già ampiamente diffuso nell'ordinamento interno ma anche a livello di *governance* globale (sul punto si rimanda a J. Coenen, S. Baeger, E. Challies, *Environmental Governance of China's Belt and Road Initiative*, cit., 10.

[48] Sulla tendenza dell'ordinamento cinese a sviluppare soluzioni innovative che tengano in considerazione le "caratteristiche cinesi" e non più solo i modelli presi a riferimento nel processo di modernizzazione del diritto cinese, si rimanda a M. Timoteo, *China Codifies. The First Book of the Civil Code between Western Models to Chinese Characteristics* (2019) 1,1 *Opinio Juris in Comparatione* 23 <http://www.opiniojurisincomparatione.org/opinio/article/view/129>.

ispirazione anche per altri ordinamenti giuridici interessati dall'Iniziativa, specialmente per quei sistemi che non si sono ancora dotati di un apparato normativo sufficientemente adeguato alle problematiche ambientali che oggi non possono essere più ignorate.

Wildlife Conservation v. Utilization: Considerations and Trends for China's Regulatory Position in the Age of Covid

Yongmin Bian*, Boyang Wang**

Abstract

Wildlife Conservation and Utilization has been the main theme of China's first Wild Animal Conservation Law of 1988 and its amendments. From the early 1950s to the late 1980s, only rare and precious animals enjoyed protection to a certain degree, and the rest of the animals were subject to utilizations or various 'rational utilizations.' The 1988 Wild Animal Conservation Law mercifully extended protection to beneficial, economically important or scientifically valuable terrestrial wildlife. The protection of wildlife was defined as a priority over utilization only in the amendment of 2016, 13 years later after the 2003 SARs which was caused by a virus passed to human beings from a species of wild animal. China adopted very efficiently a ban on hunting and eating all terrestrial wild animals after the outbreak of Covid-19. The wild animals finally won the debate between conservation and utilization. This is not only a welcomed improvement for conservation of wild

* Professor, Law School, University of International Business and Economics. The author can be reached by bianyongmin@uibe.edu.cn.

** Student in master program, Law School, University of International Business and Economics. The author can be reached by Boyang.Wong@outlook.com. The authors appreciate Professor Arthur Chiu for his valuable comments, English proof and editing to this paper.

animals in China, but also a great contribution to the conservation of wild animals globally since the trade in wild animals is under strict enforcement now.

Keywords

China's Wild Animal Conservation Law – Wildlife Conservation – Wildlife Utilization – Wild Animal Conservation and Covid Pandemic

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Introduction

The People's Republic of China ("China") once had rich wildlife resources and a long history of both the protection and use of wildlife. Since the beginning, the weight of protectionism versus utilization has been a highly controversial issue from the first modern law protecting wildlife enacted by China in 1950. On one hand, a growing consensus believes in the significance to maintain biodiversity and ecological balance, while on the other

hand, utilizing wildlife resources is deeply rooted in traditional Chinese culture. From such tradition, utilization was favored over protectionism until certain wildlife populations noticeably and sharply declined. Therefore, how to reconcile the delicate balance between protectionism and utilization is of constant challenge. The Covid-19 pandemic seems to be a turning point. For one, more stringent laws regulating the use of wildlife have been adopted. For another, wildlife administration is also undergoing a dramatic change, as the Ministry of Agriculture has issued a "whitelist" (a regulated list of all wildlife species that can be utilized) in May 2020[1], replacing the original "blacklists" (a list of wildlife species under state protection)[2]. While the eating and trading of wildlife will be strictly regulated after the Covid-19 pandemic, a ban on wildlife use for medical purposes has not yet been proposed.

This article is based on a thorough analysis of all the relevant laws and regulations in the field of wildlife protection in China, in order to present the evolution of said laws and the driving force behind each amendment. The first section provides an overview of conservation of wild animals in China, including the evolution of relevant laws and an introduction to the main scheme on wildlife protection within the current legal system. The second section introduces the implementation of wild animal protection laws in China. Some exceptions to wildlife protection, such as medical use, domestication or breeding in captivity (particularly for fur and production of traditional Chinese medicine), and food are discussed in detail. The third section contemplates the current trend of enhancing wild animal conservation due to the Covid-19 pandemic, and for which the newly issued 24 February 2020 ban on hunting and eating wildlife and its further reaching implications are analyzed in-depth. The fourth section focuses on challenges beyond law, including discussions on cultural influence and use of wildlife in Chinese traditional medical science. This article in part concludes that the great determination to forbid wildlife eating as established by the central government in its recent ban has finally shifted the balance towards the protection of wildlife instead of utilization.

[1] Ministry of Agriculture and Rural Affairs, *Guojia chuqin yichuan mulu* (National Livestock and Poultry Genetic Resources Directory), 27 May 2020, http://www.moa.gov.cn/govpublic/nybzzj1/202005/t20200529_6345518.htm (last visited 26 July 2020).

[2] These "blacklists" include *Guojia zhongdian baohu yesheng dongwu minglu* (List of Wildlife under State Priority Protection) issued by State Forestry Administration on 14 January 1989, http://www.forestry.gov.cn/main/3954/content-1063883.html (last visited 26 July 2020); *Guojia baohude youyide huozhe you zhongyao jingji, kexue yanjiu jiazhide lusheng yesheng dongwu minglu* (The List of Beneficial, Economically Important or Scientifically Valuable Terrestrial Wildlife) issued by State Forestry Administration on 1 August 2000, http://www.forestry.gov.cn/main/3954/content-959027.html (last visited 26 July 2020).

I. An Overview of Wild Conservation in China

I.1. The evolution of laws on wild animal protection

The common perception is that China had not paid much attention to wildlife conservation until the first related law in this field (i.e., the Wild Animal Conservation Law) was introduced in 1988. Contrarily, attention to wildlife protection was made immediately after the establishment of the People's Republic of China, when Measures on Protecting Rare Wild Animals ("1950 Measures") was promulgated in 1950[3]. In accordance with the policy of the 1950 Measures, the first biosphere reserve was founded in Dinghu Mountain of Guangdong Province[4]. During the following nine years, another 18 natural reserves were established[5]. Then in 1962, the State Council issued the Guidance on Positive Protection and Rational Use of Wildlife Resources ("1962 Guidance"), which laid down the principle of "utilization after protection" and also specifically identified more than 30 rare species that required special protection[6].

However, despite such regulatory efforts, the actual situation of wildlife conservation was still dire. Both the 1950 Measures and the 1962 Guidance were more of a declaratory nature and silent on many aspects, including implementation methods of the provisions and punishment enforcement for violations. Besides, eliminating the Chinese traditional habit of eating wildlife would have been challenging given that the 1962 Guidance provided ways to utilize such resources legally. Further, due to the underdeveloped economy and scarcity in food, a lot of wild animals were hunted from the 1950s to 1980s, especially during the Three-Year Famine[7]. According to local statistics, in Qinghai Province alone, more than 330,000 wild fowls were hunted from 1965 to 1985[8]. Therefore, it is unsurprising that not much actual improvements concerning wildlife protection were made during this period.

[3] Government Administration Council of the Central People's Government, *Xiyou shengwu baohu banfa* (Measures on Protecting Rare Wild Animals), 24 May 1950, http://www.scio.gov.cn/xwfbh/xwbfbh/wqfbh/2013/0521/index.htm (last visited 5 May 2020).

[4] Dinghu Mountain Biosphere Reserve, *Tese jianjie* (Brief Introduction on Dinghu Mountain Biosphere Reserve), http://www.dhs.scib.cas.cn/sy_tsjj/# (last visited 6 July 2020).

[5] Fan Zhiyong, *Yesheng dongwu baohu de hexin shi qixidi baohu* (The Core of Wildlife Protection Is the Protection of Their Habitats), *WWF China*, http://www.wwfchina.org/staffdetail.php?id (last visited 29 April 2020).

[6] State Council, *Guowuyuan guanyu jiji baohu he heli liyong yesheng dongwu ziyuan de zhishi* (Guidance on Proactive Protection and Rational Use of Wildlife Resources), 14 September 1962, http://www.china.com.cn/law/flfg/txt/2006-08/08/content_7059502.htm (last visited 30 April 2020).

[7] Almost all Chinese in 1950s–60s experienced the Three-Year Famine (1959-61). According to the government figures, millions of people died of hunger. See Yang Jishen, *Gravestone: Documentary on Great Famine in 1960s* (at 1, Tiandi Publishing House (Hong Kong) 2008).

[8] Editorial Committee of Qinghai Local Chronicles, *Qinghai Shengzhi Linzhezhi (Local Chronicles of Qinghai Province: Forest)*, 1st ed., Sanqin Publishing House, at 164. See http://book.qhdifangzhi.com/ZhiJianChengGuo/chorography/Index?QName=LinYe#p_230 (last visited 30 April 2020).

After several years of extremely lenient control on hunting and eating of wildlife, many species suffered a dramatic decline in population during the 1950s to 1980s, including tigers, panthers and snakes[9]. Finally, 21 years after the 1962 Guidance was issued, the State Department put forward the Circular Decree of the State Council Concerning Strict Protection of Precious and Rare Wild Animals, which recognized the potential danger of exhaustion of wildlife and prohibited the export of precious and rare wild animals for the first time[10]. Following this new trend, the Department of Forestry (now the State Forestry and Grassland Administration) promulgated the Measures for the Management of Forests and Wildlife Nature Reserve to extend the scope of protection to the habitat of wildlife[11]. After decades of massive hunting, the number of wild animals in China had rapidly decreased. In response to the dire need to slow down such decrease through a set of binding rules, the Wild Animal Conservation Law was enacted in 1988 ("1988 Law")[12]. The 1988 Law was the first law in China that established a comprehensive structure for wildlife protection, including measures of protection and the administration of wildlife as well as legal liability. Although the 1988 Law was a huge improvement in terms of the level of protection and comprehensiveness towards wildlife protection, it was still rough in many aspects. First, the 1988 Law did not offer a list of beneficial, economically important or scientifically valuable terrestrial wildlife corresponding to the definition of "wildlife under protection" as mentioned in Article 2 of the 1988 Law, which made the scope of protection unclear. Second, relevant provisions in Criminal Law[13] and Regulations on Administrative Penalties for Public Security[14] had not been finalized as to be consistent with policies regulated in the 1988 Law.

The Wild Animal Conservation Law fixed part of the problems in the 1988 Law by its 2009 revision ("2009 Law")[15]. In the 2009 Law, consistency between the Wild Animal Conserva-

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[9] Yang Jintao, '*Yibainian lai, zhongguoren miejuele duoshaozhong dongwu?*' (*How many species of animals have become extinct in China over the past one hundred years?*) (Tencent Views, 4 August 2017), https://view.news.qq.com/original/legacyintouch/d666.html (last visited 1 June 2020).

[10] State Council, *Guowuyuan guanyu yange baohu zhengui xiyou yesheng dongwu de tongling* (Circular Decree of the State Council Concerning Strict Protection of Precious and Rare Wild Animals), 13 April 1983, http://www.china.com.cn/law/flfg/txt/2006-08/08/content_7059519.htm (last visited 2 May 2020).

[11] Department of Forestry, *Senlin he yesheng dongwu leixing ziran baohuqu guanli banfa* (Measures for the Management of Forests and Wildlife Nature Reserve), 6 July 1985, http://www.forestry.gov.cn/main/3950/20170314/459887.html (last visited 6 December 2020).

[12] Standing Committee of the National People's Congress, *Zhonghua renmin gongheguo yesheng dongwu baohu fa (1988)* (Wild Animal Conservation Law of People's Republic of China [1988]), 8 November 1988, http://lyj.czs.gov.cn/zwgk/zcfg/content_117819.html (last visited 31 July 2020).

[13] National People's Congress, *Zhonghua renmin gongheguo xingfa (xiuding)* (Criminal Law of the People's Republic of China), 14 March 1997, http://www.npc.gov.cn/wxzl/wxzl/2000-12/17/content_4680.htm (last visited 20 July 2020).

[14] Standing Committee of the National People's Congress, *Zhonghua renmin gongheguo zhian guanli chufa tiaoli* (Regulations of the People's Republic of China on Administrative Penalties for Public Security), 22 October 1957, http://www.law-lib.com/law/law_view1.asp?id=94225 (last visited 26 July 2020).

[15] Standing Committee of the National People's Congress, *Zhonghua renmin gongheguo yesheng dongwu baohu fa (2009)* (Wild Animal Conservation Law of People's Republic of China [2009]), 27 August 2009, http://www.iolaw.org.cn/

tion Law and other laws had been greatly enhanced. Therefore, if in breach of the 2009 Law, a more precise legal basis in terms of legal liability could be found in the Criminal Law or the Law on Penalties for Administration of Public Security[16]. However, aside from that, no other improvement was made in the 2009 Law.

With lots of issues unanswered in the 2009 Law, another round of revisions was proposed in 2016 ("2016 Law")[17]. For the first time, protection of wildlife was defined as the priority in the 2016 law, which required the State "give priority to wildlife protection and regulate utilization strictly." The 2016 Law also put wildlife products under protection for the first time and made it clear that "wildlife and the products thereof as referred to in this Law shall mean the entire (including spawn or egg) and parts of its body and its derivatives." Moreover, the 2016 Law came up with more thorough provisions in relation to the administration of wildlife products, including artificial breeding and wildlife hunting, which were considered to be a huge breakthrough in the protection of wildlife. In 2018, some minor amendments in wording were made and that became the current version of the Wild Animal Conservation Law ("2018 Law")[18].

In 2020, due to the outbreak and spread of Covid-19 pandemic and the fact that some of the earliest cases in China were connected to Wuhan Seafood Wholesale Market[19] where wildlife business had taken place, the Chinese government resolved to put an end to the long-lasting tradition of eating wildlife. Therefore, on 24 February 2020, the Standing Committee of the National People's Congress issued the Decision of the Standing Committee of the National People's Congress on a Complete Ban of Illegal Wildlife Trade and the Elimination of the Unhealthy Habit of Indiscriminate Wild Animal Meat Consumption for the Protection of Human Life and Health ("2020 Decision")[20]. Three months later, the Ministry of Agriculture promulgated the National Livestock and Poultry Genetic Resources

showNews.aspx?id=24345 (last visited 31 July 2020).

[16] National People's Congress, *Law of the People's Republic of China on Penalties for Administration of Public Security*, 28 August 2005, http://english.www.gov.cn/archive/laws_regulations/2014/08/23/content_281474983042627.htm (last visited 20 July 2020).

[17] Standing Committee of the National People's Congress, *Zhonghua renmin gongheguo yesheng dongwu baohu fa (2016)* (Wild Animal Conservation Law of People's Republic of China [2016]), 2 July 2016, http://www.npc.gov.cn/wxzl/gongbao/2016-08/22/content_1995643.htm (last visited 31 July 2020).

[18] Standing Committee of the National People's Congress, *Zhonghua renmin gongheguo yesheng dongwu baohu fa (2018)* (Wild Animal Conservation Law of People's Republic of China [2018]), 26 October 2018, http://www.npc.gov.cn/npc/c12435/201811/f4d2b7a3024b41ee8ea0ce54ac117daa.shtml (last visited 31 July 2020).

[19] Z. Yongzhen, E. C. Holmes *A Genomic Perspective on the Origin and Emergence of SARS-CoV-2*, (2020) *Cell* 1, https://doi.org/10.1016/j.cell.2020.03.035, last visited 3 May 2020.

[20] Standing Committee of the National People's Congress, *Quanguo renmin daibiao dahui changwu weiyuanhui guanyu quanmian jinzhi feifa yesheng dongwu jiaoyi, gechu lanshi yesheng dongwu louxi, qieshi baozhang renmin qunzhong shengming jiankang anquan de jueding* (Decision of the Standing Committee of the National People's Congress on a Complete Ban of Illegal Wildlife Trade and the Elimination of the Unhealthy Habit of Indiscriminate Wild Animal Meat Consumption for the Protection of Human Life and Health), 24 February 2020, http://www.npc.gov.cn/englishnpc/lawsoftheprc/202003/e31e4fac9a9b4df693d0e2340d016dcd.shtml (last visited 26 July 2020).

Directory ("Directory")[21], which is one of the more important supporting legal documents to help bring the 2020 Decision into fuller effect, as the Directory specifically limits the wildlife consumption or utilization to just 16 species. However, despite the expeditious response from the national level as well as the ambitious nature of the 2020 Decision and the Directory, some key issues remained unsolved. Specifically, the 2020 Decision itself did not specify what species can be utilized, while the language of the Directory remains rather general. All wildlife in the Directory are referred to in the form of broad categories, instead of fixed species, resulting in potential conflict with the current protection lists. For example, one of the wildlife category listed as not prohibited in the Directory is Columba, which includes many different species of pigeons, such as the Columba palumbus, a species under Class II state protection. Additionally, the Directory failed to use biological names, so it is difficult to identify which species are applicable, making it less practicable[22]. Moreover, the 2020 Decision is mainly aimed at banning the consumption of terrestrial wildlife, and aquatic wildlife that are not rare or endangered were not covered by the 2020 Decision. The 2020 Decision also did not address amphibians and reptiles, therefore, whether they can be or should be protected as terrestrial wildlife remains in doubt.

On 17 April 2020, the Standing Committee issued the Work Plan on Strengthening Legislative Amendments to Safeguard the Rule of Law in Public Health, which stipulates that amendments to Wild Animal Conservation law will be made by 2021[23]. Therefore, a new version of the Wild Animal Conservation Law will be enacted soon.

Since the promulgation of the 1988 Law, a total of four revisions have been put forward in 2004, 2009, 2016 and 2018, respectively. Among them, the 2016 Law proved to be a major amendment. The frequency of amendments on wildlife conservation law is uncommon given the rather complicated procedures for revising a law. Each revision of the law and its accompanying criticisms constituted a vivid illustration of the tension between protection and utilization of wildlife. Even with the breakthroughs of the 2016 Law, the Wild Animal Conservation Law failed in meeting the expectations of environmentalists[24]. The Covid-19 pandemic, a disaster for humankind, finally brought a ban on trading and eating wildlife in

[21] See *supra* note 1.

[22] Jiang Yifan, *Experts Question China's Proposed Wildlife Utilization Whitelist* (*China Dialogue*, 20 May 2020), https://chinadialogue.net/en/nature/experts-question-chinas-proposed-wildlife-utilisation-whitelist/ (last visited 26 July 2020).

[23] National People's Congress of China, *Qianghua gonggong weisheng fazhi baozhang lifa xiufa gongzuo jihua* (Work Plan on Strengthening Legislative Amendments to Safeguard the Rule of Law in Public Health), 17 April 2020, http://www.npc.gov.cn/npc/c30834/202004/eacce363c350473f9c28723f7687c61c.shtml (last visited 8 July 2020).

[24] W. Hua, L. Meichen, *Yesheng dongwu baohu fa xiugai pingshu* (Review of the Amendment of Law on Protection of Wildlife) (2017) 45(12) *Environmental Protection*; H. Xiaoguang, *Yesheng dongwu baohu fa qidong xiuding, zhuanjia buyu buneng zhi baohu zhenxi binwei eryao quanmian "jinye"* (Wildlife Conservation Law Kicks Off Amendments, Experts Call for Overall "Wildlife-eating Ban" Beyond Protecting Rare and Endangered Species), *iNewsweek* (11 March 2020), http://www.inewsweek.cn/society/2020-03-11/8763.shtml (last visited 6 January 2021); L. Chuanyan, Y. Jianyu, C. Hui, *Xianyou yesheng dongwu baohu fa de buzu ji xiugai jianyi* (Inadequacies Of Current Wildlife Conservation Law And Proposals For Amendment), *The Paper* (28 February 2020), https://www.thepaper.cn/newsDetail_forward_6206231 (last visited 6 January 2021).

2020. Hopefully this pricy decision helps more people to remember the nature can always defeat us if we treat the nature wrongly.

I.2. The main measures on wild animal protection

From 1988 to 2016, a noticeable reconstruction in the basic value of Wild Animal Conservation Law occurred slowly. Article 1 of the 1988 Law stated that the purpose of said Law was protecting, developing and rationally utilizing wildlife resources. However, no priority between protection and utilization was clearly defined. The 2016 Law was distinguishable in that utilization was not listed as a legislative purpose under Article 1 and Article 4 clearly stated that the State shall give priority to protection of wildlife. This change to some extent addressed the public criticism that the 1988 Law was merely offering protection for the main scope of utilization. In furtherance of the 2016 Law protectionist viewpoint, the current 2018 Law offers three different types of protection scheme with some exceptions as explained below.

Protection based on classification and licensing

According to Article 10 of the 2018 Law, the State shall give priority protection to species of wildlife which are rare or near extinction. Wildlife under state priority protection can be divided into two categories, namely, wildlife under Class I protection and wildlife under Class II protection. Although no official record regarding the standard of each category can be found, the number of wildlife under Class II protection greatly outnumbers that of Class I[25]. Besides, as stipulated in Article 21, when it comes to hunting or catching of wildlife under Class I state protection, the application for a special hunting and catching license shall be made to the competent department of wildlife protection under the State Council, while for wildlife under Class II state protection, an application to the competent department of wildlife protection at the provincial level would suffice. Although it is not directly indicated that wildlife of Class I protection is superior to Class II protection, based on the limited number of species and higher level of governance for license application, it is reasonably inferred that Class I wildlife are given a more prominent status with a higher degree of protection than its Class II counterpart.

Apart from state priority protection, there are also wildlife under local priority protection, which refers to the wildlife under special protection at the provincial level. All provinces enjoy full discretion as to the drafting, revising, and issuing its list of wildlife under special local protection.

Under Article 2 of the 2018 Law, the scope of wildlife also includes the species of terrestrial wildlife which are of important ecological, scientific or social value, and the list of such

[25] According to the List of Wildlife under State Priority Protection (available at http://www.forestry.gov.cn/main/3954/content-1063883.html), there are 96 species of wildlife under Class I protection and 161 species under Class II protection.

wildlife shall be made by the competent department of wildlife protection under the State Council after scientific assessment. The original version of this provision can be traced back to the 1988 Law, the wording of which was "terrestrial wildlife which are beneficial or of important economic or scientific value"[26]. A list was therefore promulgated by the Department of Forestry in August 2000, containing 1,591 species in total which currently remains unchanged.

In addition to protection by classification, Article 21 and 22 of the 2018 Law also stipulates that a hunting license is required for hunting both wildlife under state priority protection and those that are not.

Protection of the habitat of wildlife

The 2016 Law provided more detailed provisions in relation to the protection of the habitat of wildlife and those provisions were applied to the 2018 Law verbatim. Under Article 11 of the 2018 Law, the competent department of wildlife protection of the people's government at or above the county level shall regularly organize or entrust the relevant scientific research institutions with investigation, monitoring and assessment of wildlife and its habitats, and shall establish and improve relevant files therefor. Several factors for consideration during investigation, monitoring, and evaluation of wildlife and its habitats are also listed, including distribution area, population size, phylogeny of wildlife as well as the size of habitat area, etc.

Also, in accordance with Article 12, the competent department shall determine and publish the list of important wildlife habitats according to the results of investigation, monitoring, and evaluation of wildlife and its habitats. In December 2017, the Ministry of Agriculture issued the List of Important Aquatic Wildlife Habitats, while an official list for terrestrial wildlife habitats has not yet been published[27].

Moreover, a duty to fully consider the needs of protection of wildlife and its habitats, as well as analyzing, predicting, and assessing the overall impact on wildlife and its habitats is imposed to relevant departments when formulating development and utilization plans.

Constant monitor and rescue of wildlife

First, competent authorities of wildlife protection at all levels shall keep watch on and monitor the wildlife environment. Where emergencies such as natural disasters or major environmental pollution accidents present threats to wildlife under special national or local protection, the local government shall take timely emergency measures to rescue them.

[26] The title of the list is *The List of Beneficial, Economically Important or Scientifically Valuable Terrestrial Wildlife*, which used the original language in the 1988 Law. After the 2018 Law came into force, the title of the list did not change in accordance with the new wording.

[27] It should be noted that many natural reserves have been recognized as terrestrial wildlife habitats, however, the Chinese government failed to come up with an official list for these habitats as required under Article 12.

Second, in case of epidemic or disease, competent department of wildlife protection and veterinary department of the people's government bear the burden of monitoring the sources of such epidemic or disease, as well as organizing projections and forecasts.
Third, for endangered wildlife, rescue protection is required. Specifically, relevant departments shall formulate wildlife genetic resources conservation and utilization plans, and also establish a national gene pool for wildlife genetic resources.

Intensified cooperation on international wildlife protection
Article 36 of the 2018 Law stipulates that the State shall organize international cooperation in connection with wildlife protection to prevent and combat smuggling and illegal trade of wildlife.
China has had rapid economic development in the past few decades, influencing a huge impact on the livelihood of wildlife. Importantly, this impact is not only of a domestic nature, but also a transboundary or international one. For example, studies have shown that the opening up of borders between China and its neighbors in Southeast Asia has provided a new trading source of wild animals[28] and thus, many of these neighboring Asian countries are also facing great decline in certain wildlife population[29]. Resultingly, Article 36 carries great practical significance towards not only the urgent need for China's wildlife protection but to other Asian countries as well.
Until now, China has implemented various international wildlife protection schemes in order to meet the requirements of Article 36. These include building up crossing structures for wildlife in Yunnan province (close to China's southwest border), establishing national parks for tigers in Northeastern China, as well as signing memoranda with Japan, Russia and South Korea for protection of migratory birds30. Although it is difficult to determine quantitatively how many species have been saved or the exact increase in the number of wildlife after these protective measures have been implemented, at the very least, China has further strengthened its resolve towards wildlife protection and is also gradually raising its awareness on international wildlife protection collaboration. And with this and other different international protection measures being implemented, wildlife conservation in other countries will also be directly or indirectly improved.

[28] S. Gong, A. T. Chow, J.J. Fong, H. Shi, *The Chelonian Trade in the Largest Pet Market in China: Scale, Scope and Impact on Turtle Conservation* (2009) 43(2) *Oryx*; K. Krishnasamy, C.R. Shepherd, O.C. Or, *Observations of Illegal Wildlife Trade in Boten, a Chinese Border Town within a Specific Economic Zone in Northern Lao PDR* (2018) 14 *Global Ecology and Conservation*.

[29] V. Felbab-Brown, *The Disappearing Act – The Illicit Trade in Wildlife in Asia* (2011), https://www.brookings.edu/wp-content/uploads/2016/06/06_illegal_wildlife_trade_felbabbrown.pdf (last visited 6 December 2020). V. Nijman, C. R. Shepherd, M. Sanders, K. L. Sanders, *Over-exploitation and Illegal Trade of Reptiles in Indonesi*a (2012) 22 *Herpetological Journal*.

[30] State Forestry and Grassland Administration, *Kuajing yesheng dongzhiwu baohu de daguo xingdong* (China's Action for Cross-border Wildlife Conservation), 21 March 2019, http://www.forestry.gov.cn/main/112/20190329/111816444921750.html (last visited 6 December 2020).

Aside from these notable protection schemes, the 2018 Law still provides for regulating the utilization of wildlife resources, including for the purpose of medical use, domestication or reproduction in captivity and food.

II. Implementation of China wild animal protection laws

Despite all the greatly-improved provisions in the laws on wild animal protection as mentioned in the first section, the implementation of these provisions favors utilization rather than conservation of wild animals. Some of the laws or provisions have deficiencies which allows for arbitrary discretion in implementation. Additionally, not all law-enforcing departments strictly follow the legal regulatory requirements, or sometimes it is practically impossible to effectively implement the regulation in every aspect.

II.1. The coverage of wildlife protected under the law

As mentioned above, under Article 10 the Wild Animal Conservation Law, the scope of wildlife under national protection is listed in the List of Wildlife under State Priority Protection[31] and the List of Beneficial, Economically Important or Scientifically Valuable Terrestrial Wildlife[32] (collectively, the "Lists").

Admittedly, a lot of species have been included, with the former containing 257 species and the latter containing 1,591 species. However, it is noteworthy that the Lists were issued more than a decade ago. The List of Wildlife under State Priority Protection was promulgated in January 1989, and only one slight change was made in 2003 where Moschus spp. (the ingredient for Shexiang, a well-known traditional Chinese medicine) was moved from Class II protection to Class I protection. As for The List of Beneficial, Economically Important or Scientifically Valuable Terrestrial Wildlife, it has remained unchanged for 20 years since its issuance in August 2000. In recent years, the Lists have proved to be more and more incompatible with the current status of many species, failing to reflect the changes of populations and habitats of the wildlife being threatened. For instance, one of the most authoritative list of threatened species is the IUCN Red List of Threatened Species ("IUCN Red List") provided by International Union for Conservation of Nature ("IUCN"), one of the largest environmental networks around the world. According to the IUCN Red List, the white-bellied heron is listed as "critically endangered" with only about 50 to 249 mature

[31] State Forestry Administration, *Guojia zhongdian baohu yesheng dongwu minglu* (List of Wildlife under State Priority Protection), 14 January 1989, http://www.forestry.gov.cn/main/3954/content-1063883.html (last visited 3 May 2020).

[32] State Forestry Administration, *Guojia baohude youyide huozhe you zhongyao jingji, kexue yanjiu jiazhide lusheng yesheng dongwu minglu* (List of Beneficial, Economically Important or Scientifically Valuable Terrestrial Wildlife), 1 August 2020, http://www.forestry.gov.cn/main/3954/content-959027.html (last visited 3 May 2020).

individuals left[33], yet the Lists failed to include it. Shockingly, 229 other species that are covered by the IUCN Red List did not make it onto the Lists[34]. Of course not all 229 species of wildlife actually live in China. Therefore, the real gap between the Chinese List and the IUCN List is not as big as 229 species, but the certain gap does exist.

Even inclusion on the Lists may not provide sufficient protection for some species. For example, the Chinese pangolin is categorized as "critically endangered"[35] under the IUCN Red List, while it had been only offered Class II protection under the List of Wildlife under State Priority Protection for almost 31 years, until the State Forestry and Grassland Administration finally upgraded it to Class I protection on 3 June 2020[36]. Other species such as the hawksbill turtle are also endangered by extinction[37], yet they have not been as fortunate as the pangolins to be raised to Class I protection.

In conclusion, the Lists are far behind other international measures in terms of the wildlife coverage for protection. As for their counterpart, the IUCN Red List is assessed and renewed continuously, and IUCN even pointed out that "all assessments on the IUCN Red List become officially out of date after ten years"[38]. Compared with IUCN, the wildlife coverage of the Lists have stagnated far longer than IUCN's ten year expiration timeline, causing severe deficiencies in China's wildlife protection.

Nevertheless, on a positive note, the State Forestry and Grassland Administration as well as the Ministry of Agriculture are working on revising the List of Wildlife under State Priority Protection[39], and according to the current draft, 301 out of the 621 species are new additions, and 55 species, such as the aforementioned pangolin, have been upgraded from Class II to Class I protection[40]. Thus, a more up-to-date list corresponding to the actual wildlife situation is expected soon.

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[33] IUCN, *The IUCN Red List of Threatened Species*, January 2020, https://www.iucnredlist.org/species/22697021/134201407 (last visited 6 June 2020).

[34] H. Xuesong, Z. Xiang, L. Zhi, *Yesheng dongwu baohu minglu, yiba kedu mohu de kachi* (List of wildlife under protection: a blurring standard), *Guang Ming Daily* (29 February 2020) http://epaper.gmw.cn/gmrb/html/2020-02/29/nw.D110000gmrb_20200229_2-11.htm (last visited 5 May 2020).

[35] IUCN, *The IUCN Red List of Threatened Species*, January 2020, https://www.iucnredlist.org/species/12764/168392151 (last visited 6 June 2020).

[36] State Forestry and Grassland Administration, *Guojia linye he caoyuan ju gonggao (2020 nian di 12 hao)* (Notice of State Forestry and Grassland Administration, No.12 [2020]), 3 June 2020, http://www.forestry.gov.cn/main/5461/20200611/092327112948854.html (last visited 26 July 2020).

[37] IUCN, *The IUCN Red List of Threatened Species*, February 2020, https://www.iucnredlist.org/species/8005/12881238 (last visited 26 July 2020).

[38] IUCN, *Raw Data to Red List*, January 2020, https://www.iucnredlist.org/assessment/process (last visited 6 June 2020).

[39] State Forestry and Grassland Administration, *Guojia zhongdian baohu yesheng dongwu minglu (zhengqiu yijian gao)* (List of Wildlife under State Priority Protection [Draft for Comments]), 19 June 2020, http://www.forestry.gov.cn/main/153/20200619/092731170435586.html?utm_source=CD+bilingual+newsletter_Inside+China&utm_campaign=2a205e244b-EMAIL_CAMPAIGN_2019_05_23_03_03_COPY_01&utm_medium=email&utm_term=0_5e2998620a-2a205e244b-46881150&mc_cid=2a205e244b&mc_eid=ac38ec6706 (last visited 27 July 2020).

[40] L. Lingyu, *Zhuomuniao, tianluo jiangcheng guojia zhongdian baohu duixiang, minglu tiaozheng hou naxie shi hui yingxiang ni?* (Woodpecker and Snail Will Be Offered National Priority Protection, What Will Affect you after

While the coming issuance of the 2020 Decision and the Directory (which are mainly focused on the utilization protection of terrestrial wildlife) will greatly enhance the overall protection level of terrestrial wildlife, the status of amphibians, reptiles and aquatic wildlife still remains a large concern. In the past, all versions of the Wild Animal Conservation Law failed to specify the definition of aquatic wildlife. Under Article 2 of the 2018 Law, only rare or endangered species of aquatic wildlife is protected, while other aquatic wildlife is governed by Fisheries Law[41]. Under the Fisheries Law, the aquatic wildlife are generally considered as "fishery resources", and the Fisheries Law focuses on the utilization rather than the protection of these resources. The unique biological nature of amphibians and reptiles makes it difficult to draw a clear line between it and terrestrial wildlife, therefore, the Wild Animal Conservation Law and the Fisheries Law may have overlaps in this regard. If not categorized as terrestrial wildlife under the current legislative framework of the 2020 Decision, amphibians and reptiles may continue to be overly utilized[42].

However, the legislative trend does not seem promising on this issue. On 4 March 2020, the Ministry of Agriculture and Rural Affairs had specified only that amphibians and reptiles such as pelodiscus sinensis and turtle should be categorized as aquatic wildlife[43]. If such unclarity continues, the situation of those aquatic wildlife (including amphibians and reptiles) that are not considered "rare or endangered" will not be improved after the Covid-19 pandemic.

II.2. Utilization of wild animals

The 2018 Law originally aimed at giving priority to wildlife protection while regulating utilization and tightening regulation, so it only included a limited number of exceptions to protection, attempting to provide more detailed requirements and closing legislative loopholes. However, these exceptions did not work out as intended, since many of them are used as legitimate excuses for scaling the utilization of wildlife. Before the Covid-19

the Adjustment of the List?) *China Environmental News* (21 June 2020), https://www.thepaper.cn/newsDetail_forward_7941505?utm_source=CD+bilingual+newsletter_Inside+China&utm_campaign=2a205e244b-EMAIL_CAMPAIGN_2019_05_23_03_03_COPY_01&utm_medium=email&utm_term=0_5e2998620a-2a205e244b-46881150&mc_cid=2a205e244b&mc_eid=ac38ec6706 (last visited 27 July 2020).

[41] See National People's Congress of China, *Zhonghua renmin gongheguo yuye fa* (Fisheries Law of the People's Republic of China), 28 December 2013, http://www.npc.gov.cn/wxzl/gongbao/2014-06/20/content_1867661.htm (last visited 27 July 2020).

[42] See *supra* note 22.

[43] Ministry of Agriculture and Rural Affairs, *Guanyu guanche luoshi 'Quanguo renmin daibiao dahui changwu weiyuanhui guanyu quanmian jinzhi feifa yesheng dongwu jiaoyi, gechu lanshi yesheng dongwu louxi, qieshi baozhang renmin qunzhong shengming jiankang anquan de jueding' jinyibu jiaqiang shuisheng yesheng dongwu baohu guanli de tongzhi* (Circular on Further Strengthening the Protection and Administration of Aquatic Wild Animals to Implement the Decision of the Standing Committee of the National People's Congress on a Complete Ban of Illegal Wildlife Trade and the Elimination of the Unhealthy Habit of Indiscriminate Wild Animal Meat Consumption for the Protection of Human Life and Health), 4 March 2020, http://www.moa.gov.cn/xw/bmdt/202003/t20200304_6338139.htm (last visited 28 July 2020).

pandemic, the most common exceptions included medical use, domestication or reproduction in captivity, as well as food.

Medical use

There is great significance in making medical use an exception as many types of traditional Chinese medicine contain wildlife products. According to Article 29 of the 2018 Law, anyone utilizing wildlife or wildlife products shall mainly rely on artificial domesticated population, and where wildlife or the products thereof are utilized or traded as drugs, the laws and regulations on drug administration shall also be abided. This provision was first applied in the 2016 Law and has been facing severe criticism since then, as Article 29 widely allows the utilization of wildlife for medical purpose[44].

One of the regulatory dilemmas that the Chinese government faces is that many traditional Chinese pharmaceutical companies are engaging in massive trading of wildlife or the products thereof. For example, it is estimated that the population of musk deer had dropped 60,000-70,000 annually, mainly due to overuse by traditional Chinese medicine companies, and around 1,000 kilograms of Shexiang (equivalent to 10,000 male musk deer) is utilized by the pharmaceutical industry per year[45]. Also in 2017, Tong Ren Tang, one of the largest traditional Chinese medicine companies, was accused of purchasing a shocking amount of 1,500 kilograms of pangolin scales[46].

While traditional Chinese pharmaceutical companies may be major players in wildlife medical use, there are a lot of unlicensed folk doctors practicing traditional Chinese medicine who use wildlife medicinally as well, especially in rural areas[47]. These doctors generally practice as a small private clinic and some of them may often travel domestically to practice beyond its main business location. They either learned traditional medical science from masters or from a family member who practiced traditional Chinese medical science. Since traditional Chinese medicine is mostly composed of herbs and some wildlife products, many of these folk doctors are able to gather these ingredients from nature by themselves or with the help of villagers. It was only in December 2017 that the State Council finally noticed the importance of regulating these unlicensed practices and thus

[44] L. Zhiping, *Sangzhong weishei erming? Xiezai xinxiu "Yesheng Dongwu Baohufa" tongguo zhiji* (For Whom the Bell Tolls: Writing at the Issuance of the Newly Revised Wild Animal Conservation Law) (2020) *China Law Review*, https://mp.weixin.qq.com/s/myh2xtqOWEf7i3EgNGGfRg (last visited 5 May 2020).

[45] China Wildlife Conservation Association, *Yesheng zhongyaocai yanzhong touzhi, she deng zhixi yaoyong wuzhong binwei* (Overdraft of Wild Chinese Medicinal Material Resources and Endangerment of Rare Medicinal Species such as Musk Deer), 5 May 2011, http://www.forestry.gov.cn/portal/bhxh/s/651/content-477602.html (last visited 4 May 2020).

[46] F. Shan, J. Shiyu, L. Ming, *Zhongyao gongsi beibao caigou 3000 jin chuanshanjiapian* (Traditional Chinese Pharmaceutical Company Reported to have Purchased 1,500 Kilograms of Pangolin Scales), *Beijing News* (18 February 2017), http://news.ifeng.com/a/20170218/50707705_0.shtml (last visited 4 June 2020).

[47] Y. Xiuping, *Wei "minjian zhongyi" befa xingyi dakai tongdao* (Opening up Gates for "Folk Traditional Chinese doctors" to Engage in Lawful Medical Practice), *Gansu Daily* (15 February 2019), http://szb.gansudaily.com.cn/gsrb/201902/15/c110711.html (last visited 3 October 2020).

issued the Interim Administrative Measures for Physician Qualification Assessment and Registration for Masters of Traditional Chinese Medicine[48]. However, as only about two years has passed, it is likely some folk doctors continue practicing without acquiring a legal license. Moreover, under Article 60 of the Pharmaceutical Administration Law of China, unless otherwise stipulated by the State Council, traditional Chinese medicine may even be sold at markets in addition to pharmacies[49]. Therefore, for those unlicensed traditional Chinese doctors, the procurement channels are diverse and the origin of their medicine is extremely hard to trace, thus making it very challenging to enforce comprehensive wildlife protection in this regard.

Domestication/Breeding in captivity

Under Article 25 of the 2018 Law, domestication or wildlife breeding in captivity under state priority protection undertaken by the relevant scientific research institutions is encouraged, provided that it is conducive to species conservation as encapsulated under Article 26. In reality, research on the medicinal value and sustainable utilization of wildlife have also been supported by national or provincial funding[50], which means that scholars are still trying to strike a balance between protection and utilization. However, it is Article 27 of the 2018 Law that is mainly problematic. The basic purpose of the 2018 Law was to ensure certain wildlife under state priority protection to refrain from any kind of utilization, yet Article 27 actually allows the sale, purchase, and utilization of said wildlife if it is necessary for domestication or breeding in captivity.

It should be noted that there exist great differences between breeding in captivity and domestication. The former generally aims at preserving species that are on the brink of extinction (such as China pandas, further discussed below), while the latter focuses more on utilizing different body parts of wildlife progeny that are born under artificially-controlled conditions for medical use, fur or meat.

For example, China has been for years engaging in the successful captive breeding program (also known as reproduction in captivity) of giant pandas, a scientific approach

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[48] Health and Family Planning Commission, *Zhongyi yishu queyou zhuanchang renyuan yishi zige kaohe zhuce guanli zanxing banfa* (Interim Administrative Measures for Physician Qualification Assessment and Registration for Masters of Traditional Chinese Medicine), 10 November 2017, http://fjs.satcm.gov.cn/zhengcewenjian/2018-03-24/2404.html (last visited 5 December 2020).

[49] National People's Congress Standing Committee, *Zhonghua renmin gongheguo yaopin guanli fa* (Pharmaceutical Administration Law of People's Republic of China), 1 December 2019, http://scjgj.yibin.gov.cn/sy/xxgk/zcwj/201909/t20190905_1119494.html (last visited 6 December 2020).

[50] See Z. Yiquan, Q. Xianyou, Y. Guang, L. Junde, S. Yan, L. Ying, *Woguo yaoyong dongwu fanyu biaozhun xianzhuang jiqi guanjian wenti tantao* (Research Progress on Breeding Standard of Medicinal Animals and Discussion on Several Key Problems) (2016) 41(23) *China Journal of Chinese Materia Medica*; L. Hongbo, R. Jingcheng, Y. Shitao, M. Huili, *Maolan ziran baohuqu yesheng yaoyong niaolei ziyuan diaocha* (Investigation of the Wild Medicinal Birds in Maolan Nature Reserve) (2010) 38(24) *Journal of Anhui Agricultural Sciences*; Z. Yan, Y. Hui, S. Erxin, *Dongwu yaocai de tidai kunnanxing yu renshi wuqu fenxi* (Analysis on Difficulty and Misunderstanding about Replacement of Animal Medicine Resources) (2016) 18(12) *Modern Chinese Medicine*.

designed to prevent the extinction of this national treasure. This approach has proved to be quite effective. In 2016, the giant panda was officially downgraded from 'endangered' to 'vulnerable' on the global list of species at risk of extinction provided by IUCN[51]. As of 2018, there have been more than 548 giant pandas captively bred globally[52] since the first ever captive-bred giant panda was born at the Beijing zoo in 1963[53].

While breeding in captivity focuses more on increasing the number of populations of endangered species, domestication appears to be one of the possible solutions to utilizing wildlife in a more sustainable way. For example, it is estimated that around 10,000 bears are kept in bear farms in China, waiting for their biles to be used in traditional Chinese medicine or cosmetics[54]. As for deer, whose antler velvet (also known as "lurong" in Chinese) is considered as a type of traditional Chinese medicine with powerful health-promoting properties[55], it was estimated that more than 20,000 musk deer had been bred in captivity in China as of 2009[56]. Apart from medical use, another main aim of domestication is for fur. Under Article 1.3 of the Interim Provisions on the Domestication, Breeding and Utilization of Wild Fur Animals, animal skin can only be procured from domesticated species[57]. According to the China Leather Industry Association data, the number of skins produced from American mink, fox and raccoon dog are 11.69 million, 14.43 million and 13.59 million in 2019, respectively[58].

Despite all the bright prospects, the 2018 Law mechanisms intended for wildlife protection has encountered large pragmatic challenges such as the use of a legal permit of domestication as a cover for illegal hunting of wildlife, which is not only a problem existing

[51] WWF, *Giant Panda No Longer Endangered*, 4 September 2016, https://www.worldwildlife.org/stories/giant-panda-no-longer-endangered (last visited 10 November 2020).

[52] L. Yu, *Captive pandas rise to 548 globally* (*Xinhua Net*, 8 November 2018), http://www.xinhuanet.com/english/2018-11/08/c_137592424.htm (last visited 9 December 2020).

[53] Pandas International, *Captive Breeding Program*, https://www.pandasinternational.org/program-areas-2/captive-breeding-program/ (last visited 9 November 2020).

[54] Bear Conservation, 'Bear Farming', 31 January 2020, http://www.bearconservation.org.uk/bear-farms/ (last visited 21 July 2020).

[55] New Zealand Deer Velvet, 'Traditional uses of Deer velvet', https://www.velvet.org.nz/what-is-velvet/velvet-introduction/traditional-uses-of-deer-velvet (last visited 26 July 2020).

[56] D. R. McCullough, J. Zhigang, L. Chunwang, 'Sika Deer in Mainland China' in D. R. McCullough, S: Takatsuki, K. Kaji (eds), *Sika Deer* (Springer 2009), 521.

[57] State Forestry Administration, *Maopi yesheng dongwu (shoulei) xunyang fanyu liyong jishu guanli zanxing guiding* (Interim Provisions on the Domestication, Breeding and Utilization of Wild Fur Animals), 18 June 2005, http://www.forestry.gov.cn/main/4818/content-796875.html (last visited 26 July 2020).

[58] W. Dianhua, *Zhongguo shuidiao, hu, he qupi shuliang tongji baogao (2019 nian)* [Statistical Report on Number of Mink, Fox and Raccoon Dog Skins Taken in China (2019)] (*China Leather Industry Association Official Website*, 16 March 2020), http://www.chinaleather.org/front/article/111466/ (last visited 26 July 2020).

in China[59], but also worldwide[60]. Behind such cover, consumers are misguided as to the origin of the products, believing they are purchasing products coming from legally domesticated wildlife, while others are perfectly aware of the origin yet choose to secretly purchase these products on purpose as they believe the quality of animals from the wild is better than those from the domesticated environment. Thus, the abuse of the legal trade of domesticated animals can pose great obstacle to the protection of wild animals. Nevertheless, on a positive note, China has developed advanced electronic tracking techniques to trace suspects who might violate laws, and it is possible to trace each domesticated animal and its products to reduce illegal trade and improve compliance with the help of said technology.

Food

Historically, hunting and eating wild animals once were common practices to sustain human life and has played a significant role in the evolution of mankind. Eating wildlife was necessary in the 1900s when starvation was a big threat and an unforgettable part of the national memory[61]. However, presently, eating wildlife has become a status symbol for the neoveau rich who believe they can acquire super-natural power by eating wild animals, or serves as bragging rights or as competitions amongst each other in consuming wildlife under Class I or Class II protection.62 Apart from that, it has also become common practice that after the skin of fur animals (such as the American mink, fox and raccoon dog) is taken, their meat ends up on the dinner table, pretending to be other types of meat, such as pork[63]. Although there are no statistics available as to how much wildlife have been eaten in total annually, according to a study conducted by Chinese Academy of Engineering, more than 6.26 million people were working in the food animals industry in 2016, generating a revenue of over RMB 125 billion[64].

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[59] M. Aiping, *Na hefa de zheng gan feifa de shi, zheyang de yesheng dongwu yangzhichang bixu liangliang* (Using Legitimate Permit to Shield Illegal Conduct, These Wildlife Farm must be Closed) *(Xinhua Net*, 3 March 2020), http://www.xinhuanet.com/politics/2020-03/03/c_1125655799.htm (last visited 3 January 2021).

[60] B. Martin, *Survival or Extinction? – How to Save Elephants and Rhinos*, Springer, 2019, 142.

[61] P. Beech, *What we've got wrong about China's 'wet markets' and their link to Covid-19*, *World Economic Forum*, 18 April 2020, https://www.weforum.org/agenda/2020/04/china-wet-markets-covid19-coronavirus-explained/ (last visited 10 December 2020).

[62] P.J. Li, *Enforcing Wildlife Protection in China: The Legislative and Political Solutions* (2007) XXI(1) *Sage Publications*, 83.

[63] Z. Ke, *Shuidiao, huli, hezi yichu ke shiyong mulu beihou: renchu gong huanbing yinying* (Mink, Fox and Raccoon Dog Removed from List of Edible Wildlife: the Fear of Zoonosis), *Yicai* (26 February 2020), https://www.yicai.com/news/100522734.html (last visited 30 July 2020).

[64] Chinese Academy of Engineering, *Zhongguo yesheng dongwu yangzhi chanye kechixu fazhan zhanlve yanjiu baogao* (Report on Sustainable Development Strategy of China's Wildlife Breeding Industry) on Z. Ke, "*Yesheng dongwu baohu fa" xiufa nan zai na? Dashuju jiemi chao 5000 yi da chanye* (What is the Difficulty in Amending the Wild Animal Conservation Law? Big Data Reveals an Over-500-billion Industry), *Yicai* (20 February 2020), https://www.yicai.com/news/100514161.html (last visited 30 July 2020).

After the Covid-19 pandemic, the Research Institute of People Daily and Baidu, one of the largest search engines in China, jointly issued the Big Data Report for Searches during the Covid-19 pandemic, which identified some alarming results on the continued utilization of wildlife[65]. For example, despite being generally regarded as the hosts for SARS, searches of the term "bat" and "civet" increased from 2013 to 2020. Additionally, there also have been constant searches during this period for "breeding of wildlife under state priority protection" "civet breeding" as well as "bamboo rat breeding". Moreover, even after the quick spread of Influenza A (H7N9) virus (a virus carried by poultry) in March 2013, the search for "recipe for cooking pheasant" still showed a generally upward trend.

Under the 2018 Law, eating wildlife under state priority protection, or utilizing food made of wildlife not under state priority protection but without proof of legitimate origin is prohibited. However, this provision only addresses wildlife under priority protection, thus, other wildlife with legitimate origin are not covered and can be purchased for eating. The Decision issued on 24 February 2020 by the Standing Committee of the National People's Congress was supposed to impose a complete ban on wildlife eating. This is obviously a historical step towards stronger protection of wildlife as the decision covering all wild terricolous animals.

II.3. Impact of construction of projects affecting wildlife habitats

Protection of wildlife habitats has long been considered an integral component of wildlife protection, however, it was not until the 2016 Law that provisions related to habitat protection were finally included. Under Article 13 of the 2019 Law, site and route selection for projects such as the construction of airports, railways, highways, water conservancy and hydropower shall bypass related nature reserves and wildlife migratory channels, and where it is impossible to bypass such channels, safety animal passages shall be built to eliminate or minimize any adverse impacts on wildlife. Article 13 also requires that if construction projects may affect related nature reserves or migratory channels of wildlife under state priority protection, the opinion of relevant authorities under State Council is needed before approval of the environmental impact assessment (EIA). The provision itself seems quite reasonable, however, the exception as encapsulated in the second clause of the provision has been abused to certain extents in practice.

Problematically, such abuse occurs when construction starts even before the EIA is finally approved, or many EIAs are completed without giving full or only give little consideration to wildlife in the construction area. Even if the EIA does cover a fraction of species, it will

[65] Research Institute of People Daily and Baidu, *Xinxing guanzhuang bingdu sousuo dashuju baogao* (Big Data Report for Searches during Covid-19 Pandemic), 1 February 2020, http://media.people.com.cn/n1/2020/0201/c40606-31566638.html (last visited 11 May 2020).

generally conclude that no adverse impact would be imposed to those species[66], yet in reality that is often not the case. For example, according to the EIA of Ahai Dam on Jinsha River in Yunnan Province, despite the fact that the dam's rising water-level might affect several wild birds under state priority protection including the sparrow hawk and kestrel, the birds themselves are capable of flying up high in the sky and thus can easily migrate to other places, therefore, the construction would not be detrimental[67]. Another example is the highly focused public interest litigation concerning the construction of Gasa River Hydropower Station. The case was brought up by an environmental NGO in Yunnan province, China against the constructor and project contractor. The plaintiff submitted that the construction of the hydropower station would submerge the habitats of the green peafowl, a wildlife species under Class I state protection. The case was initially brought in 2017, however, the court ruled that it lacked jurisdiction over the case[68] and the case was later assigned to a competent court. In its March 2020 decision, the competent court found that the construction indeed would cause huge harm to the survival of green peafowl and thus halted the whole project[69]. This is definitely positive news for green peafowl and for wildlife conservationists. However, the existence of these cases indicates that the current EIA requirements cannot solve all the problems, and that some current practices will only further lead to constant harm to wildlife and their habitats.

Starting the construction projects even before EIA is approved definitely constitutes a breach of law, however, what is more commonly implemented as a legal practice is dividing the EIA into two phases (the preliminary preparatory work phase and the actual construction phase). In 2005, the State Environmental Protection Administration (currently the Ministry of Ecology and Environment) and the National Development and Reform Commission issued the Circular on Strengthening Environmental Protection in Hydropower Construction ("2005 Circular")[70]. Under Article 2 of the 2005 Circular, given that hydropower projects are located in remote places, and the preliminary preparatory work

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[66] Y. Bian, *The Role of Environmental Impact Assessment in the Governance of Nu-Salween River: A comparative study of the Myanmar and Chinese Approaches, in International Governance and Rule of Law in China under the Belt and Road Initiative*, ed. by Y. Zhao (Cambridge University Press, 2018), 505.

[67] W. Yongchen, *Jianghe shinianxing zoujin jinshajiang: huanjing yingxiang pingjia zai jinshajiang de kaifa zhong* (The Jinsha River: Environmental Impact Assessment in the Development of the Jinsha River, Following the Ten-Year Journey), *ifeng.com* (3 December 2010), https://gongyi.ifeng.com/special/jiangheshinianxing2010/zuixin/detail_2010_12/03/3336044_2.shtml (last visited 11 May 2020).

[68] Beijing Chaoyang District Friends of Nature v HYDROCHINA Xinping Development Ltd. and Power China Kunming Institute of Survey and Design Ltd. [2017], Yun Min Xia No.23.

[69] W. Yan, *"Yunnan lyu kongque" gongyi susong an yishen xuanpan: liji tingzhi shuidianzhan jianshe* (First Instance Judgment of the Public Interest Case of Yunnan Green Peacock: Immediate Suspension of Construction of Hydropower Station), *Xinhua Net* (20 March 2020), http://www.xinhuanet.com/local/2020-03/20/c_1125742701.htm (last visited 11 May 2020).

[70] State Environmental Protection Administration, *Guanyu jiaqiang shuidian jianshe huanjing baohu gongzuo de tongzhi* (Circular on Strengthening Environmental Protection in Hydropower Construction), 20 January 2020, http://www.mee.gov.cn/gkml/zj/wj/200910/t20091022_172329.htm (last visited 11 May 2020).

for these projects such as construction power supply, water supply, communication and external traffic takes a long time and involves heavy workload, in order to shorten the construction period of hydropower projects, before the project EIA reports are approved, necessary preliminary preparatory work such as building roads and electricity transmission lines may be conducted upon the approval of competent local authorities, provided that the construction of main works such as dams and factory buildings, etc. shall not be carried out. This provision legitimizes the division of the EIA of a whole project into two separate ones and each of them might look deceptively small after such segmentation. In practice, the preliminary preparatory work phase could already greatly impact the habitats of wildlife[71] and even force some wildlife to migrate, therefore, during the EIA of project construction phase, with many species already migrating, the accuracy of that EIA will be compromised. From the authors' perspective, this phenomenon accurately reflects the long-lasting conflicts between economic development and wildlife protection as the rapid economic development since the 1980s has caused overexploitation of wildlife resources[72], and how to deal with such conflict should be thoroughly considered.

II.4. Judicial enforcement for the protection of wildlife

Since the earliest judgment in relation to the Wild Animal Conservation Law dates back to 1992, this section focuses on the trend of cases in this field of law starting from 1992 to the present, including the number of cases, causes of actions and geographic distributions of the cases[73].

Changes in total number of cases

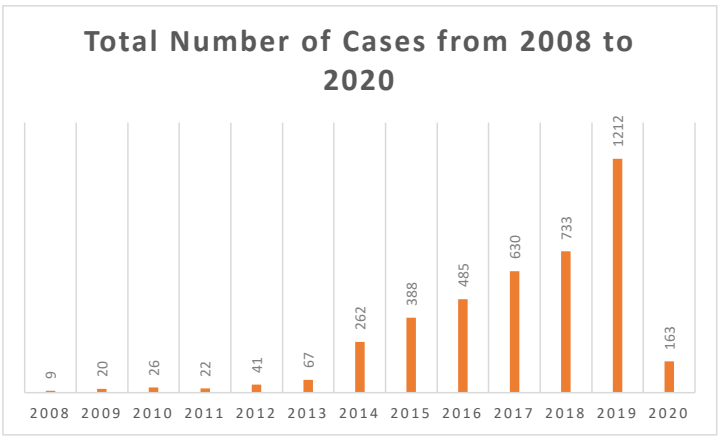
First, it is noteworthy that before 2009, there were no more than 10 cases each year[74] and most of them were about illegal purchase, transportation or sale of wildlife. Interestingly, after 2009, more and more cases emerged and the number kept rising every year (except for a slight decline in 2011), which may be due to the fact that the Wild Animal Conservation Law went through material revisions in 2009. 2014 was another watershed year for judicial enforcement as the number of cases rose to 262. In 2019, the number of cases has reached its highest number to more than 1,200.

[71] M. Zhanpo, C. Na, *Daxing shuili shuidian gongcheng "san tong yi ping" huanjing yingxiang guanli youguan wenti tantao* (Environmental Impact Analysis on Construction of Large Dams for Hydropower Development) (2014) 6 *China Water Resources*.

[72] R. B. Harris, *Approaches to Conserving Vulnerable Wildlife in China: Does the Colour of Cat Matter – if it Catches Mice?* (1996) 5 *Environmental Values*; J. Mcbeath, J.H. Mcbeath, *Biodiversity Conservation in China: Policies and Practice* (2006) 9 *Journal of International Wildlife Law and Policy*; Z. Ke, S. Sijia, *Yesheng dongwu liyong falv zhidu de shanbian yu poju* (The Evolution of and Solution to the Legal System of Wildlife Utilization) (2020) 6 *Law Review*.

[73] The following 4 diagrams are generated based on the analysis of judgments citing the Wild Animal Conservation Law at various levels of Chinese courts in different areas. See Wolters Kluwer, https://law.wkinfo.com.cn/judgment-documents/.

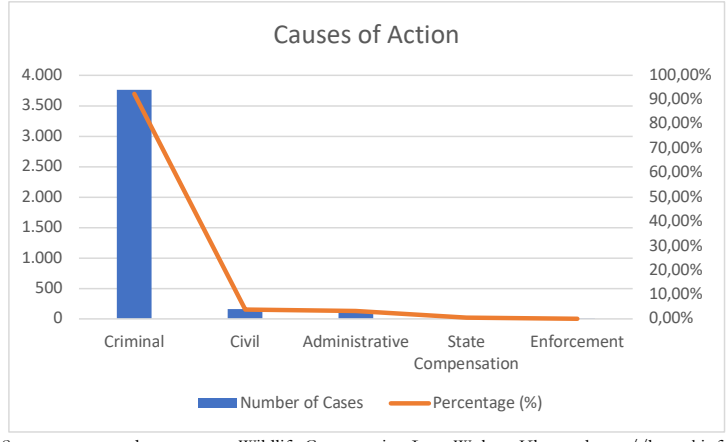
[74] All the statistics in this paragraph comes from the data of cases on 'wildlife conservation law' collected in Wolters Kluwer, https://law.wkinfo.com.cn.



Source: processed on cases on Wildlife Conservation Law, Wolters Kluwer, https://law.wkinfo.com.cn

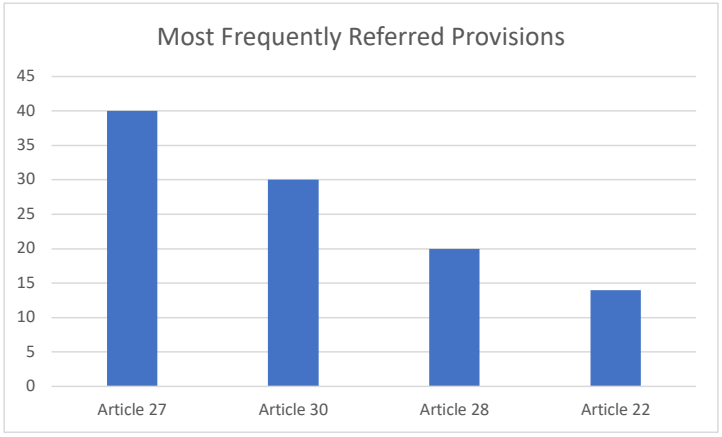
Causes of Action

Cases under the Wild Animal Conservation Law are predominantly criminal, constituting more than 90% of cases, while the number of those only involving civil or administrative liability is extremely limited.



Source: processed on cases on Wildlife Conservation Law, Wolters Kluwer, https://law.wkinfo.com.cn

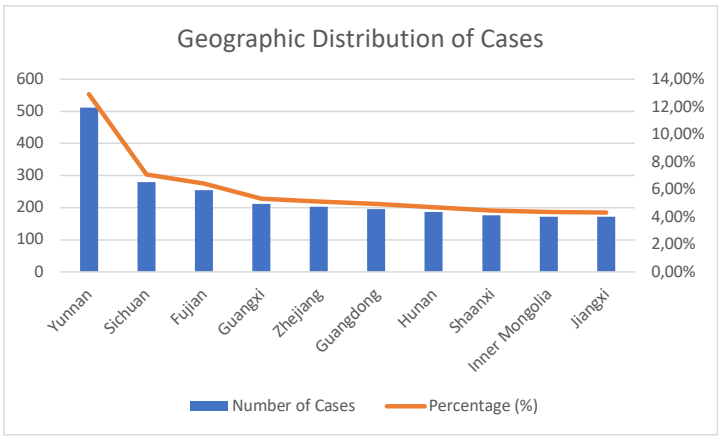
As for specific material provisions in the Wild Animal Conservation Law, the most frequently referenced provision is Article 27, which stipulates that sale, purchase, and utilization of wildlife under state priority protection or the products thereof shall be banned. The second most frequently referenced provision is Article 30 which deals with illegal eating of wildlife. Also frequently referenced, Article 28 and 22 are about domestication or reproduction in captivity and hunting of wildlife, respectively. However, it is necessary to note that since the Wild Animal Conservation Law witnessed a major revision in 2016 and most of the provisions have been changed, the statistics provided here mainly indicate the situation after 2016.



Source: processed on cases on Wildlife Conservation Law, Wolters Kluwer, https://law.wkinfo.com.cn

Geographic distribution of the cases

Among the top ten most common geographic areas for cases concerning wildlife, nine of them are southern provinces in China, which is in line with the general understanding that people from southern part of China tend to eat wildlife more[75] (this may also be partly due to the fact that China southern provinces generally have richer wildlife resources).



Source: processed on cases on wildlife conservation law, Wolters Kluwer, https://law.wkinfo.com.cn

In conclusion, the implementation of the Wild Animal Conservation Law is still a concern. On one hand, the law itself offers several exceptions and these exceptions are often abused. On the other hand, the awareness of both the government and the citizens regard-

[75] S.L. Myers, *China's Omnivorous Markets Are in the Eye of a Lethal Outbreak Once Again*, *The New York Times* (New York, 25 January 2020), https://www.nytimes.com/2020/01/25/world/asia/china-markets-coronavirus-sars.html (last visited 12 May 2020).

ing protection of wildlife is not adequate. Governments often do not prioritize the welfare of wildlife over economic development when making construction plans, and individuals may prioritize personal pleasure over conservation when eating wildlife. Therefore, there is still a long road ahead before the principle of wildlife protection becomes deeply rooted in societal consciousness.

III. Enhancing wild animal conservation in response to Covid pandemic

In response to the Covid-19 pandemic, the Standing Committee of National People's Congress in China issued the 2020 Decision, a blanket ban on the illegal trade of wildlife, and intended to eliminate the adverse tradition of wildlife consumption. Consistent with the 2020 Decision, both the Ministry of Agriculture and Rural Affairs and State Forestry and Grassland Administration issued supporting measures for wildlife protection and administration[76]. Apart from these national laws and measures, at the local government level, several provinces and cities have issued more specific implementing regulations, including Beijing, Zhejiang, Hubei, Shenzhen, etc.[77]. Some of the provisions in these implementing

[76] Ministry of Agriculture and Rural Affairs, *Guanyu guanche luoshi 'Quanguo renmin daibiao dahui changwu weiyuanhui guanyu quanmian jinzhi feifa yesheng dongwu jiaoyi, gechu lanshi yesheng dongwu louxi, qieshi baozhang renmin qunzhong shengming jiankang anquan de jueding' jinyibu jiaqiang shuisheng yesheng dongwu baohu guanli de tongzhi* (Circular on Further Strengthening the Protection and Administration of Aquatic Wild Animals to Implement the Decision of the Standing Committee of the National People's Congress on a Complete Ban of Illegal Wildlife Trade and the Elimination of the Unhealthy Habit of Indiscriminate Wild Animal Meat Consumption for the Protection of Human Life and Health), 4 March 2020, http://www.moa.gov.cn/xw/bmdt/202003/t20200304_6338139.htm (last visited 7 June 2020); State Forestry and Grassland Administration, *Guanyu guanche luoshi 'Quanguo renmin daibiao dahui changwu weiyuanhui guanyu quanmian jinzhi feifa yesheng dongwu jiaoyi, gechu lanshi yesheng dongwu louxi, qieshi baozhang renmin qunzhong shengming jiankang anquan de jueding' de tongzhi* (Circular on Implementing theDecision of the Standing Committee of the National People's Congress on a Complete Ban of Illegal Wildlife Trade and the Elimination of the Unhealthy Habit of Indiscriminate Wild Animal Meat Consumption for the Protection of Human Life and Health), 27 February 2020, http://www.forestry.gov.cn/main/4812/20200302/111010964335151.html (last visited 7 June 2020).

[77] Beijing Municipal People's Congress Standing Committee, *Beijingshi yesheng dongwu baohu guanli tiaoli* (Regulations of Beijing on Wildlife Protection and Management), 1 June 2020, http://www.beijing.gov.cn/zhengce/zhengcefagui/202005/t20200506_1890225.html (last visited 7 June 2020); Zhejiang Municipal People's Congress Standing Committee, *Zhejiangsheng renmin daibiao dahui changwu weiyuanhui guanyu quanmian jinzhi feifa jiaoyi he lanshi yesheng dongwu de jueding* (Decision of the Standing Committee of Zhejiang Provincial People's Congress on the Comprehensive Banning of Illegal Trading and Eating of Wildlife), 26 March 2020, http://www.zj.xinhuanet.com/2020-03/27/c_1125776406.htm (last visited 6 June 2020); Hubei Municipal People's Standing Committee, *Hubeisheng renmin daihui changwu weiyuanhui guanyu yanli daji feifa yesheng dongwu jiaoyi, quanmian jinzhi shiyong yesheng dongwu, qieshi baozhang renmin qunzhong shengming jiankang anquan de jueding* (Decision of the Standing Committee of Hubei Provincial People's Congress on Severely Cracking Down on Illegal Trading in Wildlife, Completely Prohibiting the Eating of Wildlife and Effectively Safeguarding the Health and Safety of the People), 5 March 2020, http://119.36.213.154:8088/fgk/index_xq.jsp?Rileid=622 (last visited 6 June 2020); Shenzhen People's Congress Committee, *Shenzhen jingji tequ quanmian jinzhi shiyong yesheng dongwu tiaoli* (Regulations of Shenzhen Special Economic Zone on the Comprehensive Prohibition of Eating Wild Animals), 1 April 2020, http://sz.people.com.cn/n2/2020/0402/c202846-33921287.html (last visited 6 June 2020).

regulations are merely a recitation of existing provisions from the 2018 Law, but there are also many new measures. This section therefore presents notable changes that have been made in terms of wildlife conservation in both national and local legislative actions.

III.1. Ban on hunting and eating wild animals

When compared to the 2018 Law, the 2020 Decision moved a step forward in terms of combating hunting and eating wildlife. Article 21 of the 2018 Law deals with illegal hunting, according to which hunting, catching or killing of wildlife under state priority protection shall be banned. And under Article 22 of the 2018 Law, anyone who desires to hunt or catch wildlife that is not under state priority protection must obtain a hunting license issued by the competent department of the government at or above the county level according to law and observe the hunting quota assigned. These two former articles are distinguishable from Article 2 of the 2020 Decision, which prohibits the capture and hunting of terrestrial wild animals that naturally grow and breed in the wild for edible purpose, which essentially means it is now illegal to hunt any wildlife for food.

Article 30 of the 2018 Law regulates both the seller and the buyer in terms of trading and utilizing wildlife. According to said Article, it is prohibited to produce food made from wildlife under state priority protection or the products thereof, or produce food made from wildlife not under state priority protection or the products thereof without the proof of legitimate origin. As for the buyer, it is prohibited to illegally purchase wildlife under state priority protection or the products thereof for edible purpose. It can be therefore inferred that as long as the wildlife is not under state priority protection or a proof of legitimate origin is presented, it is not prohibited to produce, utilize or purchase them. Article 30 was criticized for allowing the consumption of wildlife not under state priority protection[78]. Fortunately, the 2020 Decision well recognizes those criticisms and thus prohibits not only eating protected terrestrial wildlife with important ecological, scientific and social value, but also other wildlife, even including artificially bred ones[79]. Aside from that, the 2020 Decision also emphasizes that where wildlife needs to be used for scientific research, medicinal purposes, display or other special non-food purposes, strict examination and approval as well as quarantine and inspection shall be conducted according to relevant national regulations.

Local governments have also made contributions in banning wildlife consumption. For example, Beijing's implementing regulation stipulates that shopping malls, supermarkets, farmers' markets as well as online shopping platforms are prohibited from providing trad-

[78] Y. Zhaoxia, *Xiugai yesheng dongwu baohu fa daji lanshi yewei xingwei* (Revise the Wild Animal Conservation Law to Combat Consumption of Wildlife), *Chinareports* (16 February 2020), http://www.chinareports.org.cn/rdgc/2020/0218/13224.html (last visited 6 June 2020).

[79] The 2020 Decision focuses on banning the consumption of wildlife as food, while using wildlife for medicine is not explicitly banned. Therefore, it is theoretically possible to eat certain type of wildlife if it is in the form of medicine.

ing services for food made of wild animals. Shenzhen, goes a step further by imposing a fine on those who knowingly and intentionally consume prohibited wildlife, and restaurants or canteens that serve wildlife are subject to harsher punishment.

III.2. More restrictions on wildlife trade

Apparently, in order to achieve the goal of eliminating the habit of eating wildlife, merely putting up a prohibition on hunting and eating wildlife is not sufficient, and a more comprehensive restriction on trading of wildlife is required. Under Article 33 of the 2018 Law, with proof of legitimate origin, such as a hunting license, as well as a quarantine certificate, wildlife not under state priority protection can be traded domestically or internationally. This would no longer be the case as Article 2 of the 2020 Decision stipulates that trade and transportation of all naturally-bred wildlife for food is completely banned, including imported wildlife which also serves to support the global conservation of wildlife. Article 3 of the supporting measures promulgated by State Forestry and Grassland Administration requires that the competent departments of forestry and grassland at all levels shall carry out a thorough inspection on all the institutions engaging in artificial breeding, operation and utilization of wild animals for the purpose of food. As for institutions which have already obtained an artificial breeding license and engaged in the artificial breeding of terrestrial wildlife for edible purpose, their licenses shall be revoked, and the sale and transportation of wildlife for the purpose of food thereof shall be stopped; and for the institutions engaged in operation and utilization of wild animals for edible purpose, their business licenses shall also be revoked, and all the business operation and utilization of terrestrial wildlife for food must be dissolved.

The local implementing regulations have offered more specific guidance. For instance, Hubei, Shenzhen and Beijing all prohibit the consumption or illegal trading of wildlife, including advertising, making signboards or recipes. Zhejiang, on the other hand, clearly states that if the organizer of a farmers' market finds out that the commodities served in that market fall within the scope of the wild animals prohibited to be eaten, it shall desist and stop such business operation, and report to the market supervision and administration department. As for the e-commerce platform operator, where it discovers that the goods on its platform are wild animals, it shall adopt requisite measures such as deleting, shielding or removing the hyperlink, terminate transactions and services, and report to the relevant supervision authorities. Based on these above provisions, it can be determined that if for food, all wildlife trading, utilization and transportation (including both those under state priority protection and those not) will be banned.

Apart from all the changes in laws and regulations discussed in the previous two sections, it is noteworthy that Article 1 of the 2020 Decision also emphasizes that any wildlife hunting, trading, transportation or consumption prohibited by the Wild Animal Conservation Law or other relevant laws must be strictly enforced. Thus, any violation of this provision will be given a more severe punishment than that based on the 2018 Law and related regulations. This means that wildlife under state priority protection in accordance with the 2018 Law is subject to an even higher level of protection under the 2020 Decision.

Implications to international wildlife trade

The 2020 Decision not only effects the protection of wildlife and eliminating the habit of wildlife consumption in China, but it also bears more significant implications to international wildlife trade.

First, China's ban will help to reduce international wildlife trading and trafficking such as with China's 2017 ban on ivory trade. Before 2017, China was believed to be the world's largest illegal ivory market, with an estimate of 70% of the world's ivory trade destined in China[80]. Nevertheless, in 2016 the State Council issued a notice to completely ban ivory trade in China by December 31, 2017. According to the survey conducted by WWF and TRAFFIC, respondents' future intention to buy ivory products dropped by almost half to 26% compared with prior to the ban taking effect, and the number of stores selling ivory products decreased by 30% from pre-ban to post-ban[81]. This game-changing ban was thus highly appreciated by the international community as a major contribution to reversing the decline of the wild African elephant population[82]. As precedent, the ivory trade ban is indicative that the 2020 Decision will have a similar effect on reducing other international wildlife trade and trafficking.

Another example is the trafficking of pangolins and donkeys from Africa. Due to the huge price gap between pangolins in China (approximately RMB 3000 per kilogram) and those in Africa (approximately RMB 200 per kilogram), many Africans as well as Chinese engaged in the trafficking of pangolins[83]. However, it is reported that a total of 14,833 tons of pangolins and their scales were seized in Nigeria valued at approximately $900 million, thus through regulatory enforcement, the number of pangolins in Africa trade was decreasing rapidly[84]. As an example, In February 2019, about 8,300 kilograms of pangolin scales from Nigeria were seized by Hong Kong Customs, becoming the largest smuggling of pangolin scales ever recorded by Hong Kong Customs[85]. Similarly, donkeys in Africa are facing the same regulatory scrutiny. Donkey skin (also known as "ejiao" in Chinese) is believed to be a blood tonic for treating ailments like anemia, therefore, many donkeys

[80] BBC News, *China announces ban on ivory trade by end of 2017*, *BBC News* (30 December 2016), https://www.bbc.com/news/world-asia-china-38470861 (last visited 24 May 2020).

[81] W. Meijer, S. Scheer, E. Whan, C. Yang, E. Kritski, *Game-changing ban takes effect but further efforts needed to ensure long-term gains (TRAFFIC and WWF*, 27 September 2018) https://www.traffic.org/site/assets/files/11150/demand-under-the-ban-2018-1.pdf (last visited 24 May 2020).

[82] Z. Yuankun, X. Ling, X. Yu, G. Jing, W. Lau, *New study finds China's ivory market shrinking ahead of incoming domestic ivory ban* (*TRAFFIC*, 12 August 2017), https://www.traffic.org/publications/reports/new-study-finds-chinas-ivory-market-shrinking-ahead-of-incoming-domestic-ivory-ban/ (last visited 24 May 2020).

[83] L. Yukun, *Zhongguo nvhai zifei qianwang feizhou yiyue, jielu niriliya chuanshanjia jiaoyi* (A Chinese Girl Travel to Africa at her Own Expense for a Month to Expose the Nigerian Pangolin Trade), *The Beijing News* (Beijing, 20 April 2020), http://www.bjnews.com.cn/news/2019/04/20/570306.html (last visited 31 July 2020).

[84] *Ibid.*

[85] *Ibid.*

in China were killed for their skin, and the donkey population shrank from 11 million to less than 6 million in the 1990s[86]. Because of the dire domestic situation, the donkey trade shifted its focus to Africa. It was estimated that 80,000 skins were sold within just nine months in Nigeria in 2016, even raising concerns of local African donkey extinction[87]. The 2020 Decision will further prevent such illegal trades and can help to restore the ecological balance and biodiversity in these regions.

Second, China may serve as a role model for other Asian countries. Immediately after China issued its 2020 Decision, Nguyen Xuan Phuc, the prime minister of Vietnam, has asked the country's agriculture ministry to draft a directive to stop illegal trading and consumption of wildlife in March 2020.88 Similar to the situation of China, illegal trading of wildlife is rampant in Vietnam. It is estimated that wildlife trading has become a billion-dollar industry in Vietnam[89]. Currently, Vietnam is attempting to formulate a directive that aims at clamping down on street-side markets as well as online platforms that serve wildlife illegally or use legal licenses as a disguise for illegally hunted wild animals. The 2020 Decision and all the other national and local implementing provisions seemingly have influenced Vietnam to take similar actions, and even modeling China's laws and regulations.

Third, the ban itself might help shape consumers' awareness of wildlife protection and further guide companies' marketing strategies. With the severity of the Covid-19 pandemic and the instant issuance of the 2020 Decision, citizens may well recognize the urgency of wildlife protection and administration, and thus refrain from utilizing or purchasing wildlife and related products thereof. To cater to such evolving consumer preference, companies and organizations may voluntarily choose to cease providing channels for wildlife trade or using wildlife component as its selling point. Currently, many companies in China are cooperating with international organizations and NGOs to combat illegal wildlife trade online. In 2018, WWF, TRAFFIC and International Fund for Animal Welfare (IFAW) started The Coalition to End Wildlife Trafficking Online, aiming at allying global e-commerce, with search engine and social media companies reducing illegal wildlife trafficking on its online platforms by 80% by 2020. Currently 34 companies have joined this coalition, including many well-known Chinese companies such as Alibaba, Baidu and Tencent[90]. Companies in this coalition are committed to review its own policy regularly, block illegal

[86] K. De Greef, *Rush for Donkey Skins in China Draws Wildlife Traffickers*, *National Geographic* (22 September 2017), https://www.nationalgeographic.com/news/2017/09/wildlife-watch-donkey-skins-china-wildlife-trafficking/ (last visited 31 July 2020).

[87] *Ibid*.

[88] C. Humphrey, *Billion-dollar wildlife industry in Vietnam under assault as law drafted to halt trading*, *The Guardian* (London, 18 March 2020), https://www.theguardian.com/environment/2020/mar/18/billion-dollar-wildlife-industry-in-vietnam-under-assault-as-law-drafted-to-halt-trading (last visited 23 December 2020).

[89] *Ibid*.

[90] M. Harvey, *A Progress Report of the Coalition to End Wildlife Trafficking Online*, *WWF*, https://static1.squarespace.com/static/5b53e9789772ae59ffa267ee/t/5e5c32496b59fb4dac1baf55/1583100496539/Offline+and+In+the+Wild+-+Coalition+2020+Progress+Report.pdf (last visited 7 June 2020).

information of wildlife trade and make sure that its actions are in line with the purpose of the coalition. With the promulgation of the 2020 Decision, it is highly likely that more companies will join this or similar coalitions or take similar initiatives on their own.
In conclusion, by heightening wildlife protection measures and enforcing restrictions, the 2020 Decision would bring dramatic positive changes to the long-lasting tradition of wildlife hunting, consumption and trading, and would also play a significant part in reshaping the international wildlife supply chain.

Future legislative trend after the 2020 Decision
Since the 2020 Decision is more of an immediate reaction and stop-gap nature, a long-term outlook in amending the Wild Animal Conservation Law is a necessary consideration. As mentioned above, the Standing Committee of National People's Congress has made amending the Wild Animal Conservation Law a crucial part of the legislative plan this year[91]. Based on the contents of the 2020 Decision and the Directory, the newly revised Wild Animal Conservation Law might reflect a fundamental change in approaching wildlife protection and administration.
Although currently no proposed draft has been issued, experts have been proactively raising suggestions. For example, the Research Group of Administrative Law Research Society of China Law Society has proposed suggestions in the following aspects: (a) enlarge the protection scope of Wild Animal Conservation Law to all wildlife; (b) revise the lists of protected wildlife in accordance with their current status; (c) enhance administration of wildlife by focusing on the entire supply chain (including breeding, transportation, trading, etc.); and (d) strictly regulate the behavior of wildlife eating and trading by using a "whitelist"[92]. These suggestions are generally touched upon by the 2020 Decision, the Directory and other supporting policies issued by the Ministry of Agriculture and the State Forestry and Grassland Administration, therefore, it can be reasonably inferred that the revised Wild Animal Conservation Law will further consolidate these aspects accordingly.

Issues beyond law
Despite all the promising prospect and potential changes that the 2020 Decision may result, there remain a lot of concerns and uncertainties. Some of these concerns are closely related to issues beyond law, including the potential impacts on Chinese traditional medical science and the deeply-rooted traditional Chinese culture of wildlife consumption. The

[91] See *supra* note 23.

[92] Research Group of Administrative Law Research Society of China Law Society, *Guanyu yesheng dongwu baohu fa xiugai de shitiao jianyi* (Ten Suggestions on Revising the Wild Animal Conservation Law), *Economic Information Daily*, 3 March 2020, http://dz.jjckb.cn/www/pages/webpage2009/html/2020-03/03/content_61999.htm (last visited 31 July 2020).

existence of these complicated non-legal issues are the challenges to the actual impact of the 2020 Decision.

Chinese traditional medical science

A tough issue to manage is the balance between a clampdown on wildlife consumption and the demand for developing Chinese traditional medical science. There are several dozens of Chinese traditional medicines that contain animal products. Although most of them are arthropods, insects and worms, a few parts of some important terrestrial animals such as snake gallbladders, rhinoceros horns, pangolin scales, deer horns, etc. are believed to have medicinal value as well. Regarding insects, Compendium of Materia Medica (known as "Ben Cao Gang Mu" in Chinese), one of the most important scholarly works on traditional Chinese medicine, has identified 43 species of insects capable of curing various diseases[93]. For example, the scorpion is believed to be good for the kidney, while spiders may help counteract insect bites.[94] Both rhino horns and pangolin scales were also very valuable medicinal ingredients. According to the Compendium of Materia Medica, rhino horns were believed to be good to treat high-grade fevers[95] and pangolin scales were described as good for promoting circulation of blood or lactation[96]. On the other hand, more and more recent scientific research seem to contradict the ancient belief as some researchers hold that there is no conclusive scientific evidence as to the above-mentioned curative effects of rhino horns[97] and pangolin scales[98].

Every law and regulation regarding wildlife protection and administration has always given allowances for wildlife utilization by traditional Chinese medicine, and the more stringent 2020 Decision is no exception. Article 4 of the 2020 Decision again recognizes medical use as a legitimate exception to the absolute ban on wildlife consumption. The central government's firm support for traditional Chinese medicine may not only be for preserving traditional culture, but also for the protection of a fast-growing and potentially lucrative industry. According to the statistics of the National Administration of Traditional Chinese Medicine, the number of hospitals providing traditional Chinese medicine had

[93] L. Shizhen, *Compendium of Materia Medica*, https://www.gswen.cn/bookindex/24.html (5 June 2020).

[94] *Ibid*, at Insect Section.

[95] *Ibid*, at Animals with Scales Section.

[96] *Ibid*, at Animals Section.

[97] T. Milliken, J. Shaw, *The South Africa – Vietnam Rhino Horn Trade Nexus* (*TRAFFIC*, 2012), 15, https://www.traffic.org/publication/12_The_SouthAfrica-VietNam_RhinoHorn_Trade_Nexus.pdf (last visited 7 June 2020).

[98] W. Bo, Z. Tianhua, *Chuanshanjia zhishang: shengcun xianzhuang burong keguan, yaoyong jiazhi dai lunzheng* (Pangolin Tragedy: Survival Status Not Optimistic, Medicinal Value to be Demonstrated) (*China.org*, 16 June 2016), http://news.china.com.cn/cndg/2016-06/16/content_38680040.htm (last visited 3 January 2021).

risen almost 40% from 39,30599 in 2012 to 54,243 in 2017[100], with total revenue growth from RMB 205.16 billion[101] to RMB 416.02 billion[102] over the same five year period. In 2016, boosting the development of traditional Chinese medicine was even raised to a national development strategy and the State Council issued the Outline of the Strategic Plan for the Development of Traditional Chinese Medicine (2016-2030) ("2016 Plan")[103]. Later in 2017, the Traditional Chinese Medicine Law was promulgated, in which Article 1 clearly held that the State guarantees and promotes the development of traditional Chinese medicine[104]. During the Covid-19 pandemic, traditional Chinese medicine is believed by many to have played a significant role in combating the virus[105]. Therefore, it is reasonable to conclude that with the market demand and with the support from the national government level, traditional Chinese medicine industry will continue and keep developing. Thus, how to strike a balance between the need for development of this industry and protection of wildlife has become a key issue.

In this regard, the role of law is rather limited and alternatively, it is the advancement of science and technology that offers more effective solutions.

Commonly, there is an understanding in China that traditional Chinese medicine with artificially-bred wildlife component is not as effective as its naturally-bred counterpart. Yet, according to recent studies, many of these naturally-bred wildlife components can be

[99] National Administration of Traditional Chinese Medicine, *2012 nian quanguo weisheng jigou, zhongyi jigou de jigou, renyuan qingkuang* (Information on Institutions and Personnel of National Health Institutions and Institutions of Traditional Chinese Medicine in 2012), http://www.satcm.gov.cn//2017tjzb/%E5%85%A8%E5%9B%BD%E4%B8%AD%E5%8C%BB%E8%8D%AF%E7%BB%9F%E8%AE%A1%E6%91%98%E7%BC%96/atog/2012/A01.htm (last visited 25 November 2020).

[100] National Administration of Traditional Chinese Medicine, *2017 nian quanguo weisheng jigou, zhongyi jigou de jigou, renyuan qingkuang* (Information on Institutions and Personnel of National Health Institutions and Institutions of Traditional Chinese Medicine in 2017*)*, http://www.satcm.gov.cn//2017tjzb/%E5%85%A8%E5%9B%BD%E4%B8%AD%E5%8C%BB%E8%8D%AF%E7%BB%9F%E8%AE%A1%E6%91%98%E7%BC%96/atog/2017/A01.htm (last visited 25 December 2020).

[101] National Administration of Traditional Chinese Medicine, *2012 nian quanguo zhongyi yiliao jigou shouru zhichu qingkuang* (Income and expenditure of national medical institutions of traditional Chinese medicine in 2012), http://www.satcm.gov.cn//2017tjzb/%E5%85%A8%E5%9B%BD%E4%B8%AD%E5%8C%BB%E8%8D%AF%E7%BB%9F%E8%AE%A1%E6%91%98%E7%BC%96/atog/2012/A10.htm (last visited 25 December 2020).

[102] National Administration of Traditional Chinese Medicine, *2017 nian quanguo zhongyi yiliao jigou shouru zhichu qingkuang* (Income and expenditure of national medical institutions of traditional Chinese medicine in 2017), http://www.satcm.gov.cn//2017tjzb/%E5%85%A8%E5%9B%BD%E4%B8%AD%E5%8C%BB%E8%8D%AF%E7%BB%9F%E8%AE%A1%E6%91%98%E7%BC%96/atog/2017/A10.htm (last visited 25 December 2020).

[103] State Council, *Zhongyiyao fazhan zhanlve guihua gangyao (2016-2030 nian)* (Outline of the Strategic Plan for the Development of Traditional Chinese Medicine [2016-2030]), 22 February 2016, http://gcs.satcm.gov.cn/zhengcewenjian/2018-11-08/8253.html (last visited 7 June 2020).

[104] Standing Committee of the National People's Congress, *Zhonghua renmin gongheguo zhongyiyao fa* (Traditional Chinese Medicine Law), 25 December 2016, http://fjs.satcm.gov.cn/zhengcewenjian/2018-03-24/2249.html (last visited 6 December 2020).

[105] L. Yanan, *Guojia zhongyiyao ju: yanjiu tichu xinxing guanzhuang bingdu ganran feiyan zhongyiyao zhenliao fangan* (State Administration of Traditional Chinese Medicine: Study and Propose Diagnosis and Treatment Scheme of Pneumonia Caused by Coronavirus), *Chinanews* (21 January 2020), http://www.chinanews.com/sh/2020/01-21/9066690.shtml (last visited 24 December 2020).

substituted with other components. Therefore, scientists in the field of traditional Chinese medicine can keenly work on researching and developing adequate substitutes of rare and endangered species in order to protect them. The Ministry of Science and Technology as well as the National Administration of Traditional Chinese Medicine have jointly issued the 13th Five-year Special Plan for Technological Innovation of Traditional Chinese Medicine ("13th Special Plan"). The 13th Special Plan includes research and development of new technology, such as biosynthetic technology (used for analyzing components of traditional Chinese medicine and synthesizing substitute components), digital tracing techniques (used for tracing ingredients and products during the entire manufacturing process) and purification technology[106]. The 14th Five-year Plan released in 2020 decided to promote western and traditional medicine equally and develop traditional medicine vigorously[107]. With the issuance of this new Plan, it can be anticipated that more resources will be invested in the research and production of traditional Chinese medicine. The replacement of ingredients from wildlife subject to strict protection shall be one of the research tasks.
As the Wild Animal Conservation Law is planned to be revised in 2021, it is likely that a ban on using wildlife as ingredients in traditional Chinese medicine would still not be imposed. With the strict ban set forth in the 2020 Decision, many people may either voluntarily or involuntarily choose to give up their enterprise in artificial breeding or wildlife trading. Therefore, it is possible that only licensed hospitals or pharmacies will be allowed to sell traditional Chinese medicine. Although even licenses can still be abused, it is still a feasible way to strengthen wildlife administration within this industry.

IV.2. Culture

Apart from the need to develop traditional Chinese medicine industry, the 2020 Decision also has to contend with some cultural obstacles since the habit of hunting and eating wildlife has always been a crucial part of traditional Chinese culture.
The explanations for Chinese people's preference to wildlife food are various, but one of the most predominant is the long-lasting belief that "food is better tonic than medicine" and thus some people believe they can be stronger and healthier by consuming wildlife[108].Despite the fact that such belief actually lacks scientific evidence, it has been widely spread in China for almost two millennium. Another common belief is that "medicine and food are of the same origin" (medicine and food homology, "*Yao Shi Tong Yuan*" in Chinese), namely,

[106] Ministry of Science and Technology and State Administration of Traditional Chinese Medicine, '*Shi San Wu' zhongyiyao keji chuangxin zhuanxiang guihua* (13th Five-year Special Plan for Technological Innovation of Traditional Chinese Medicine), 12 June 2017, http://www.most.gov.cn/tztg/201706/t20170612_133478.htm (last visited 6 January 2021).

[107] China's 14th Five-year Plan, para. 46, adopted on 29 October 2020, https://www.163.com/dy/article/FQMF8PDL0512D71I.html (last visited on 6 January 2021).

[108] G. Yemin, *Zhongguoren weishenme aichi yewei? Laizi Li Shizhen de jinggao!* (Why Do Chinese People Like to Eat Wildlife? Warning from Li Shizhen!), *The Paper* (22 January 2020), https://www.thepaper.cn/newsDetail_forward_5603294 (last visited 24 May 2020).

some medicine is food themselves, while some food has certain curative effects. Although this belief only became a formal theory in the 1920s-1930s, the origin of this theory can be dated back to at least almost 1,900 years to the Han Dynasty[109]. Based on this understanding, even healthy people like to eat this kind of "medicinal" food as part of their diet to keep fit. Moreover, people also tend to believe in the theory of "figural association" ("*Yi Xing Bu Xing*" in Chinese), in which you can heal or nourish a body part by eating something that is visually similar to the respective body part, often the corresponding body part of an animal. Despite being criticized of lacking concrete evidence[110], many people still regard it as a golden rule and relevant recipes are abundant on the Internet. Therefore, one of the biggest challenges the 2020 Decision faces is the conflicting nature and reshaping of a traditional belief which has been molded and passed on for generations.

There have indeed been some successful examples of turning the tide against such traditional beliefs. For instance, former Chinese NBA star Yao Ming has dedicated himself and starred in a TV commercial urging people not to consume shark fin soup since 2006. Shark fin soup was a traditionally popular Chinese dish. Annually, approximately 73 million sharks were killed in making this soup and the sharks were treated cruelly during this process as their fins were sliced off while they were still alive[111]. After Mr. Yao's commercial aired, it is reported that the shark fin prices and sales declined in China by 50-70%[112]. It is encouraging to see how huge an impact a TV commercial can bring on people's eating habits. Similarly, after the outbreak of the Covid-19 pandemic, a survey showed that more than 95% of people who have consumed wildlife before are willing to refrain from eating them in the future[113]. Therefore, the pandemic may at least have a positive impact as a starting point for long-term change in the traditional Chinese wildlife eating customs.

In conclusion, many factors are to be considered when it comes to realizing the goal of wildlife protection, some of them are related to law, while some of them are issues beyond law, which requires a comprehensive interface of law, culture and technology. However, to what extent people's beliefs and behaviors may be altered with more stringent laws, and the reconciliation of deep-rooted traditional culture and advancement of new technologies is yet to be seen.

[109] Z. Jianping, D. Wenxiang, W. Bincai, X. Ming, H. Yan, H. Huiyong, X. Mengzhou, *"yao shi tong yuan" yuanliu tantao* (Theoretical Orientation of Medicine and Food Homology) (2015) 35(12) *Journal of Hunan Uni. of CM* 28.

[110] China Science Communication, *Chi hetao bu bubao, "yi xing bu xing bu kexue" ying chengwei changshi* (Eating Walnuts Does Not Make up the Brain and "Yi Xing Bu Xing Lacks Scientific Evidence" Should Become Common Sense), *Xinhua Net* (26 August 2019), http://www.xinhuanet.com/science/2019-08/26/c_138357450.htm (last visited 6 June 2020).

[111] WILDAID, *Yao Ming Calls for a Shark Fin Ban in China*, 22 September 2011, https://wildaid.org/yao-ming-calls-for-a-shark-fin-ban-in-china/ (last visited 31 July 2020).

[112] WILDAID, *Shark Fin Demand in China Down, Report Finds*, 24 October 2014, https://wildaid.org/shark-fin-demand-in-china-down-report-finds/ (last visited 31 July 2020).

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V. Conclusion

With the Covid-19 pandemic, the relationship between protection and utilization of wildlife was again brought to the attention of the leadership and the public. Starting from 1988, the earliest version of the Wild Animal Conservation Law has attempted to strike a balance between protection and utilization. Afterwards, three minor amendments and one major amendment of the law were made to readjust the focus on protection of wild animals. Especially in the 2016 Law, the priority appears to be gradually leaning towards protectionism with more enacted protective mechanisms established compared to the 1988 Law, such as protection based on classification and licensing, protection of wildlife habitat, constant monitoring of wildlife and international cooperation on wildlife protection. However, despite these progresses, there are still significant exceptions that stifle wildlife protection including medical use, domestication and reproduction in captivity, and the protection mechanisms aforementioned are facing various implementation problems, some of which may have contributed to the chaotic conditions of the Wuhan wet market where the early cases of Covid-19 were reported.

The 2020 Decision may serve as a turning point as it intends to prohibit any forms of eating, hunting or trading of wildlife in order to eliminate the habit of wildlife consumption. Along with the 2020 Decision, many local governments have also issued corresponding implementation regulations. These provisions are stricter which will help reduce wildlife consumption in China and also contribute to clamp down on international wildlife trade. The 2020 Decision also has significant impacts on Chinese traditional medicine, which is very important in the Chinese medical system and valued greatly by the government and by society. Following the on-going revision and changes in conserving wildlife, experts in the traditional Chinese medical science has to find new ways to avoid the use of wildlife in the medicines containing natural wildlife ingredients. Along with regulatory measures, parallel education has been launched to change the habit of eating wildlife which is deeply rooted in traditional Chinese culture for thousands of years. With these noted positive regulatory effects and the governmental and societal growing trend towards wildlife conservation, it can be said that the overwhelming damages and losses caused by the Covid-19 pandemic have at least served to put an end to the long-standing debate between the protection and utilization of wildlife in China.

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It is an electronic full open access journal devoted to "Studies in Comparative and National Law".
It aims at enhancing the dialogue among all legal traditions in a broad sense. The intend of diffusing contributions on national law as well and not only to focus on comparative issues, is to expand access to foreign legal materials and ideas to those who do not already have access to the traditional avenues (such as journals in the language of the explored legal system). All contributions will be inserted in the *Opinio Juris in Comparatione* website.
Opinio Juris offers the benefits of a preliminary and early diffusion of the contributions before the papers are actually published somewhere else.
The different languages of preferred submission are English, French, Italian and Spanish. The constraints set out for dealing with purely national law contributions is to give descriptions of domestic law in a language other than the language of the system itself (please see instructions for the submission on Opinio Juris in Comparatione website for further details).

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LEADS

LEgality Attentive Data Scientists

(https://cordis.europa.eu/project/id/956562)

Bridging the gap between data science and law

The emergence of data science has raised a wide range of concerns regarding its compatibility with the law, creating the need for experts who combine a deep knowledge of both data science and legal matters. The EU-funded LeADS project **will train early-stage researchers** to become legality attentive data scientists (LeADS), the new interdisciplinary profession aiming to address the aforementioned need. These scientists will be **experts in both data science and law**, able to maintain innovative solutions within the realm of law and help expand the legal frontiers according to innovation needs. The project will create the theoretical framework and the practical implementation template of a common language for co-processing and joint-controlling basic notions for both data scientists and jurists. LeADS will also produce a comparative and interdisciplinary lexicon.

Overall LEADs envisage to open 15 position for ESRs and hopes to enable all ESR to enrol in a PhD program.

Sant'Anna School of Advanced Studies, Pisa, Italy
www.santannapisa.it
CONTACT PERSON: g.comande@santannapisa.it

PHD "DATA SCIENCE"
https://www.santannapisa.it/en/formazione/data-science
Ph.D in LAW
https://www.santannapisa.it/en/education/phd-law

N.1	Project Title: Reciprocal interplay between competition law and privacy in the digital revolution
Objectives: Data are more and more important resources in the so-called Digital Revolution: the impact on competition law is increasingly relevant and so are the implications of data protection law on competition law. The researcher will address these implications, analysing some relevant topics: the impact of data portability and the requirements in terms of interoperability in the new GDPR compared to the barriers to entry and to market dominance; how customer data can be "assessed" as an index of market dominance for the big information providers (Google, Apple, Facebook, Amazon); and how SMEs can benefit from data protection law and competition law in order to increase their volume in the market.	
N. 2	**Project Title: Unchaining data portability potentials in a lawful digital economy**
Objectives: Empirically test the potentials of the right to data portability. The research in the framework of LeADS will relate data portability not only to data protection law, but also to competition law and unfair business practices (e.g., offer or price discrimination between groups of consumers through profiling operations), setting the scene for their regulatory interplay in line with current and forthcoming technologies. In doing so specific attention will be offered to the possible technical solutions to guarantee effective portability. Addition ally, the technical, statistical, and privacy implications of the new right will be evaluated, such as the need for standard formats for personal data, and the exception in Article 20.2 of the GDPR, according to which the personal data, upon request by the data subject, should be transmitted from one controller to another "where technically feasible".	
N. 3	**Project Title: Differential privacy and differential explainability in the data sphere: the use case of predictive jurisprudence**
Objectives: Human life and economy are exponentially data driven. The switch from residential to cloud based data storage is making increasingly difficult to reap the maximum from data while minimizing the chances of identifying individuals in datasets. Researcher will explore the interplay between differential privacy technologies and the data protection regulatory framework in search of effective mixes.	
N.4	**Project Title: Neuromarketing and mental integrity between market and human rights**
Objectives: ESR's research question is whether and how neuromarketing can affect human rights of individuals, considering in particular recent interpretations of rights contained in the European Convention of Human Rights and in the EU Charter of Fundamental Rights, in particular "mental privacy", "cognitive freedom", and "psychological continuity". Indeed, advanced data analytics provide a very high level of understanding of users' behaviour, sometimes even beyond the conscious self-understanding of the users themselves exploiting all user's idiosyncrasies, including user's vulnerabilities harming the exercise of free decision making	

Université Toulouse III - Paul Sabatier, Toulouse, France

www.univ-tlse3.fr

CONTACT PERSON: afonso.ferreira@irit.fr

PHD "Mathematics, Informatics and Telecommunications"
https://en.univ-toulouse.fr/sites/default/files/Doctoral-school_MITT-Mathematics-Informatics-Telecommunications_UFTMP.pdf

N. 5	Project Title: Distributed reliability and blockchain-like technologies

Objectives: Guarantee a reliable and secure implementation of instruments that implement innovative and transversal data protection principles without the need of centralized authorities or trusted third parties. Explore, for instance, the potentials of blockchain-like technologies as instruments to guarantee data integrity in a distributed manner and without the need to know otherwise sensitive information. Study and relate the current and forthcoming techniques for big-data storage, retrieval, and management from a legal and technological perspective. Especially on the impact of moving from traditional local/internal database management systems to novel geo-distributed data storage and of processing techniques that leverage public and hybrid cloud- based solutions. ESR will develop methodologies and actual tools to produce legal analytics useful for policy analysis, interrelating various legal domains

N. 6	Project Title: Big data, small data, and business practices

Objectives: In an ideal identity and access management system, the user should not have to present more credentials to a service provider than are needed to access its resources (data minimization/least privileges). The user should consent to the release of her credentials to make it compliant with GDPR. And (s)he should not be trackable though the use of his/her credentials, except in cases of abuse. The objective of this research is to define a complete framework covering both technical and legal aspects in order to guarantee the privacy of users while allowing the service providers to prevent and react to unlawful behaviours for complying with legal requirements.

CNR, Pisa, Italy

https://kdd.isti.cnr.it/

CONTACT PERSON: rinzivillo@isti.cnr.it

PHD Social-AI
https://www.phd-ai.it/

N. 6	Project Title: Personal information as currency for the Supply of Digital Content.

Objectives: The aim of this research will be to understand the legal implications of the "provision of personal data" in the exchange of digital content and how the existing European legal framework of contract for the supply of digital content (considering the new proposed EU directive in this field) can coexist with the principles of personal data protection (data minimisation, purpose limitation, etc). The researcher will first identify general contractual issues arising in relation to contracts for the supply of digital content, and then consider the actual gap and how the new proposed directive will shape the law in this field, as well as examining its impact on existing contractual notions and consumer protection.

Vrije Universiteit Brussel – VUB, Brussel, Belgium

https://www.vub.be/en

CONTACT PERSON: paul.de.hert@uvt.nl

PHD within the Law, Science, Technology and Society research group (LSTS)
https://www.vub.be/en/phd#phd
https://lsts.research.vub.be/

N. 8	Project Title: Public-private data sharing from "dataveillance" to "data relevance"

Objectives: The use of private databases by States and in particular by enforcing authorities (i.e. police, secret services) is an emerging reality. Systematic government access to private databases and so-called "web crawling" are two new technological challenges that should be considered by lawyers, in particular after important rulings from the EUCJ. ESR will analyse the feasibility of a new paradigm of public-private data sharing, which reconceptualises the principle of purpose limitation and strengthens the concept of "data quality", thereby reconciling public interests with fundamental individual rights.

N. 9	Project Title: Solving the conflicts between data owners and data exploiters through a spectrum of quasi- property models

Objectives: The research is supposed to (a) classify the types of information currently subject to commercial exploitation in their original or anonymized and/or aggregated form, (b) map in an intuitive, simple (but comprehensive) matrix the conflicting interests related to each information asset, and (c) define a set of proprietary entitlements, characterized by flexible structure and content and different degrees of exclusivity, to be attributed to each player in order to solve with a unitary tool the clash between concurrent interests over the same information asset. The goal is to provide balancing tools that follow—instead of opposing—market trends and are closer to consumers' actual perceptions. The, aim is fostering consumer trust and helping business players respect users' fundamental rights without renouncing to competitive market strategies

Jagiellonian University, Kraków, Poland

https://en.uj.edu.pl/

CONTACT PERSON: fryderyk.zoll@uj.edu.pl

PhD
https://social-sciences.phd.uj.edu.pl/en_GB/doctor_programs/legal_sciences
(some classes in Polish)
https://social-sciences.phd.uj.edu.pl/society-of-the-future

N. 10	Project Title: Technical and legal aspects of privacy-preserving services: the case of Health Data

Objectives: Technical and legal aspects of medical data protection using traditional encryption techniques, coupled with proper key management schemes, as well as anonymization and/or privacy-preserving data management techniques using efficient cryptography (e.g. homomorphic, secure multi-party computations)

N. 11	Project Title:The boundaries of information property: from concepts to practice

Objectives: (1) Construct a theoretical framework defining the concept of information and information property, and classify in a single, unitary spectrum the various types of information regulated and protected at EU and domestic levels. Perform a wide analysis of legal regimes affecting information, including data protection and the various forms of IP protection, distinguishing the legal regimes affecting corporate information (such as patents or software) and user information (data collected from or stored by users).(2) Research business practices and business models related to the management and exploitation of information assets, their impact on development of a public regulatory framework, as well as compatibility of the commodification/propertization of information and personal data at both the EU and transnational level with the dogmatic pillars of national private law systems. (3) Develop business guidelines to assist producers, service providers, and consumers in managing and contracting over their information assets and data in a less antagonistic, more unitary fashion, and define policies that can effectively guarantee the exercise of property and intellectual property rights over the information.

SnT, Université du Luxembourg, Luxembourg
https://wwwen.uni.lu/
CONTACT PERSON: gabriele.lenzini@uni.lu

PhD "Computer Science and Computer Engineering"
https://wwwen.uni.lu/studies/fstm/doctoral_programme_in_computer_science_and_computer_engineering

N. 12	Project Title Processing of biometric data to support the use of e-identities in key activities of the EU digital society

Objectives: Study processes, services and protocols that require biometric data in user authentication in the context of services supporting the EU Digital Single Market, such as: e-education (e.g., digital diploma certificates), e-health (e.g., electronic patient records, biomedical data), and e-commerce (e.g., intellectual property rights, fintech). The technology will be discussed in relation to the various legal regimes that protect data in their different forms, including the recently approved and forthcoming EU regulations, comparative law and business practice

N. 13	Project Title Technologies for algorithms and algorithmic transparency and fairness

Objectives: Understand the reasons for existing opacity and inscrutability in algorithms and protocols (e.g., technical, economic, and social aspect) and discuss the application of principles of algorithmic transparency and accountability, such as awareness, explanation, data provenance, auditability, validation and testing (e.g. ACM Public Policy Council statement23). Explore ways to ensure algorithmic transparency and accountability and study solutions to ensure that critical outputs are not biased or erroneous but trustworthy, lawful, and fair.

University of Piraeus, Piraeus, Greece
https://www.unipi.gr/unipi/en/
CONTACT PERSON: dimos@unipi.gr

PhD

N. 14	Project Title: From Privacy by design to Privacy by Using

Objectives: Analysing the tools designed to protect against risks related to the exploitation of personal data and thereby refine the methodology of analysis of such risks; drawing a scheme of implementation of the process of privacy by design and legal design in order to modulate prevention of the risks and promotion of innovation. In addition it will: a) Suggest a renewed approach for contractual instruments (Terms and conditions, Privacy charter) in order to balance the asymmetry of information which is detrimental to the user and inefficient from an economic perspective; create appropriate instruments of information for the user, best practices for data brokers, and collective assessment of their efficiency through various processes (label, control by a rating agency, fostering class or collective action); promote such instruments at an international level. b) Establish learning processes driven by the concept of "Privacy by using" in order to increase the user's ability to define in a more accurate way his own behaviour as regards the protection of his privacy. c) Draw the architecture of the regulation according to a "principle of action" which rests on two pillars: action of the data broker and action of the individual from whom data are extracted

N. 15	Project Title: Empowering data owners by promoting PIMS

Objectives: (1) Study digital platform and personal data. The project will study digital innovation and business models (e.g. multisided markets, freemium) dependent on the collection and use of personal data (in different sectors such as creative industries, media, travel, housing, etc.). It will also: a) link this analysis to the exploration of online behaviour and IT use (browsing, contribution, participation) that generate personal data as well as large network effects; b) assess (efficiency, impact studies) the many specific privacy regulations that apply to online platforms, business models , and behaviours. (2) Proposal of a user centric data valorisation scheme by analysing user-centrics patterns, the project aims to: a) Identify alternative schemes to data concentration, to place the user at the heart of control and economic valorisation of "his" data, whether personal or not (VRM platforms, personal cloud, private open data); b) Assess the economic impact of these new schemes, their efficiency, and the legal dimension at stake in terms of liability and respect of privacy. Starting from the analysis of "the economy of the gratuity" based on a barter model, the project will suggest new models allowing the user to benefit from the value of the data

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